Natural and synthetic materials for frontalis suspension in severe congenital ptosis (Comparative study)

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Short title: Different materials in management of severe congenital ptosis

Abstract:

Purpose: To compare a variety of materials that were used in frontalis suspension surgery for correction of severe congenital ptosis. Treating severe congenital ptosis can be challenging and a proper preoperative evaluation may help prevent unexpected outcomes.

Patients and method: This study included 60 patients suffering from severe congenital ptosis, patients will be randomizelly allocated in two equal interventional groups: First group (38 eye included) underwent FS ptosis surgery using Fascia lata and the second group (70 eye included) underwent FS ptosis surgery using synthetic material

Results: at the end of the follow-up period (6 months postoperatively), most of the patients in both groups (89.5% of group A, 75.7% of group B) achieved good to excellent cosmetic results.

Conclusion: considering the use of the Facia lata sling material and Synthetic material, Using Crawford technique were both safe and effective with comparable results in the correction of severe ptosis with poor levator Function.

Keyword: Congenital Ptosis, Facia lata, Synthetic material, Frontalis suspension, Crowford.

Introduction

Blepharoptosis (ptosis) could be described as the inferior displacement of Upper eye lid (UEL) when the case looking for the primary position. Besides esthetic appearance, cases with blepharoptosis complain from troubles with regard to visual the quality. Some are interfered with the lost superior field, whereas others might suffer from the difficult reading owing to reduction in light amount reaching the macula and the increase in drooping of UELs throughout downgaze. In pediatric population, blepharoptosis is of great concerns as it could be associated with amblyopia. Abrupt diagnoses followed by appropriate assessment have been demonstrated to be main essential factors aiding treatment of such condition that could enhance the QoL of the affected subjects. In general, it is categorized into classes according to the fundamental pathogenesis: aponeurotic, myogenic, neurogenic, mechanical, and traumatic. Within these classifications, there are further subdivisions to aid diagnosis and management according to whether the blepharoptosis is congenital or acquired, on one side or on both sides, isolated or as a part of a syndrome, or symptomatically driven by aesthetic or functional deficits[1-3].

Frontalis suspension (FS) is the surgical approach occasionally utilized for management of extensive blepharoptosis with poor or absent levator functions. Poor levator function has been broadly defined as levator muscle functions of 2mm or less and no more than 6mm in different papers. It could create a link among the frontalis muscle and the tarsus of the UEL which permitted for a better UEL position in primary gaze[4-5].

FS is often utilized in the context of congenital

blepharoptosis treatment on the other hand, it is could in addition utilized to manage blephrophimosis syndrome, congenital fibrosis syndrome, 3Rd CN palsy as well as double elevator palsy. Treatment is of great importance when the UEL blocks the visual axis with a subsequent development of amblyopia, or in cases when an anomalous head posture is evident[6-7].

Complication of forntalis sling comprises recurrent blepharoptosis, postoperative infection, and granuloma formation. Esthetic concerns are raised with standard forntalis sling surgery include scarring in young children[8], unsatisfactory tenting of the pretarsal and preseptal skin, obliteration of UEL crease, and a poor tarso-corneal interface noted with brow elevation and downgaze. These might be associated with the choice of sling material and to the superfacial location of the sling in the UEL[9].

Autogenous facia lata is the best approach with which other material have to be compared. Sling surgery with autogenous fascia lata is still considered the gold standard procedure for congenital ptosis, having a long-lasting effect. When a piece of free autogenous fascia is transplanted to the eyelid, it can easily survive. Autogenous fascia lata should only be performed in patients over 3 years of age because inadequate amounts of material could be harvested in younger patients, However, a more recent study has shown that fascia lata can also be used successfully in children under 3 years of age[10].

As a result, this research was conducted to compare the results of FS using non autogenous and autogenous material, using the Crowford technique.

Patients and methods

This study is prospective comparative study was included patients attending the outpatient clinic of Mansoura university ophthalmic center with severe congenital ptosis with poor levator function medical record review of all patients who underwent frontalis suspension surgery. The data that were retrieved included age, gender, diagnosis, type of surgery, preoperative and postoperative photographs, visual acuity, margin reflex distance (MRD), lagophthalmos, and related complications. Patients were examined 1 day, 1week, 1, 3, 6 months after the operation and. The study included 60 patients suffering from severe congenital ptosis, patients were simply randomized allocated in two equal interventional groups: First group (38 eye included) underwent FS ptosis surgery using Fascia lata and the second group (70 eye included) underwent FS ptosis surgery using synthetic material.

