

## Frontalis Suspension Using Autogenous Fascia Lata versus Gore-tex Sheet for Treatment of Congenital Ptosis with Poor Levator Function

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### Abstract:

**Objective:** To compare the results of frontalis suspension using autogenous fascia lata versus Gore-tex sheet for treatment of moderate to severe congenital ptosis with poor levator function.

**Design:** Prospective randomized controlled study

**Participants:** Sixty eyelids of 47 patients, who attended health service in Menoufia University Hospitals.

**Methods:** patients were divided into two groups. In group I (30 eyelids), upper eyelid tarsus was suspended to frontalis muscle using autogenous fascia lata. In group II (30 eyelids), upper eyelid tarsus was suspended to frontalis muscle using a ribbon of 0.3 mm Gore-tex sheet. Follow up of eyelid level and reporting postoperative complications and incidence of recurrence were done.

**Results:** At 24 months postoperative (end of follow up period), there was no statistically significant difference between both groups regarding eyelid level. Three eyelids in group I, and 4 eyelids in group II had under-correction. Gore-tex related complications were detected in 6 eyelids of group II. Donor site complications were detected in 3 cases of group I. There was no significant difference regarding the complications between both groups. The recurrence rate was 10% (3 of 30 eyelids) for group I, and 16.7% (5 of 30 eyelids) for group II. The difference in recurrence rates was statistically insignificant.

**Conclusion:** We conclude that use of Gore-tex sheet in frontalis suspension surgery is comparable to use of autogenous fascia lata with advantage of avoiding donor site complications.

**Keywords:** Ptosis; Frontalis suspension; Gore-tex; Fascia lata

### Introduction

Frontalis sling operation is the classic procedure used for treatment of upper eyelid ptosis with poor levator function [1]. The purpose of the procedure is to use a sling material to connect the upper eyelid tarsus to the frontalis muscle. The patient then employs the frontalis muscle to open the eyelid [2].

Because of its long-lasting effect and few complications, the fascia lata has been established as the gold standard sling material for this procedure [3]. However, several sling materials and several modifications of the surgical techniques have been used to improve the outcomes and to avoid the drawbacks of fascia lata use. Expanded polytetrafluoroethylene (Gore-tex) is one of these sling materials which proved good efficacy relative to the fascia lata [4].

The aim of this study is to compare the results of using fascia lata versus Gore-tex as a frontalis sling material fixed directly to the tarsus after exposure through an open technique.

### Patients and Methods

This is a prospective randomized study conducted on 60 eyelids of 47 patients who attended the health service in Menoufia University Hospitals in Shebin El Kom and during the period from August 2010 to April 2012.

Patients included in the study had moderate to severe ptosis with poor levator function (less than 5 mm excursion on looking up from down gaze). Exclusion criteria included patients with mild to moderate ptosis with fair to good levator function, patients with recurrent ptosis and or previous upper eyelid surgery. As well, we excluded patients less than 3 years old as it is difficult to harvest suitable length of fascia lata from their thighs.

Patients were randomly enrolled in two groups. Group I included 30 eyelids of 23 patients which underwent frontalis suspension using autogenous fascia lata. Group II included 30 eyelids of 24 patients who underwent frontalis suspension using Gore-tex sheet. Patients younger than 3 years old were excluded from the study.

A comprehensive ophthalmic examination, including best-corrected visual acuity testing, slit-lamp examination, fundus examination, and examination of ocular motility, was carried out for all patients. Margin reflex distance I (MRD I) and levator muscle

function were documented. As well, corneal sensations, manifestations of dry eye and presence or absence of Bell's phenomenon were checked. A written informed consent was taken from all patients after explanation of the procedure and its consequences. The research was approved by the institutional review board and all measures were in accordance with the tenets of the Declaration of Helsinki. All operations were performed by a single oculoplastic surgeon.

Follow-up examinations were performed in all patients to assess eyelid position and symmetry and any postoperative complications. Recurrence of ptosis was defined by a decrease of MRD I by 1 mm or more than the immediate stable postoperative level.

