Pre-Operative Stability of Infantile Esotropia and Post-Operative Outcome

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• PURPOSE: To define the prevalence and time course of significant changes in angle of deviation during the first months after the diagnosis of infantile esotropia and to determine whether long-term alignment and sensory outcomes differ when surgical alignment is performed on infants with stable vs unstable angles of deviation.
• DESIGN: Prospective cohort study.
• METHODS: SETTING: Institutional and clinical practice. PATIENT POPULATION: Newly diagnosed patients with infantile esotropia (N = 208). OBSERVATION PROCEDURE: Preoperative measurements of the angle of deviation on the initial visit and at approximate six-week intervals until surgery was performed. MAIN OUTCOME MEASURES: Ocular alignment at six weeks, one year, and four years postoperative and stereoacuity at age five to nine years.
• RESULTS: Overall, 57% of infants had an esodeviation on the second visit that was within 10 prism diopters (p.d.) of the deviation measured on the initial visit (stable group), 33% had an increase of 10 p.d. or more (unstable group), and 11% had a decrease of 10 p.d. or more. Among the 127 patients with additional preoperative visits, many switched between the stable and unstable categories during follow-up. Long-term, stable and unstable preoperative alignment groups had similar postoperative motor alignment, re-operation rates, rates of prescription of hyperopic, or bifocal spectacle correction and stereoacuity.
• CONCLUSIONS: It may not be necessary to wait for a "stable" angle of esodeviation before surgery since both alignment and sensory outcomes were similar for stable and unstable groups. (Am J Ophthalmol 2004;138: 1003–1009. © 2004 by Elsevier Inc. All rights reserved.)

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INFANTILE ESOTROPIA (ET) THAT PERSISTS BEYOND 24 months of age is associated with irrevocable stereoacuity deficits in essentially all patients.[1–12] About 35% of children who have surgery between 6 and 24 months have some stereopsis but ≤4% achieve high-grade stereopsis.[1–12] However, almost twice as many children with surgical alignment before 6 months of age have stereopsis compared with those who have surgery at 7 to 24 months.[8,10–12] Additionally, high-grade random dot stereoacuity outcomes can be found in a small percentage of patients surgically-realigned at 3 to 5 months of age; one study reported that 29% were able to achieve high-grade stereoacuity with early surgery[8] while most others report less than 5%.[9–12]

Successful early surgery can establish alignment during the initial phase of the maturation of stereopsis[13–15] and reduce the duration of misalignment during a period when the infant visual system is most susceptible to abnormal visual experience.[16] In fact, when the two factors are dissociated, it appears that better random dot stereoacuity outcomes occur primarily because early surgery minimizes the duration of misalignment.[17] Indeed, random dot stereoacuity can be achieved in infantile ET patients with later surgery provided that the duration of misalignment is not prolonged.[2,17]

While prompt surgical alignment has the potential benefit of improved long-term stereopsis outcomes, this benefit must be weighed against the possibility of a decreased rate of successful motor alignment in patients whose angle of strabismus may not be stable at the time of surgery. Progressive increases in the angle of deviation are common in newly diagnosed patients with infantile esotropia (40%), whereas approximately 10% have decreases in the angle of deviation and approximately 50% of angles remain stable [within 10 prism diopters (p.d.)].[10,18,19]

While it is clear that instability is common in patients with newly diagnosed infantile ET, the time course of the instability remains undefined. It is often assumed that the angle of deviation stabilizes eventually, but we do not know when stability is typically achieved, nor do we know whether patients remain in one of the subgroups (for example, continue to show progressive increases in angle

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of deviation) or switch among subgroups (for example, stable on one visit but increasing angle on the next visit). Additionally, some of the patients in these studies were being treated with occlusion therapy and/or spectacle correction before surgery, so it is difficult to separate spontaneous changes in angle of deviation from changes that resulted from or were influenced by treatment. The present study is designed to address these gaps in our understanding of the natural history of infantile ET.

