Research Article

Dermatology Research

Early Surgical Adverse Events and Incidence Rates in Bidirectional Barb Suspension Thread Surgery

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Received: 21 July 2019; **Accepted:** 28 August 2019

Citation: Kacey HAU. Early Surgical Adverse Events and Incidence Rates in Bidirectional Barb Suspension Thread Surgery. Dermatol Res. 2019; 1(2); 1-3.

ABSTRACT

Background: *There is a constant upsurge in the use of minimal invasive surgery in aesthetic practice globally. Barb thread suspension has been used to reshape and reposition facial contour. However, the safety, incidence of adverse events is not well defined.*

Objectives: *To study the incidence of adverse events in the first four weeks after thread surgery.*

Results: *The incidence of adverse events at week four is 5.5%. Most of them are mild (5%). Significant events include parotid gland tear and surgical site infection. Majority of the patients (86%) and the physicians (89%) give a global score for the recovery issues from none to mild and acceptable.*

Conclusion: *Barb suspension surgery is a safe office-based procedure. Among different variables, standardized surgical protocol, sterile handling and hands-on training may help to secure the safety.*

Keywords

Barb suspension surgery, Double needle thread, Incidence, Adverse events, Complications.

Introduction

Among the surgical arena for reshaping and redraping the contour of our ageing face, currently one may resort to suture thread materials or other energy-based devices or formal face-lifting surgery. There is a constant upsurge in the application of thread suspension surgery globally. Sterilization and synthetic polymers that degrade in a commensurate fashion with wound healing have been the most significant improvements in these age-old suture devices in surgical practice. The evolution of barbed suture technologies and their application in the field of plastic surgery is now in its third decade [1].

Face-lifting is the 4th commonest surgical procedure globally [2]. Barb suspension thread can be an alternative option to formal surgery as thread surgery is minimal invasive, office-based procedure, bearing lower risks and less down time. Successful thread use started in 50s and later with the introduction of permanent thread system by Sulamanidze in late 90s [3].

Designs developed primarily for use in aesthetic facial procedures include free-floating, bidirectionally barbed sutures; unidirectional barbed sutures; anchored, bidirectional double- threaded sutures. In summary, the major thread system in the market are barb and smooth suture materials. In the barb suture, it can be either unidirectional and bidirectional barb system. Theoretically, bidirectional barb thread system can give better mechanical advantage by positioning more barb in the suspension and the antagonistic traction between the barbs in two opposite directions [4].

In addition to the mechanical traction created by barb suture, the tissue-suture interaction or biostimulation may play a role in aesthetic outcome. The long-term results once after the resolution of the physical thread materials also relies on the effective biostimulation. There is an upsurge of thread materials in aesthetic arena and the use are increasingly common. The composition, design and the clinical applications dictate the product and as a result the treatment outcome specificities. With more understanding

on the facial anatomy and the tissue interaction with the physical composition we can define the treatment outcome by the physical traction and biostimulation effects [5].

Barb suspension surgery is getting popular as a supplementary choice for facial contouring and reshaping. Compared with formal face lifting, barb suspension provides a safer, minimally invasive and office-based surgical procedure. With the downward trend in the numbers of formal face-lifting surgery globally, barb suspension thread surgery can be a useful adjunct and serves the purpose of minimally-invasive surgery [6,7].

However, barb suspension procedure does have certain risks due to the invasive nature. Further, the foreign materials that retaining inside underneath the skin might create further tissue interactions like granuloma or foreign body reaction. Likewise, in other medical procedures involving the placement of foreign materials, there are risks of infection, and sometimes can be delayed in onset. There are reports in the literature about different adverse events related to the thread surgery but the incidence of the procedure is not well defined [6,8-10].

Adverse surgical events in aesthetic practice can be delayed recovery (significant downtime such as bruises or pain), unsatisfactory aesthetic outcomes or complications like infection or tissue organ injury such as parotid gland injury [11,12].

Objectives

We would like to evaluate the incidence of adverse events after thread suspension procedure. Through this retrospective analysis, we would like to standardize and define the possible adverse events to facilitate future reporting and prevention strategies.