### Surgical technique

As for group I, surgery was performed under general anesthesia in all patients including adults due to retrieval of fascia lata. The upper eyelid was infiltrated with 2% lidocaine with 1:100,000 epinephrine.

Autogenous fascia-lata strip of about 13 cm long and 3 mm wide was passed in a closed cerclage-type fashion through skin entry by way of two supra-lash and three supra-brow incisions forming a single loop design (Figure 1a). Two stab incision sites that were approximately 10 mm apart were marked 3 mm above the lash line that was centered over the area of desired maximal elevation. Another two stab incision sites were marked above the eyebrow, approximately in line with the lateral and medial canthi; additional stab incision sites were made above the eyebrow in the middle of the previous incisions.

The fascia lata strip was threaded, using Wright needle, in a sub-orbicularis plane between the five stab wounds forming a pentagon (Fox method) [5]. The two ends of the fascia strip were retrieved from the middle supra-brow incision (Figure 1b), tied together and fixed to underlying frontalis muscle using 5/0 Vicryl stitches after adjustment of the upper eyelid level. The incision sites were closed with 6/0 Vicryl suture.

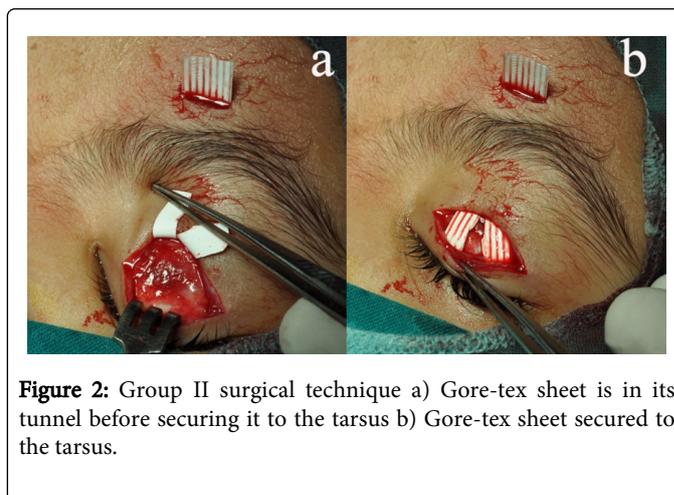


**Figure 1:** Group I surgical technique a) marking incisions for fascia lata sling b) fascia lata strip is retrieved from the middle supra-brow incision.

As for group II, surgery was performed under general anesthesia in all children and adolescent patients and under local monitored anesthesia care in all adults. The upper eyelid was infiltrated with 2% lidocaine with 1:100,000 epinephrine.

Crease incision was marked and made followed by dissection of orbicularis muscle to expose the tarsus. Single supra-brow incision was

made centered between medial and lateral limbus. A ribbon of 25 mm X 6 mm was cut from the Gore-tex sheet 0.3 mm thick (Preclude MVP Dura substitute, W.L. Gore & Associate, Inc., Arizona, USA). The ribbon was cut at one end along its long axis for 15 mm forming inverted Y configuration. Dissection was performed through the orbicularis muscle to expose the tarsus. The two limbs of the split end of the Gore-tex ribbon were anchored directly onto the tarsus with four 6/0 Vicryl sutures. The other end was passed from the crease incision to the suprabrow through a deep, pre-tarsal passage (Figure 2). The Gore-tex ribbon was then tied carefully to underlying frontalis muscle using 5/0 Vicryl stitches, and adjusted to achieve the desired eyelid elevation and contour. The skin incision sites were closed with 6/0 silk sutures.



**Figure 2:** Group II surgical technique a) Gore-tex sheet is in its tunnel before securing it to the tarsus b) Gore-tex sheet secured to the tarsus.

