Comparison of Materials Used in Frontalis Suspension

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Objective: To compare various materials used in frontalis suspension surgery for incidence of infection and/or granuloma formation and incidence of recurrent ptosis.

Design and Methods: A retrospective medical record analysis was performed for 102 frontalis suspension operations performed on 43 patients between January 1, 1991, and December 31, 1996, at Indiana University Medical Center, Indianapolis. Materials used for surgery were compared for incidence of infection and/or granuloma formation and incidence of recurrent ptosis. Materials included autogenous fascia lata, banked fascia lata, monofilament nylon, braided polyester, expanded polytetrafluoroethylene, and polypropylene.

Results: Infection and/or granuloma formation occurred in 10.8% of all frontalis suspensions and in less than 10.0% for each material used except expanded polytetrafluoroethylene. Five (45.5%) of the 11 frontalis suspensions using expanded polytetrafluoroethylene required removal of the material because of suspected infection. Ptosis recurred in 32 cases (31.4%). Low incidence of recurrence was found with autogenous fascia lata and expanded polytetrafluoroethylene.

Conclusions: Of the materials compared in this study, autogenous fascia lata may be the material of choice for frontalis suspension surgery in congenital ptosis. Other materials are useful for temporary eyelid elevation. All materials carry the risk of potential infection and/or granuloma formation.


FRONTALIS suspension is the operative procedure often used for treatment of severe blepharoptosis with poor or absent levator muscle function. Poor levator function has been broadly defined as levator muscle movement of 2 mm or less and no more than 6 mm by various authors.1-3 Frontalis suspension is most commonly used for congenital ptosis but is also used to treat blepharophimosis syndrome, Marcus Gunn jaw-wink phenomenon, congenital fibrosis syndrome, cranial nerve III palsy, and double elevator palsy. Treatment is most important when an eyelid blocks the visual axis causing amblyopia, or when an anomalous head posture is apparent. Complications of frontalis suspensions include recurrent ptosis, postoperative infection, and granuloma formation.

Autogenous fascia lata has long been considered the material of choice for frontalis suspension.5-6 It was first described in the treatment of congenital ptosis by Payr in 19095-7 and again by Wright in 1922.8 However, difficulty harvesting the material, insufficient amounts of material, and scarring in children younger than 3 years compelled surgeons to find alternative materials.3,9 Banked fascia lata, a popular option, has been compared with autogenous fascia lata for efficacy and long-term viability of the material.4-6 Autogenous fascia lata is generally more effective, with a lower rate of infection and granuloma formation.8 Recurrent ptosis rates have been reported to be as low as 5% with the use of autogenous fascia lata, and 8% with the use of banked fascia lata.3,6

Synthetic materials also have been investigated for use in frontalis suspension surgery. These are more readily available and do not carry the risk of transmitting infectious diseases.10 A study using 4-0 woven polyester suture reported a recurrent ptosis rate of 43%.11 The use of polyfilament nylon cable suture was evaluated in 2 separate studies that suggested that nylon was useful as a temporary measure for young children with severe ptosis.1,3

In the mid-1980s, ocularplastic researchers began investigating the use of expanded polytetrafluoroethylene (ePTFE). This synthetic material, used previously in vascular and abdominal surgery, is inert, extremely biocompatible, and resistant to infection. It is easily sutureable and biointegrates by means of fibroblastic ingrowth.2,10

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MATERIALS AND METHODS

A retrospective medical record analysis was performed on all patients who underwent frontalis suspension surgery in the Department of Pediatric Ophthalmology, Indiana University Medical Center, between January 1, 1991, and December 31, 1996. All patients had severe ptosis with poor levator muscle function. Indications for surgery were ptosis either obscuring the visual axis or with anomalous head position. One hundred two procedures were performed on 43 patients. The median age at surgery for the group was 18 months (range, 1-25 years). Sixty-five of these were primary procedures and 37 were secondary or tertiary procedures. Autogenous fascia lata was not used for any child younger than 3 years. Of the 65 primary procedures, 22 were bilateral (44 eyelids) and 21 were unilateral (11 on the right upper eyelid and 10 on the left). Congenital ptosis was the initial diagnosis in 29 patients; blepharophimosis syndrome in 8; cranial nerve III palsy in 2; and Marcus Gunn jaw-wink phenomenon, chronic progressive external ophthalmoplegia, double elevator palsy, and congenital fibrosis syndrome in 1 each. No patients had diagnoses that might limit surgical success, such as atopic disease or immune suppression.

