



# Twenty-four months long-term follow-up report on the effect of poly lactic-co-glycolic acid suspension suture in Asian with mild-moderate face laxity

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**Background:** There was evidence of improvement in mid-face laxity using three pairs of suspension sutures in mid-face lifting in our early and mid-term follow-up.

**Objective:** This 24-month prospective follow-up study aimed to determine the efficacy of mid-face lifting and lower jawline contouring using poly lactic-co-glycolic acid (PLGA) sutures in Asian patients.

**Methods:** Ten healthy volunteers received three pairs of 8-cones bidirectional cones sutures at the mid-face. One of the ten volunteers lost to follow-up, and all remaining patients followed up for 24 months. Our primary outcome measure is the change in the facial laxity rating scale (FLRS), an "improvement" defined as at least "one-grade change" in FLRS. Other assessment parameters include the severity of the nasolabial fold (NLF), assessed on the wrinkle severity rating scale (WSRS). The secondary outcome measures were the self-satisfaction rating scale (SSRS) and global aesthetic improvement scale (GAIS), rated by participants at each follow-up interval.

**Results:** A linear improvement in the mid-face was observed almost immediately after treatment, with progressive improvement up to at least 12 months following the intervention and no deterioration by 24 months. This improvement was significant ( $p < 0.05$ ), and the differences between before and after treatment at each follow-up interval were large (Cohen's  $d > 0.8$ ). Contour improvement for the lower face followed a similar trend, except for a delay in the observable differences at three months (Cohen's  $d = 0.29$ ,  $0.8$  at six weeks and three months, respectively). The differences in the level of patient satisfaction were significant ( $p < 0.05$ ) from 6 weeks to 24 months, peaking between 12 and 18 months, based on both the GAIS and SSRS ratings. No observed complications.

**Conclusion:** Mid-facing lifting in Asian patients with mild-to-moderate laxity is safe and effective with PLGA bidirectional cone sutures, with concurrent improvement in the lower face contour and elevated patient satisfaction over the 24-month follow-up period.

**Keywords:** fascia; ligaments; nasolabial fold; rejuvenation; rhytidoplasty

Received February 25, 2022; Accepted April 9, 2022

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## Introduction

Asians have a less robust skeletal support, yet heavier soft tissue, bulkier malar fat, thicker skin, and weaker chin compared to Caucasians, thus making Asian faces more vulnerable to gravitational descent, and requiring greater tissue suspension to lift sagging soft tissue [1,2]. The unique suture configuration of cones and knots provides a 360-degree surface area on each cone along the thread, which helps first, an even distribution of burden load over anchoring points with a much greater surface area; second, a stronger attachment to the subdermal fascia compared to other thread designs. Physiochemically, the poly lactic-co-glycolic acid (PLGA) material elicits a minimal acute inflammatory reaction in tissue which promotes the ingrowth of fibrous tissue around the main suture, allowing subsequent gradual encapsulation for more stable attachment. Thus, PLGA bidirectional cone suture is more effective and sustainable for lifting. However, to date, there have been no reports evaluating the use of this suture device in treating mid-face laxity in Asians.

The aim of this twenty-four months ongoing prospective single-center study was to evaluate the long-term treatment effect of bi-directional 8-cones-PLGA sutures in mid-face lifting, and concurrent changes in the lower facial profile in healthy Asians with mild-to-moderate facial laxity.

## Materials and methods

### Participants

Ten (nine females and one male) healthy volunteers, between the age of 24–53 years (average 42.4 years) with mild-to-moderate facial laxity, with a normal or positive orbit vector, and no history of aesthetic procedures, were recruited. Those with excessive thinness, thickening, or laxity and those who underwent treatment for facial volume loss or thread lift within six months were excluded.

### Procedure

Each participant had three pairs of 8-cones PLGA bidirectional cone sutures inserted into the mid-face in a straight parallel vector using an aseptic technique under local anesthesia.