### Statistical analysis

Statistical analysis was performed using SPSS version 16 (IBM corporation, Somers, NY) software. Paired t test was used to detect the difference between pre and post-operative data in the study groups, and the independent samples test was used to calculate the difference between both groups in numerical variables. Fischer exact, and Pearson chi square tests were used to calculate the difference between groups in categorical variables.

### Results

In group I the mean age was  $9.96 \pm 4.9$  years (range 4-20 years), 12 cases (52.2%) were males, and 11 cases (47.8%) were females. In group II the mean age was  $8.71 \pm 4.7$  years (range 4-19 years), 14 cases (58.3%) were males, and 10 cases (41.7%) were females.

Comparing preoperative data in both groups, there was no statistical difference regarding age ( $P=0.317$ ), sex ( $P=0.896$ ), degree of levator excursion ( $P=0.419$ ), and the preoperative MRD I ( $P=0.443$ ) as shown in Table 1. There was statistically highly significant difference between both groups regarding the operative time as shown in Table 1.

Variant	Group I	Group II	P value
Age (years)	$9.96 \pm 4.9$	$8.71 \pm 4.7$	0.317 <sup>a</sup>
Gender (male/female)	12/11	14/10	0.896 <sup>b</sup>
Levator excursion (mm)	$1.4 \pm 1.0$	$1.6 \pm 0.9$	0.419 <sup>a</sup>
Preoperative MRD I (mm)	$0.72 \pm 0.6$	$0.85 \pm 0.7$	0.443 <sup>a</sup>

Operative time (min.)		61 ± 6.97	31 ± 3.77	0.001 <sup>a</sup>
Postoperative MRD I (mm)	at 1 month	3.33 ± 1.0	3.43 ± 0.9	0.685 <sup>a</sup>
	at 12 months	2.60 ± 1.2	2.77 ± 1.1	0.656 <sup>a</sup>
	At 24 months	2.57 ± 0.9	2.58 ± 0.9	0.540 <sup>a</sup>

<sup>a</sup>Independent samples test, <sup>b</sup>Pearson chi square test

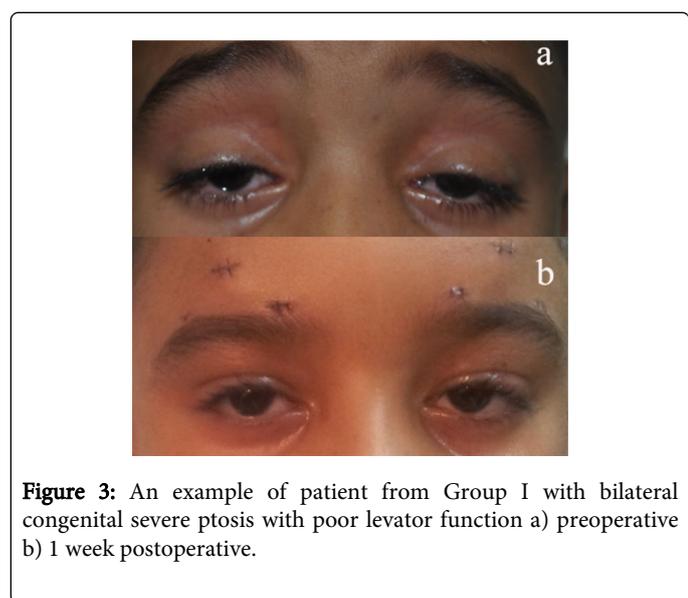
**Table 1:** Descriptive and clinical preoperative, operative and postoperative data of both groups.

One month postoperative, mean MRD I was 3.33 ± 1.0 mm in group I, and 3.43 ± 0.9 mm in group II, with no statistically significant difference between both groups (P=0.685). At 12 months postoperatively, mean MRD I was 2.60 ± 1.2 mm in group I, and 2.87 ± 1.1 mm in group II, with no statistically significant difference between both groups (P=0.656). At 24 months postoperatively, (end of follow up period) mean MRD I was 2.57 ± 0.9 mm in group I, and 2.58 ± 0.9 mm in group II, with no statistically significant difference between both groups (P=0.540). These data are illustrated in Table 1. However, there was statistically significant difference between pre and postoperative MRD I values in each group (p=0.001) as shown in Table 2. Examples of patients from group I are shown in Figure 3 and 4 and patient from group II in Figure 5.