Inclusion criteria: Patients included in this study had criteria of severe ptosis with poor levator function. Poor levator function has been broadly defined as levator muscle function of 2mm or less and no more than 6mm.

Exclusion criteria: Included weak Bell phenomenon, positive phenylephrine test, jaw winking phenomenon, blepharophimosis syndrome, systemic or myopathic disorders with secondary ptosis such as myotonic dystrophy, myasthenia gravis, chronic progressive external ophthalmoplegia, and Graves' disease, history of eyelid surgery, sharp or blunt trauma to the eyelids, eyelid tumors and scars and patients with vertical squint.

Sample size: This study included 60 patients, these patients underwent FS ptosis surgery using different materials. First group underwent FS ptosis surgery using Fascia lata and the second group underwent FS ptosis surgery using synthetic materials.

Complete preoperative assessment was performed:

Ophthalmic examination

- Visual acuity using Landolt broken rings, Refraction using Topcon Auto Refractometer RM 800, pupillary reactions using direct ophthalmoscope, extraocular muscle examination and fundus examination by indirect ophthalmoscope.

Ptosis evaluation

- History taking to inquire about:

Age of onset Gender Previous operation

- Degree of ptosis (marginal reflex distance) and levator muscle function.
- Lid crease position and lagophthalmos assessment.
- Bell's phenomenon and corneal sensation.
- Measurement: MRD1,MRD2 and levator function.

- ❖ Preoperative and postoperative photographs were recorded.

Postoperative data had been collected:

All patients had been examined first day, 1 week, 1, 3, 6 month after the operation to assess the following:

- **Functional success** defined as improved eyelid position above papillary margin with good (>50%) linkage among the frontalis muscle and the UEL, no ptosis recurrence during the follow up period. Linkage is assessed by manual elevation of the eyebrow on the operated side and measurement of motion of UEL along with eyebrow elevation. If manual eyebrow elevation results in similar eyelid elevation, then one hundred per cent linked was achieved with surgery. If only 1/2 of the elevation is observed in the eyelid, then 50% linkage was achieved with surgery. So it is assessed via measuring MRD-I for evaluation of upper eye lid position postoperative.
- **Cosmetic outcome** had been graded on 0 to 2 scale, with 0 score indicative of excellent results, 1 as good, 2 as poor. Outcome will be defined as excellent if the eyelid was within 1mm height among the eyelids with an acceptable crease and contour, and poor if there will poorly defined eyelid crease, all pre and postsurgical photographs had been reviewed and scored.

Surgical procedure:

Anesthesia: General anesthesia was used for all patients.

The patient was prepped and draped, leaving the face fully exposed. Damp gauze was placed over the non-operated eye.

Skin marking: three supraciliary incisions (3-mm long) were made 2-3 mm above the lash line; the first was in line with the lateral limbus, and the second was slightly medial to the medial limbus, another third incision mark was added among the previous two. Two suprabrow incision sites were marked with the brow hairline, approximately midway among the previous supraciliary incisions, these incision sites were marked approximately in a vertical line with the lateral and medial canthi. an additional incision site was marked 8-10 mm above and midway among the two suprabrow incision **marks. (Fig.1)**

