

Straight-Line Vector Planning for Optimal Results With Silhouette InstaLift in Minimally Invasive Tissue Repositioning for Facial Rejuvenation

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ABSTRACT

Background: Absorbable suspension sutures for tissue repositioning represent a minimally invasive approach to facial rejuvenation. With 2015 FDA 510(k) approval of Silhouette InstaLift™ (Sinclair Pharma, Irvine, CA), a completely absorbable device comprised of 82% PLLA/18% PLGA sutures and bi-directional cones, came the challenge of developing optimal technique for achieving effective, precise, and durable tissue repositioning. Here, the authors discuss the importance of straight-line vector planning (SLVP) and positioning of the suture perpendicular to the plane to be elevated in obtaining optimal results for tissue repositioning. Both the scientific underpinnings of SLVP are presented, along with detailed discussion of technique for suture placement in the mid-face, jawline/jowls, and neck.

Methods: The authors are some of the earliest adopters of absorbable suspension sutures in the United States and have both used InstaLift™ sutures for tissue repositioning and facial recontouring in treatment of more than 500 patients and developed the principles of SLVP as a method to ensure optimal outcomes.

Results: Patient case studies illustrating the importance of SLVP are presented. In over 500 patients treated within the authors' practices since InstaLift approval there have been no serious adverse events and noticeable bruising has occurred in less than 5% of patients. Results of repositioning and recontouring are evident for up to 24 months.

Conclusions: Absorbable suspension sutures are a highly adaptable, non-invasive device for lifting and repositioning of descended facial tissue. Outcomes are dependent upon proper technique, including SLVP.

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INTRODUCTION

Facial aging may be apparent through the appearance of wrinkles, volume loss, and sagging. For sagging in particular, reductions in elastin and the supportive capacity of collagen result in greater skin laxity and volume loss.¹ Further, thinning of connective tissues in conjunction with involution of ligament bony attachments and age-related decrease in ligament stability^{2,3} contribute to the sagging and descent of facial features.

Several products have been introduced over the past two decades in response to the need for non-surgical approaches to soft-tissue repositioning and suspension. Between 2001 and 2006, a variety of permanent and absorbable barbed sutures (originally developed for wound closure and tendon repair) were adapted for facial rejuvenation.⁴⁻⁶ However, early results were short-lived, and several difficult-to-correct complications emerged,^{4,5,7,8} ultimately leading to withdrawal of the 2004 FDA approval for ContourThreads (Surgical Specialties Corp., Reading, PA) in 2007.

In 2006, the FDA approved Silhouette Lift (Kolster Methods, Inc., Corona, CA) a device for use in facial surgery. This suture is permanent, with resorbable, unidirectionally oriented cones made of poly-L-lactic acid (PLLA) and glycolide polymer (PLGA) and is held in position by knots along the length of the suture. These cones serve to fix overlying skin in a lifted position and promote ingrowth of fibrous tissue around the main suture and knots via the same foreign body reaction and low-grade inflammatory response initiated by PLLA/PLGA.⁹ Despite high patient satisfaction, the required technique for placement (open dissection of the deep temporal fascia in the temporal region, mastoid fascia in the retroauricular area, and periosteum in the scalp for suture fixation), along with the permanent nature of the suture material, limits the utility of this treatment, leaving clinicians without a viable non-surgical approach to tissue suspension.

The FDA granted 510(k) approval for Silhouette InstaLift™ (Sinclair Pharma, London, UK) in 2015. Silhouette InstaLift differs from its predecessor in two important respects: both the

InstaLift suture and cones are composed of 18% PLGA and 82% poly-L PLLA, so the device is entirely resorbable, and the cones are bidirectionally oriented (Figure 1). Further increasing the utility of this treatment, the FDA issued an update to the Silhouette InstaLift label in June 2017, modifying instructions for placement by making the use of a permanent monofilament suture to secure the suspension suture to the fascia optional, thereby making instructions more consistent with clinical practice. While InstaLift is FDA approved exclusively for use in the mid-face,¹⁰ successful results can be achieved in the jowl/jawline and neck areas as well.

