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Congenital Ptosis Correction with an Expanded Polytetrafluoroethylene (GORE-TEX) sling: Comparative Study Between Crawford and Fox Techniques

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ABSTRACT

Background: Frontalis suspension is the procedure of choice for surgical management of congenital ptosis associated with poor elevator function.

Objective: The aim of the work was to compare the results of two different frontalis suspension surgery techniques, i.e., the Crawford and Fox techniques, using GORE-TEX for the correction of congenital ptosis with poor levator function.

Patients and Methods: fifty eyelids of 30 patients with severe ptosis and poor levator function (≤ 4 mm) were randomly divided into two groups: Group A included 26 eyelids of 16 patients corrected with the Crawford technique, and Group B included 24 eyelids of 14 patients corrected with the Fox technique. The results were evaluated and statistically compared.

Results: at the end of the follow-up period (18 months postoperatively), most of the patients in both groups (80.8% of group A, 79.2% of group B) achieved good to excellent cosmetic results. The intergroup difference was not statistically significant ($P < 0.05$). Regarding contour, Group A was 96.2 %, and Group B was 95.8 %. Regarding symmetry, Group A was 88.5%, and Group B was 79.2%.

Conclusion: considering the use of the same sling material (GORE-TEX suture), the Crawford and Fox techniques are both safe and effective with comparable results in the correction of severe ptosis with poor levator function.

Keywords: Congenital Ptosis, GORE-TEX, Frontalis suspension, Crowford, Fox.

INTRODUCTION

Nasal eyelid surgery is one of the most common eye surgery operations in the field of ophthalmology. The purpose of this surgery is to scan the optic axis, reduce the period and correct any abnormal anomalies. Another important goal is to improve appearance [(1)].

The choice of surgical procedure depends on the levator muscle function. Frontalis suspension surgery using an exogenous or autogenous material is often used as the procedure of choice for patients with severe congenital blepharoptosis and poor levator function [(2)]. The authors also described different alternative muscular slings, including the orbicularis sling [(3)], frontalis muscle strip[(4)]and levator sling[(5)].

Because of its long-lasting effect and few complications, the fascia lata has been established as the gold standard sling material for this procedure [(6)]. However, several sling materials and several modifications of the surgical techniques have been used to improve the outcomes and avoid the drawbacks of fascia lata use. Expanded polytetrafluro ethylene (GORE-TEX) is one of the sling materials that proved to have good efficacy relative to the fascia lata[(7)].

Therefore, this clinical trial was conducted to compare the results of frontalis suspension using Gore-tex suture material, using either the Crowford technique or the Fox technique.

PATIENTS AND METHODS

This study included a total of thirty-nine patients (68 eyelids) with severe congenital blepharoptosis associated with poor levator function of less than 5 mm. Patients were examined, operated upon and followed upat Al-Azhar University Hospitals. A written informed consent from all patients or their guardians were obtained. This study was conducted between March 2015 to November 2017.

Nine patients (18 eyelids) were excluded due to insufficient follow up (less than 18 months). The remaining 30 patients (fifty eyelids) were compliant until the end of the follow up period. Patients were managed with a GORE-TEX frontalis sling.

Exclusion criteria included patients with mild tomoderate blepharoptosis with fair to good levator function, acquired severe blepharoptosis, jaw winking phenomenon, absent or poor Bell's phenomenon, and patients with previous eyelid surgery.

A preoperative history was collected and a clinical examination was carried out. The history included the age of onset of blepharoptosis, its duration, and a review of old photographs. The examination included the measurement of the marginal reflex distance (MRD1), levator function, extraocular muscle motility, jaw-winking phenomena, and Bell phenomena.

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Patients were randomly divided into two groups, namely, Group A (patients carrying hospital registration odd numbers, included 26 eyelids of 16 patients corrected with the Crawford technique) and Group B (patients carrying hospital registration even numbers, included 24 eyelids of 14 patients corrected with the Fox technique).

Surgical procedure:

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

Skin marking:

In both groups, two 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. In group A,another third incision mark was added between the previous two (Figure 1).

Two suprabrow incision sites were marked with the brow hairline, approximately midway between the previous supraciliary incisions, in group A. In group B, these incision sites were marked approximately in a vertical line with the lateral and medial canthi.For both groups, an additional incision site was marked 8-10 mm above and midway between thetwo suprabrow incision marks.

Figure (1): Skin markings for Crowford technique (Left), Skin markings for Fox technique (Right).

Anesthesia:

Surgery was performed under general anesthesia for all patients.

Operative steps:

A 5/0 silk traction suture was made through the gray line in the central part of the upper eyelid.

A McCallan eyelid spatula was used to prevent ocular trauma throughout the surgery. Incisions at the previously marked sites were performed using a 15# blade.

