Sutured Protective Occluder for Severe Amblyopia

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Objective: To investigate the feasibility, acceptability, efficacy, and cost of a newly developed translucent shield that can be fixed by sutures to the orbital rim for a month of amblyopia therapy.

Methods: In an institutional review board–approved protocol for patients with amblyopia who do not adhere to the use of conventional patching, shield occluders were fashioned from heat-moldable sturdy black or translucent (20/4000) plastic with holes drilled for attachment. Under brief general anesthesia, patients aged 5 to 10 years had a thorough examination before the shield occluder was sewn to the brow and cheek of the nonamblyopic eye with 3-0 monofilament polypropylene sutures.

Results: Ten children completed this protocol from December 1999 through January 2002. All tolerated the occluder for 12 to 36 days. The resultant skin scars were acceptable to parents, patients, and investigators. The amblyopic eyes improved from a mean (SD) of 0.77 (0.30) logMAR (Snellen equivalent, 20/119) to 0.45 (0.29) logMAR (Snellen equivalent, 20/57), a change of 0.32 (0.16) logMAR lines. There was no damage to the sound (occluded) eye.

Conclusion: Sew-on occluder shields are an alternative when adherence to the use of other types of patching (often referred to as compliance with patching) is not satisfactory.

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Successful amblyopia therapy is dependent on adherence to treatment (often referred to as compliance),1,2 a factor influenced by patient behavior, patient age,3 parental effort,4,5 and physician emphasis.6 Adherence may improve in children treated with spectacles alone7,8 or with atropine penalization.9,10 Conventional patch compliance has been augmented by adding an adhesive dressing11 and by placing objects around the child’s arms (eg, paper towel rolls, arm immobilizers, or water wings).12 Family adherence is assisted by enrolling the children in “amblyopia camp” or admitting them to the hospital.13 For children who live in a cold climate, a snowsuit with mittens taped on also helps.

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Amblyopia occlusion therapy has been successfully enhanced even in nonadherent patients who were fitted with opaque soft contact lenses,14-16 stained hard contact lenses,17 or myopic contact lenses.18 The lid of the better eye can be closed temporarily with tarsorrhaphy,19 cyanoacrylate glue to the lids,20 or injection of purified botulinum A toxin to the levator muscle.21,22 To date, it has been very difficult to determine the degree of adherence to home patching.23-25 We found opaque extended-wear contacts less than ideal in our dry climate because of keratitis. We were also concerned about protecting the better eye during an interval of intense patching. Combining technology from the Spielman occluder or flexible static vinyl sheets (Bangerter Occlusion Foils; Western Ophthalmics Corp, Lynnwood, Washington), post–cataract surgery protective shields, and the experience of plastic surgeons and body piercers, we developed a translucent sew-on occluder that can be fixed to the orbital rim for a month of amblyopia therapy. We investigated the feasibility, acceptability, and efficacy of this alternative and then estimated its cost.

METHODS

With consent from the institutional review board at Providence Alaska Medical Center, Anchorage, from December 1999 through January 2002, 10 consecutive children aged 5 to 10 years with severe amblyopia, in whom conventional methods of occlusion and atropine penalization had been exhausted, were entered into this study protocol. Three additional patients were considered, but they either recommitted to conventional occlusion or withdrew from the surgery. We excluded children in whom keloids were known to form and children with severe behavioral problems.

The primary outcome was whether such a shield would be tolerated by patients and their families. The secondary outcome was the impact

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of this experimental therapy on visual acuity. This was a noncomparative, nonrandomized interventional series. It was also noncontrolled, other than considering as controls the 2 patients who decided to comply with conventional patching and the 1 who withdrew from therapy. Severe amblyopia was defined as visual acuity in the worse eye less than or equal to 20/70. Visual acuity beyond the range of risk for amblyopia was defined as visual acuity of the sound eye from 20/20 to 20/4000 but allowed close examination of ocular health. The acuity of the sound eye remained within 1 line of baseline within minutes after shield removal.