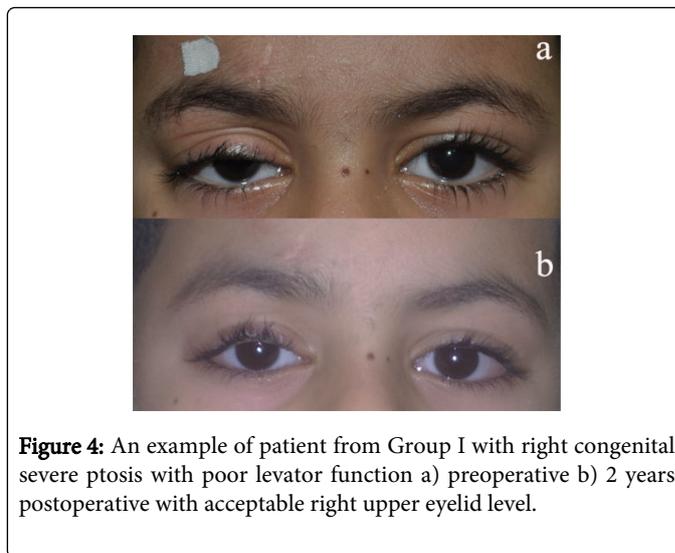
Variant		Preoperative	At 12 months postoperative	At 24 months postoperative	P value
MRD I	Group I	0.72 ± 0.6	2.60 ± 1.2	2.57±0.9	0.001 <sup>a</sup>
	Group II	0.85 ± 0.7	2.87 ± 1.1	2.58±0.9	0.001 <sup>a</sup>

<sup>a</sup>Paired t test

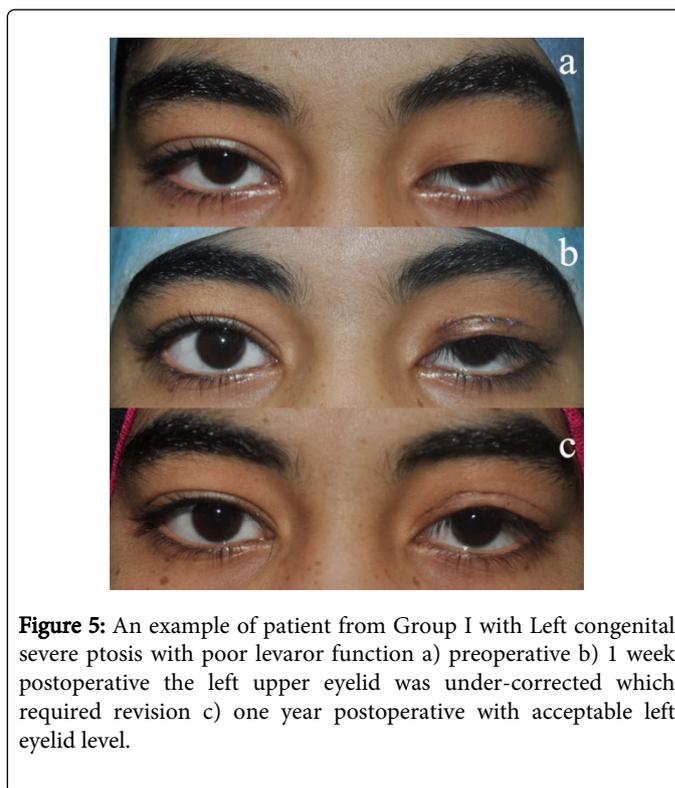
**Table 2:** Preoperative and 12 months and 24 months postoperative MRD I of both groups.