Eyelid incisions were performed throughthe skin and orbicularis to expose the tarsus, and forehead incisions were made down to the periosteum. The sling material used was GORE-TEX suture (CV-2, Gore medical, USA) (Figure 2). Stringing was performed using a Wright needle.

Figure (2):GORE-TEX. Suture used as sling material.

The lid height and contour were adjusted by pulling on the ends of the sling material just at the limbus provided that the globe was dead central. 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, 6 months, 12 months and 18 months in the absence of complications. Complicated patients required closer follow-up intervals.All patients were evaluated at each visit for upper eyelid margin reflex distance 1 (MRD-1) for symmetry of the lid height andlid contour as well asfor post-operative complications such as corneal epithelial defects, granuloma formation, and suture abscesses.Photographs were obtained at each visit.

Recurrent ptosis was defined as ptosis that obscured the visual axis and/or resulted in an anomalous head position.

Functional success was defined as an improvement of the eyelid position above the pupillary margin (i.e., MRD1 measurement) without serious complications. Cosmetic outcomes were assessed in terms of lid contour andsymmetry of height bilaterally.

Results were categorized as ***good***, ***acceptable*** or ***poor*** at the last office visit after surgery according to criteria shown in Table 1.

Table (1): Preset criteria for result evaluation.

Criteria	*Good*	*Acceptable*	*Poor*

MRD1	≥ 3 mm	2-3 mm	≤ 2 mm
Asymmetry	≥ 1 mm	1-2 mm	>2 mm
Contour	Smooth lid margin curve	Mild arching, flattening (bridging) or lateral ptosis	Severe arching, flattening or lateral ptosis

Results were recorded as "***Poor***" if recurrence or corneal ulceration had occurred, or if any of the poor criteria were encountered. The results were recorded as "***Acceptable***" if 2 or more of the acceptable criteria were encountered. Otherwise, the results were recorded as "***Good***".

Statistics:

The Statistical Package for Social Sciences (SPSS) software, version 24, was used to analyze the data (IBM® SPSS® Statistics, New York, United States, 2017).

RESULTS

In this comparative study, 50 eyelids of 30 patients were operated on and evaluated. Twenty patientspresented with bilateral ptosis,while the other 10 patientshad 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.

The mean preoperative MRD1 in group A was -0.42 ± 1.40 mm, which increased to 3.58 ± 0.60 mm after surgery. The mean MRD1 in group B was-1.1 ± 1.05 mm, which increased to 3.42 ± 0.60 mm after surgery. The improvement in MRD1 was 4.0 ± 1.41 mm in group A and 4.5 ± 1.27 mm in group B, which was statistically significant in both groups.

Two eyelids (7.7%) in group Ashowed undercorrection with postoperative MRD1 values of 2 mm, and both cases had unilateral ptosis. However, in group B, 5 eyelids (20.8%) showed undercorrection with postoperative MRD1 values of 1 mm in two eyelids and 2 mm in 3 eyelids. Three cases had unilateral ptosis,and 2 had bilateral ptosis. Difference between both groups was non-significant (P: 0.122).None of the cases had overcorrection.

Group A showed asymmetry of only 1 mm in one case (3.8%) with bilateral ptosis (good result) and asymmetry of 2 mm in 2 cases (7.6%) with unilateral ptosis (acceptable result). In group B, an asymmetry of 1 mm was found in 2 cases (8.3%) with bilateral ptosis (good result) and asymmetry of 2 mm in 3 cases (12.5%) with unilateral ptosis (acceptable result).Difference between both groups was non-significant (P: 0.370).

Regarding the postoperative eyelid contour, onecase in group A (3.8%) had a bad result with lateral ptosis. In group B, 2 cases had an acceptable result with mild flattening. Difference between both groups was non-significant (P: 0.367).

One case (3.8%) of group A with unilateral ptosis showedrefractory infection despite systemic antibiotics and wound debridement, which necessitated sling removal one month postoperatively. No subsequent drooping in the eyelid was noticed after sling removal. Another case (4.2%) in group B developed a mild infection but responded well to antibiotic treatment and local wound care.

One patient in group A who had bilateral sling surgery arrived at the first follow-up visit after 1 week with good functional and cosmetic results, but he had severe refractory exposure keratopathy, which required sling removal 1 month postoperatively. Unfortunately, ptosis recurred in both eyelids after sling removal. These 2 eyelids (7.7%) of the same patient were the only eyelids with ptosis recurrence in our series.

Based on preset criteria (Table 1), the overall results forGroup A were 21eyelids (80.8%)with a good result, 2 eyelids (7.7%) with an acceptable result and 3 eyelids (11.5%) with a poor result. The Group B results were 19 eyelids (79.2%) witha good result, 5 eyelids (20.8%) with an acceptable result and none of the eyelids (0.0%) had a poor result.Difference between both groups was non-significant (P: 0.116).