Table 1. Characteristics of Patients Undergoing Shield Occlusion

<table>
<thead>
<tr>
<th>Patient No./Sex/Age, y</th>
<th>Amblyopic Eye</th>
<th>Mechanism</th>
<th>Initial Visual Acuity</th>
<th>Amblyopic Eye</th>
<th>Sound Eye</th>
<th>Refraction</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Sphere</td>
<td>Cylinder</td>
<td>Sphere</td>
<td>Cylinder</td>
</tr>
<tr>
<td>1/M/9.5</td>
<td>L</td>
<td>Mixed</td>
<td>125</td>
<td>25</td>
<td>8</td>
<td>2</td>
</tr>
<tr>
<td>2/M/7.4</td>
<td>R</td>
<td>Strabismus</td>
<td>200</td>
<td>30</td>
<td>5.75</td>
<td>0.75</td>
</tr>
<tr>
<td>3/M/8.8</td>
<td>L</td>
<td>Mixed</td>
<td>70</td>
<td>25</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>4/M/10.0</td>
<td>R</td>
<td>Mixed</td>
<td>160</td>
<td>20</td>
<td>8.75</td>
<td>0</td>
</tr>
<tr>
<td>5/M/5.7</td>
<td>R</td>
<td>Trauma, mixed</td>
<td>600</td>
<td>20</td>
<td>9</td>
<td>3</td>
</tr>
<tr>
<td>6/M/7.2</td>
<td>L</td>
<td>Strabismus</td>
<td>65</td>
<td>30</td>
<td>3.5</td>
<td>1.75</td>
</tr>
<tr>
<td>7/M/8.8</td>
<td>L</td>
<td>Mixed</td>
<td>65</td>
<td>16</td>
<td>6.5</td>
<td>2</td>
</tr>
<tr>
<td>8/F/9.4</td>
<td>L</td>
<td>Strabismus</td>
<td>100</td>
<td>20</td>
<td>5</td>
<td>1.75</td>
</tr>
<tr>
<td>9/M/6.1</td>
<td>R</td>
<td>Strabismus</td>
<td>100</td>
<td>20</td>
<td>0.25</td>
<td>0.5</td>
</tr>
<tr>
<td>10/F/9.6</td>
<td>L</td>
<td>Strabismus</td>
<td>80</td>
<td>25</td>
<td>7.75</td>
<td>1</td>
</tr>
<tr>
<td>Mean (SD)/8.2 (1.5)</td>
<td></td>
<td></td>
<td>156.5 (162.0)</td>
<td>23.1 (4.7)</td>
<td>6.1 (2.7)</td>
<td>1.4 (0.9)</td>
</tr>
</tbody>
</table>

and tied through the occluder holes. This prototype occluder was tolerated for more than 5 weeks without resultant infection; after the first 10 days, we reduced tugging by taping over the shield. Of the 3 attachment types, the 3-0 polypropylene was best tolerated.

Shield occluders were manufactured from heat-moldable plastic according to each patient’s face. Four pairs of holes were drilled in the edges for attachment by sutures. The initial shield occluders were opaque and black. The second edition of the shield occluder (Figure 1) (used in patients 7-10) was fashioned from translucent material resembling a firm occlusive foil. Fractureresistant, plastic shower-stall windows were cut according to predetermined shapes for the right and left eyes, and 4 sets of 2 holes were drilled for suture attachment. The eye was easily viewed through the shield by investigators and parents. However, distance visual acuity of the sound eye through the shower-stall window material was reduced from 20/20 to 20/4000.

Each patient underwent an examination under anesthesia with cycloplegia and careful indirect and direct ophthalmologic examination of the amblyopic eye to rule out structural obstacles to improved acuity. The prefabricated shield occluder was then heat-molded (an optician’s hot-salt box worked best) for ideal fit to the orbital rim of the better eye. The periocular skin was prepared with povidone-iodide solution. An outline of the occluder was drawn, identifying the predrilled holes with a surgical marking pen. Four sutures were then placed to a subcutaneous, but less than orbicularis, depth with a noncutting needle and 3-0 monofilament polypropylene. The sutures were then passed through the corresponding holes and tied with triple square knots. Tape was applied to reduce initial suture tugging, and the patient was allowed to emerge from general anesthesia.

Each patient was examined 1 day postoperatively to confirm complete occlusion of the better eye and to recheck visual acuity in the amblyopic eye (Figure 1 and Figure 2). Spectacle nose pads were adjusted to accommodate the shield occluder. We dispensed a tube of antibiotic/corticosteroid ophthalmic ointment but encouraged clean, dry care of the suture sites unless redness occurred. The patient returned for occluder removal after about 4 weeks (this was variable depending on office and family scheduling). At that time, visual acuity was measured and the polypropylene sutures were cut. Photographs were taken of the suture sites on the day of removal. Parents were encouraged to keep the suture sites clean and apply vitamin E ointment as desired. We urged parents to continue conventional patching, and we specifically asked them how the skin looked after healing.
RESULTS

In all 10 cases, parents, patients, and investigators were satisfied with the durability of the occlusion and the appearance of scars after use of the sew-on occluder (Figure 3). Two patients each rubbed 1 stitch out near the end of the therapy but complied with adhesive tape fixation until completion. No patient had a skin infection that required systemic antibiotics. No patient was injured because of falls during occlusion therapy. There were no cases of reverse amblyopia.