Prompt surgical alignment, while the angle may still be unstable, may increase the rate of residual or recurrent ET and negatively affect long-term sensory outcomes. A second goal of this study is to compare long-term motor alignment and sensory outcomes for children who had a stable angle of deviation before surgery with those from children who had increasing angle of deviation before surgery.

METHODS

• **PATIENTS:** Participants were 208 consecutive patients enrolled in a prospective study of infantile ET who were examined at least twice before surgery. These patients were referred to the Retina Foundation of the Southwest for the study by nine Dallas-Fort Worth area pediatric ophthalmologists. All patients had a history of onset of constant ET by six months of age which was confirmed by the referring pediatric ophthalmologist by eight months of age. None of the patients had known neurological defects or other coexisting disease. All patients fit the diagnostic criteria for infantile ET described by the American Academy of Ophthalmology Basic Science & Clinical Course[20] and their long-term alignment and sensory outcomes are similar to other cohorts in the literature.[2,11,21–25]

Informed consent was obtained from one or both parents before the patient's participation. This research protocol observed the tenets of the Declaration of Helsinki and was approved by the Institutional Review Board of the University of Texas Southwestern Medical Center.

• **PREOPERATIVE OBSERVATION PROCEDURES:** On the initial visit with the ophthalmologist the angle of deviation was measured at near with prism and cover testing, or when necessary for some of the youngest patients, using the modified Krimsky method. Distance measurements were obtained whenever possible and rarely differed by more than 5 p.d. from near measurements. All were re-measured approximately six weeks later, before surgery. All alignment measurements were made by the referring pediatric ophthalmologist or by an experienced orthoptist. Some patients had additional measurements before surgery, according to the referring ophthalmologist's usual practice pattern, at approximate six-week intervals. Age of presumed onset of constant esotropia stratified at four-week intervals, by history (based on the parents' and pediatrician's reports), and age at initial examination and each subsequent examination were recorded.

• **POSTOPERATIVE OUTCOME MEASURES:** Postoperative outcomes included assessment of successful vs unsuccessful motor alignment at approximately six weeks, one year, and four years postoperatively and stereoacuity at age five to nine years. Unsuccessful motor alignment was defined as the need for additional horizontal eye muscle surgery for a deviation ≥10 p.d. before the follow-up visit in question or residual horizontal deviation ≥10 p.d. with or without hyperopic spectacles. Random dot stereoacuity was evaluated using the Randot and Randot Preschool stereoacuity tests. If the patient was unable to demonstrate any random dot stereopsis, the Titmus fly was used to determine the presence/absence of coarse stereopsis. Not all infants were available to the study to provide data for all postoperative outcomes. All alignment measurements were made by the referring pediatric ophthalmologist or by an experienced orthoptist. All sensory testing was conducted by Retina Foundation research staff unaware of the alignment data.

RESULTS

• **AGE AT ONSET AND AGE AT INITIAL VISIT:** The age at onset of constant ET and the age at initial visit are summarized in Table 1. Over half of the infants had onset between 8 and 13 weeks of age, that is, before three months of age. Included within the group of 82 infants with onset reported at eight weeks of age are 23 infants whose parents and pediatricians suspected that constant ET was present soon after birth. For most infants, the initial visit to the pediatric ophthalmologist occurred within 12 weeks of onset. Most infants initially presented to a pediatric ophthalmologist by 31 weeks of age.

• **INITIAL ANGLE OF DEVIATION:** The angle of deviation on the initial visit is summarized in Table 2. Most infants presented initially with 25 to 50 p.d. of constant ET. In general, the distribution of angles of deviation were similar, regardless of the age at initial visit, with the exception that very few infants under 14 weeks of age presented with 55 p.d. or greater deviations.