Postoperative results for both groups and their significance are summarized in Table 2.

Table (2): Summary of postoperative functional and cosmetic results, complications and the overall results for both groups.

		Group A (26 eyelids)		Group B (24 eyelids)		P-value	Significance
		N0	%	No	%		
MRD1	Good	24	92.3%	19	79.2%		
	Acceptable	2	7.7%	5	20.8%		
	Poor	0	0.0%	0	0.0%		
						0.181	Non-Sig.
Symmetry	Good	23	88.5%	19	79.2%		
	Acceptable	3	11.5%	5	20.8%		
	Poor	0	0.0%	0	0.0%		
						0.370	Non-Sig.
Contour	Good	25	96.2%	23	95.8%		
	Acceptable	0	0.0%	1	4.5%		
	Poor	1	3.8%	0	0.0%		
						0.367	Non-Sig.
Undercorrection		2	7.7%	5	20.8%	0.122	Non-Sig.
Overcorrection		0	0.0%	0	0.0%	-	-
Infection		1	3.8%	1	4.5%	0.725	Non-Sig.
Exposure keratopathy		2	7.7%	0	0.0%	0.104	Non-Sig.
Recurrence		2	7.7%	0	0.0%	0.104	Non-Sig.
Rate of complications		5	19.2%	6	25%	0.524	Non-Sig.
Overall results	*Good*	21	80.8%	19	79.2%		
	Acceptable	2	7.7%	5	20.8%		
	Poor	3	11.5%	0	0.0%		
						0.116	Non-Sig.

DISCUSSION

Frontalis suspension was first introduced in the second decade of the 19th century by Hess and by Lexer and then refined by other authors[8]. In the mid-1980s, oculoplastic researchers began investigating the use of GORE-TEX. This synthetic material, used previously in vascular and abdominal surgery, is inert, extremely biocompatible, and resistant to infection. It is easily suturable and biointegratable by means of fibroblastic ingrowths[9].

In their systematic review of suspensory materials for blepharoptosis surgery, Pacella and coworkers concluded that GORE-TEX showed the best rate of successful surgeries (99% success rate) among the other materials[10]. **Bajaj and colleagues** stated that the GORE-TEX suture form is superior to GORE-TEX soft tissue patches[11].

Moreover, GORE-TEX suture can be placed through much smaller incisions, reducing scar formation. Patches may be more appropriate for open sling designs[11].

Although a wide range of sling designs have been described, fewer data are available concerning comparing different designs or defining certain design indications.

Custer *et al.*[12] recommended rectangular or pentagonal implants to be used in patients who diffusely elevate their brow and a triangular implant for individuals who have segmental elevation with a peaked brow contour. **Collin** recommended a Crawford frontalis sling for autogenous fascia lata and a Fox pentagon for Non-autogenous materials[13].

The aim of our study was to assess the influence of the sling design on the functional and cosmetic outcomes of the frontalis sling operation.

The Fox pentagon is one of the simplest techniques, requires the least material and is preferred for non-autogenous material. The Crawford double triangle technique gives the best control of the eyelid contour and height and is usually used with autogenous fascia lata. It gives the best long-term results. This technique can, however, be used with non-autogenous material to gain the best possible contour of the eyelid in selected cases[14].

Both techniques differin the number of knots. While three knots secure the sling in the Crawford design, only one knot does the job in the Fox design; this is supposed to have an effect on the longevity and stability of the sling.

The Fox pentagon and Crawford triangles differ also in the positions of the incisions and the continuous loop used for the Fox method, compared with the two largely independent loop systems employed with the Crawford method; the distribution of stresses within these systems is expected to be different. Kwonand coworkers studied the mechanics of both designs and suggested

that the Fox pentagon might be a better design for distribution of the load within the sling material[15].

Functional success assessment relied on achievement of ≥ 3 mm postoperative MRD1. This was achieved in 86% of cases (92.3% in group A and 79.2% in group B).

We reported under correction in 14% (7 of 50 eyelids). **Nakauchi and coworkers**[19] reported under correction in 37 % of the cases (10 of 27 eyelids) [19]. In our study, under correction occurred more often in the Fox group (20.8%) than in the Crawford group (7.7%).

The presence of 3 knots (in Crawford technique) rather than one (in Fox technique) may be useful in maintaining the sling, and hence, the eyelid at the desirable level. However, none of our cases showed overcorrection, as was reported by some authors [16].

Rates of under- and overcorrection in our study reflected our conservative attitude. In all cases, we adjusted the lid margin just at the upper limbus during surgery. A desirable level was achieved in 86% of the cases.