Data on visual acuity (initial and final) of the sound and amblyopic eyes and cycloplegic refraction are given in Table 2. Visual acuity of the patched eye did not decline; in all patients it immediately returned to prepatching levels a few minutes after removal of shield occluder. The initial and final visual acuity of the amblyopic eye plotted against age is shown in Figure 4. The amblyopic eyes improved from a mean (SD) of 0.77 (0.30) logMAR (mean visual acuity, 20/119) to 0.45 (0.29) logMAR (mean visual acuity, 20/57), a change of 0.32 (0.16) logMAR lines. Visual acuity gained did not correlate with age at the time of patching (ΔlogMAR = 0.38−0.007[age], r² = 0.005, P = .85).

To provide a point of comparison, results were obtained from the 2 patients who, during the course of the study, seriously considered the procedure but instead decided to adhere to conventional patching. They were aged 8 and 9 years at the onset of adherence to patching, and their visual acuity improved 0.2 and 0.3 logMAR lines from initial amblyopia of 0.6 logMAR. One additional 7.5-year-old patient with anisometric amblyopia of 0.7 logMAR who had not adhered to conventional patching was scheduled for a shield occluder, but the parent was so apprehensive in the preoperative area that surgery was canceled. The patient remained nonadherent to conventional patching and had neither improvement nor degeneration in corrected amblyopic acuity 1½ years later.

Seven of the 10 original patients had relatively long-term follow-up (mean [SD], 3.5 [1.6] years). The parents and patients remained positive regarding the long-term appearance of the shield occluder scars. Parents reported imperfect adherence to routine patching after removal of the shield occluders, but most complied with spectacle wear. There was minimal (0.06 [0.12]) loss in logMAR lines in the amblyopic eyes (Table 2). Original visual acuities were isolated Snellen BVAT values, while follow-up values were surround electronic visual acuities (EVAs).

We estimated the cost in Alaska of therapy with the shield occluder to be $3300 (US dollars, 2007) for surgery, anesthesia, and examination under anesthesia. Given an average 0.32-logMAR improvement, the treatment cost was $1024 per line of vision gained.

COMMENT

We observed a reduction in severe amblyopia when patching adherence was surgeon-controlled by means of a sew-on, opaque or translucent occluder used for about 1 month. Hiscox et al26 had similar success in patients with severe amblyopia who adhered to the use of full-time occlusion by patches or occlusive contact lens. Our intent was (1) to determine the feasibility of imposed adherence to treatment and (2) to investigate whether this might effectively treat amblyopia in patients living in remote areas of Alaska or other parts of the world.

Recidivism can occur during the amblyopia years27: if a patient with or without treatment gains acuity in the amblyopic eye of 0.5 logMAR by age 5 years, then with non-adherence slips to an acuity of 0.8 logMAR by age 9 years, amblyopia treatment started at that point might “retrieve” a best-corrected visual acuity of 0.5 logMAR. We do not believe the improvements in amblyopia in this study were merely due to elimination of recidivism, since we had been following up these children, urging conventional patching and penalization adherence, for years. The 1 non-adherent patient who canceled surgery on the day of the procedure did not have a change in amblyopic acuity.

Most of our patients with severe amblyopia had a combination of anisometropia and strabismus. Mixed anisometropia and strabismus is overrepresented in severe amblyopia.128 Early detection can improve treatment adherence and amblyopia treatment successes.28 Even at an age before verbal acuity screening becomes feasible, large-angle

Figure 2. Previously treatment-nonadherent brothers aged 7 and 10 years from the younger brother in Figure 2.

Figure 3. Residual scars 1 year after removal of shield occluder (left side)

Figure 4.
strabismus can be detected by the observations of parents or pediatricians, whereas anisometropia can be detected early by photoscreening.

In our small series, the age of the patients did not correlate with the degree of visual acuity gained. Others have noted little effect of age at the start of treatment. Adolescent patients with amblyopia who adhered to extended full-time occlusion realized substantial acuity gains. Part-time patching plus penalization better reduced amblyopia than did spectacles alone in children aged 7 to 12 years. There was similar improvement in patients treated with opaque and translucent occluders; we favored the ability to monitor ocular and adnexal health with the translucent material.

Some have suggested that sewing a device to the orbital rim of a child is “barbaric.” We compared and contrasted this effort (retrieving potential acuity from a legally blind eye while protecting the sound eye) with the long-established cosmetic fascia lata frontalis sling procedure for congenital ptosis. We reviewed photographs and queried parents, concluding that the resultant scars were universally considered acceptable or imperceptible in light of acuity gained. The degree of scarring was similar to skin changes after frontalis suspension sling surgery.

Ten of our families accepted, even if reluctantly, the concept of sewing a semipermanent occluder to their children’s facial skin. On the other hand, 2 children were then motivated to increase their own adherence to conventional patching, and 1 parent abandoned the procedure at the last moment. Sew-on occlusion in some ways resembles the relatively common practice of body piercing. Complications of body piercing, including bleeding, tissue trauma, and infection, may occur in 17% of body piercing.