### Pre-procedural marking

The last cone of each distal suture was positioned within the superficial fat pad that produced the most efficient pulling point (EPP) and the distal suture perpendicular to the line of the nasolabial fold (NLF) along the direction of straight-line force (ef-

factor vector, EV) that directly repositioned the target treatment area. The entry and exit points (approximately 6 and 12 cm proximal to the EPP, respectively) were found and pre-marked in the sitting position.

### Treatment procedure

After sterilization of the face, 0.2–3 cc of xylestein (1:800,000) was injected at each pre-marked entry and exit point. Small skin punctures were created at each position using an 18-G needle. Both double-arm sutures were passed perpendicularly until the 5-mm mark, and the needle pivoted into and continued within the subdermal plane. The two needles were transferred in opposite directions, proximally and distally, along the direction of the desired vector of movement. Three pairs were placed in a straight line parallel to each other, about one finger breathe apart. The soft tissue was gently massaged over the suture cones until the needles passed through the exit points, and any excess length was trimmed to achieve the desired effect.

### Outcome measures

An “*improvement*,” defined as “*one-grade change*” in the facial laxity rating scale (FLRS), was set as the primary outcome measure. Other assessment parameters, including evaluation of the severity of the NLF, wrinkle severity rating scale (WSRS), subjective patient assessment of self-satisfaction rating scale (SSRS), and global aesthetic improvement scale (GAIS), were the secondary outcome measures. Results were assessed by seven independent reviewers, all experienced and senior aesthetic physicians from Hong Kong; three to judge the mid-face, and four the lower face, using standardized validated grading scales. The participants returned for follow-up at 6 weeks, and 3, 6, 12, 18, and 24 months after treatment.

### Statistical analysis

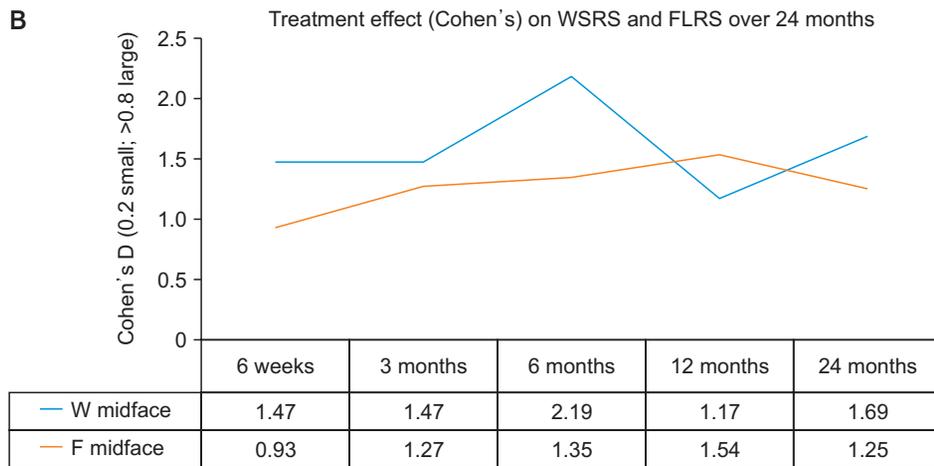
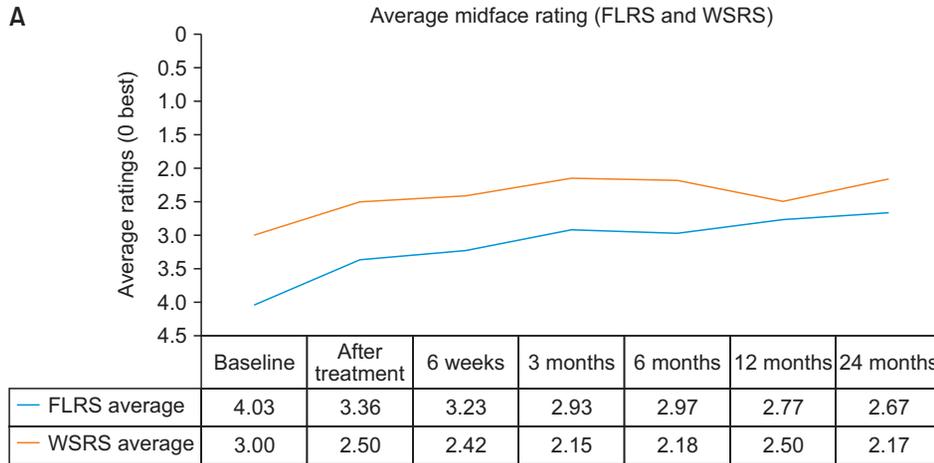
Data were analyzed by a statistician and computer software program to compare the baseline and treatment results. The trend in the averaged ratings of the different outcome measures before and after treatment at each interval were compared, and a paired t-test analysis was used to determine if the difference between before and after treatment was statistically significant and the level impact of intervention (t-test effect size using Cohen’s d) at different time intervals. Statistics analysis was carried out by an external statistics analyst with programme and software.