Methodology

Materials

We use Happy Lift™ (Revitalizing) Double Needle threads (or in Europe and some other countries known as Definisse™ threads). This is a range of absorbable, monofilament, suspension-barbed threads of synthetic origin (poly-L-lactic acid and caprolactone, p(LA-CL). The thread ends have two straight sharp needles 100 mm long with a diameter of 0.462-0.488 mm for the thread with the 12 cm barbed section. The thread with the 23 cm barbed section has two 150 mm long needle with the same diameter. The barbs distribution is bidirectional and convergent. The sutures interact with the tissues with a double action.

The first one is the immediate lifting action for the support and repositioning of the tissues, thanks to the mechanical action determined by the anchoring of threads barbs once inserted in the tissue. The second is the revitalizing action, due the fibrosis and slight inflammation that is determined along the thread.

Procedure

The field of procedure involves midface, lower face and neck areas. The procedure is performed under local anaesthesia with adrenaline using standard aseptic technique in all cases. Depending on the vector for reshaping, the surgical procedures are standardized into five categories [13] for different approaches of facial reshaping as follows:

Techniques with lateral vectors (percentage of cases):

- Jawline Reshaping (JR) that corrects the defects of jawline due to inferior jowl fat ptosis (18%);
- Malar Reshaping (MR) that lifts laterally the malar fat pad (37%);
- Lateral Reshaping (LR) that lifts laterally the midface and lower face fat compartment combining the actions of previous techniques (13%).

Techniques with vertical vectors:

- Oval Reshaping - Vertical Reshaping (ORV) that lifts vertically the central and medial fat compartments of cheek (18%);
- Oval Vertical Reshaping-H (ORH) that lifts vertically the central and medial fat compartments of cheek (14%).

All the techniques include an entry point, two exit points, sometimes an intermediate point and the thread sutures lie in the sub-SMAS plane under the preoperatively designed reshaping lines that indicate the direction of thread insertion.

Post-operative care

All patients were discharged with standard dressing materials including chlorhexidine, fusidic acid or equivalent ointment and paracetomol after the procedure. The patients were followed up one week, two weeks and four weeks after surgery. All the recorded adverse events are defined in Table One.

Documentation and data collection

The adverse events are stratified according to defined categories using Microsoft Excel®. Photos were taken for documentation after patients' consent.

Adverse outcome	Definition
Headache	Sudden onset of headache after the procedure with unprecedented history
Redness	Persistence of erythema after 24 hours
Swelling and bruising	Persistence of swelling and bruising after one week
Persistent surgical site pain	Pain related to the barb thread location and/or pain aggravated by facial movement in the thread path like smiling, mastication and talking
Surgical site infection	Appearance of infection in the related surgical site (puncture and/or thread path) in first 28 days
Asymmetry	Asymmetry which is aesthetically unpleasant
Palpability/visibility of threads	Easy recognizable of underlying thread visually from social distance or on simple palpation like washing face
Early recurrence	Reappearance of original facial laxity by 28 days
Protrusion and extrusion	a. Appearance of the thread outside or b. tenting of the thread end
Injury of the local anatomical parts	Examples like parotid gland, vessels and nerves with related sign and symptoms

Post-inflammatory hyperpigmentation	Appearance of pigmentation along the path or near the path when edema resolves
Bunching, pleating and dimpling	a. unnatural folding of the skin due to traction or mobilization of tissue by the thread; b. depression related to the puncture site
Transient motor paralysis of facial muscles	Partial weakness of facial muscles due to infiltration of anaesthetic solution
Others	Alopecia, granuloma, allergic reaction, hematoma, life threatening conditions

Table 1: Definition of all adverse events.

Results

Demographics

This is a single center retrospective cohort study on the surgical outcomes. A collection of 200 pairs of thread (patient number n=200) used in the period of 2017-2019 (two years). These are all ethnic Hong Kong Chinese. Age range from 20 to 76 (mean 44.2). Male subjects accounts for 27%.

The thread materials are either 12cm (used in 76% of cases) or 23cm in length. The surgery was either performed by the trainer or the author (KC HAU, n=136, 68%) or by trainees attending the hands-on workshops under author's onsite supervision.