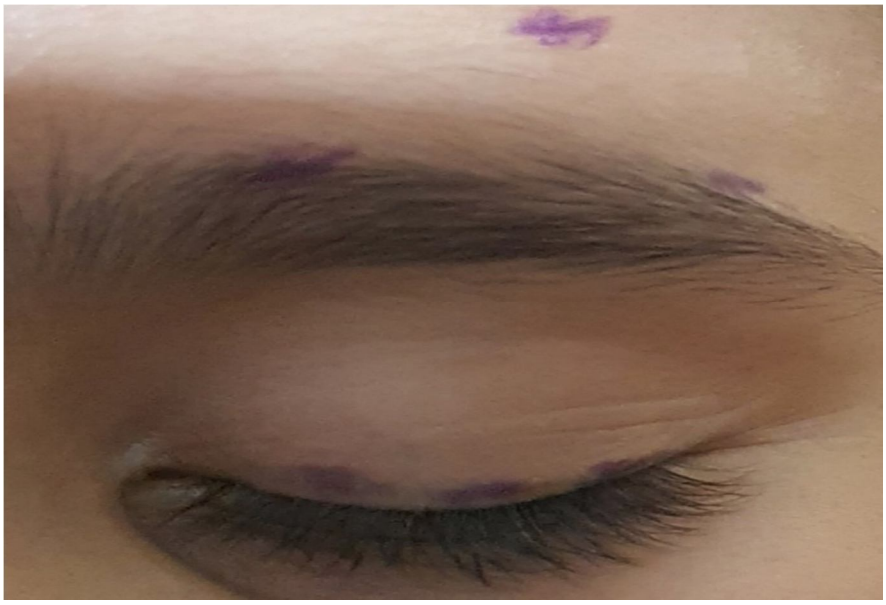


Figure 1: Skin marking for Crowford technique

Surgical procedure:

FS using Fascia lata: First Fascia latta harvesting: A strip of FL (minimum length 12 cm) was harvested from a line drawn from the anterior superior iliac crest and the lateral tibial condyle. This strip was cut into smaller horizontal strips, each approximating 2 mm in width. Four to five strips can normally be obtained A lid crease incision was carried out, and the pretarsal orbicularis was excised to subject the tarsal plate. The FL was stitched to the tarsal plate and passed throughout a Wright needle via the 2 suprabrow incisions. The UEL incision

was closed by utilizing 7.0 vicryl sutures with lid crease development. The brow incisions were closed in layers following titrations of the UEL height and shape to an accepted degree**.**

FS using synthetic materials: A 5/0 silk traction suture was made through the gray line in the central part of the UEL. A McCallan eyelid spatula was utilized to prevent ocular trauma throughout the surgery. Incisions at the previously marked sites were performed using a 15# blade. Eyelid incisions were performed through the skin and orbicularis to expose the tarsus, and forehead incisions were made down to the periosteum. With a blunt scissors, a pocket was dissected superiorly beneath the frontalis muscle in the central forehead incision. Sling material stringing was performed using Wright needle. Frontalis Suspension was done using Crawford procedure .The lid height and contour were adjusted. The knots were buried properly into a preformed pocket under the frontalis muscle. Only forehead wounds were sutured with 5/0 vicryl sutures. A frost suture was then placed at the center of the lower lid that was fixated to the forehead. All patients were prescribed topical antibiotic ointment for skin wounds, which was to be used for one week. The frost suture was removed after one week. Frequent lubricant eye drops and gel were prescribed for the first 2 weeks, and medication intervals were then adjusted according to lagophthalmos and exposure keratopathy. Patients were followed up primarily at intervals of 1, 2, 3 and 4 weeks, 3 months and 6 months in the absence of complications.

Statistical analysis:

Data had been collected, tabulated and analyzed using statistical product and service solutions program (SPSS) (Version 16) for windows. The appropriate statistical tests used when needed. P values less than 0.05 (5%) considered to be statistically significant.

Ethical considerations:

The study objectives and tools were explained to the participants and informed consent was obtained from all participants before enrollment in the study, and the study protocol was approved by IRB of the Faculty of Medicine for Mansoura University (No.17 .03.101). All data were anonymous and coded to assure confidentiality of participants and they had the right to refuse participation or withdraw from the study without any reason without affection of their rights of medical care. In addition, approval for recruitment of the patients was taken from the concerned authorities.

RESULTS

Table 1: shows demographic data of patients in groups. Data are expressed as number and percent for gender and type of ptosis and as mean and standard deviation for age.

Total (60 child)		**Group 1 Fascia lata (n = 21 child)**	**Group 2 Other material (n = 39 child)**	**Test**	**P value**
Gender	Male	8 (38.1%)	15 (38.5 %)	χ^2= 0.001	1
	Female	13 (61.9%)	24 (61.5 %)		
	Unilateral ptosis	4 (19 %)	8 (20.5 %)	χ^2=0.018	0.892
	Bilateral ptosis	17 (81%)	31 (79.5%)		
Age (year)		6.76 ± 1.13	6.08 ± 2.28	MW=366.5	0.499

χ^2 =chi-square, MW: Mann Whitney U

Table (1) shows demographic data of group 1 patients who's ptosis were corrected by facia lata where most of sample were female children (61.9%) with higher incidence of bilateral ptosis (81%) than unilateral (19%) with mean age 6.76±1.13.

