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EVALUATION OF FRONTALIS SLING USING AUTOLOGOUS FASCIA LATA VERSUS POLYTETRAFLUOROETHYLENE FOR CORRECTION OF BLEPHAROPTOSIS WITH POOR LEVATOR FUNCTION

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ABSTRACT

Objective: To compare the results of frontalis suspension using autogenous fascia lata versus Gore-tex suture material for treatment of moderate to severe congenital ptosis with poor levator function. **Design:** Prospective randomized controlled study, **Participants:** forty eyelids of 25 patients, who attended Al-Azhar University Hospitals. **Methods:** patients were divided into two groups. In group Group A: included 20 eyelids in 13 patients corrected by frontalis sling using autologous fascia lata. In Group B: included 20 eyelids in 12 patients, corrected by frontalis sling using polytetrafluoroethylene suture material. **Results:** At 12 months postoperative (end of follow up period), there was no significant difference regarding MRD I, PFW, cosmetic results and complication rate in both groups. Longer operative time was reported in group A because of the time consumed in harvesting fascia lata from the donor site. **Conclusion:** We conclude that use of Gore-tex suture material in frontalis suspension surgery is comparable to use of autogenous fascia lata with advantage of avoiding donor site complications.

KEYWORDS: To compare the results of frontalis autogenous complications.

INTRODUCTION

Blepharoptosis surgery is one of the most common oculoplastic procedures performed in the pediatric age group. The aim of surgery is to clear the visual axis, reduce amblyopia and to correct any adopted anomalous head posture. Another important goal is to improve appearance by pro-ducing symmetric eyelid creases and contours.[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 ptosis and poor levator function.[2] However, super-maximum levator resection or Whitnall ligament sling have been used by some surgeons[3] and reverse use of protractor muscles (frontalis and orbicularis oculi) as retractors is recommended by others.[4,5]

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 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.[7]

Therefore, we conducted this clinical trial to compare results of frontalis suspension using autogenous fascia lata versus Gore-tex suture material.

Patients and Methods

Forty eyelids in 25 patients with ptosis associated with poor levator function were included in this study. Patients were examined, operated upon and followed up at Al-Azhar university hospitals during the period from April 2014 till October 2016.

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 certain ophthalmologic problems (corneal scarring, dry eyes, squint, Horner's syndrome, jaw-winking phenomenon and absent Bell's phenomenon) also Patient with frontalis muscle trauma or disease.

Preoperative careful history taking and clinical examination were carried out. History included the age

of onset of ptosis, its duration and review of old photographs. Examination included the marginal reflex distance, levator function, palpebral fissure height, extraocular muscle motility, ice bag test, jaw-winking phenomena, Bell's phenomena, and corneal sensitivity. Exclusion criteria were jaw-winking phenomena, abnormal ocular motility, or absent Bell's phenomena.

Skin marking

Three incisions (3-mm long) were marked 2-3 mm above the lash line, the first in line with the lateral limbus, the second slightly medial to the medial limbus and the third in between.

Figure 1: Skin marking.

Another two incision sites were marked above the eyebrow with the hair line, approximately one midway between the previous first and second incision and the second between the previous second and third incision; an additional incision site was marked 8-10 mm above the eyebrow midway between the eyebrow two incision sites as seen in (Figure ***1***1).

Anaethesia: Surgery was performed under general anesthesia for children and uncooperative patients and local anesthesia 1 to 1.5 ml of mepecaine (2% mepivacaine HCL with 1:20000 levonordefrin) was infiltrated with sedation for adults.

Surgical procedure

The patient was prepped and draped leaving the face fully exposed. Damp gauze is placed over the non-operated eye. A 5/0 silk suture was placed through the gray line of the upper eyelid and used for traction.

McCallan eyelid spatula with ointment was used to prevent ocular trauma during skin incision and when the needle is passed. Incisions at the previously marked sites were done using a blade # 15.

Eyelid incisions were done through skin and orbicularis to expose the tarsus, 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 Sling Suspension well be done using Crawford procedure (double pentagon configurations) (Figure 2).