The incidence of adverse events is subsectored into 1. Mild (either improves with time, or manageable by simple, conservative and non-surgical intervention) and 2. Significant (needs active, aggressive or surgical intervention, one case of surgical site infection and one case of parotid gland injury). At Week 4, the incidence rate of adverse events is 5.5% (5.0% mild, 0.5% significant).

Some of the adverse events are shown in the pictures below:
Protrusion (week 2)

Extrusion (week 2)

Bruise and traction (2 days)

Transient muscle paralysis right after surgery (1 hour and last 2-3 hours with complete resolution)

Dimpling (1 hour) and resolution (week 2)

The reported adverse events in week one, week two and week four are summarized in table two.

Adverse outcome	Week1	Week2	Week3	Remarks
Headache	2	0	0	
Redness	16	6	0	
Swelling and bruising	26	12	0	
Persistent surgical site pain	10	6	0	
Surgical site infection*	0	0	1	Onset of purulent discharge from entry point at day 22, culture showed Staph. Aureus; completely resolved by drainage & 2 weeks of antibiotic. No extraction needed
Asymmetry	6	1	0	
Palpability/ visibility of threads	6	3	0	
Early recurrence	0	0	0	
Protrusion and extrusion	2	12	5	
Injury of the local anatomical parts*	1	0	0	parotid gland tear presented on day one, completely resolved by day seven with conservative treatment.
Post-inflammatory hyperpigmentation	0	8	0	
Bunching, pleating and dimpling	32	18	5	
Transient motor paralysis of facial muscles	6	0	0	
Others (Alopecia, granuloma, allergic reaction, hematoma, life threatening conditions)	0	0	0	
Total:	109	68	11	

Table 2: Number of cases in each adverse event.

Finally, both physician and the subject gave a global score on the impact, severity and challenges in management related to the recovery from the thread surgery at week four (Figure 2).

Category	Client Global Score, % of subject choice	Physician Global Score, % of cases
None	6	11
Mild and acceptable	80	78
Significant but resolvable	13	10
Significant and unacceptable	1	1
Permanent disfigurement or disability	0	0

Table 3: Global score by clients and physician at week four.

Discussion

Office-based procedures have risen substantially every year. According to the American Society for Aesthetic Plastic Surgery (ASAPS), there was over approximately 5% increment each year. The art of aesthetic procedures, as well as from the expectations of the clienteles in this category require not only good aesthetic outcome, but also a tidy, swift and uneventful recovery. Overall, across all facilities, 1.9% of patients developed one major complications (2016). A 6-year retrospective review by Byrd et al demonstrated a complication rate of 0.73% [14], compared with 1.9% in another study by Gupta et al. [9]. Among these vascular complication like haematoma and infections were the major complication risks. In another study focusing on lasers, energy devices, and injectables neurotoxins and fillers, a complication rate of 0.24% is noted [8].

In thread surgery, the previous published results are more heterogenous. In this study we are able to demonstrate the post-operative progress of thread surgery. With the complication rate of 0.5% per patient or 0.25% per thread use, the rate of adverse events of thread suspension is close to that from other injectable procedures. There are several factors that we believe may contribute to control the rate of adverse events. All doctors performing the surgery are properly trained in terms of relevant clinical anatomy and the surgical skills. Thus, operator factor is brought to a minimum. Throughout the entire procedure, strict asepsis and field sterilization is emphasized.

The surgeon places the thread using 5 standard approaches (see procedure). In this way the aesthetic outcomes are more predictable. Surgeons can have better surgical handling in the field by improvising the surgery of each individual based on the standard techniques. Apart from home care counseling, routine structured follow-ups are helpful as well (one week, two weeks and four weeks after the surgery). We believe this will facilitate reporting of any issues related to the recovery and early intervention if necessary.

Conclusion

Barb suspension thread surgery is a generally safe procedure compared with most other aesthetic procedures. Patient factor,

operator factor, material and surgical field can contribute to the incidence of adverse outcomes. With careful selection of candidates, well-planned procedure and respect to the sterility of surgical field and individual anatomical structures, majority of the incidents are avoidable. Clear post-operative care instruction and prompt intervention should issues arise are essential.

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