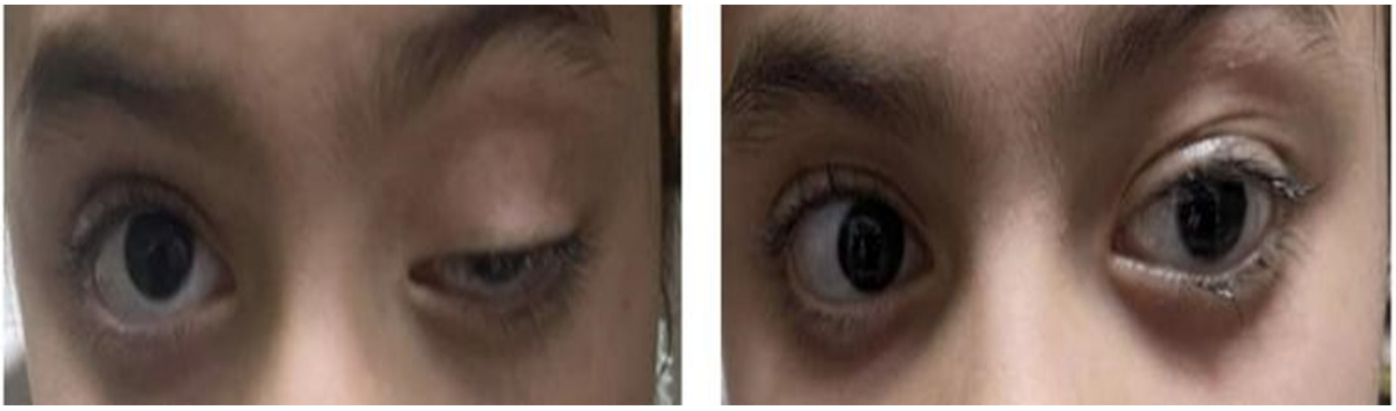
Concerning group 2 patients who's ptosis were corrected by synthetic material where most of sample were female children (61.5%) with higher incidence of bilateral ptosis (79.5%) than unilateral (20.5%) with mean age 6.08±2.28.

Table 2: shows preoperative and postoperative marginal reflex distance in studied groups. Data are expressed as mean and standard deviation.

	Unilateral				**Bilateral**			
	Group 1 (4)Childs	Group 2 (8)Childs	Test	P value	Group 1 (17)Childs	Group2 (31)Childs	Test	P value
MRD1 Preoperative	1.46±0.44	1.38±0.0.65	MW=1092	0.095 Non-significant	1.41±0.54	1.36±0.71	MW=1094	0.094 Non-significant
MRD 1(mm) 6 month postoperative	4.56±0.52	4.34±1.09	MW=1293	**0.765 Non-significant**	**4.54±0.51**	4.35±1.03	MW=1295	0.752 Non-significant

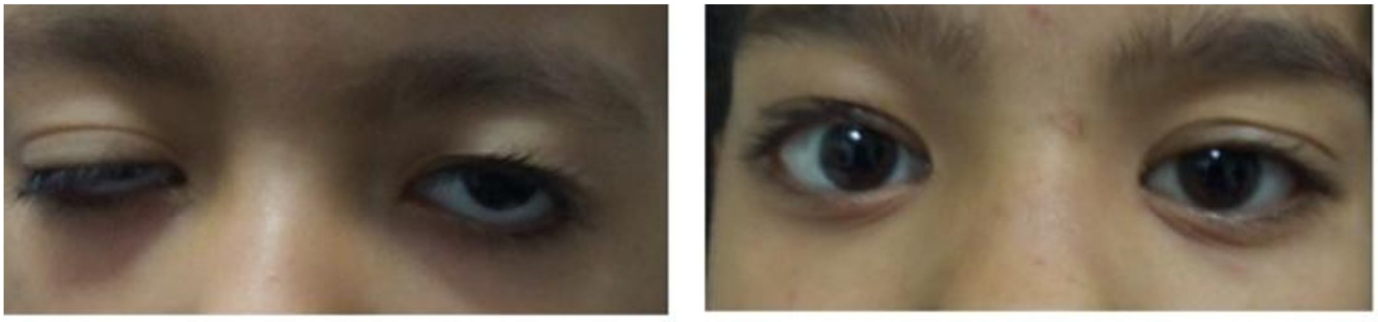
MW: Mann Whitney U

Table (2) illustrated that preoperative MRD 1 was 1.46±0.44 mm in unilateral cases of group 1 in comparison to 1.41±0.54 in bilateral cases, while Preoperative MRD1 1.38±0.0.65mm in unilateral 1.36±0.71 in bilateral cases among group 2. While postoperative MRD 1 was 4.56±0.52mm in unilateral cases of group 1 in comparison to 4.54±0.51in bilateral cases, Postoperative MRD1 4.34±1.09mm in unilateral 4.35±1.03 in bilateral cases among group 2. **(Fig.2).**