• **PRE-OPERATIVE CHANGES IN ANGLE OF DEVIATION:** Of the 208 patients enrolled in the study, 21 (10%) were prescribed spectacles on the initial visit. Criteria for prescribing spectacles varied among the nine referring ophthalmologists. Four patients achieved orthophoria with spectacles, one improved to intermittent ET, five had reductions in angle of deviation but still had residual ET ≥ 20 p.d., nine had either the same or a larger angle of deviation on the second visit, and two were noncompliant

TABLE 1. Age of Onset and Age at Initial Visit to a Pediatric Ophthalmologist

Onset (Weeks)	N	%	Initial Visit (Weeks) 8 to 13	14 to 19	20 to 25	26 to 31	32 to 37
8	82*	39%	40%	33%	9%	11%	7%
13	44	21%	7%	57%	18%	14%	5%
17	34	16%	0%	35%	29%	21%	15%
21	25	12%	0%	0%	20%	60%	20%
26	23	11%	0%	0%	0%	43%	57%
Total	208	Overall	17%	31%	14%	23%	15%

*Includes infants whose parents and pediatricians suspected that constant esotropia was present soon after birth.

TABLE 2. Age at Initial Visit and Angle of Deviation

First Visit (Weeks)	N	≤20 pd	25–30 pd	35–40 pd	45–50 pd	55–60 pd	>60 pd
8 to 13	36	8%	17%	31%	31%	8%	6%
14 to 19	64	6%	14%	25%	17%	17%	20%
20 to 25	30	10%	13%	17%	27%	7%	27%
26 to 31	47	2%	13%	32%	19%	11%	23%
31 to 36	31	0%	26%	26%	19%	16%	13%
Overall	208	5%	16%	26%	22%	13%	18%

TABLE 3. Angle of Deviation at the Initial Visit and Change in Angle at Second Visit*

Initial Visit Angle (p.d.)	N	Within 10 p.d.	Increase ≥10 p.d.	Decrease ≥10 p.d.
≤20	11	4	6	1
25 or 30	27	11	11	5
35 or 40	49	33	14	2
45 or 50	42	26	14	2
55 or 60	23	11	7	5
>60	35	21	9	5
	187	106	61	20
		57%	33%	11%

*The second visit occurred 6 ± 3 weeks after the initial visit.

with spectacle wear at the time of their second visit. Since the use of spectacles might influence subsequent measurements, these patients were excluded from further analysis. For all of the remaining 187 patients, a second measurement was obtained at 5.6 ± 3.2 weeks after the initial visit.

As shown in Table 3, 57% of infants had an esodeviation on the second visit that was within 10 p.d. of the deviation measured on the initial visit, 33% had an increase of 10 p.d. or more, and 11% had a decrease of 10 p.d. or more. The percentage of infants who showed an increase in angle of deviation of 10 p.d. or more was relatively constant across age at first visit, with the exception of a slight but statistically significant decrease among those infants whose initial visit was at >31 weeks of age; only 23% of the infants first seen at > 31 weeks of age showed an increase in angle by 10 p.d. or more between the initial visit and the second visit.

The percentage of infants who showed an increase in angle of deviation was relatively constant for various angles of esodeviation at the initial visit (Table 3); whereas a slightly higher percentage of infants who initially presented with smaller angles of esodeviation (≤20 p.d. or 25 to 30 p.d.) showed increases of 10 p.d. or more on the second visit, this percentage was not significantly greater than found for infants who initially presented with larger angles of esodeviation (≥35 p.d.); that is, 44% vs 30%; $z = 1.58$, n.s.

The percentage of infants who showed an increase in angle of deviation by ≥10 p.d. was similar for infants who had part-time occlusion therapy (ranging from 1 hour/d to half-time occlusion) between the initial and second visits and those who did not have occlusion therapy (34% vs 33%). There was no trend for increased instability with increased number of hours of occlusion (up to half-time occlusion).

One hundred and twenty-seven (68%) of the 187 infants had a third preoperative measurement at 6.1 ± 5.9 weeks after the second visit. Changes in angle of deviation for this group of infants are summarized in Figure 1. Overall, 40 (31%) of these 127 infants had an increase of ≥10 p.d. between the second and third visits.

