

Frontal suspension for congenital ptosis using an expanded polytetrafluoroethylene (Gore-Tex®) sheet: one-year follow-up

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Background: The frontalis suspension technique is the surgical method of choice in patients with ptosis and a levator function of 4 mm or less. Several types of materials have been used, including Gore-Tex®, which has been used successfully as a frontalis sling material since 1986. Recently, a Gore-Tex sheet (wider than a sling or strip) suspension was reported. This paper reports the results of 27 eyes from 20 patients with congenital ptosis treated using the frontalis suspension technique with the newly developed Gore-Tex Most Versatile Patch (MVP) sheet.

Methods: All patients underwent surgery between April 2007 and September 2011 and were followed up for at least one year. The average follow-up duration was 18 months, with a range of 12–36 months. The average patient age was 45 (5–85) years, and the group included 11 males and nine females. Thirteen cases demonstrated ptosis in one eye, and seven cases involved both eyes. The patients were divided by age into a younger group and an older group. All ptosis procedures were performed using the Gore-Tex MVP sheet. The implant was normally 7 mm wide for adults and 5 mm wide for children. The implantation method was the same as that used for the sheet shape fascia.

Results: In all patients, satisfactory functional results were observed at the 6-month follow-up examination. Eyelid opening heights were also obtained. The average marginal reflex distance (MRD) was –0.5 mm preoperatively, which improved to +1.9 mm after surgery. After one year, average MRD was +1.6 mm. MRD attenuation was more frequent in the younger group. There were no cases requiring redo surgery and only one case of exposure.

Keywords: polytetrafluoroethylene, Gore-Tex®, frontalis suspension, congenital ptosis, recurrence

Introduction

The frontalis suspension technique is the surgical method of choice in patients with ptosis and a levator function of 4 mm or less. Several types of material have been used, including expanded polytetrafluoroethylene (Gore-Tex®), which has been used successfully as a frontalis sling material since 1986.¹ Sheet-type fascia implantation for frontalis suspension has been reported by plastic surgeons.^{2,3} Recently, frontalis suspension using a Gore-Tex sheet was also reported.⁴ To avoid leakage of fluid, Gore-Tex has been improved to have a triple-layer wafer structure, marketed as PDX®. To lessen glare under the microscope, a new dual-surface Most Versatile Patch (MVP) type of Gore-Tex was developed. This material has been assessed for frontalis suspension only in Japanese patients.⁵ We used this material in 27 eyes from 20 patients, followed

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them for at least one year, and describe herein the surgical technique and results achieved.

Materials and methods

In this retrospective study, we performed frontalis suspension procedures for patients with congenital or severe ptosis using a Gore-Tex MVP sheet at the Hyogo College of Medicine Hospital and Ide Eye Hospital between April 2007 and September 2011. We selected 27 eyes from 20 cases that we could follow for at least one year. We then checked their records for any complications and marginal reflex distance (MRD) changes at 6 months and one year after surgery. MRD was judged on the basis of photographs taken before and after surgery. The differences in prevalence among the category variables were compared using the χ^2 test, and the *P* value was calculated.

Cases

All patients underwent surgery between April 2007 and September 2011 and were followed for at least one year. The average follow-up duration was 18 (range 12–36) months. The average patient age was 45 (range 5–85) years and included 11 males and nine females. Thirteen cases demonstrated ptosis in one eye, and seven cases involved both eyes. The patients were divided by age into a younger group and an older group. The younger group (average age 10 [range 5–17] years) included 12 eyes from nine patients (four boys and five girls). The older group (average age 72 [56–85] years) included 15 eyes from 11 patients (seven males and four females, see Table 1).

Surgery

All ptosis procedures were performed using the Gore-Tex MVP sheet. The implant was normally 7 mm wide for adults and 5 mm wide for children. The sheet was originally 60 × 100 mm, and was cut uniformly to 7 × 45 mm (a sufficient length for all patients) before surgery, packed individually, and then sterilized using ethylene oxide gas. The surgery was performed under general anesthesia in children and under local anesthesia in adults.

A skin incision was made 5 mm from the eyelid margin for children and 6 mm for adults. This incision forms a lid

crease in the oriental eyelid. Vertical lateral skin marker lines showed the margin of the pupil, and a long middle line showed the pupil center (Figure 1A). After traction sutures were positioned above and below the incision, the orbicularis palpebrae was observed and incised until the tarsal plate was exposed. The lowest part of the aponeurosis was pulled caudally, and the orbital fat was then observed (Figure 1B). An 8 mm wide skin incision was made just above the eyebrow. A tunnel was bluntly dissected to maintain the depth of orbital fat from the brow frontalis muscle to the tarsus using mosquito forceps. By way of the tunnel, the orbital septum was penetrated using the forceps tip. The Gore-Tex sheet was inserted into the tunnel by pulling back the forceps.