Along with approval of these sutures comes a need to properly define the optimal technique so that patient experience is consistently positive. In this report, the authors emphasize the importance of patient selection and straight-line vector planning (SLVP) and provide a detailed description of optimal technique for areas from the malar eminence to jowl/jawline, as well as special considerations for off-label treatment in the neck.

As part of a holistic approach to facial rejuvenation that includes relaxation with neuromodulators, revolumization with injectable agents, resurfacing with energy-based treatments or cosmeceuticals, and repositioning,¹¹ Silhouette InstaLift offers a non-surgical approach that can effectively reposition descended tissue and tighten those facial features most susceptible to sagging. Recovery time is minimal, and results may be appreciated immediately. Furthermore, the cones and sutures are not only completely resorbable, but provide added benefit through the documented collagen-stimulating abilities of PLLA and PLGA.¹²⁻¹³ For comparison, three 8-coned InstaLift sutures contain the same amount of PLLA as one vial of Sculptra (Sculptra Aesthetics, Galaderma Laboratories, Fort Worth, TX.).¹⁴ This biostimulatory property allows the sutures to also address age-related volume loss, offering another mode by which repositioning with this particular product can yield optimal results.¹⁵

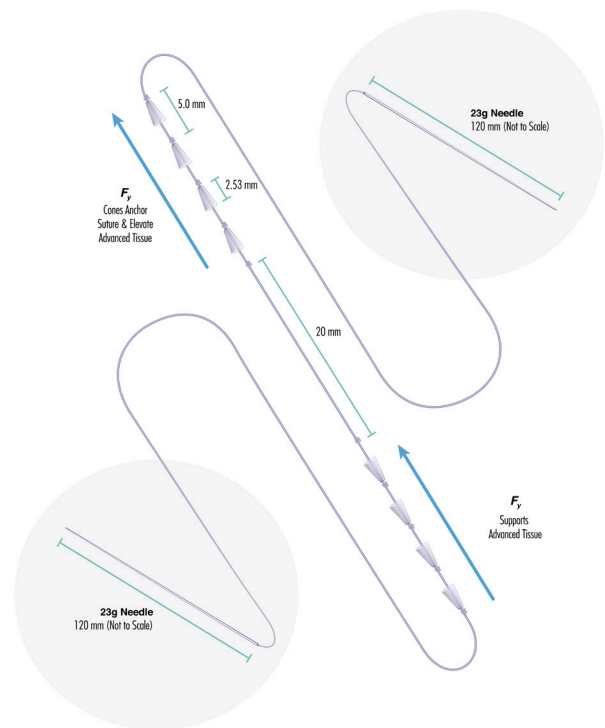
MATERIALS AND METHODS

Patient Selection

As with any medical procedure, proper patient selection is key to obtaining optimal outcomes. When evaluating a patient for potential treatment with absorbable suspension sutures, it is important to remember that this medical device, along with all other non-invasive/minimally invasive techniques, is not a substitute for the traditional surgical facelift often required in older patients with significant skin laxity/skin excess and advanced signs of facial aging. Rather, absorbable suspension sutures are best suited for patients with early to moderate aging changes and without significant skin laxity, loss of elasticity, excessive fibrosis, excessively thick skin, or sun damage.¹¹ It is important that patient tissue can be mobilized during examination and that underlying bony projections are strong. Absorbable

FIGURE 1. The Silhouette InstaLift™ suture. The bidirectional cones are free-floating and spaced between suture knots. Both the suture and cones are composed of 82% PLLA and 12% PLGA, and each suture is packaged with two 23-gauge, 120 mm needles to be used in threading the suture from a central entry point to proximal and distal exit points.

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suspension sutures are also a useful complementary technique for secondary improvements in patients who have previously undergone an open facelift and may be combined with other rejuvenating treatments such as dermal fillers, botulinum toxin, and energy-based devices for a synergistic approach to facial restoration.¹¹ Though the Silhouette InstaLift material is entirely absorbable, sutures may not be the optimal technique in very thin patients, where cones and knots may initially be palpable or even visible. Absorbable suspension sutures are not indicated in patients who are significantly overweight or have very thick non-compliant skin.