## Results

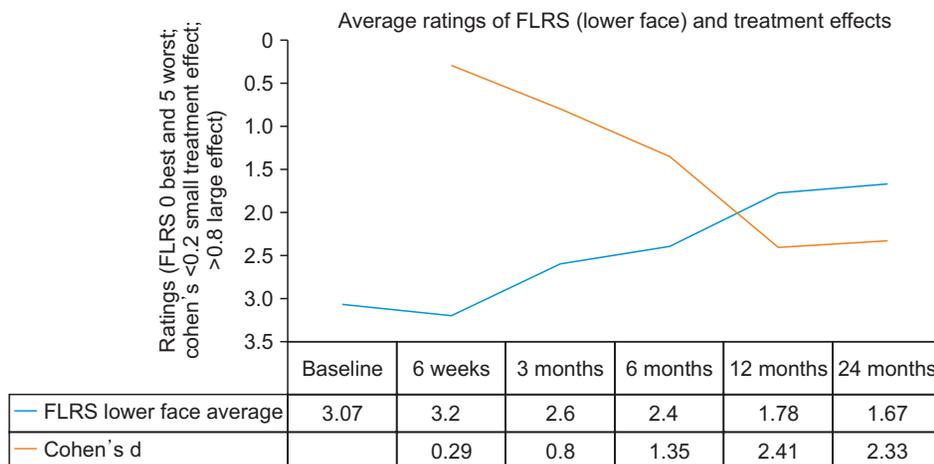
### Changes in the mid-face

Our results indicated an “improvement” in the mid-face almost immediately after treatment, with gradual progressive changes throughout the subsequent 24 months (FLRS; Fig. 1A).

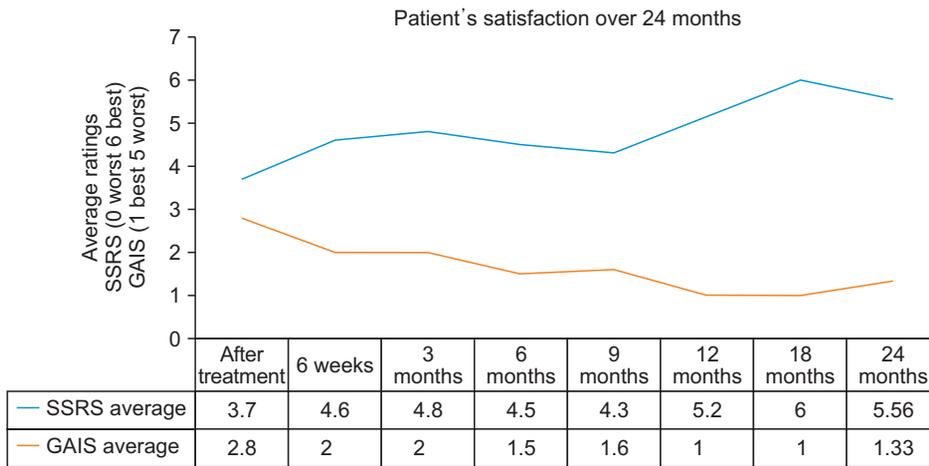
The score peaked around 9 months and plateaued around 12 months, but the overall average rating between 12–24 months were still higher compared to baseline (Fig. 2). The “improvement” was both clinically and statistically significant ( $p < 0.05$ ). The treatment impact was large (Cohen’s  $d > 0.8$ ) at each follow-up interval during the follow-up period (Fig. 1B).



