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The Relationship Between Preoperative Alignment Stability and Postoperative Motor Outcomes in Children with Esotropia

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Abstract

Purpose—To examine the effect of preoperative alignment stability on postoperative motor outcomes in children who underwent surgery for esotropia.

Methods—167 subjects (68 with infantile esotropia and 99 with acquired esotropia) aged less than 6 years had surgery after completing 18 weeks of follow up as part of an observational study. Preoperative alignment was classified as stable, uncertain, or unstable, based on measurements taken at baseline and every 6 weeks for 18 weeks. If the absolute value of the difference between the largest and smallest of the four measurements was within 5 PD inclusive, preoperative alignment was classified as stable; if the difference was 15 PD or greater, alignment was classified as unstable; and if neither of these criteria were met, alignment was classified as uncertain. Distance alignment measured by prism and alternate cover test was compared among stability classification groups at 6 weeks and 6 months after surgery.

Results—Among subjects with infantile esotropia, median 6-week postoperative deviation was 2 prism diopters (PD), 6 PD, and 2 PD for subjects with stable, uncertain, and unstable preoperative alignment, respectively ($P = 0.73$ for stable vs. unstable). Median 6-month postoperative deviation was 1 PD, 9 PD, and 1 PD for stable, uncertain, and unstable, respectively ($P = 1.00$ for stable vs. unstable). Among subjects with acquired esotropia, median 6-week postoperative deviation was 6 PD, 4 PD, 4 PD for subjects with stable, uncertain, and unstable preoperative alignment, respectively ($P = 0.69$ for stable vs. unstable). Median 6-month postoperative deviation was 8 PD, 4 PD, 6 PD, for stable, uncertain, and unstable, respectively ($P = 0.22$ for stable vs. unstable).

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Conclusions—Postoperative alignment at 6 weeks and 6 months appears similar in children with stable versus unstable preoperative esotropia. Nevertheless, our finding should be interpreted with caution due to small sample size.

Introduction

Alignment instability in children with infantile esotropia and acquired esotropia is common.^{1–6} We recently reported the results of an 18-week prospective observational study in which almost 50% of children with infantile esotropia and about 20% of children with acquired esotropia had unstable alignment.⁶ By contrast, about 20% of children with infantile esotropia and about 40% of children with acquired esotropia had stable alignment, whereas the remainder could not be classified as stable or unstable.⁶

For infantile esotropia, the impact of preoperative alignment stability or instability on postoperative outcomes is uncertain. In a retrospective case series, Lueder and Galli found no difference in motor outcomes between children with ≤ 5 prism diopters (PD) change in alignment prior to surgery and those who had ≥ 10 PD change preoperatively.⁷ In a prospective study, Birch et al. compared children with < 10 PD (stable) and ≥ 10 PD change in preoperative alignment, and reported that postoperative alignment was better in the stable group at 6 weeks but this difference disappeared by 1 year postoperatively.⁵ We are unaware of reports that compare surgical outcomes between subjects with acquired esotropia who had stable or unstable preoperative alignment.

In this study, we compare 6-week and 6-month postoperative alignment data from children with infantile esotropia or acquired esotropia whose preoperative misalignment was classified as stable, unstable, or uncertain in our previously-reported prospective observational study.⁶

Subjects and Methods

The Pediatric Eye Disease Investigator Group (PEDIG) conducted this study with funding provided through a cooperative agreement with the National Eye Institute of the National Institutes of Health, Department of Health and Human Services. The respective institutional review boards approved the protocol and the Health Insurance Portability and Accountability Act-compliant informed consent forms. The parent or guardian of each study participant gave written informed consent.