All operations were performed by the attending surgeon (including D.T.S. and E.M.H.) using the technique described by Helveston and Ellis12 (Figure 1). After the eyelids were compared for contour and crease, a corneoscleral protector was placed under the eyelid. Incisions were performed through skin and orbicularis muscle. A Wright fascia needle (Katena Products Inc, Denville, NJ) was used to bring the sling material under the orbicularis muscle from one incision out through another. In cases in which fascia lata or ePTFE was used, a nonabsorbable suture was placed through the skin incision. In procedures using ePTFE, strips were fashioned intraoperatively from ePTFE sheets. Materials were prepared with isotonic sodium chloride solution only; none were soaked in antibiotics. Only the skin of the superior central incision was sutured closed with a 6-0 absorbable suture. Antibiotic ointment was then placed over each incision and into the palpebral fissure, and such treatment was continued for 2 weeks. Postoperative systemic antibiotics were not used.

Twenty-four eyelids had ptosis surgery using autogenous fascia lata. In 35 eyelids, banked irradiated allogenic fascia lata (from the Hospital for Sick Children, Toronto, Ontario) was the suspensory material used. Of the remaining eyelids, 13 were repaired with monofilament nylon suture (Ethilon; Ethicon, Somerville, NJ), 11 with braided polyester (Ticron; United States Surgical, Norwalk, Conn), 11 with ePTFE (Gore-Tex; W. L. Gore & Assoc, Flagstaff, Ariz), and 8 with polypropylene (Prolene; Ethicon).

Outcomes were based on clinical examination findings. Success depended on eyelid height and symmetry, with particular regard to visual axis. Improvement in head position was noted when applicable. The same factors were used to define recurrent ptosis as for the primary cases, ie, ptosis that obscured the visual axis and/or resulted in anomalous head position. Accurate eyelid height measurements to define recurrent ptosis are often difficult to obtain in young children, and specific measurements were not used for clinical judgments.

Postoperative infections and foreign body granulomas, often difficult to differentiate clinically, may develop concomitantly in the postoperative period. Both may develop with edema, erythema, and purulent exudate at the incision sites. These cases are treated similarly with systemic antibiotics and selected surgical drainage. Infections and/or granulomas are combined in our analysis of surgical outcomes.

Our study retrospectively evaluated the experience of surgeons at Indiana University Medical Center, Indianapolis, who used various materials for frontalis suspension procedures. Autogenous fascia lata, banked fascia lata, monofilament nylon, braided polyester, ePTFE, and polypropylene were compared for incidence of infection, granuloma formation, and recurrent ptosis.

RESULTS

One hundred two frontalis suspension operations were performed on 43 patients (Table). 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. Thirty-seven eyelids (36.3%) required secondary or tertiary frontalis suspension surgery. (Five of the 11 eyelids with infections and/or granuloma formation and all 32 eyelids with recurrent ptosis had undergone subsequent operations at the time of this report.) None of the patients had any lasting complications from exposure of the cornea after frontalis suspension.

Follow-up time is defined as the duration from the last procedure to the last available office visit or the duration between the procedure and the recurrent ptosis or infection and/or granuloma formation (Table). The median follow-up from the last surgery was 24 months (range, 1 week to 9 years). Eyelid procedures with less than 6 months of follow-up were included only when infection and/or granuloma formation or recurrent ptosis occurred within that period. No procedure using braided polyester or ePTFE had follow-up longer than 2 years.

Infection and/or granuloma formation occurred in 10.8% of all frontal suspensions and in less than 10.0% for each material used except ePTFE (Figure 2). Five (45.5%) of the 11 procedures using ePTFE required reoperations to remove the material because of suspected infection. Six (54.5%) of the 11 infections and/or granulomas occurred within 1 month of the surgery, and the remaining 5 occurred 3 or more months after surgery. Culture and sensitivity tests were performed in most cases, and systemic antibiotics were adjusted based on sensitivity (Figure 3).

Ptosis recurred in 32 (31.4%) of the 102 procedures (Table). Median time to reoperation for recurrence was 24 months. Reoperation for recurrence was necessary for each material used except ePTFE (Figure 4). Although recurrence was most frequent for monofilament nylon and banked fascia lata, patients with these materials were followed up for longer periods (Table). For example, 10 (37.0%) of the 27 reoperations for recurrent ptosis in the

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monofilament nylon and banked fascia lata groups occurred after at least 3 years of follow-up. In contrast, in the group of patients with ePTFE, none were followed up for more than 2 years.