The caudal (tarsal) side of the Gore-Tex sheet was divided into double 8 mm long strips. These strips were sutured with 7-0 Prolene and a 3/8-circle round needle (using care to avoid tearing the sheet) at one half to one third the height of the tarsal plate (Figure 1C). The cranial (frontalis) side of the sheet was sutured to the frontalis muscle using 7-0 Prolene while opening of the eye was confirmed (Figure 1D). The patients under local anesthesia were required to sit on the surgical table during surgery, and their eyelid heights were measured. The target MRD was 2–3 mm; however, if manual closing could not shut the eye, the MRD needed downward adjustment. If the opening height of the eyelid was not adequate, the suture was cut at the frontalis part, and the sheet was adjusted until optimal opening was achieved. The brow and eyelid incisions were sutured with 7-0 Nylon for adults and 7-0 Vicryl for children. Oral and topical ofloxacin ointments were spread to prevent infection.

Results

Satisfactory functional results were observed at follow-up in all patients (Tables 2 and 3). The levator function had been less than 4 mm before surgery; however, eyelid elevation was enabled by frontalis muscle contraction. Patients who had lesser levator function and younger patients were better at blinking. In addition, eyelid opening heights were also maintained for 6 months. The average MRD was –0.46 mm preoperatively, but improved significantly to +1.89 mm by 6 months after surgery (*P* < 0.0001). After one year had passed, the MRD was attenuated to 1.65 mm (*P* = 0.05). MRD in the younger age group at one year after surgery was relatively lower than that in the older group (1.46 versus 1.8 mm, *P* = 0.04).

Ten of 27 (37%) operated eyes experienced partial recurrence, which was more common in the children.

Table 1 Age distribution of patients

Age distribution	Average age
All (20 patients 27 eyes)	44.5 ± 32.0 (years old)
Younger group (5–17 yo, 9 patients 12 eyes)	10.3 ± 5.4
Elder group (56–85 yo, 11 patients 15 eyes)	71.9 ± 8.3