The study prospectively collected post-operative motor outcome data on 167 subjects who underwent surgery for esotropia after completing at least 18 weeks of follow up as part of an observational study, the details of which are described in a previous manuscript on stability of preoperative alignment.⁶ In brief, the observational study enrolled subjects aged 2 months to less than 5 years of age who had onset of constant esotropia within the previous six months. Patients with onset of esotropia before 6 months of age were considered to have infantile esotropia whereas patients with onset at 6 months or later were considered to have acquired esotropia. Ocular alignment was measured by the prism and alternate cover test (PACT) at near (or by modified Krinsky at near for the 22 infantile esotropia subjects in whom the PACT could not be performed) at baseline and every six weeks for 18 weeks. Each subject's preoperative alignment stability was classified as follows: if the absolute value of the difference between the largest and smallest of the four measurements was within 5 PD inclusive, alignment was classified as stable; if the difference was 15 PD or greater, alignment was classified as unstable; and if neither of these criteria were met, alignment was classified as uncertain. After 18 weeks, the timing of surgery was at investigator discretion. The type of surgery and the amount of surgery were also at investigator discretion. Subjects who had surgery had their ocular alignment measured at distance fixation at six weeks and six months

postoperatively. Alignment was measured by the PACT for all subjects and also by the simultaneous prism and cover test (SPCT), in subjects with acquired esotropia. If the subject was wearing spectacles, alignment was measured with the subject wearing spectacles.

Of the 195 subjects who enrolled in the pre-surgery observational study and completed all four visits during the 18-week preoperative follow up, 167 (86%) underwent subsequent surgery. Of these, 148 had baseline angles between 20 to 50 PD for infantile esotropia and 15 to 50 PD for acquired esotropia (i.e. subjects from the cohort reported in our previous manuscript on stability of preoperative alignment⁶), 1 had baseline angle smaller than 15 PD (8 PD), and 18 had baseline angles larger than 50 PD (range = 52.5 to 65 PD).

For each type of esotropia, at both the 6-week and 6-month postoperative visits, we compared the median absolute deviation between subjects with stable and unstable preoperative alignment using the Wilcoxon rank sum test with exact computation of P values. The proportion of subjects with a postoperative deviation 10 PD or larger was compared between subjects with stable and unstable preoperative alignment using Fisher's exact test. For the 8 subjects who underwent a second surgery during the study (5 with infantile esotropia and 3 with acquired esotropia), the last strabismus measurement prior to the reoperation was used for analysis. Postoperative deviations were analyzed without respect to whether they were constant, intermittent, or variable (i.e. changing in magnitude during the examination but not intermittent).

Analyses were conducted using SAS version 9.1 (SAS Institute, Cary, NC) and StatXact version 6.0 (Cytel, Cambridge, MA).

Results

Of the 167 subjects who underwent surgery, 68 had infantile esotropia and 99 had acquired esotropia (63 had non-accommodative and 36 had partially-accommodative). Age at surgery was a mean of 11 ± 2 months (range 7 to 18 months) for infantile esotropia subjects and a mean of 34 ± 12 (range 13 to 71 months) for acquired esotropia subjects. Among infantile esotropia subjects, preoperative alignment was classified as stable in 14 (21%) subjects, uncertain in 23 (34%), and unstable in 31 (46%). Among acquired esotropia subjects, preoperative alignment was classified as stable in 41 (41%) subjects, uncertain in 41 (41%), and unstable in 17 (17%). Other characteristics of the cohort are listed in Table 1.

Six-week data were missing for 15 (22%) infantile esotropia subjects and 8 (8%) acquired esotropia subjects; six-month data were missing for 8 (12%) infantile esotropia subjects and 8 (8%) acquired esotropia subjects. Table 2 shows the number of subjects with available data according to both esotropia type and preoperative alignment stability.

Among subjects with infantile esotropia, those with stable vs. unstable preoperative alignment had similar postoperative alignment as measured by PACT at distance at both 6 weeks and 6 months in terms of median deviation ($P = 0.73$ and $P = 1.00$, respectively), and in the proportion of subjects with a deviation of 10 PD or more ($P = 0.38$ and $P = 1.00$, respectively) (Table 2).

Similarly, among subjects with acquired esotropia, those with stable vs. unstable preoperative alignment had similar postoperative alignment as measured by PACT at distance at both 6 weeks and 6 months in terms of median deviation ($P = 0.69$ and $P = 0.22$, respectively), and in the proportion of subjects with a deviation of 10 PD or more ($P = 0.71$ and $P = 0.13$, respectively) (Table 2). Subjects with stable vs. unstable preoperative alignment also had similar postoperative alignment as measured by SPCT at distance at both 6 weeks and 6 months postoperative in terms of median deviation ($P = 0.18$ and $P = 0.30$, respectively) and in the

proportion of subjects with a deviation of 10 PD or more ($P = 1.00$ and $P = 0.70$, respectively) (Table 3).