Straight-Line Vector Planning

Lifting the tissues along the appropriate vectors is of paramount importance for a successful outcome. Sutures should be placed in the subcutaneous layer as straight lines. Placement of sutures in a curved pattern, a "U," or "V" shape undermines the design of the device, and not only guarantees poor results, including puckering and uneven lifting, but is tantamount to ensuring suture displacement following the procedure. For absorbable suspension sutures, there is no single anchor; rather, the cones

in the upper part of the suture are placed in less mobile and more fibrous and adherent tissue (eg, subcutaneous tissue superior-lateral to the zygomatic ligament) where they serve as an anchor so that sagging tissue may be advanced over the lower cones. The bidirectional cones act in concert to keep both the suture and advanced tissue in place, but can only do so if the cones emanating from the center of the suture are pointed in opposite directions so that they may act in direct opposition to one another. Furthermore, in order to maximize the additive capacity of the cones to provide lift to the advanced tissues, each of the cones on each side of the suture (ie, the superior side, which serves as an "anchor," and the inferior side, which serves to support advanced tissue from the point of action to the midpoint of the suture) must lie along a single straight-line vector. Therefore, optimal planning must begin with the assumption that the suture will be placed in a straight line.

Vector Placement

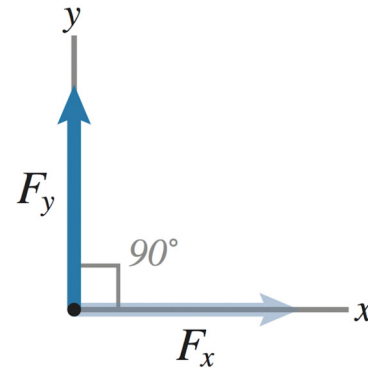
To best counteract aging effects, vectors must be placed perpendicular to the plane they are intended to elevate. This recommendation is based not only on the clinical experience of the authors, but in basic scientific principles as well. While the clinical reasons for exclusively placing the sutures in a straight line are covered above, here the authors present the scientific basis for placing the vectors perpendicular to the plane they are intended to lift.

Both force and the direction of motion may be represented by vectors. By aligning the soft-tissue structure to be elevated with the x-axis, one may calculate the percentage of total force applied by a suture placed at any given angle in both the X and Y direction (by determining values for component vectors F_x and F_y). When placing the suture directly along the y-axis, at a 90° angle to the x-axis, we are eliminating the need for the suture to exert force in any direction other than up through the y-axis, thus maximizing the force and efficiency of the lift (Figure 2A). Mathematically: $F_y = F \sin \theta$, or $1 * (\sin 45^\circ) = 0.71$. Thus, 71% of the total force applied acts in the y-direction, (remember, the y-axis is the desired direction of lift). Therefore, when placing a suture at a 45° angle, the force provided by the suture that is actually lifting the tissue in the right direction is diluted by more than one third (Figure 2B). When placing sutures, it is important to maximize the work done by the device in the desired direction of lift by placing the suture at a 90° angle to the plane to be elevated with the point of action (inferior-most suture exit point), on the x-axis.

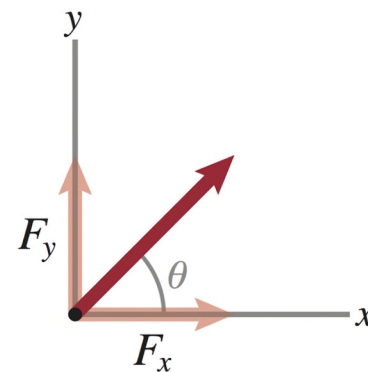
For example, to correct sagging of the nasolabial crease, the suture should be placed perpendicular to this feature (Figure 3A). As discussed above, vectors placed at angles not equal to 90° provide suboptimal support (Figure 3B). This principal also holds true for suture placement in the neck, where the x-axis is routinely overlying the medial border of the platysma muscle and is defined by the medial extent of the neck's redundancy. The suture

FIGURE 2. By examining simple vectors, it is evident how placement of a suture perpendicular to the facial feature it is designed to elevate ensures that the force applied by the suture is unidirectional (A) and not diluted by dividing the percentage of work applied between component vector in both the X and Y direction (B).