A **B**

Figure 2: A case of bilateral sever congenital ptosis preoperative and B after 6th month of follow-up after frontalis suspension using Fascia lata.



A **B**

Figure 5: A case of bilateral sever congenital ptosis preoperative and B after 6th month of follow-up after frontalis suspension using polyester.

Table 3: Summary of postoperative functional and cosmetic results, complications and the overall results for both **groups.Fig(4)**

		Group 1 (n = 38 eyelid)		**Group 2 (n=70 eyelid)**		**P value**	**significance**
MRD1 postoperative	Good	34	89.5%	53	75.7	0.171	Non-significant
	Acceptable	4	10.5 %	14	20		
	Poor	0	0 %	3	4.3		
Overcorrection		1	2.6%	1	2.9%	1	Non-significant
Under correction		3	7.9 %	8	11.4%	0.744	Non-significant
Infection & Granuloma		1	2.6%	6	8.6%	0.417	Non-significant
Exposure Keratopathy	1st week	1	2.6%	3	4.3%	1	Non-significant
	1st month	1	2.6%	3	4.3%	1	Non-significant
	3rd month	0	0 %	2	2.9%	0.54	Non-significant
Recurrence	3rd month	0	0 %	6	8.6	0.088	Non-significant
	6th month	1	2.6%	24	34.3	< 0.001*	**significant**

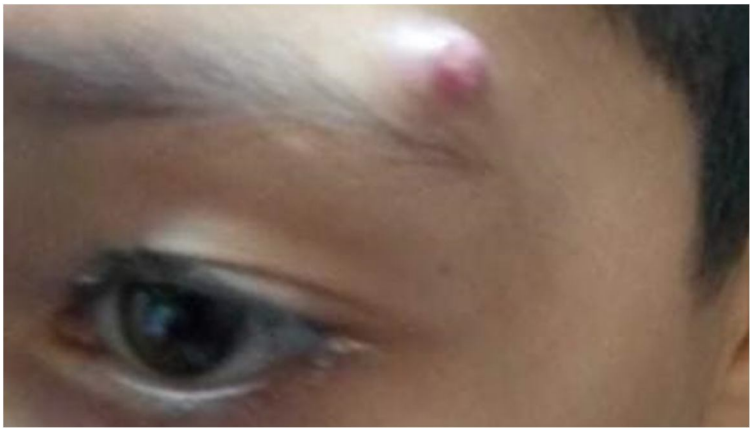


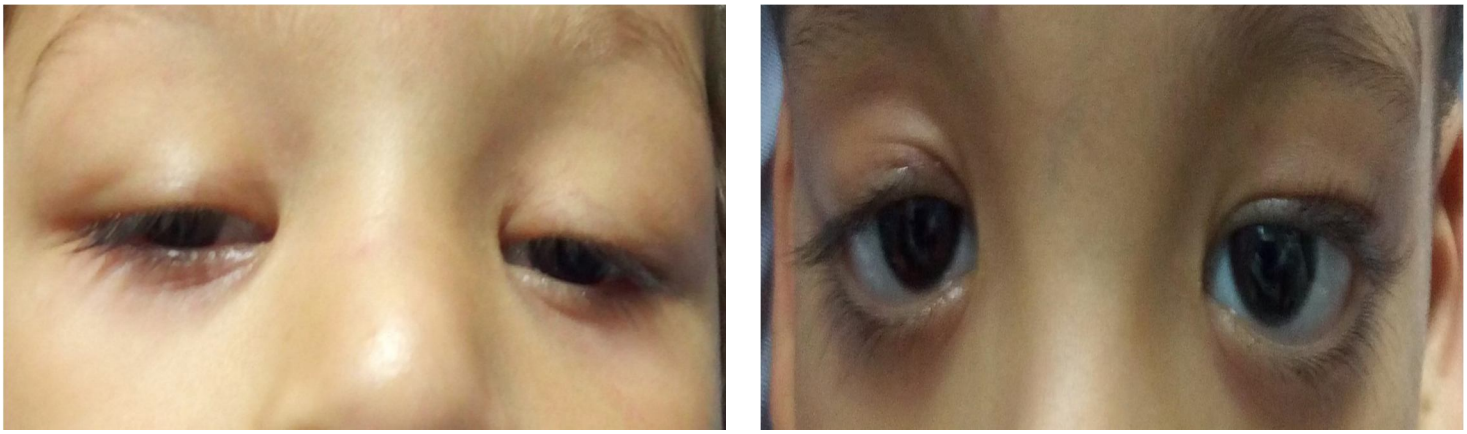
Figure 4: A case shows Lt granuloma after frontalis suspension using polyester material