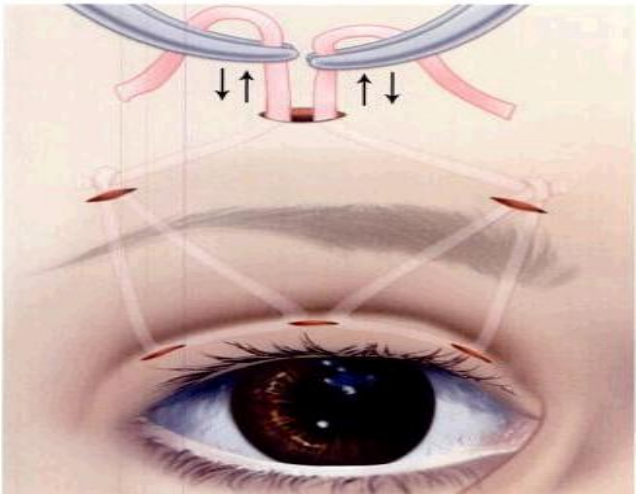

Figure 2: Crawford procedure (double pentagon configurations).

The sling material used was autologous fascia lata for group (A) and polytetrafluoroethylene suture material for group (B) (Figure 3).

Figure 3: Gore-tex sutur material.

Obtaining fascia lata

Under general anesthesia, with the knee and hip in flexion on one side, the thigh was fixed with adhesive plaster to both sides of the surgical table and a 2-cm incision was made in the skin and subcutaneous tissues on the lateral thigh starting about 6 cm above the lateral femoral condyle and another incision was done 12 cm from the first one toward the anterior superior iliac spine.

Figure 4: Fascia lata harvesting.

The incision was deepened till the fascia lata was reached; this fascia can be identified as a white glistening tissue with fibers running parallel to the axis of the leg. Two skin retractors were used to give better exposure. Subcutaneous fat was undermined above and below the incision. A 2-cm full-thickness horizontal incision was made with a scalpel through and perpendicular to the fascial fibers. Two additional vertical cuts, parallel to the fascial fibers, were then made at the ends of the horizontal incision and extended towards the anterior superior iliac spine for approximately 12 cm. Blunt dissection was then carried out above and below the whole length of the strip, using long curved scissors, to free it completely (Figure).

Strips of fascia lata, 12 cm in length and 3 mm to 12 mm in width were harvested according to the surgical technique and number of eyelids undergoing surgery. Fascial strips were cleaned of unwanted tissue and cut in 3-mm wide strips (Figure 5).

Figure 5: Fascia lata after preparation.

The lid contour and height were adjusted by pulling on the ends of sling material. The lid contour was adjusted as well, usually having the nasal third slightly higher than the lateral third. Both ends of the sling were tied together and the knot was secured with a 5/0 vicryl suture to avoid slippage. The sling is then sutured to the frontalis, ends of sling material were trimmed about 3 mm from the knot. The knot was buried into the preformed pocket.

All patients were prescribed topical antibiotic ointment for skin wounds for one week. Frequent lubricant eye drops every 1 hour and lubricant gel every 2 hours and before sleeping, were prescribed for the early postoperative period, medication intervals were then adjusted according to lagophthalmos and exposure keratopathy.

Patients were followed up primarily at intervals of 1 week, 4 weeks, 12 weeks, and then every 3 months in the absence of complications. Complicated patients required closer follow up intervals. All patients were evaluated each visit for palpebral fissure width (PFW), upper eyelid margin reflex distance (MRD), cosmetic outcome (lid crease appearance, lid contour, symmetry of lid height), presence of lagophthalmos and post- operative complications such as corneal epithelial defect, overcorrection, undercorrection, granuloma formation, suture abscess as well as thigh scar and gait abnormalities. Facial photo-graphs were taken at each evaluation.

Functional success was defined as improvement of eyelid position above the pupillary margin with-out serious complications such as infection, kerat-opathy resulting from entropion, or exposure. Cosmetic outcomes were graded as 3 (excellent), 2 (good), or 1 (poor) (Table 1).

RESULTS

In this study, 40 eyelids of 25 patients were analyzed. 15 patients presented with bilateral ptosis while the other 10 had unilateral ptosis. Patients were assigned randomly to either group A or B each including 20 eyelids.