Five subjects with infantile esotropia and three with acquired esotropia underwent a second surgery during the study. Of the 5 subjects with infantile esotropia, 2 were judged to have stable alignment prior to the first surgery, and 3 had alignment of uncertain stability. Of the 3 subjects with acquired esotropia, 1 was judged to have stable alignment prior to the first surgery and 2 had alignment of uncertain stability.

Discussion

One approach taken by strabismus surgeons is to delay surgery for childhood esotropia until the alignment stabilizes. Underlying this approach is a presumption that preoperative alignment instability reduces the certainty of surgical dose and may portend poor postoperative alignment. Nevertheless, the results of the present study suggest that there is no difference in postoperative alignment at 6 weeks and 6 months between subjects with esotropia who have stable versus unstable preoperative alignment measured over 18 weeks.

There are limitations to our study which should be considered when interpreting our results. First, we had a small sample size. It is possible that there were postoperative differences between subjects with stable versus unstable preoperative alignment that this study did not have sufficient statistical power to detect. Second, examiners were not masked to the preoperative stability status of subjects at the outcome measurement of alignment. Third, SPCT measurements were not performed in infantile esotropia patients. Fourth, no post-operative angle measurements were collected for any patient other than at 6 weeks and 6 months, so the postoperative alignment stability is unknown. Finally, with regard to interpretation of our findings, because none of the patients in this study underwent surgery at presentation, our results do not address the question of whether postoperative alignment is different if the surgeon waits for alignment stability vs. operating immediately.

The overall proportion of children who had 6-month postoperative misalignment of more than 10 PD measured by PACT – 37% of infantile esotropia subjects and 31% of acquired esotropia subjects – is higher than expected based on previous reports.^{5, 7} This high rate of postoperative misalignment ≥ 10 PD in our study may have been the result of our inclusion of intermittent deviations and phorias. Nevertheless, if we look at only SPCT measurements, thereby excluding postoperative deviations which were pure phorias and intermittent deviations which were not manifestly tropic at the time of testing, 19% of acquired esotropia subjects had ≥ 10 PD deviation at 6 months. Additional reasons for a high rate of postoperative deviations ≥ 10 PD may have been the protocol-mandated surgical delay and/or other unknown surgical and non-surgical factors.

Despite the limitations of our study, our findings suggest that in the first six postoperative months, alignment appears similar in children with stable versus unstable preoperative esotropia.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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Table 1

Characteristics of the cohort

Characteristic	Infantile esotropia (N = 68)	Acquired esotropia (N = 99)
	N (%)	N (%)
Female gender	35 (51)	51 (52)
White race	57 (84)	85 (86)
Type of esotropia		
Infantile	68 (100)	----
Acquired non-accommodative	----	63 (64)
Acquired partially-accommodative	----	36 (36)
Age at surgery, in months		
Mean (SD)	11 (2)	34 (12)
Range	7 to 18	13 to 71
6 to <12	42 (62)	----
12 to <18	26 (38)	7 (7)
18 to <24	----	18 (18)
24 to <48	----	61 (62)
48 to <60	----	10 (10)
≥60	----	3 (3)
Duration of Misalignment, in months[*]		
Mean (SD)	9 (2)	9 (2)
Range	5 to 14	4 to 17
<8	26 (38)	45 (45)
8 to <10	29 (43)	33 (33)
≥10	13 (19)	21 (21)
Last PACT at distance measurement prior to surgery, in prism diopters[†]		
Mean (SD)	50 (14)	30 (11)
Range	16 to 80	8 to 60
0 to 19	1 (2)	18 (19)
20 to 29	0 (0)	26 (27)
30 to 39	9 (20)	30 (32)
40 to 49	9 (20)	14 (15)
≥50	25 (57)	7 (7)
Preoperative Alignment Stability		
Stable	14 (21)	41 (41)

Characteristic	Infantile esotropia (N = 68)	Acquired esotropia (N = 99)
	N (%)	N (%)
Uncertain	23 (34)	41 (41)
Unstable	31 (46)	17 (17)

PACT, Prism and Alternate Cover Test

* Duration of misalignment was calculated from the time of onset of constant esotropia (as estimated from parent history, photographs, and physician records) to the time of surgery.

