Utility of Adjustable Sutures in Primary Strabismus Surgery and Reoperations

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Purpose: To evaluate the success of adjustable suture (AS) and nonadjustable suture (NAS) strabismus surgery in primary procedures and reoperations.

Design: Retrospective case series.

Participants: Four hundred four patients older than 12 years who underwent strabismus surgery over a 13-year period.

Methods: All eyes underwent the same hang-back suturing technique by a single surgeon (S.P.K.) in both the AS and NAS groups. Success was defined as alignment within 10 prism diopters (PD) for horizontal recti and within 5 PD of orthophoria for vertical recti without diplopia or further surgery.

Main Outcome Measures: Surgical success rate of AS and NAS primary surgery or reoperations was the primary outcome measure. Effects of amblyopia, binocularity, and strabismus type on success were secondary outcome measures and were analyzed using multiple logistic regression.

Results: Patients in the AS group required adjustment in 28.8% of cases. Higher overall success was seen with AS (77.7%) compared with NAS (69.1%) surgery, although this did not reach significance ($P = 0.059$). Overall success for AS in exotropia surgery (80.8%) was significantly higher than that in the NAS group (65.9%; $P = 0.011$). This was because of higher success in patients undergoing primary surgery (82.5% vs. 50%; $P = 0.003$), but not in patients undergoing reoperation (80.2% vs. 77.6%; $P = 0.71$). On multiple regression analysis, male gender and not having a mechanical or neurogenic cause for strabismus were significant factors for a successful outcome. Overall, other factors including amblyopia, binocularity, strabismus type, and primary or reoperation were not significant.

Conclusions: These results suggest that primary surgery in adults with exotropia has a more successful outcome with AS surgery. This advantage was not present with esotropia and vertical deviations in this series.

Financial Disclosure(s): The author(s) have no proprietary or commercial interest in any materials discussed in this article. *Ophthalmology 2012;119:629–633 © 2012 by the American Academy of Ophthalmology.*

Although it is widely accepted that strabismus surgery in adolescents and adults is successful, safe, and effective, the long-term need for further surgery remains a problem.[1] Adjustable suture (AS) strabismus surgery was popularized in 1975 by Jampolsky and aimed to improve the outcome of strabismus surgery in complicated cases. The 2-stage procedure involves the initial surgery followed by the adjustment of sutures when the patient is awake from anesthesia.[2,3] This allows the surgeon to optimize the alignment result in the postoperative period, with the aim of obtaining the best long-term success. However, the routine use of adjustable sutures in all patients is controversial.[4]

There are few studies that have compared the results of surgery using AS with those of surgery using nonadjustable sutures (NASs). Two studies used rates of reoperation to compare the results of AS with NAS surgery, and they both found that the rates were 10% to 18% lower in cases using AS.[5,6] A third study, limited to children, defined success as a postoperative alignment of less than 8 prism diopters (PD), and the authors reported 15% better rates with AS compared with NAS cases.[7]

This article reports the postoperative results of patients older than 12 years who underwent rectus muscle strabismus surgery, with or without AS. To the best of the authors' knowledge, this is the largest series comparing alignment success in AS and NAS patients and answers the following 4 questions: (1) Do AS cases have a higher rate of success than NAS surgeries overall? (2) Are the success rates different when comparing primary cases with cases of repeat surgery? (3) Do patients with esotropia and exotropia have different rates of success? and (4) Does the presence of amblyopia affect the success rates?

Patients and Methods

The research ethics board at the Hospital for Sick Children in Toronto approved this study. A retrospective chart review was performed on all patients who had undergone surgery in the practice of 1 surgeon (S.P.K.) from January 1995 through December 2008. Patients who underwent strabismus surgery on rectus muscles in the form of recession, resection, advancement, or a combination of these with AS or NAS were included. Primary procedures and reoperations for esotropia, exotropia, hypertropia, and hypotropia with a minimum of 6 months of follow-up were included. Patients requiring reoperations before 6 months of follow-up also were included.

Exclusion criteria were patients younger than 12 years (and hence not usually considered for AS surgery), those who had

Published by Elsevier Inc.
ISSN 0161-6420/12/$–see front matter
doi:10.1016/j.ophtha.2011.08.025

combined surgery with oblique muscles, posterior fixation sutures, and eye muscle transpositions of more than 5 mm. Patients who underwent transpositions of less than 5 mm were included. Patients who did not have early postoperative measures of their deviations also were excluded because the long-term drifts of their deviations could not be calculated. Patients with systemic neurologic disorders or conditions affecting cooperation for measurements were excluded.