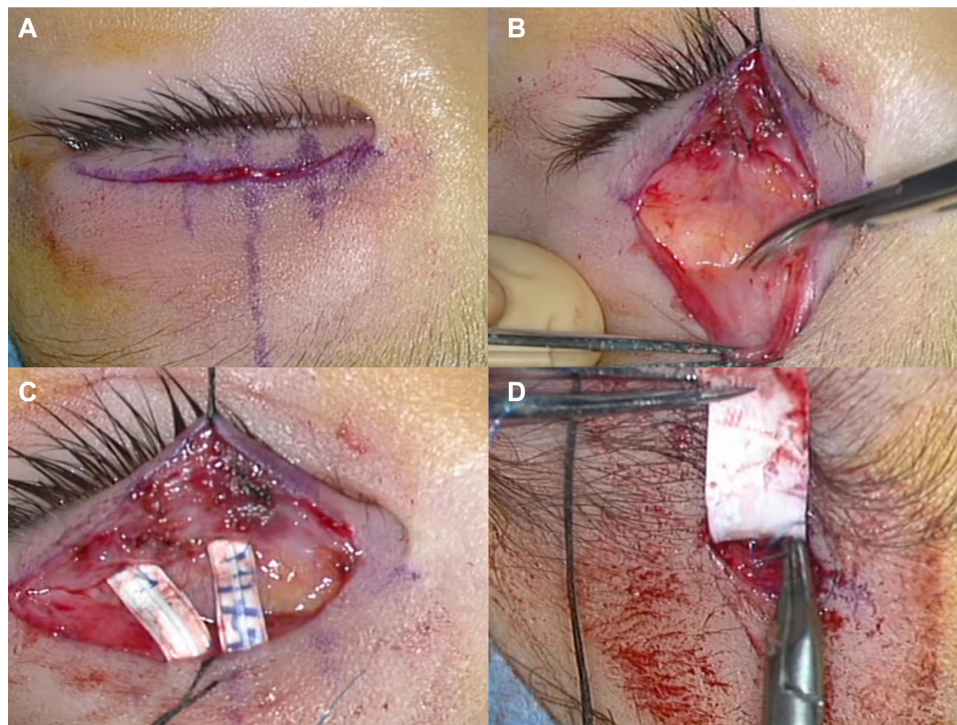


Figure 1 (A) A skin incision was made 5 mm from the eyelid margin for children and 6 mm for adults. This incision was used to create a lid crease in the oriental eyelid. Vertical lateral skin marker lines show the pupil margin and a middle long line shows the pupil center. (B) After the traction sutures were positioned above and below the incision, the orbicularis palpebrae was observed and incised until the tarsal plate was exposed. The lowest part of the aponeurosis was pulled caudally, and the orbital fat was then observed. (C) Gore-Tex® strips (tarsal part) were sutured with 7-0 Prolene using a 3/8-circle round needle (to avoid tearing the sheet) at one half to one third the height of the tarsal plate. Two Prolene sutures were needed to fix one strip on the tarsus. This photograph shows the mid course of surgery. (D) The cranial (frontalis) part of the Gore-Tex sheet was sutured to the frontalis muscle using 7-0 Prolene while eye opening was confirmed.

Fifty-eight percent of the eyes in the younger age group showed partial recurrence, with an average MRD of 0.4 mm, whereas 20% of the eyes in the older age group attenuated at 0.1 mm. The incidence was higher in the younger group ($P = 0.04$). However, no case has needed redo surgery at the time of writing.

One case of exposure of the Gore-Tex sheet occurred. This was in a 71-year-old man who experienced more bleeding than the other patients, and wound recovery was slow. At 2 months after surgery, the Gore-Tex sheet was visible in the wound, and a skin infection had occurred. The infection was treated conservatively with iodine sterilization and antibiotic ointment for 2 months, but the eyelid skin did not cover

the exposure area. Finally, the 5 mm edge of the Gore-Tex sheet over the tarsus was removed, after which shrinkage of the tunnel still occurred, along with mild lagophthalmos, although no corneal damage was seen. He experienced a mild sensation of suspension, which made eyelid closure slightly difficult.

A 5-year-old boy (Figure 2) and a 76-year-old female (Figure 3) are shown as representative successful cases.

Discussion

In Japan, both oculoplastic surgeons and plastic surgeons perform frontalis suspension surgeries. Plastic surgeons prefer to use autologous material, (ie, fascia lata, fascia temporalis) and sometimes fabricate harvested fascia into slings. Recently, sheet-type materials have become popular

Table 2 Eyelid height before and after surgery

MRD (mm)	Pre op	6 m post op	1 year post op
Eyelid height			
All	-0.46	1.89	1.65
	$P = 2.1 \times 10^{-22}$		$P = 0.05$
Younger	-0.63	1.88	1.46
	$P = 0.2$		$P = 0.9$
Elder	-0.33	1.9	1.8
			$P = 0.04$

Table 3 Recurrence rate according to age group

	No change	Partial recurrence
Recurrence rate		
Younger group (12 eyes)	5	7 (58%)
Elder group (15 eyes)	12	3 (20%)
All (27 eyes)	17	10 (37%)

$P = 0.04$



Figure 2 A 5-year-old boy with a congenital ptosis of the left eye.

Notes: His marginal reflex distance in the left eye was -0.5 mm, and his vision acuity was 14/20, which did not improve as a result of interrupted amblyopia. A modified Hotz procedure was simultaneously performed for lower eyelid congenital trichiasis in both eyes. After surgery, the marginal reflex distance was increased to 2 mm, and his visual acuity was increased to 20/20. However, the marginal reflex distance was attenuated to 0.5 mm after one year. His left eyebrow is further down than his right, indicating he did not have the strength to pull up his eyelid.

because they require only one tunnel and are more easily adjusted than strips or slings.^{2,3} In contrast, oculoplastic surgeons prefer using artificial material to avoid an accessory wound, bleeding, and extended surgical time. Several artificial materials (eg, nylon suture, silicone rods) have been used for congenital ptosis surgery, and Gore-Tex is becoming a popular material for frontalis suspension.⁶⁻⁸

Gore-Tex is a well known microporous material, which is often used in brain or cardiac surgery.^{9,10} To avoid leakage of fluid, Gore-Tex PDX was improved with a triple-layer wafer structure. Also, to lessen glare under the microscope, a dual-surface type of Gore-Tex MVP was developed with a textured and smooth surface (Figure 4). In our procedure, which followed the technique reported by Kanemori,⁵ the textured surface is buried in contact with the orbicularis or dermis, while the smooth surface stays in contact with the orbital fat or septum.

The Gore-Tex sheet is available in various sizes and can be cut into any form needed during surgery. At our institution, the width of the MVP sheet is 5–7 mm, which is wider than a sling. Once we tried a 10 mm wide sheet, but it was found to be too bulky for the oriental eyelid. As an additional advantage, its striped nature helps the surgeon to cut the sheet vertically and horizontally in a straight line.