† 24 infantile esotropia subjects and 4 acquired esotropia subjects did not have a PACT at distance measurement taken prior to surgery, presumably due to poor patient cooperation.

Table 2
Postoperative prism-and-alternate-cover test (PACT) at distance according to preoperative alignment stability

	Infantile esotropia			Acquired esotropia		
	Preoperative alignment stability			Preoperative alignment stability		
	Stable (N = 14)	Uncertain (N = 23)	Unstable (N = 31)	Stable (N = 41)	Uncertain (N = 41)	Unstable (N = 17)
Prism-and-alternate-cover test at distance						
6 weeks postoperative						
N with data	12	17	24	38	36	17
Angle size (PD)						
Median	2	6	2	6	4	4
25th pctl, 75th pctl	0, 8	0, 18	0, 6	0, 8	1, 8	3, 6
Range	0 to 20	0 to 35	0 to 14	0 to 18	0 to 20	0 to 16
Any deviation $\geq 10^\Delta$						
N (%)	3 (25)	6 (35)	3 (13)	8 (21)	7 (19)	2 (12)
[95% CI on %]	[5 to 57]	[14 to 62]	[3 to 32]	[10 to 37]	[8 to 36]	[1 to 36]
Exodeviation $\geq 10^\Delta$						
N (%)	1 (8)	1 (6)	1 (4)	4 (11)	1 (3)	1 (6)
[95% CI on %]	[0 to 38]	[0 to 29]	0 to 21]	[3 to 25]	[0 to 15]	[0 to 29]
6 months postoperative						
N with data	12	22	26	40	35	16
Angle size (PD)						
Median	1	9	1	8	4	6
25th pctl, 75th pctl	0, 11	4, 18	0, 16	3, 15	0, 8	3, 6
Range	0 to 30	0 to 38	0 to 25	0 to 45	0 to 25	0 to 18
Any deviation $\geq 10^\Delta$						
N (%)	3 (25)	11 (50)	8 (31)	17 (43)	8 (23)	3 (19)
[95% CI on %]	[5 to 57]	[28 to 72]	[14 to 52]	[27 to 59]	10 to 40]	[4 to 46]
Exodeviation $\geq 10^\Delta$						
N (%)	1 (8)	2 (9)	1 (4)	8 (20)	1 (3)	1 (6)
[95% CI on %]	[0 to 38]	[1 to 29]	[0 to 20]	[9 to 36]	[0 to 15]	[0 to 30]

PD, prism diopters.

Table 3

Postoperative simultaneous-prism-and-cover test (SPCT) at distance according to preoperative alignment stability—acquired esotropia only

	Acquired esotropia		
	Preoperative alignment stability		
	Stable (N = 41)	Uncertain (N = 41)	Unstable (N = 17)
Simultaneous Prism and Cover Test at distance			
Six weeks postoperative			
N with data	29	26	13
Angle size, in prism diopters			
Median	0	4	4
25th pctl, 75th pctl	0, 6	0, 4	2, 6
Range	0 to 16	0 to 10	0 to 16
Any heterotropia $\geq 10^A$			
N (%)	3 (10)	2 (8)	1 (8)
[95% CI]	[2 to 27]	[1 to 25]	[0 to 36]
Exotropia $\geq 10^A$			
N (%)	1 (3)	1 (4)	1 (8)
[95% CI]	[0 to 18]	[0 to 20]	[1 to 36]
Six months postoperative			
N with data	31	27	12
Angle size, in prism diopters			
Median	6	4	3
25th pctl, 75th pctl	0, 10	0, 6	0, 6
Range	0 to 20	0 to 25	0 to 18
Any heterotropia $\geq 10^A$			
N (%)	8 (26)	3 (11)	2 (17)
[95% CI]	[2 to 45]	[2 to 29]	[2 to 48]
Exotropia $\geq 10^A$			
N (%)	3 (10)	0 (0)	1 (8)
[95% CI]	[2 to 26]	[0 to 13]	[0 to 38]