Group A included 9 males (69.2%) and 4 females (30.8%) while group B included 5 males (41.7%) and 7 females (58.3%). Mean age was 13.77 years in Group A and 12.33 years in group B. Age and sex distributions in both groups were comparable.

Table (1): Definition of Cosmetic Grading Scale [8].

Cosmetic Outcome	Grade	Definition
Lid contour	Excellent (3)	Natural, symmetic contour without peaking or flattening
	Good (2)	Mild peaking or flattening, but acceptable to parents and doctors
	Poor (1)	Eyelid tenting needed to be corrected
Symmetry of lid height	Excellent (3)	≤ 1 mm of lid height difference
	Good (2)	1 mm < lid height difference ≤ 2mm
	Poor (1)	2 mm < lid height difference
Lid crease	Excellent (3)	Symmetric without obliteration
	Good (2)	Mild obliteration causing asymmetry, but acceptable
	Poor (1)	Complete oblieration of lid crease

Mean Operative time for each eyelid including the time for harvesting fascia lata was 41.75 ± 3.04 minutes in Group A and 19.85 ± 2.08 minutes in group B. There was statistically highly significant difference between the studied groups regards operative time.

Mean preoperative palpebral fissure width in group A was 5.25 ± 1.37 mm, which increased to 10.05 ± 1.05 mm after surgery. Corresponding figures for group B were 6.25 ± 1.33 mm and 10.25 ± 0.85 mm respectively. Palpebral fissure width increased by 4.8 ± 1.47 mm in group A and 4 ± 1.30 mm in group B. The intergroup difference was not statistically significant *(*Figure 4).

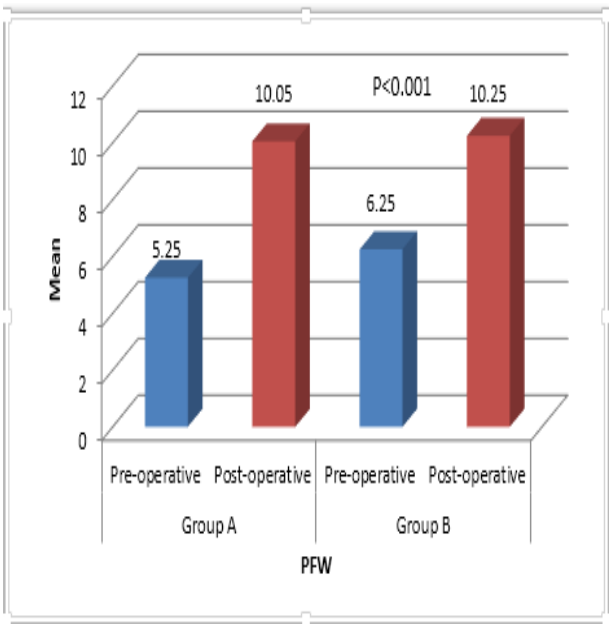

Figure 5: Bar chart representing comparison between pre& post-operative regards PFW.

Mean preoperative Margin Reflex Distance in group A was -0.80 ± 1.40 mm, which increased to 3.45 ± 0.60 mm after surgery. Corresponding figures for group B were 0.40 ± 1.05 mm and 3.20 ± 0.70 mm respectively. Upper eyelid margin reflex distance increase was 4.25 ± 1.41 mm in group A and 3.60 ± 1.27 mm in group B, which was statistically significant but the intergroup difference was not (Figure 7).

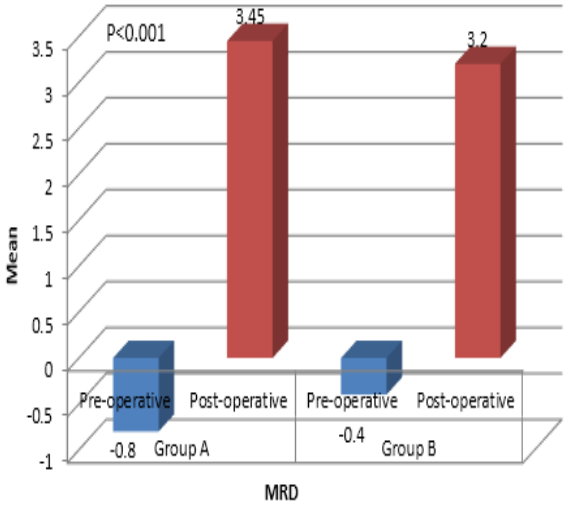

Figure 7: Bar chart representing comparison between pre& post-operative regards MRD1.