**COMMENT**

Although autogenous fascia lata has been considered the most desirable material for frontalis suspension, physicians have continued to search for alternatives.1-4,11,13 This study evaluates the rate of infection and/or granuloma formation and the rate of recurrent ptosis with the use of several materials. In our study, the treatment outcomes for autogenous fascia lata compared favorably with those of other materials. Of the 24 frontalis suspensions using autogenous fascia lata, only 2 (8.3%) developed an infection and/or granuloma, and only 1 (4.2%) developed recurrent ptosis. The case of recurrent ptosis appeared more than 5 years after the initial surgery. Of the materials compared, autogenous fascia lata may be the material of choice when fascia can be harvested.

Banked fascia lata is a popular alternative for young children undergoing frontalis suspension surgery. In his 20-year review of cases, Crawford4 reported an increased incidence of inflammatory reactions with banked fascia lata compared with autogenous fascia lata. He suggested that this may have more to do with the suture used to tie the material under the frontalis muscle, and he suggested the use of 6-0 plain gut for that suture when using autogenous fascia lata vs 6-0 polyglycolic acid (Dexon; United States Surgical) when using banked fascia lata. Wagner et al3 found no incidence of infection or granuloma formation in their series with banked fascia lata. They also reported a recurrent ptosis rate of 8.3% in patients followed up for an average of 31.5 months. Broughton et al13 also found a low incidence of complications with the use of lyophylized fascia lata, but average follow-up was limited to just 8.4 months. In that report, no conclusion could be drawn regarding the long-term efficacy of the material.

Of our 35 eyelids using banked fascia lata, we found 2 cases (5.7%) of infection and/or granuloma formation and 18 cases (51.4%) of recurrent ptosis. Three cases of recurrent ptosis appeared within the first year after surgery and 15 appeared later. This late recurrent ptosis may be related to host reabsorption of material.4,5 Crawford4 performed histologic studies on rabbits and suggested that banked fascia lata acts as a bridge for host fibroblasts that eventually replace the fascia lata. However, in biopsy specimens taken from human patients up to 16 years after surgery, Beyer and Albert5 observed banked fascia lata that was histologically intact without absorption.

Our patients’ higher rates of recurrent ptosis were similar to those reported by Wilson and Johnson,14 who found increasing recurrent ptosis rates with each year beyond the first 9 years of follow-up. They reported that 50.0% of frontalis suspensions using banked fascia lata had failed at 9 years after surgery.14 Our study suggests that banked fascia lata is not as efficacious as autogenous fascia lata, but it may be an acceptable alternative in selected cases.

**Summary of Complications by Material**

<table>
<thead>
<tr>
<th>Material</th>
<th>No. of Eyelids</th>
<th>Length of Follow-up, Median (Mean) [Range], mo</th>
<th>No. (%) With Infection and/or Granuloma</th>
<th>No. (%) With Ptosis Recurrence</th>
<th>Median Time to Ptosis Recurrence, Median (Mean) [Range], mo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Autogenous fascia lata</td>
<td>24</td>
<td>30.0 (32.0) [33-60]</td>
<td>2 (6.3)</td>
<td>1 (4.2)</td>
<td>60</td>
</tr>
<tr>
<td>Banked fascia lata</td>
<td>35</td>
<td>18.0 (30.0) [0.25-108.00]</td>
<td>2 (5.7)</td>
<td>18 (51.4)</td>
<td>30 (41) [12-108]</td>
</tr>
<tr>
<td>Monofilament nylon</td>
<td>13</td>
<td>24.0 (10.0) [1-48]</td>
<td>1 (7.7)</td>
<td>9 (69.2)</td>
<td>24 (28.2) [1-48]</td>
</tr>
<tr>
<td>Braided polyester</td>
<td>11</td>
<td>8.0 (8.0) [1-17]</td>
<td>1 (9.1)</td>
<td>3 (27.3)</td>
<td>6 (4.3) [1-6]</td>
</tr>
<tr>
<td>ePTFE</td>
<td>11</td>
<td>8.0 (7.5) [0.50-18.00]</td>
<td>1 (9.1)</td>
<td>3 (27.3)</td>
<td>6 (4.3) [1-6]</td>
</tr>
<tr>
<td>Polypropylene</td>
<td>8</td>
<td>24.0 (25.0) [10-36]</td>
<td>0</td>
<td>1 (12.5)</td>
<td>36</td>
</tr>
<tr>
<td>Total</td>
<td>102</td>
<td></td>
<td>11 (10.8)</td>
<td>32 (31.4)</td>
<td>...</td>
</tr>
</tbody>
</table>