Bajaj and coworkers used GORE-TEX sutures in the Crawford design and reported ptosis correction results as good (residual ptosis ≤ 1 mm) in 40%, satisfactory (residual ptosis 1-2 mm) in 53% and unsatisfactory (residual ptosis ≥ 2 mm) in 7% [11].

We defined ptosis correction success in terms of postoperative MRD1 (Table1) rather than residual ptosis. Our results for both the Crawford and Fox designs, respectively, were good (92.3% and 79.2%), acceptable (7.7% and 20.8%) and poor (0.0% and 0.0%).

Steinkogler *et al.*[17] reported slight asymmetry in 13.5% (5 of 37) of the eyelids. We reported asymmetry in 16% of the eyelids (11.5% in the Crawford group and 20.8% in the Fox group). The results regarding asymmetry were comparable in both groups.

Steinkogler *et al.*[17] reported that all patients achieved satisfactory functional and cosmetic final results, **Bajaj *et al.***[11]also concluded that all patients in the GORE-TEX group achieved a good lid fold and lid contour formation.

In our study, contour results showed one eyelid in the Crawford group with lateral drooping (bad result), and this was not evident intraoperatively. Limited horizontal cheese wiring with resultant medialization of the lateral sling limb may be the cause of this rare result.

Two cases in the Fox group showed a mildly flattened contour. This can be explained by the relatively long horizontal path of the sling in the lid margin, but it should have been compensated for by the upward lateral direction of traction toward the eyebrow incisions. All other cases in both groups achieved good contour results (96.2% in Group A and 95.8% in Group B). The results were comparable in both groups.

Wasserman and coworkers reported infection and/or granuloma formation in 5 of 11 patients (45.5%). They explained this very high rate by the highly porous nature of GORE-TEX that allows sequestration of bacterial contaminants with proliferation and abscess formation. They proposed altering the technique by adding suture closure of all incisions[9].

There were two cases of presumed infection (4.88%), which were both in the exposed GORE-TEX strips group in the Kersten's review, One was resolved with oral antibiotic therapy, whereas the other required reoperation and sling removal [18].

In the closed group in their series, **Wei and Liao reported** infection in the eyelids of 2 of 40 (5%) children and one of 40 (2.5%) adult eyelids. Another eyelid (2.5%) in the adult group showed granuloma formation. The overall rate of infection and/or granuloma in that study was 5% [7].

No cases of infection were reported by **Nakauchiand coworkers,** they used a Gore-Tex sheet that was divided and sterilized by ethylene oxide gas without soaking in an antibiotic solution[19].

We reported 2 eyelids (4%) with infection, one in each group. We operated under complete aseptic conditions, used sterile Gore-Tex sutures and did not soak it in antibiotic solution preoperatively. Infection was attributed to bad personal hygiene; patients were fromrural areas with poor compliance for postoperative treatment and local wound care. We had to admit these patients to assure treatment compliance. The case in the Fox group had a mild infection that responded well to medical treatment. On the other hand, conservative treatment and debridement failed in the case from the Crawford group; the sling had to be removed, but fortunately ptosis did not recur.

Many other authors reported maintained elevated eyelids after sling removal. **Steinkogler and coworkers** reported a case with GORE-TEX sling exposure 3 years postoperatively that had to be removed; the eyelid was maintained as sufficiently elevated[17].

Wojno and Green[20]reported 3 cases at more than 3 years after removal of the silicone sling with no recurrence of ptosis. This was explained by the fibrous track that forms along the sling path that keeps the eyelids in a high position.

Exposure keratopathy is the most serious complication that could happen after a frontalis sling operation. Bajaj and coworkers 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)[11].

We carefully assessed patients preoperatively for protective mechanisms (orbicularis tone, Bell's phenomenon and dry eye manifestations) and used a frost suture at the end of surgery to be kept in place for a week postoperatively to avoid exposure keratopathy. We had one case in Group A with bilateral extensive and persistent exposure keratopathy where we had to remove the sling to save the cornea. That patient did not tolerate the frost suture and removed it at home less than 24 hours after surgery. It is likely that the sling track fibrosis was insufficient to keep the eyelids elevated after sling removal in this case. Neither sling infection nor exposure keratopathy could be linked to the sling design.

Recurrence occurred only in these two eyelids (4% of all cases) after sling removal, and none of our cases showed ptosis recurrence while the sling was still in place. Many authors reported zero recurrence with GORE-TEX[9, 11].

In their review, **Steinkogler*et al.*[17]**reported one case (2.7%) that required reattachment of the sling that was loosened from the frontalis at 9 months after surgery.

Simon *et al.*[21]reported a recurrence rate of 15%in the GORE-TEX group. Despite being relatively high, it was the lowest percent relative to other materials.

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