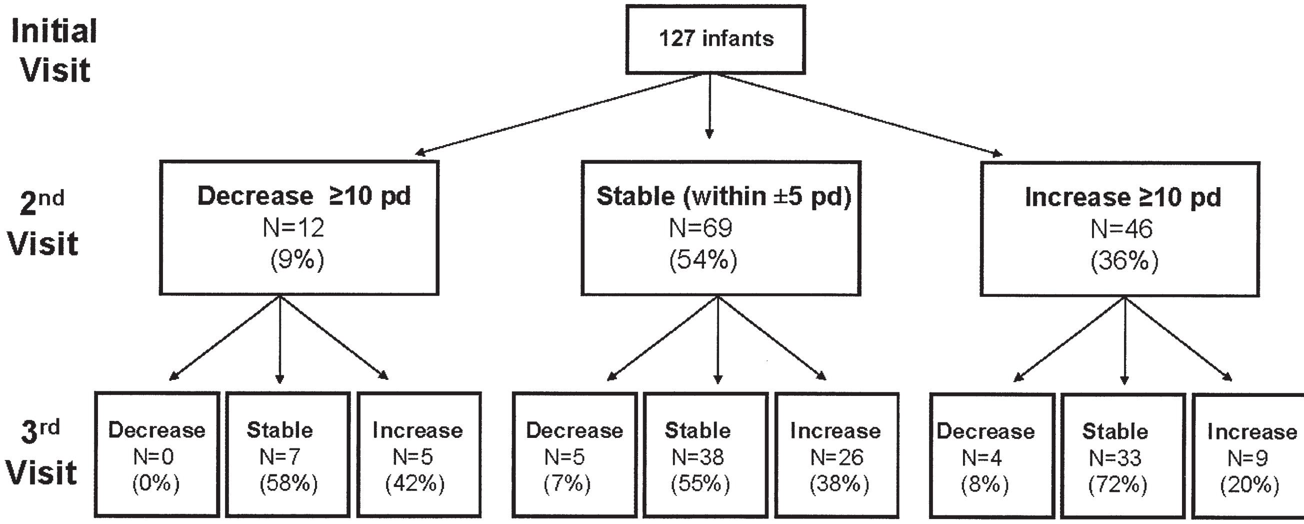

FIGURE 1. Changes in angle of deviation in patients with infantile esotropia on three preoperative visits separated by approximately six-week intervals.

TABLE 4. Stereoacuity at Age 5 to 9 Years

	N	≤60	100–800	3000	nil
Stable*	93	2%	20%	24%	54%
Unstable†	43	2%	21%	16%	60%

*Stable alignment on the last two pre-operative visits (two measurements within 10 p.d.).

†Unstable alignment on the last two pre-operative visits (≥10 p.d. increase in angle of deviation between the last two pre-operative visits).

Of the 12 patients who had a decrease of ≥10 p.d. between the initial and second visits, 58% (7/12) were stable between the second and third visits and 42% (5/12) had an increase in angle of 10 p.d. or more. Of the 69 patients who were stable between the initial and second visits, 55% (38/69) continued to exhibit a stable angle of deviation but 38% (26/69) had an increase in angle of ≥10 p.d. and 7% (5/69) had a decrease in angle of ≥10 p.d. between the second and third visits. Of the 46 who had an increase of ≥10 p.d. between the initial and second visits, 72% (3/46) were stable between the second and third visits but 20% (9/46) had an additional increase in angle of ≥10 p.d. and 8% (4/46) had a decrease in angle of ≥10 p.d. between the second and third visits.

• **PREOPERATIVE STABILITY OF ANGLE AND POST-OPERATIVE OUTCOMES:** Postoperative data were available for 180 of the 187 infants. Infants were divided into two groups, stable and unstable. The stable group was composed of infants whose last two preoperative measurements differed by less than 10 p.d. (N = 117); the unstable group was composed of infants whose last two preoperative measurements differed by 10 p.d. or more (N = 54). The group of children who had a decrease of 10 p.d. or more between the last two postoperative visits was too small for analysis (N = 9). The stable and unstable groups had similar ages at onset of ET (15 vs 14 weeks, respectively), age at initial visit (24 vs 22 weeks), and number of preoperative visits (3 vs 3). The stable group had a slightly older age at surgery (38 vs 33 weeks). None of these differences were statistically significant by t-tests.