**Fig. 1.** The trend of average FLRS ratings and WSRS ratings for mid-face over 24 months (A) and treatment effect with Cohen’s  $d$  on FLRS and WSRS respectively (B). Cohen’s  $d$ : 0.2, small effects; 0.5, moderate; and 0.8, large effects. There was a steady linear rating (i.e., mid-face lifting) improvement over 24 months (0, best; 5, worst) (A) and the impact of treatment effect peaked around 6 months (WSRS) to 12 months (FLRS) and was large in the mid-face throughout the 24 months ( $>0.8$ ) (B). FLRS, facial laxity rating scale; WSRS, wrinkle severity rating scale.



**Fig. 2.** The chart shows the FLRS average rating (0, best; 5, worst) and treatment effect with Cohen’s treatment effect (0.2, small effects; 0.5, moderate; and 0.8, large effects). For the lower face, only from 3 months onwards, the treatment effect was large together with a steady improvement of lower face ratings, unlike the mid-face that started soon after thread insertion. FLRS, facial laxity rating scale.



**Fig. 3.** SSRS (blue) rating worst, 0 and best, 6; GAIS (orange) 5, worst and 1, best. From the charts, we can see there was a steady increase in satisfaction, peaking around 12 (GAIS) to 18 (both GAIS and SSRS). Even by 24 months, both satisfaction ratings were higher compared to their respective baseline. SSRS, self-satisfaction rating scale; GAIS, global aesthetic improvement scale.

### Changes in the lower face

Improvement in the FLRS rating showed a lag of 3 months, reflecting the lower face contour improvement. Treatment effect is small at 6 weeks (Cohen’s d=0.29) and largen at 3 months (Cohen’s d=0.8; Fig. 2).

### Patient satisfaction

The differences in the improved level of satisfaction from 6 weeks to 24 months, based on both GAIS and SSRS ratings, were significant (p<0.05), with satisfaction peaking between 12- and 18-months post-procedure (Fig. 3).

### Side-effects and complications

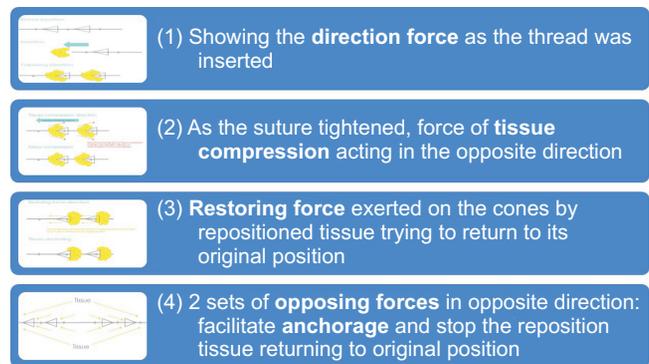
All subjects tolerated the procedure well, and side effects, such as swelling and bruising, were transient and minimal. No major common side effects following thread-lifting [3], such as skin dimpling, irregularity, ecchymosis, hematoma, and suture migration, were reported by our patients.

## Discussion

The unique knot and cone configuration of the thread lifting described here allows the lifting of sagging tissue and is capable of sustaining the tissue in its new position over time for the following reasons, as follows:

**Engagement:** When the thread is inserted, the cones on the proximal half of the thread attach to the fixed tissue, whereas those on the distal half reposition descended (mobile) soft tissue. Restoring forces (reverting to the original position) act in two opposing directions on the bidirectional device, balancing the forces that keep the suture in the lifted position (Fig. 4).