**Figure 3:** An example of patient from Group I with bilateral congenital severe ptosis with poor levator function a) preoperative b) 1 week postoperative.



**Figure 4:** An example of patient from Group I with right congenital severe ptosis with poor levator function a) preoperative b) 2 years postoperative with acceptable right upper eyelid level.

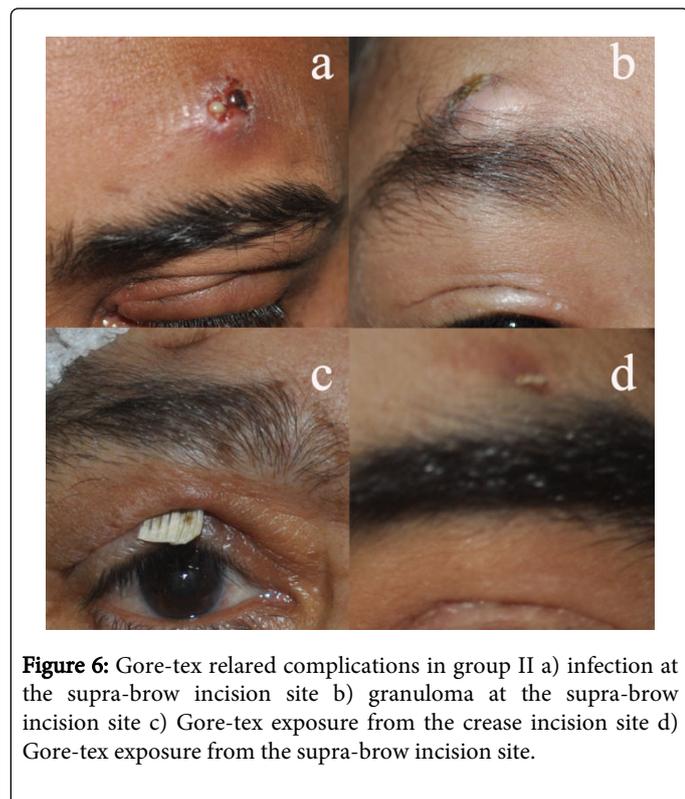


**Figure 5:** An example of patient from Group I with Left congenital severe ptosis with poor levator function a) preoperative b) 1 week postoperative the left upper eyelid was under-corrected which required revision c) one year postoperative with acceptable left eyelid level.

Regarding complications, 3 eyelids (10%) in group I, had under-correction which required revision in the first postoperative week in the 3 eyelids. In group II 4 eyelids (13.3%) had under-correction, 2 of them were revised in the first postoperative week (in which the attachment of the Gore-tex to underlying frontalis was loosened as patient in Figure 5 and the other 2 eyelids (belonged to one patient) were cosmetically acceptable and required no interference.

One eyelid had overcorrection in group I (3.3%) which was conservatively followed up till improved spontaneously after 3 months. No overcorrection was detected in group II. Gore-tex related complications were detected in 6 eyelids of group II (two of them had granuloma at the suprabrow incision that was surgically excised and four eyelids had Gore-tex exposure and was managed surgically as

well). Infection occurred in one eyelid in group II (3.3%) in the form of an abscess formation at the supra-brow incision site and no infection occurred in group I. complications of group II are shown in Figure 6. Donor site complications in group I were in the form of ugly thigh scar in 2 cases and herniation of the vastus lateralis muscle in one case (Figure 7). There was no significant difference regarding the complications between both groups as shown in Table 3.

