Introduction

In 2015, the United States Food and Drug Administration (FDA) granted 510(k) approval for Silhouette InstaLift™ [Sinclair Pharma; London, UK]. This entirely resorbable 82% poly-L-lactic acid (PLLA) and 18% glycolic polymer (PLGA) suture is comprised of bi-directionally oriented cones (Figure 2) to remodulate the skin’s own collagen to produce a more adherent and firm texture and suspend overlying skin as it is advanced over the cones. In addition to its supportive function, the PLLA within the suture promotes the body’s inflammatory response to provoke collagen remodeling. The data presented here are derived from an initial prospective, masked, controlled pilot study and a 12-month extension study that evaluated facial lifting treatment with Silhouette InstaLift™.

Study Objectives

- Provide proof of concept for the use of Canfield 3D Vectra face and neck surface imaging system [Canfield Scientific, Inc. Fairfield, NJ USA] to quantitate and document qualitative changes.
- Provide short- and long-term data for Silhouette InstaLift™ suture and document the nature, duration, and type of improvement.
- Provide data in support of an FDA-approved label change to the InstaLift™ Instructions for Use that eliminates the required use of a permanent monofilament for fixation of the suspension suture to the fascia.
- Subjects served as their own control.
- 8-cone sutures were used exclusively, and all sutures were placed as straight-line vectors.
- A total of 6 sutures were used in the treatment of each subject.
- Strict post-operative care regimens were adhered to, and specific post-procedure care instructions were provided to subjects.
- Adverse events were reported through subject diaries and at post-procedure visits.

Study Design

This prospective, masked, controlled 8-week study (N=20) and 12-month extension (12-month data from the 18-month extension study) (N=17) measured facial lift and recontouring as well as subjective satisfaction following treatment with Silhouette InstaLift™ in men and female subjects 22 to 75 years of age with moderate facial skin laxity.

Secondary Endpoints

- GAIS scores were reported by both subjects (Figure 4A) and investigators (Figure 4B) at post-treatment weeks 1, 2, 8, 12, and at 12 months.
- The FACE-Q Questionnaire, a validated and sensitive patient-reported outcome instrument, was used to measure both satisfaction with appearance and quality-of-life outcomes at enrollment, post-treatment weeks 1, 2, 8, and 12, and at 12 months (Figures 5, A and B).
- Digital imaging to both quantitate and document qualitative changes was obtained using both the Canfield 3D Vectra M3 face and neck imaging system (Table 1; Figures 2, C and D).

Conclusions

The InstaLift™ suture offers a safe, minimally invasive approach to tissue lifting, repositioning, and recontouring. In addition to the suture’s lifting capacity, the PLLA within the suture has a biostimulatory effect, which may further contribute to the impact of the suture of facial recontouring. Data from this prospective, masked, controlled 8-week study and 12-month extension provide much needed short- and long-term data on the nature and duration of the impact of InstaLift™ suture placement. Though the 8-week lift data certainly support the use of sutures for tissue repositionalizing, 12-month data offer a glimpse of the capacity of InstaLift™ sutures to support "contouring" beyond the window of time in which they provide lift. Importantly, this feature is reflected in ongoing patient satisfaction.

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