*ePTFE indicates expanded polytetrafluoroethylene.
Previous studies using polyfilament nylon cable for frontalis suspension have reported recurrent ptosis in approximately 30.0% of eyelids.1,3 Katowitz1 reported a 29.0% recurrence rate but an otherwise very low complication rate after 55 eyelids followed for up to 10 years. Wagner et al3 found a recurrence rate of 28.1% and a rate of granuloma formation of 12.4%. Our results with 13 eyelids using monofilament nylon found a recurrence rate of 69.2%, including 4 eyelids with recurrent ptosis more than 3 years after the initial surgery. Longer follow-up data in the other studies may have yielded data more consistent with this report. We found only 1 case (7.7%) of infection and/or granuloma formation after surgery using monofilament nylon. Others have reported rates of less than 2.0% to 12.0%.1,3 Although the recurrent ptosis rate is relatively high, monofilament nylon is readily available and may be a reasonable option for temporary frontalis suspension in young children.

We found that polypropylene and braided polyester had low rates of infection and/or granuloma formation for our small number of cases (Figure 2). However, of the 3 eyelids with recurrent ptosis treated with braided polyester, all occurred within 6 months (Table). Many of the remaining patients have less than 1 year of follow-up. These materials may be alternatives for temporary frontalis suspension in the young, but further study and additional cases are required to elucidate their true long-term efficacy.

Expanded PTFE has shown great potential for long-term biocompatibility; it is reportedly nonantigenic and both biologically and chemically inert.2,10 In a series of 37 frontalis suspensions using ePTFE that were followed up for an average of 3 years, Steinkogler et al2 reported only 1 case of recurrent ptosis requiring surgical repair and 1 “rejection” requiring surgical excision. They stated that use of ePTFE would obviate the need for fascia lata in frontalis suspension surgery. Our findings with 11 eyelids using ePTFE showed no recurrent ptosis in patients observed for up to 18 months (Figure 4). However, we found a percentage of infection and/or granuloma formation (45.5%) more than 4 times higher than that with any other material used (Figure 2). The reason for this finding is not clear. The highly porous nature may allow sequestration of bacterial contaminants, with proliferation and abscess formation. We propose altering the technique by adding suture closure of all incisions. Although the data do not achieve statistical significance, the high incidence of infection and/or granuloma formation warrants further study of ePTFE before recommending it as an alternative in frontalis suspension surgery.

Our retrospective evaluation did not include other materials used in frontalis suspension, such as silicone rods. These were not used at our institution and therefore could not be included in the analysis. Most of the patients in the study had congenital ptosis and relatively few had other diagnoses; therefore, comparison by diagnosis was not possible. Our study population did not have enough biostatistical power to yield statistically significant differences between diagnoses or materials.

Synthetic materials were used in primary cases in children too young to undergo harvesting of autogenous fascia lata. Perhaps the rapid growth of these younger children, or simply their age, affected the recurrent ptosis. Comparison is difficult, as the young patients did not receive autogenous fascia lata. In
addition, longer follow-up time for some materials may clarify their true efficacy. Although determination of ptosis in children is generally based on clinical judgment, quantitative measures, when feasible, would aid in comparison of surgical outcomes within and between studies. Accurate measurements are often difficult to obtain in children and were not used to determine surgical cases at our institution. For children younger than 3 years, several reasonable alternatives for temporary frontalis suspension are available. In addition to recurrent ptosis, families should be counseled regarding the potential for infections or granuloma formation.

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In addition to Drs Sprunger and Helveston, surgery was performed by Forrest D. Ellis, MD; David A. Plager, MD; and Naval Sondhi, MD. Corresponding author: Barry N. Wasserman, MD, Princeton Eye Laser Center, 100 Canal Pointe Blvd, Suite 112, Princeton, NJ 08540 (e-mail: http://www.princetonlaser.com).

REFERENCES


100 Years Ago in the Archives

D or (Lyons): Optic neuritis in infectious diseases and particularly mumps. Dor found optic neuritis in a series of cases of epidemic parotitis. This occurrence is not infrequent in military hospitals when there are epidemics of mumps. In general the prognosis is favorable, yet in exceptional cases atrophy of the nerve results. The treatment consists in the use of purgatives and diuretics.