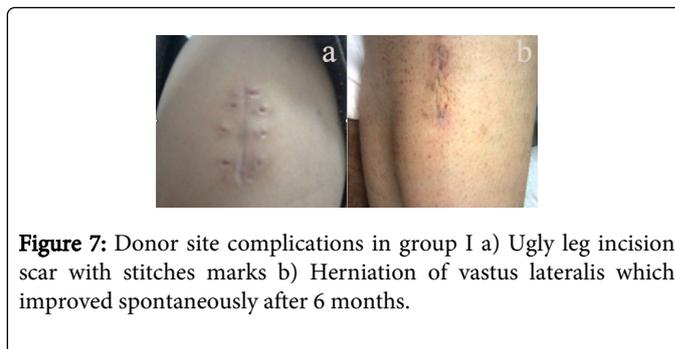


**Figure 6:** Gore-tex related complications in group II a) infection at the supra-brow incision site b) granuloma at the supra-brow incision site c) Gore-tex exposure from the crease incision site d) Gore-tex exposure from the supra-brow incision site.

Variant		Group I	Group II	P value
Complications	Under-correction	3 (10 %)	4 (13.3 %)	1 <sup>a</sup>
	Over-correction	1 (3.3 %)	0 (0 %)	1 <sup>a</sup>
	Granuloma	0 (0 %)	2 (6.7 %)	0.492 <sup>a</sup>
	Infection	0(0 %)	1 (3.3 %)	1 <sup>a</sup>
	Gortex exposure	0 (0 %)	4 (13.3 %)	----
	Donor site complications	3 (13 %)	0 (0 %)	----
Recurrence rate		3 (10%)	5 (16.7 %)	0.706 <sup>a</sup>
Fischer exact test <sup>a</sup>				

**Table 3:** Postoperative complications, recurrence rate, and reoperation rate of both groups.

The recurrence rate was 10% (3 of 30 eyelids) in group I, and 16.7% (5 of 30 eyelids) in group II and the difference between both groups was statistically insignificant (p=0.706) as shown in Table 3.



**Figure 7:** Donor site complications in group I a) Ugly leg incision scar with stitches marks b) Herniation of vastus lateralis which improved spontaneously after 6 months.

### Discussion

Frontalis suspension using autogenous fascia lata is still thought to be the gold standard for congenital ptosis repair. When a piece of free fascia is transplanted in the same animal, the fascia receives an adequate supply of lymph, which allows continuous survival of the graft [6]. Thus, autogenous fascia lata is considered to be a living graft, which can provide long-lasting adequate elevation of the upper eyelid. As well, the fascia lata sling has a low risk of complications such as infection, granuloma formation, extrusion, and breakage [7].

However, difficulty in harvesting sufficient amount of the fascia in children younger than 3 years, and the risk of donor morbidity represent significant drawbacks [8]. As well, histopathologic findings showed that the fascia lata had scarring a very long time after surgery leading to cicatricial contracture of the upper eyelid, which cannot be easily repaired [9].

To improve the outcomes, several new sling materials and several modifications of the surgical techniques have been used. Two comparative studies have shown that a fascia lata sling is more efficacious than a sling made of other materials, except for that made of expanded polytetrafluoroethylene (Gore-tex) [7,10]. Ben Simon and associates reported that Gore-tex strip surgery had the lowest percentage of ptosis recurrence (15%) as compared with fascia lata (22%), Nylon (25%), and Silicone (44%), although these differences were not statistically significant [10].

The current study was designed to compare the results of use of autogenous fascia lata versus Gore-tex sheet for frontalis suspension in moderate to severe congenital ptosis with poor levator function over 24 months follow up period. There was no significant difference regarding age, sex, MRD I and degree of levator excursion nullifying the effect of these factors on surgical outcome in both groups.

Gore-tex is a synthetic microporous polymer, comprised of nodules interconnected by multidirectional minute fibers [11]. It is one of the most biologically and chemically inert, biocompatible and autoclavable materials [11-14]. However, Gore-tex has high risk of soft tissue complications, possibly caused by its highly porous nature, which allows for proliferation of bacterial contaminants and abscess formation [7].

Although Gore-tex has many micropores, these pores are too small to allow tissue ingrowth [11]. In addition, its hydrophobic character also prevents tissue integration [11]. Therefore, the removal of Gore-tex and length adjustment are easy because only the fibrovascular tissue surrounds Gore-tex [11,15]. The incomplete integration is strong enough to maintain the sufficient upper eyelid elevation even after the removal of the material [16].