(A)



(B)



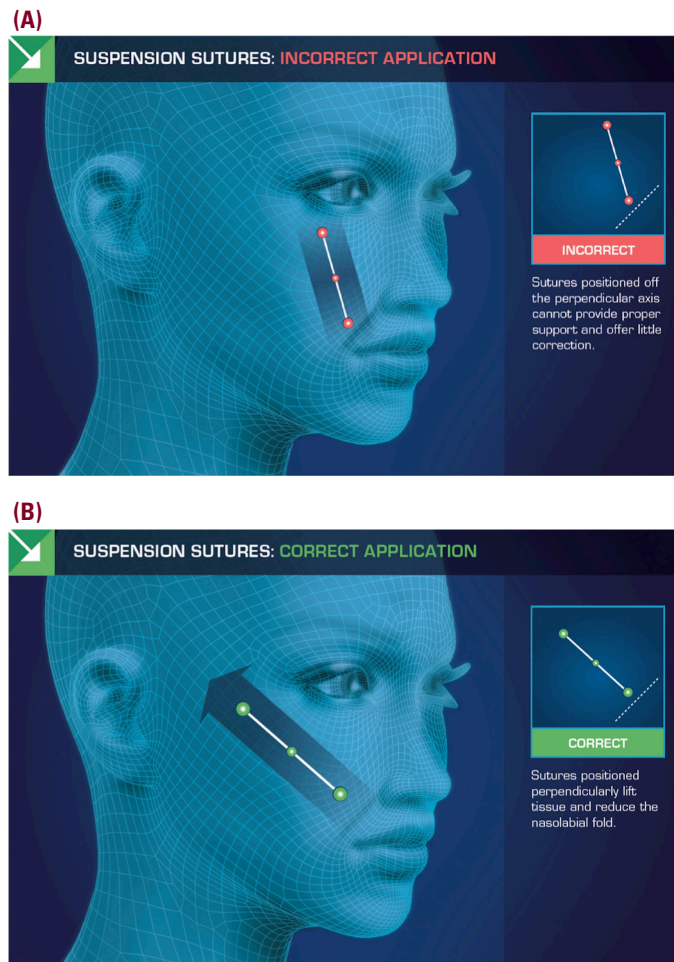
is placed at a 90° angle to this plane, in accordance to the SLVP principles. For the jowl and jawline, identification of the optimal vector of correction is less straightforward. Unlike the nasolabial fold, where the plane of elevation is also the facial feature identified as sagging, the jawline itself should not be viewed as the plane to be elevated. Rather, both the direction of gravitational force and the direction of tissue descent due to volume loss should be taken into account. The x-axis should be placed so that it transects the encircled jowl at an angle perpendicular to the direction of descent (Figure 4). The vector should then be planned with its point of action at the center of this circle and the vector placed at a 90° angle to the x-axis, or plane of elevation.

Suture Placement

Suture placement is a sterile procedure. Treatment areas are prepped and draped in routine sterile fashion. The number of sutures is dictated by the degree and distribution of lift required. One entry site and two exit sites are marked for each suture,¹⁶ according to the vectors chosen, beginning with the inferior exit points (points of action), then measuring along the planned vector line to mark the center entry point and most

FIGURE 3. (A) The correct and most efficient suture placement to correct sagging of the nasolabial crease, on the perpendicular axis. (B) Incorrect and inefficient placement of suture.

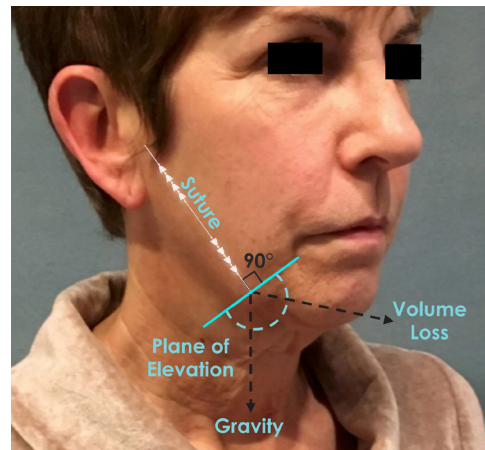
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proximal exit point. While there are three suture sizes (8, 12, and 16 cones; See Table I), in the experience of the authors, the 8-cone suture is sufficient for most applications. 1% Lidocaine with epinephrine (1:100,000 dilution) is injected into the skin and subcutaneous layer at entry and exit sites using a 32-gauge needle (approximately 0.5 cc/ site). Local anesthetic is not required for needle pathways, which traverse the sub-cutaneous plane, and injection into these pathways may cause tissue distortion. The procedure should be painless: if the patient shows any sign that the procedure is painful, the sutures are in the incorrect plane. Importantly, the knots in the InstaLift suture must be tightened before placement: this may be done by applying steady tension to the ends of the suture. This step is critical to ensure the integrity of the device.