At one year after surgery, the number of patients in group A that showed excellent cosmetic outcomes (grade 3 on Seider's scale) were: 14/20 in terms of lid contour (70%), 17/20 in terms of lid height symmetry (85%) and 16/20 in terms of lid crease appearance (80%). Corresponding figures for group B patients were (12/20, 60%), (17/20, 85 %) and (15/20, 75%), respectively.

Short term complications are summarized in the (Figure 8). Long term complications are summarized in the (Figure 9). No statistically significant difference in complication rate was observed between the two groups.

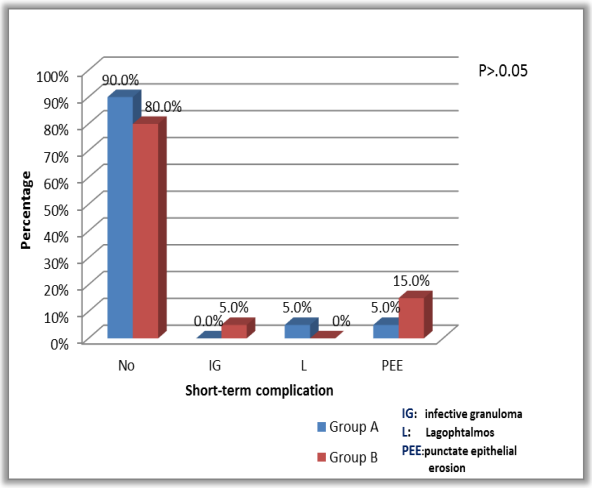

Figure 8: Bar chart representing comparison between the studied groups regards short-term complication.

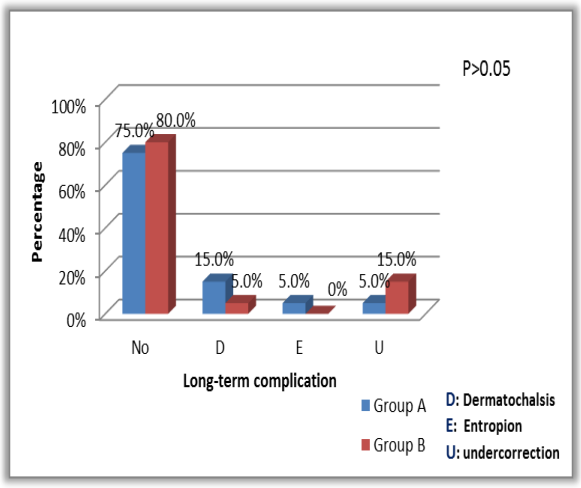

Figure 9: Bar chart representing comparison between the studied groups regards long-term complication.

No cases with severe recurrence (marginal reflex distance of 0 mm or less) were observed, and no patients required further surgery in either group. In the two groups, eyelid edema was universal and was resolved after 1 Week.

Figure 10: Left blepharoptosis with poor levator function corrected by fascia lata frontalis sling. (A) Preoperative (B) 1week postoperative (C) 1 month postoperative (D) 6 month postoperative.

Figure 11: Bilateral blepharoptosis with poor levator function corrected by gore tex frontalis sling. (A) Preoperative (B) 1week postoperative (C) 1 month postoperative (D) 6 month postoperative.