All surgical steps in the AS and NAS groups were identical throughout the 13 years of the study other than that the suture for AS patients was a bow-tie knot, as previously published.[8] In summary, limbal incisions were made in all cases. A hang-back suture technique was used on all recessions and for advancements that fell short of the original insertion in both the AS and NAS suture surgery groups. A central and 2 locking edge bites of the muscle were taken using a double-ended 6-0 polyglactin (Vicryl, Ethicon Inc, Somerville, NJ) suture. The bites through the sclera at the original insertion were performed in a crossed sword fashion and were secured in a bow-tie fashion for the AS group and were tied permanently for NAS patients. The same surgical table was used to plan the amount of muscle recession, resection, or both whether AS or NAS sutures were used. Surgery was carried out in the morning, and adjustments were made as appropriate on the same afternoon under topical anesthesia. The conjunctival closure was also reversible for AS patients to allow easy access to the bow-tie knot if required. Patients administered a combined antibiotic and steroid combination eye drop to the operated eyes several times per day for 3 weeks after surgery.

All patients were given the option of AS for their procedure. The decision for AS or NAS was made by the patient on a case-by-case basis. Thus, although the 2 groups were not randomized, they were not assigned to either procedure according to any other criterion.

Data collected included patient demographics, visual acuity, presence or absence of binocularity and amblyopia, type and magnitude of strabismus, previous surgery, surgical procedure and complications, need for adjustment and degree of deviation after adjustment, alignment within 1 week of surgery, and the deviation at a minimum of 6 months of follow-up. The postoperative drift was calculated, and the absolute angle of undercorrection or overcorrection was noted. Failure was defined as postoperative deviation more than 10 PD for horizontal deviations and 5 PD for vertical deviations, the presence of constant diplopia, or a need for a reoperation. The angle of deviation was measured by an alternating prism-and-cover test for distance, or by the Krimsky reflex when the vision in 1 eye was less than best-corrected 6/60. Absence or presence of binocularity was assessed with the Bagolini lenses and the Titmus stereotest.

Statistical analysis was performed using the t test for continuous variables and the chi-square test for categorical data. For binary outcome data, a logistic regression analysis was performed. Independent variables that were uncorrelated with each other and had a P value less than 0.25 were entered into multiple logistic regression. At the final stage, selected variables with a P value less than 0.05 were considered statistically significant. Statistical analysis was performed using SAS software version 9.2 (SAS Inc., Cary, NC).

A literature search of articles in English was carried out using PubMed for articles published from 1975 through December 2010. Search terms included the following alone or in some combination: *strabismus*, *surgery*, *adjustable sutures*, *fixed sutures*, *esotropia*, *exotropia*, and *hypertropia*. Additional sources included articles cited in the reference lists of other articles.

Results

Nineteen hundred sixty-three patients underwent strabismus procedures over the 13-year period. Of these, 798 were younger than 12 years, 458 were complex and had oblique muscle surgery or incomplete data, and 303 had fewer than 6 months of follow-up. Therefore, 404 patients met the inclusion criteria for the study.

Table 1 summarizes the demographics of the study population. Adjustable suture surgery was performed in 264 patients and NAS surgery was performed in 140 patients. The patients in the NAS group were significantly younger, with a mean age of 22 years (range, 12–83 years) compared with the AS group (39.9 years; range, 14–83 years; $P<0.01$). There were no statistically significant differences between the 2 groups in terms of gender distribution, frequency of amblyopia, presence of binocularity, strabismus type, history of previous surgery, preoperative angle of deviation, or comitance (Table 1).

The mean follow-up was 14.4 months (range, 6–131 months) and 12.6 months (range, 6–103 months) in the AS and NAS groups, respectively ($P = 0.59$). Seventy-six patients (28.8%) in the AS group had adjustments performed after surgery. No surgical complications occurred in either group. Mean change in immediate postoperative angle after adjustment was 6.5 PD (range, 2–18 PD). Success was achieved in 205 patients (77.7%) undergoing AS surgery and in 96 patients (69.1%) undergoing NAS surgery. Although this difference did not reach statistical significance ($P = 0.059$, chi-square test), there was a strong trend toward higher success with adjustable sutures (Table 2).

In Table 3, results according to strabismus type are summarized. Overall, the exotropic patients had significantly higher success with AS surgery compared with NAS surgery (80.8% vs. 65.9%; $P = 0.011$, chi-square test). However, on further analysis, there was a significantly better success rate for AS compared with NAS surgery in primary exotropia (82.5% vs. 50.0%; $P = 0.003$, chi-square test), but no difference in the 2 groups for exotropia cases that were undergoing repeat surgery ($P = 0.71$).