At six weeks postoperatively (N = 138), a significantly higher percentage of unstable than stable infants had residual esotropic or consecutive exotropic deviations of 10 p.d. or more (eight patients with ET and two patients with XT in the stable group (N = 45) and 10 patients with ET in the unstable group (N = 93); 22% vs 10%; $z = 1.74$, $P < .05$).

At one year postoperatively (N = 120), both the stable and unstable groups had similar rates of unsatisfactory horizontal alignment as assessed by presence of a constant manifest deviation ≥10 p.d. and/or occurrence of a second surgery for a horizontal deviation of ≥10 p.d. (24% vs 21%). However, prescription of hyperopic or bifocal spectacle correction as a treatment for constant manifest deviation ≥10 p.d. was less common in the stable than in the unstable group (3% vs 18%; $z = 2.36$, $P < .01$).

By four years postoperatively (N = 128), 44% (39/88) of the stable group and 40% (16/40) of the unstable groups had had additional surgery for horizontal alignment. Prescription of hyperopic and/or bifocal spectacle correction as a treatment for constant manifest deviation was prescribed in 47% (41/88) of the stable group and for 48% (19/40) of the unstable group.

Stereoacuity at age five to nine years was available for 136 of the 187 participants. The distribution of stereoacuity outcomes for the stable and unstable groups was similar and is shown in Table 4. More than half of the children in each group had no measurable stereoacuity. The majority of the children with measurable stereoacuity had either coarse or moderate stereoacuity (3000 to 200), with only 2% achieving 60 arc sec.

Within the stable group was a subset of 37 patients who were stable over 3 to 5 preoperative visits (all measurements were within 10 p.d of the initial visit measurement). The postoperative outcomes for this subset of patients were similar to that for the stable group as a whole; 11% had unsatisfactory horizontal alignment six weeks postoperatively, 26% had unsatisfactory horizontal alignment or had had a second surgery for horizontal alignment at the one year visit, and 44% had had a second surgery for horizontal alignment by the four year visit. However, the stereoacuity outcomes were slightly better in this group. Fifty-nine percent had some stereopsis, significantly more than in the unstable group (40%; $z = 1.73$, $P < .05$).

• **MODERATE ANGLE ESOTROPIA:** The criterion of preoperative stability may not be relevant for patients who initially present with large angle ET since many surgeons will perform the same type and amount of surgery for all cases with ≥55 p.d. ET.[26] To address the potential benefits of operating only after achieving stability in the population of infants with moderate angles of deviation, the data were re-analyzed, including only those cases who initially presented with ≤50 p.d. ET (N = 119).

Similar to the overall data six weeks postoperatively, a significantly higher percentage of unstable than stable infants had residual esotropia or consecutive exotropia (>10p.d.) (21% vs 8%; $z = 1.79$, $P < .05$). However unlike the overall data one year postoperatively, alignment outcome for the stable group was significantly better than for the unstable group; 14% of the stable group had a constant manifest deviation ≥10 p.d. and/or occurrence of a second horizontal surgery vs 38% of the unstable group did ($z = 2.19$, $P < .02$). Rates of prescription of hyperopic and/or bifocal spectacle correction as a treatment for constant manifest deviation ≥10 p.d. were similar for stable and unstable groups 41% of the stable group and to 52% of the unstable group. As with the overall data analysis, the stable and unstable groups had similar outcomes at four years postoperatively; 43% of the stable group and 48% of the unstable groups had had additional surgery for unsatisfactory horizontal alignment. Prescription of hyperopic or bifocal spectacle correction as a treatment for constant manifest deviation was given to 41% of the stable group and to 52% of the unstable group. Finally, stereoacuity outcome for this subgroup of moderate angle patients was similar to the overall data analysis; more than half of the children in each group had no measurable stereoacuity. Most of the remaining children had either coarse or moderate stereoacuity, with only the rare patient achieving 60 arc sec.