We suspect a temporary tarsorrhaphy (cyanoacrylate glue, marginal suture, or levator botulinum A toxin) would be less effective than the sew-on occluder because the amblyopic youngster could manually induce an optical opening in the lids over the sound eye.

The sewn-on occluders provided a mechanism of ensuring adherence to occlusion; as such, we were able to estimate the maximum improvement with opaque or markedly blurred occlusion for about 4 weeks compared with that in patients from the Pediatric Eye Disease Investigator Group Amblyopia Treatment Studies and adolescents treated with full-time occlusion.

### Table 2. Outcomes of Patients Undergoing Shield Occlusion

<table>
<thead>
<tr>
<th>Patient No.</th>
<th>Days Patched</th>
<th>LogMAR Pretreatment</th>
<th>LogMAR Posttreatment</th>
<th>Change</th>
<th>Follow-up, y</th>
<th>LogMAR Loss</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>27</td>
<td>0.8</td>
<td>0.7</td>
<td>0.1</td>
<td>0.8</td>
<td>0.0</td>
</tr>
<tr>
<td>2</td>
<td>27</td>
<td>1.0</td>
<td>0.7</td>
<td>0.3</td>
<td>3.5</td>
<td>0.3</td>
</tr>
<tr>
<td>3</td>
<td>12</td>
<td>0.5</td>
<td>0.2</td>
<td>0.3</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>4</td>
<td>27</td>
<td>0.9</td>
<td>0.3</td>
<td>0.6</td>
<td>2.7</td>
<td>0.0</td>
</tr>
<tr>
<td>5</td>
<td>27</td>
<td>1.5</td>
<td>1.0</td>
<td>0.5</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>6</td>
<td>36</td>
<td>0.5</td>
<td>0.4</td>
<td>0.1</td>
<td>5.2</td>
<td>−0.1</td>
</tr>
<tr>
<td>7</td>
<td>25</td>
<td>0.5</td>
<td>0.2</td>
<td>0.3</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>8</td>
<td>21</td>
<td>0.7</td>
<td>0.5</td>
<td>0.2</td>
<td>5.5</td>
<td>0.0</td>
</tr>
<tr>
<td>9</td>
<td>20</td>
<td>0.7</td>
<td>0.3</td>
<td>0.4</td>
<td>3.8</td>
<td>0.1</td>
</tr>
<tr>
<td>10</td>
<td>34</td>
<td>0.6</td>
<td>0.2</td>
<td>0.4</td>
<td>3.4</td>
<td>0.1</td>
</tr>
</tbody>
</table>

Mean (SD) 25.8 (6.9) 0.77 (0.30) 0.45 (0.29) 0.32 (0.16) 3.5 (1.6) 0.06 (0.12)

Abbreviation: NA, not available.

a LogMAR lines gained by shield occlusion (isolated Snellen).

b Time after removal of the shield.

c Regression in acuity (surround) after follow-up interval.

Figure 4. Improvement in visual acuity of the amblyopic eye as a result of shield occluder application in 10 children as a function of age.

Figure 5. Average logMAR visual acuity improvement over time in the current series of 10 patients with confirmed adherent occlusion compared with that in patients with moderate amblyopia with part-time patching, patients with more severe strabismic amblyopia with or without refractive amblyopia patched 6 hours to full time, and adolescents treated with full-time occlusion.

PEDIG indicates Pediatric Eye Disease Investigator Group.
acceptance of 1 month of intense, sewn-on occlusion, we continued to encourage conventional occlusion for all patients who had not yet achieved a visual acuity of 20/40 or better. Most continued to have difficulty with patch adherence, although some persisted with atropine penalization. None has achieved better than 20/32 visual acuity in the amblyopic eye. We do not know what value an additional month of sewn-on occlusion would afford.

The sew-on occluder offers a protective, consistent interval of full-time occlusion for school-aged amblyopic children who have not adhered to other therapy, or for whom access to pediatric eye care is remote. We recommend the sew-on shield occluder only for families who have exhausted conventional methods to enhance amblyopia therapy adherence. A local optician should be able to manufacture the shield occluders to custom fit amblyopic patients. (Information on the manufacture and availability of shield occluders can be found at http://www.abcd-vision.org.)

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Financial Disclosure: The authors have no financial interest in this device, in surgical staples or sutures, or in occlusive patches. Dr Arnold and Ms Armitage are site investigators with the Pediatric Eye Disease Investigators. Ms Armitage is site investigator with the Pediatric Eye Disease Investigator Group Amblyopia Treatment Studies.

Previous Presentation: This study was presented as a poster at the American Association for Pediatric Ophthalmology and Strabismus Annual Meeting; March 22, 2002; Seattle, Washington.

REFERENCES