**Mid-face improvement:** Goldberg reported that the size



**Fig. 4.** (1) Showing the direction (force) of each half of the bidirectional cones when inserted into tissue, pushed along the tissue and the knots within the cones (now) will stop the cones from returning to their original position. (2) The tissue compression force will act in an opposite direction to direction of thread insertion. (3) Restoring forces of repositioned tissue will try to return to its position. (4) Opposing actions of the varying forces will facilitate anchorage and fixation.

of the collagen deposit is correlated with the improvement (repositioning and effacement) of the NLF, which peaked between 90–180 days (i.e., 1–3 months) and 270 days (9 months) post-procedure [4]. Our study results concur with these previous findings, which showed a gradual linear improvement in both mid-face and lower face laxity throughout the 24 months follow-up, peaking around 9 months and leveling out around 12 months. The “improvement” in the mid-face was both clinically and statistically significant (p<0.05) with large treatment impact.

**Lower face improvement:** Because jowl formation results from ptosis of both volume loss and descent of cheek fat together with unsupported skin, an improvement in the lower face became noticeable after the superficial fat compartment within

the mid-face was lifted, that is, less fat descent, the jowl together with the lower facial contour was enhanced [5]. Such changes were more visible three months after neocollagenesis around the inserted absorbable suture.

**Side-effects and complications:** One of the most common complications of thread lifting is skin dimpling (30%), which is often associated with the subcutaneous thread being too shallow or uneven [6]. This was not reported in our study patients but can occur if suture threads are placed within an incorrect placement plane. Other complications, such as slippage or breakage of sutures, have previously been reported [6].

These side-effects are less commonly found with this suture design as the cones are freestanding and mobile within the intercalated knots, and the diameter of the suture is not compromised and is capable of withstanding the opposite forces (Fig. 4), unlike barbed sutures that cut into the primary suture, contributing to suture breakage. Experimental data revealed that the 'pull-out tension' in this suspension suture is higher, meaning that this prevents suture slippage from soft tissue, based on its intrinsic design and material, when compared to other sutures in the market. Thus, these absorbable suspension sutures are capable of producing a long-lasting mid-face and lower face lift, which are effective in Asians with mild to moderate laxity, without the complications of suture splitting and slip-out. Significant prior evidence has suggested that once the soft tissue slips out from its suture engagement, progression to dislodgement and extrusion is rapid [7].

These sutures also trigger less damage to the surrounding tissue and discomfort to the patient because the loading force upon each focus was spread over the cone bases with a larger diameter; therefore, as reflected in the elevated level of patient satisfaction as early as 6 weeks of follow-up and mid-face improvements sustained up to 24 months without regression. This prolongs the time to degradation of the polydioxanone suture, that is, within 4 to 6 months following insertion [7].

Most patients also reported an improvement in skin quality around a month post treatment; however, future studies with larger patient groups should be conducted to evaluate this effect.

In conclusion, case selection is one of the most crucial factors affecting treatment success; ideal cases are those with minimal signs of aging, mild-to-moderate skin, and mid-face laxity with reasonable expectation of treatment results. Conversely, those with severe skin and mid-face laxity or soft tissue, history of

facial implants, permanent fillers, immunological diseases, and treatment with absorbable sutures for face-lifting should be avoided.

Despite the intrinsic anatomical differences in Asians and the greater need for tissue suspension [2,7], three pairs of eight-cone absorbable bidirectional suspension sutures for the mid-face, as well as lower face contouring, are safe and effective. A significant treatment effect was observed for up to 24 months, with an elevated level of patient satisfaction. The treatment results were visible and an earlier onset in the mid-face (soon after treatment) as compared with the lower face was seen 3 months after treatment.

Future long-term studies with a larger number of patient groups to evaluate the effects on skin quality may be useful.

## Conflicts of interest

The authors have nothing to disclose.

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