Entry-site openings are made by placing an 18-gauge needle into the subcutaneous tissue in a perpendicular fashion past

FIGURE 4. Illustration of the placement of the x-axis, or plane of elevation, for suspension of the jawl. The suture is placed perpendicular to the x-axis, which is determined by considering the impact of both gravity and volume loss on the direction of tissue descent.



the deep aspect of the dermis, into the subcutaneous tissue. Sutures are then placed using the long, 23-gauge, 12cm needle that comes with the InstaLift sutures. This needle is placed into the single-entry point in a perpendicular fashion until it reaches the subcutaneous plane. The 5mm depth mark on the needle may be used as a guide. Once the needle reaches this point, it can be turned to a 90° angle to begin suture placement. The initial direction of the suture from the center point may be inferior or superior, depending on the preference of the surgeon. The needle is then advanced toward and through the previously marked exit site, pulling the cones with their closed sides first, which causes the free-floating cones to cover the intercalated knots. Once the needle is completely through the exit site, it should be immediately amputated from the suture. The same procedure is then performed using the second needle to advance the other side of the suture from the entry site toward and through the second exit point. The authors recommend slightly depressing the tissue just to the side of the entry point where the cones are already in place in order to stabilize them as the other half of the suture is placed. To ensure that the cones have not caught on the dermis and that there is no puckering, each of the suture ends may be gently tensioned. A finger or thumb is then passed over the entry site to ensure that there is no excess suture remaining.

Once the sutures are in place, it is important that the superior cones are engaged and remain aligned: a small amount of tension may be applied to the superior suture, and a thumb or finger gently run over the surface of the suture, without advancing the tissue. To advance the tissue over the inferior cones, place firm tension on the inferior suture and advance the tissue over the cones up to the entrance point. As the tissue is engaged (the patient and surgeon may

TABLE 1.**InstaLift Specifications**

	InstaLift™ 8 Cones SMS 29	InstaLift™ 12 Cones SMS 28	InstaLift™ 16 Cones SMS 30
USP designation	3		
Number of cones	8	12	16
Length	30cm±10%	27.5cm±10%	26.8cm±10%
Direction of the cones	Bidirectional		
Space between cones	5mm	8mm	8mm
Suture material	82% PLLA and 18% PLGA		
Needle	2 needles (23G); of 12cm each		
Depth mark	5mm below the tip of the insertion needle		

feel “clicks” under the skin), there may be some visible gathering in the skin, but this should dissipate within 2-3 days.

After suture placement and tissue advancement, visible sutures are amputated. If a knot or cone appears when the suture is pulled taut, it should be removed as well. A finger may be passed over the exit sites to ensure the suture end is below the surface of the skin.

Additional Considerations for Suture Placement in the Neck

Placement of sutures in the neck is very different from placement in the mid-face, and the resident anatomy is much less forgiving. It is imperative that the physician has a thorough understanding of anatomy, including the platysma and other neck muscles, resident vasculature, as well as the course of the marginal mandibular nerve. Knowledge of fat distribution in the neck is also critical, as this represents the anatomical area in which the sutures are placed. Finally, it is critical that the treating physician be aware of all available treatment options for the neck, as well as the difference between apparent excess tissue caused by excess fat, excess skin laxity, or descent of the skin. Suspension sutures are best suited for patients who require tissue suspension.

Patient Selection for Suture Placement in the Neck

In order to be a good candidate for suspension sutures in the neck, the patient must have redundant skin that is easily displaced by postero-lateral force applied during pretreatment evaluation. Sufficient subcutaneous fat must be present in order for the device not to be visible or palpable post procedure. The limitations imposed in the mid-face by excessively thick or damaged skin also apply in the neck.

Notes on Technique for Suture Placement in the Neck

In addition to the application of SLVP principles and an understanding of the above-described techniques for suture placement,

additional factors are important to achieve optimal outcomes in the neck.