DISCUSSION

Several sling materials are available such as fascia lata, whether autogenous or banked, or synthetic materials like polytetrafluoroethylene (Gore-Tex), polypropylene, nylon, silicone and mersilene. Synthetic slingmaterials are more readily available and are not associated with donor-site morbidity or cross-infection possibility. However, they are believed to have a higher recurrence rate and risk of extrusion, infection, granuloma formation, and breakage after trauma.[9]

Despite the fact that autogenous fascia lata has better biocompatibility than alloplastic materials, similar functional and cosmetic outcomes may be achieved with alloplastic materials.[10]

Gore-Tex® is a synthetic microporous nontoxic polymer, comprised of nodules interconnected by multidirectional minute fibers. Gore-tex is suitable for suspension surgery because it is less bulky and less stretchable.[11]

Fascia lata harvesting requires special instruments and can take up to 20 minutes, including wound closure. On the other hand, Gore-Tex needs no time to prepare, except for soaking them in antibiotics.[12]

However, it had a shorter follow-up in comparison to other studies, which were up to one year after the initial surgery, in our study no change of the results were noted between 3 months and one year. This may indicate that changes after a longer period are less likely to occur.

A wide range of sling designs have been described; authors discussed results and advantages of their techniques. Although, less data are available concerning comparing different designs or defining certain design indications.

In our study we used Crawford design which is commonly described as double triangle despite being pentagonal with double triangles; the name double pentagon is more accurate.

The current study was designed to compare the results of use of autogenous fascia lata versus Gore-tex for frontalis suspension in moderate to severe ptosis with poor levator function over 12 months follow up period. There was no significant difference regarding age, sex,

nullifying the effect of these factors on surgical outcome in both groups. Also there was no significant difference regarding MRD I, PFW, cosmetic results and complication rate in both groups.

There was statistically significant difference between both groups regarding the operative time. Longer operative time was reported in group A because of the time consumed in harvesting fascia lata from the donor site.

Our results indicate that the tensile strength of fascia lata and Gore-Tex remains stable for a relatively long time and results in less need for redo surgery as we have no case of recurrence in both groups.

Undercorrection was more observed in patients with unilateral ptosis (75% of undercorrection occurs with unilateral ptosis and 25% with bilateral ptosis). A finding similar to that reported by Yoon and colleagues who conducted their study on 239 patients with an average follow up period of 18 months. 32 patients (13.4%) with undercorrection, 27 (84.3%) had undergone unilateral suspension for unilateral ptosis.[13]

However, Callahan suggested that in cases of unilateral suspension, it seems better to adjust the eyelid 1 mm higher than the other eyelid position, instead of adjusting it to the contalateral eyelid as we did, to attain less undercorrection and better postoperative symmetry.[14]

In our fascia lata group leg pain and walking difficulties were reported in the first week postoperatively, but there were no complaints after the first week. The most important potential long-term problem is thigh scars, but scars become less noticeable by time, and no complaints were reported. Mandour et al reported donor site complications in fascia lata group were in the form of ugly thigh scar in 2 cases and herniation of the vastus lateralis muscle in one case.[15]

On comparing the results of our PTFE group with previous studies on efficacy of other synthetic materials (e.g. nylon and dacron) we found that PTFE was associated with lesser recurrence of ptosis and fewer complications.

Using Gore-tex sutures as in the current study was proved to be associated with lower postoperative complication rate than Gore-tex soft tissue patches or strips. This was attributed to fashioning of the patches may occasionally result in strips of unequal dimensions. Moreover, PTFE sutures can be placed through much smaller incisions, thereby reducing the extent of scarring of the eyelid.[16]

Most of the studies, including ours, have shown that PTFE material has achieved several desirable and improved characteristics over other synthetic materials.[16]

At one year after surgery, the number of patients in group A that showed excellent cosmetic outcomes (grade 3 on Seider's scale) were: 14/20 in terms of lid contour (70%), 17/20 in terms of lid height symmetry (85%) and 16/20 in terms of lid crease appearance (80%). Corresponding figures for group B patients were (12/20, 60%), (17/20, 85 %) and (15/20, 75%), respectively.

These results went along with those reported by Yoon and Lee in their study using fascia lata. They reported excellent cosmetic success rates in their 239 patients at 6 months after surgery regarding lid contour (85.4%), lid height symmetry (65.7%) and lid crease appearance (66.9%) (p<_0.001).[13]

CONCLUSION

We conclude that the use of Gore-tex in frontalis suspension is comparable to the use of autologous fascia lata with the advantage of shorter operative time and avoiding the need for a second surgical site with its potential morbidity.

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