Table (4) shows MRD before and after repair in both groups. Data are expressed as mean and standard deviation

Total (108 eyelid)	**Group 1 (n = 38 eye lid)**	**Group 2 (n= 70 eyelid)**	**Test**	**P value**	
MRD1 preoperative	1.46 ± 0.44	1.31 ± 0.38	MW=1092	0.095	Non-significant
MRD1 postoperative	4.67 ± 0.75 mm	4.34 ± 1.19 mm	MW=1293	0.765	Non-significant

MW: Mann Whitney U

Table (4) shows that the mean preoperative MRD1 was1.46±0.44 in group 1 compared to 1.31±0.38 in group 2 with no statistical significance, postoperative MRD1 in group 1 was 4.67±0.75mm compared to 4.34±1.19mm in group 2 with no statistical significance too. (**Fig. 5)**



A B

Figure 5: A case of bilateral sever congenital ptosis preoperative and B after 6th month of follow-up after frontalis suspension using Fascia lata.

DISCUSSION

The current study is a comparative study in which frontalis suspension had been performed for patients with severe congenital ptosis in whom levator function had been 4 mm or less to compare the functional results, complications and cosmetic issues of different surgical materials used for frontalis suspension. This study included 108 eyes of 60 patients. Frontalis suspension was in the form of a double pentagon suture (Crawford procedure). Materials included autogenous fascia lata and alloplastic materials such as polypropylene suture, silicone rod, and ePTFE (Gore-Tex). Autogenous fascia lata is considered more effective with comparably low rates of

recurrent ptosis and infection, but it is not well developed until preschool age (4–5 years). Therefore, in cases of severe congenital ptosis, in which autogenous facia lata was difficult to harvest. The mean follow-up duration had been for 6 months. Regarding sociodemographic data in the studied groups. The current study showed that patients with severe congenital ptosis involved in this study had higher frequency of ptosis in female patients (61.7%) than male (38.3%) with mean age 6.31±1.96.

Regarding to cases presentation most of the sample were presented with bilateral ptosis (80%). Demographic data of group 1 shows patients who's ptosis were corrected by facia lata where most of sample were female children (61.9%) with higher incidence of bilateral ptosis (81%) than unilateral (19%) with mean age 6.76±1.13.

Supporting our study, in Salama (2019)[13].there were twenty patients presented with bilateral ptosis, while the other 10 patients had unilateral ptosis. Group A included 7 males (43.8 %) and 9 females (56.3 %), while group B included 5 males (35.7 %) and 9 females (64.3 %). The mean age was 7.38 years in Group A and 7.36 years in group B. The age and sex distributions in both groups were comparable.

In concordance with our study, Salama (2019)[13] found that The mean preoperative MRD1 in group A was -0.42 ± 1.40 mm. The mean MRD1 in group B was- 1.1 ± 1.05 mm. While postoperative MRD1 in group 1 was 3.58 ± 0.60mm compared to 3.42 ± 0.60 mm in group 2 with statistical significance.

In addition in Chung and Seah (2016)[14] found that The mean preoperative MRD1 in group A was 0.29 ± 0.89 mm. The mean MRD1 in group B was 0.03 ± 0.84 mm. And the mean preoperative levator function was in group A was 3.21 ± 1.20 mm. The mean Levator function in group B was 1.88±1.03mm. While postoperative MRD1 in group 1 was 1.25±1.35mm compared to 2.34 ± 1.49 mm in group 2 with statistical significance.