The thickness of an MVP sheet is 0.3 mm, which is thin enough to suspend the eyelid. The normal Gore-Tex sheet is softer and more pliable than MVP. Because of the sheet-like shape, the surface area that attaches to the frontalis portion is larger than that of slings or strips. Therefore, we suggest that the suspension achieves more stable traction than linear traction. The partitioning dual strips were fixated at the nasal and middle parts of the tarsus and would have contributed to the acceptable contour at the eyelid margin. Our results also indicate that the tensile strength of the Gore-Tex sheet

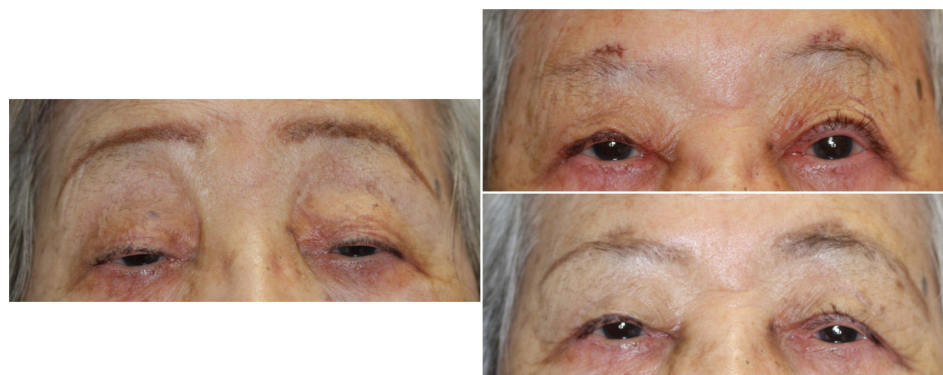


Figure 3 A 76-year-old woman with congenital ptosis in both eyes.

Notes: Her levator function was 3 mm bilaterally. Strong frontalis muscle contraction caused her eye brow to stay up for a long time. After surgery, exertional opening of the eyelid and eye brow position was lowered. Her marginal reflex distance was maintained at 1.5 mm during follow-up.



Figure 4 Photograph showing the textured and smooth dual surface of the MVP® sheet magnified under a microscope.
Note: Each strip is 0.8 mm in length.

remains stable for a relatively long time and results in less need for redo surgery (0%).

One report⁸ has indicated a higher infection rate with Gore-Tex if it is not soaked in an antibiotic solution before use. Gore-Tex has a microporous structure which may allow proliferation of bacterial contaminants and lead to abscess formation.⁸ In our series, the Gore-Tex sheet was divided and sterilized by ethylene oxide gas preoperatively. No cases of infection occurred despite lack of soaking in an antibiotic solution.

The micropores are too small to allow infiltration of fibrovascular tissues.¹¹ However, sheath formation around Gore-Tex material has been reported.¹² In addition, capsular formation around the Gore-Tex sheet might enable easy removal or manipulation to adjust eyelid height after surgery.

We experienced one case of exposure (4%), for which we followed a conservative course of management as reported,¹³ but unfortunately, removal of the Gore-Tex was necessary. In this case, eyelid shrinkage continued after the exposed portion of Gore-Tex was removed. The cause of the shrinkage is unknown, but may be related to a foreign body reaction. Fibrovascular tissue is reportedly strong enough to maintain a sufficient upper eyelid height even after removal of the material.⁶ In sum, its unique biocompatible surface, together with its thinness, may contribute to a lower exposure rate.

It is commonly assumed that the frontalis suspension procedure will promote contracture of the eyelid in younger patients because the length between the brow and eyelid gets wider as the face grows. In addition, the implanted fascia sometimes shrinks after surgery.^{3,14} The incidence in children

is higher than in older patients (58% versus 20%, $P=0.04$). If the strips are not adjustable in length, the eyelid contour will contract in children. However, the 0.4 mm decrease suggests material expansion, tearing of loose tissue, or an anatomical defect in the patient. In our opinion, preadolescent patients are likely to stop using the frontalis muscle because they become tired of holding the eyelid open and are not vigilant about their appearance (Figure 2). Yoon and Lee reported the same problem,¹⁵ observing an attenuation of approximately 0.4 mm during one year of follow-up by using autologous fascia lata. Among our cases, we observed no severe recurrent cases, with MRD of 0 mm or under and no patients requiring redo surgery. However, with longer follow-up, severe recurrence or cases with contraction requiring reoperation may develop.

Conclusion

Experimentally, we have shown that frontalis suspension using a Gore-Tex sheet is safe and effective. Although there was a high rate of partial recurrence, no redo surgeries were necessary. Further observation is needed for more comprehensive evaluation of this technique.

Disclosure

The authors report no conflicts of interest in this work.

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