We adopted the open technique for fixation of Gore-tex sheet directly to the tarsus in the current study. This was proved to yield better functional and cosmetic results than supralash stab incision (closed-type method) in frontalis sling operations [17,18]. Passing the sling material behind the orbital septum by direct visualization, in the eyelid crease approach, is one of the main factors affecting the success of frontalis sling procedures [19].

Using Gore-tex sheet as in the current study was proved to be associated with lower postoperative complication rate than other designs of Gore-tex (strips and sutures) [10,12,16,20]. This was attributed to the tied knots at the ends of the strip or suture which had to be buried under the skin. The tied knots of the strip were most likely large, leading to direct contact of the Gore-tex with the skin wound, which could lead to inflammation and infection, granuloma formation, or a combination thereof. These changes may be the main cause for the higher complication rate seen with the Gore-tex strips [20].

In the current study, postoperative MRD I at follow up visits was significantly larger than the preoperative level in each group independently. This clarifies that both surgeries were efficient in elevating the upper eyelid significantly from preoperative level. Comparing MRD I between both groups in the follow up visits demonstrated that there was no statistically significant difference between both groups at 12 months and at the end of the follow up period.

There was statistically significant difference between both groups regarding the operative time. Longer operative time was reported in group I because of the time consumed in harvesting fascia lata from the donor site. Postoperatively, it was quite easy to revise the eyelid position in group II by manipulating the Gore-tex sheet which was clearly identified and re-secured to underlying frontalis posing an advantage to the Gore-tex use in group II [21].

There was no statistically significant difference between both groups regarding the complications over the follow up period. However, there was more cases complicated by under-correction in group II (4 cases), than in group I (3 cases). This may be explained by the mode of retrieval of Gore-tex sheet which was passed through a tunnel connecting the tarsus to frontalis muscle directly allowing easy slipping of the sheet under the effect of postoperative edema. Therefore, Gore-tex sheet had to be secured effectively to the underlying frontalis muscle. Gore-tex related complications in group II included 2 eyelids (6.7%) with granuloma formation and four eyelids (13.3%) with Gore-tex exposure and one eyelid (3.3%) with infection.

In the current study, the recurrence rate was 10% (3 eyelids) in fascia lata group and 16.7% (5 eyelids) in Gore-tex sheet group. There was no statistically significant difference between both groups in this regard as well. However, recurrence was lower in fascia lata group.

Hayashi et al. used the same technique for frontalis suspension with Gore-tex sheet as in group II in the current study, and found no recurrence [20]. However, they reported the occurrence of other complications in 3 of 42 (7%) eyelids with a mean follow-up period of 33 months. Infections occurred in 2 (5%) eyelids, and an under-correction of the ptosis was seen in 1 (2%) eyelid [20].

In another work done by Nakaochi et al. who used the same technique for Gore-tex suspension; partial recurrence was found in 37% of cases where most of them were children. There was no need for

redo surgery in any of these cases in one year follow up period of the study [22]. As well, they had one case of exposure of the Gore-Tex sheet in a 71-year-old man who experienced more bleeding than the other patients, and wound recovery was slow [22].

The recurrent ptosis rates of autogenous fascia lata have been reported to be as low as 4%, and the complication rate of fascia lata can be as low as 8% [7]. Postoperative shrinkage of grafted fascia lata was reported to be 15.5%, with a range of 8.8% to 25.6% after 6 months [23]. In the current study, we had a recurrence rate of 10% in fascia lata group but no postoperative shrinkage was noted. This may be due to the relatively short term follow up period.

We conclude that the use of Gore-tex in frontalis suspension is comparable to the use of autogenous fascia lata with the advantage of shorter operative time and avoiding the need for a second surgical site with its potential morbidity. However, the follow up period is relatively short and more time is needed for longer term assessment of the procedure.

### Acknowledgement:

No competing financial interests exist.

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