The vectors in the neck are more horizontal than those placed in the mid-face. Even so, they still follow the principals of SLVP. They must be placed in a straight line and at a 90° angle to the medial border of the platysma muscle, defined by the medial extent of the neck's redundancy.

The suture placement is more superficial than in the mid face.

Use of neuromodulators to lessen the mimetic forces in the neck (medial platysma muscle) is routinely performed one week prior to absorbable suspension suture placement.

Post-Procedure Care

Aquaphor may be used on puncture sites. Ice is applied in the office for 30 minutes and patients are encouraged to continue icing the treated area for 24 hours. Patients may wash their face and use makeup after 48 hours, but should avoid exercise, stay on a soft diet, avoid excessive facial motion, and keep their head elevated on two pillows for one week. Patients are seen at follow up after one week.

For patients who have sutures placed in the neck, placement of Steri-Strips or an Ace bandage over the advanced tissue can ensure tissue integration in the correct place and serve to remind the patient to keep their neck relatively immobile and expressions to a minimum.

RESULTS

The lifting effect provided by the sutures, as well as the neo-collagenesis they incite, may last for up to 18-24 months depending on the characteristics of the patient's skin.¹⁶ The authors have been using Silhouette InstaLift for mid-face lifting since its approval in November 2015 and together have treated more than 500 patients. The authors report that there have

been no serious adverse events and that noticeable bruising has occurred in less than 5% of patients. While irregularities and tissue dimpling, secondary to tissue advancement, are not uncommon, they resolve within one week.

Representative results of patients treated with the technique outlined above are presented here.

Patient 1: A 50-year-old female patient shown at baseline, 10 months, and 24 months post-treatment (Figure 5). The patient was treated with 8-cone Silhouette InstaLift™ sutures: two in the mid-face and one in the jowl (SVLP pictured, Panel A). Note the effect on the nasolabial fold and jowl, as well as the revolumization present, due to the biostimulatory effects of the suture. *Courtesy Z. Paul Lorenc, MD, FACS.*

Patient 2: A 60-year-old female patient with jowling around the mandibular boarder and obtuse neck angle (Figure 6). The patient was treated with three 8-cone Silhouette InstaLift™ sutures, 1 in the jowl area and 2 in the neck at the first cervical crease (SVLP pictured, Panel A). Immediately post-procedure (Panel B), a pronounced advancement was apparent with a concomitant elimination of the jowl, along with a delineation of the cervico-mental angle. *Courtesy Z. Paul Lorenc, MD, FACS.*

Patient 3: A 55-year-old female patient shown at baseline, 6 months, and 24 months post-treatment (Figure 7). The patient was treated with six 8-cone Silhouette InstaLift™ sutures: three in the mid-face R/L (SVLP pictured, Panel A). Note the enduring reconntouring in the midface at 24 months. *Courtesy Z. Paul Lorenc, MD, FACS.*

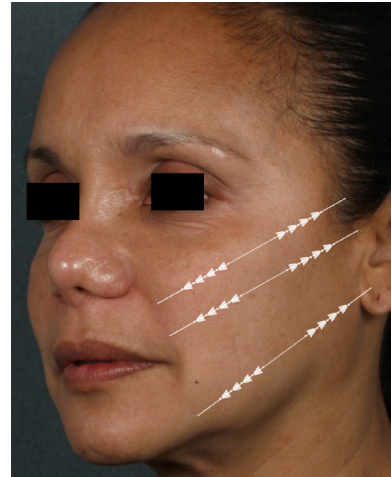
CONCLUSION

Utilization of absorbable suspension sutures provides unique benefits due to its biomechanical and physiochemical composition. In addition to the ability to reposition soft tissue along a two-dimensional axis, the InstaLift suture provides three-dimensional correction due to it's biostimulatory nature. For example, as tissue is advanced along the supero-lateral vector, atrophied and ptotic fat compartments are compressed, alleviating some of the deflation characteristic of the volume loss that accompanies aging.¹⁷ Furthermore, the PLLA/PLGA composition of the suture/cones stimulates fibroblasts, which culminates in the synthesis of Type I collagen, thereby addressing volume loss through yet another avenue.⁹ Even as the sutures themselves dissolve, the fibrotic response continues to bolster the durability of the initial procedure.¹⁷ While the application of Silhouette InstaLift alone is rarely a complete answer to correcting facial aging, it is a powerful tool for use in concert with other approaches such as fillers, neurotoxins, or energy-based devices, or as a secondary approach for patients who have already undergone a surgical facelift.