DISCUSSION

MANY PATIENTS IN OUR COHORT WITH NEWLY DIAGNOSED infantile ET had a change in the angle of deviation of 10 p.d. or more over a six-week period between their first and second visits to their pediatric ophthalmologist; 33% had an increase in angle of esodeviation and 11% had a decrease. These results are similar to prior reports that 27% to 31% of infants had an increase of 10 p.d. or more between their initial visit and a visit at 26 weeks of age.[10,19]

Changes in angle of esodeviation were similar over a wide range of ages at first visit (8 to 36 weeks) and initial angles of esodeviation. Additionally, changes in angle of esodeviation were similar for infants who had part-time occlusion therapy and those who had no occlusion therapy. This finding is similar to a previous report that children with treated for strabismic amblyopia with full-time occlusion therapy had a similar prevalence of changes in angle of deviation to that of a group of strabismic children with alternate fixation who were not treated.[27]

When followed for more than two visits, many infants switched among subgroups of stable, increasing, or decreasing angles of esodeviation. Thus, the identification of a patient as stable on the basis of the last two preoperative visits may be illusory. While 57% of infants would be identified as stable by looking only at visits 1 and 2, only 49% of infants who had three visits were stable across all three visits, and even fewer remained stable across four visits (28% of infants who had four visits).

There are three potential sources of bias in our data. First, some of the instability observed in the present study may have resulted from use of the Krimsky test on the initial visit and the prism and cover test on the second visit. However, the Krimsky method has been shown to lead to overestimation of the angle of deviation in only approximately 10% of cases.[28] Additionally, most of our infants who had unstable angles showed increases between the initial visit and the second visit, so it is unlikely that changing from a method which may overestimate the angle of deviation (Krimsky) to the more accurate prism and cover method led to a substantial overestimation of instability. Second, all measurements of angle of deviation were obtained as part of routine clinical care. On follow-up visits, then, the examiner may have reviewed records from the initial visit and been aware of prior measurements. It is possible that this knowledge influenced measurements on follow-up visits. Third, while all children had at least two preoperative visits, additional preoperative visits were available only for children whose ophthalmologists chose not to proceed to surgery. Thus, children with three or more preoperative visits may differ in some unknown way from the overall cohort.

The second goal of this study was to compare alignment and sensory outcomes for children who had a stable angle of deviation before surgery with those from children who had increasing angle of deviation before surgery. The long-term outcome data suggest that it may not be necessary to wait for a "stable" angle of esodeviation before surgery since both alignment and sensory outcomes were similar for stable and unstable groups.

We also evaluated two other factors that could have limited our ability to detect a difference in alignment and sensory outcomes between the stable and unstable groups. First, separating the infants into stable and unstable groups solely on the basis of the last two preoperative visits may have been inadequate. However, even when we defined a stable group of infants more strictly, on the basis of three to five preoperative measurements within 10 p.d., most alignment and sensory outcomes were similar. The single difference we found using the strict definition of stability was that the long-term stereoacuity outcome was slightly but significantly better in stable group than in the unstable group.

A re-analysis of only those cases who initially presented with ≤50 p.d. ET was similar to the overall data with the single exception that, at one year postoperative, alignment outcome for the stable group was significantly better than for the unstable group. The failure to find a difference in long-term alignment or sensory outcomes, even when the analysis is limited to a more strictly defined stable group or limited to only small and moderate esodeviations, suggests that preoperative stability may not be an important criterion for functional outcome.

These data support the hypothesis that surgery on an unstable angle of esodeviation (>10p.d. variation between visits) can be as successful as surgery on a stable angle in terms of motor alignment and stereopsis. Thus potential benefits of prompt surgery may outweigh any benefit that may be derived from numerous measurements and the consequent delay in surgery to achieve alignment. Indeed, the improved stereoacuity outcomes resulting from prompt surgery are associated with a lower rate of consecutive ET and exotropia requiring surgery, lower prevalence of dissociated vertical deviation, lower risk for moderate to severe amblyopia, and lower risk for the development of accommodative ET after successful surgical alignment of infantile ET.[29,30]

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