Another study by Bajaj et al. (2004)[15] found that The mean preoperative MRD1 in group A was 1.44 ± 1.03 mm. The mean MRD1 in group B was 1.48 ± 0.79 mm. While postoperative MRD1 in group 1 was 3.67±0.32mm compared to 3.2±0.46mm in group 2 with statistical significance.

In our study the incidence of complications among studied cases in group 1 were less than their counterparts in group 2 including incidence of overcorrection 2.6%in group 1 compared to 2.9 % in group 2, under correction and infection were 7.9% and 2.6% in group 1 respectively compared to 11.4% and 8.6% in group 2 respectively with no statistical value between studied groups. Also, the incidence of complications which noticed in gortex group compared to other synthetic material including overcorrection, under correction, infection& granuloma with no statistical value. Cases who showed infection respond effectively to antibiotic with no need for material removal.

Salama (2019)[13] study, there were two eyelids (7.7%) in Gortex group showed under correction with postoperative MRD1 values of 2 mm.

There were two cases of presumed infection (4.88%), which were both in the exposed GORETEX strips group in the Kersten et al. (2005)[16] review, One was resolved with oral antibiotic therapy, whereas the other required reoperation and sling removal.

In the closed group in their series, Wei and Liao (2009)[17] reported infection in the eyelids of 2 of 40 (5%) children. The overall rate of infection and/or granuloma in that study was 5%.

No cases of infection were reported by Nakauchi et al. (2013)[18], they used a Gore-Tex sheet that was divided and sterilized by ethylene oxide gas without soaking in an antibiotic solution.

In Wasserman (2001)[6] found that Eleven eyelids(10.8%) developed infections and/or granulomas. Eight (72.7%) of these required incision and drainage and removal of the sling material, and 3 (27.3%) resolved with administration of systemic antibiotics. Thirty-two eyelids (31.4%) required further surgery for recurrent ptosis. None of the patients had any lasting complications from exposure of the cornea after frontalis suspension.

Elsamkary and Roshdy (2016) study[19] reported that functional outcome for fascia lata group was better than gortex group as it showed a lower failure rate including fewer recurrence or postoperative complication in the same manner the facia lata group had statistically better outcome related to lid height symmetry and contour.

This study demonstrated that incidence of exposure keratopthy in group 1 was found in first week 2.6%and first month 2.6% while group 2 shows incidence of exposure keratopathy as 4.3% in first week, 4.3% in first month and 2.9% in third month with no statistical value**.** For cases showed overcorrection with incomplete eyelid closure at the 6-month follow-up visit; in these cases artificial lubricating drops were applied to prevent exposure keratitis. And for those who developed mild exposure keratitis were treated successfully with topical antibiotics, therapeutic contact lens, lid massage and lubricants.

Bajaj et al. (2004)[15] study reported a significantly higher postoperative lagophthalmos in the GORE-TEX group than in the Ethibond group. However, the cornea did not show signs that were suggestive of keratopathy in any eye (30 eyelids).

In our study there was less incidence of recurrence in group 1 compared to group 2 8.6% in third month with no statistical value, while incidence of recurrence in 6 months was 2.6% in group 1 in comparison to 34.3% in group2 with high statistically significant value.

Against our study Yoon and Lee (2009)[20] reported better functional and cosmetic results in pediatric congenital ptosis using sillicon versus facia lata at 3 years follow up but the study was limited to using preserved facia lata, banked facia lata was to be associated with higher ptosis recurrence rates.compared to auto genus facia lata.

Supporting our study Chung and Seah (2016)[14] reported higher rates of complication in silicon group than facia lata group with 6 out of 9 patients 66.6% experiencing problems either with implant exposure, wound infection or wound granuloma.

CONCLUSION

Fascia lata sling surgery is considered the gold standard procedure for management of severe congenital ptosis, having long lasting effect for upper eyelid elevation. Precise preoperative evaluation play an important role in decision making.

DATA AVAILABILITY

All data are included in this article.

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None

Conflict of Interest

Authors declare no conflicts of interest.

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Ethics declarations

Conflict of interest

Marwa S. EL-Najar, Mohammad N. Roshdy, Ayman E. Abd El-Ghaffar, Ayman M. Fawzy, all authors have no conflicts of interest that are directly relevant to the content of this review.

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