While the evaluation of Silhouette InstaLift technology and techniques is still at an early stage, the success of the authors

FIGURE 5. A 50-year-old female patient at baseline (A), at 10 months post-treatment (B), and 24 months post-treatment (C). SLVP is shown in (A), with two sutures in the mid-face and one in the jowl area.

(A)



(B)

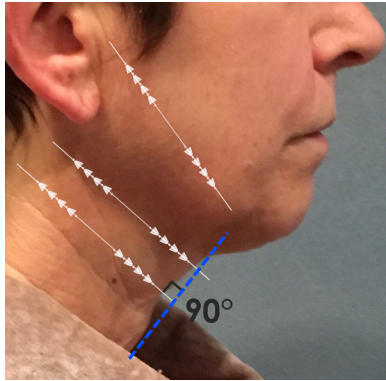


(C)



FIGURE 6. A 60-year-old female patient at (A) baseline and (B) immediately post-treatment. SLVP is shown in Panel (A), with one suture in the mid-face and one in the jowl area. The plane of elevation is shown in Panel (A) (dashed line).

(A)



(B)



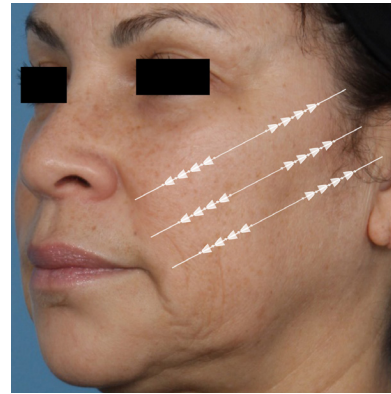
with this technique is supported by the European experience. In Europe, this procedure (marketed as Silhouette Soft [Sinclair Pharma, London, UK]) has been performed on more than 100,000 patients with excellent results and a complication rate of less than 0.2%.¹⁴ As with many new technologies, physicians are often faced with the question of how to best apply this new tool. While investigations surrounding the longevity of results, the occurrence of later complications, and approaches to areas other than the mid-face have yet to be thoroughly explored, the experience of the authors illustrates the advantages of SLVP, as well as the finer points of optimal technique.

DISCUSSION

Absorbable suspension sutures represent a significant improvement in minimally invasive tissue lifting and repositioning technologies. Not only is the InstaLift suture device entirely absorbable but has a biostimulatory effect that leads to revolumization and sustained recontouring. The technique is straightforward with predictable results and minimal recovery time. Coupled with proper patient selection, the application of SLVP ensures that this device is able to perform

FIGURE 7. A 55-year-old female patient at baseline (A), 12 months post-treatment (B) and 24 months post-treatment (C). SLVP is shown in (A).

(A)



(B)



(C)



at its best. Given proper preparation and technique, patient results are excellent.

DISCLOSURES

Dr. Lorenc is a consultant for Johnson & Johnson, Merz, Allergan, Galderma, Sinclair Pharma, CorMedix, ThermiAesthetics, and Almirall Pharma. Dr. Goldberg is a consultant for Sinclair Pharma.

Dr. Nestor is a consultant and advisory board member for and has received research grants from Sinclair Pharma; a consultant, advisory board member and speaker for Thermi-Almirall; is a consultant and advisory board member for Almirall; is a consultant for Bayer Healthcare, Consultant and Speaker for Sensus Healthcare, Speaker and Principal Investigator for IFC, S.A., Principal Investigator and Consultant for CROMA Pharma, Ferndale, Johnson & Johnson, Principal Investigator for Actavis, Allergan, Annacor Pharmaceuticals, Biofrontera, Brickell Biotech, Cynova Laboratories, DUSA Pharmaceuticals, Demira, Evolus, Intraderm, LEO Pharma, MC2 Therapeutics, SASIF & Sonoma. Industry Support: Editorial support provided by X-Medica, LLC.

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