Among all patients with esotropia, AS and NAS surgery resulted in no statistically significant difference in successful outcome (75.0% vs. 76.7%, respectively; $P = 0.83$). There were also no differences in success rates when AS and NAS procedures were compared for the primary and repeat surgery groups ($P = 0.41$ and 0.51, respectively).

Finally, Table 3 lists the results for patients with vertical deviations. The success rates were not significantly different overall for the AS versus NAS groups ($P = 0.86$) or when the AS and NAS groups were compared for primary cases and repeat surgery cases ($P = 0.94$ and $P = 0.29$, respectively).

Table 1. Patient Demographic Data

	Adjustable (n = 264)	Nonadjustable (n = 140)	P
Mean age (yrs)	39.9	22	<0.01
Male:female (%)	93:171 (35:65)	53:87 (38:62)	0.60
Strabismus type, no. (%)			All NS
XT	146 (55.3)	85 (60.7)	
ET	96 (36.4)	44 (31.4)	
HT	22 (8.0)	11 (7.8)	
Preoperative angle of deviation	29.3 PD	28.1 PD	0.40
Amblyopia, no. (%)	80 (30.3)	45 (32.1)	0.70
Binocularity, no. (%)	102 (38.6)	49 (35)	0.32
Comitance, no. (%)	176 (66.7)	96 (68.6)	0.35
Previous surgery, no. (%)	153 (58)	76 (54.3)	0.48

ET = esotropia; HT = hypertropia/hypotropia; NS = not statistically significant; PD = prism diopters; XT = exotropia.

Table 2. Overall Results of Patients Undergoing Adjustable and Nonadjustable Suture Surgery

	Adjustable (n = 264)	Nonadjustable (n = 140)	P
Mean final postoperative angle (PD)	6.2	7.6	0.10
Mean follow-up (mos)	14.4	12.6	0.38
Successful cases, no. (%)	205 (77.7)	96 (69.1)	0.059
Mean undercorrection drift, PD (range)	7.2 (0–55), SD =7.2	7.7 (0–38), SD =7	0.69
Mean overcorrection drift, PD (range)	5.7 (0–28), SD =7.3	3.2 (0–22), SD =5.2	0.025

PD = prism diopters; SD = standard deviation.

Various factors were analyzed that may have influenced the success of strabismus surgery. These factors included gender distribution, primary versus repeat surgery, presence of amblyopia, preoperative evidence of binocularity, and diagnosis of neurologic or mechanical strabismus versus neither factor involved (Table 4). In the exotropic patients, men had higher success than women (83.5% vs. 70.6%; $P = 0.03$), and primary surgery was less successful than repeat surgeries (67.1% vs. 79.5%; $P = 0.04$, chi-square test). The presence of a neurogenic or mechanical cause adversely affected the success rates for exotropia and hypertropia patients.

Univariate analyses was performed on the entire cohort (Table 5). The only factors that had a statistically significant effect on a successful outcome were male gender ($P = 0.026$; odds ratio [OR], 1.8), not having a mechanical or neurogenic cause for strabismus ($P = 0.004$; OR, 2.5), and having undergone previous surgery ($P = 0.01$; OR, 1.8). Presence of amblyopia and binocularity, strabismus type and angle, and age were not significant factors (Table 5). Multiple regression analysis then was performed and demonstrated that male gender ($P = 0.024$; OR, 1.82) and not having a mechanical or neurogenic cause for strabismus ($P = 0.03$; OR, 2.1) were statistically significant, whereas a history of previous surgical procedure was not ($P = 0.067$; Table 6).

Table 3. Success of Adjustable and Nonadjustable Suture Surgery in Different Types of Strabismus as Primary or Repeat Surgeries

	Success Rates			
	Adjustable	*Nonadjustable*	P	Odds Ratio
XT	80.8% (118/146)	65.9% (56/85)	0.011	
Primary operation	82.5% (33/40)	50% (18/36)	0.003	4.71
Reoperation	80.2% (85/106)	77.6% (38/49)	0.71	1.17
ET	75% (72/96)	76.7% (33/43)	0.83	
Primary operation	70.4% (38/54)	80% (16/20)	0.41	0.60
Reoperation	81% (34/42)	73.9% (17/23)	0.51	1.50
HT	66.7% (14/21)	63.4% (7/11)	0.86	
Primary operation	58.8% (10/17)	57.1% (4/7)	0.94	1.10
Reoperation	100% (4/4)	75% (3/4)	0.29	1.30

ET = esotropia:, HT = hypertropia/hypotropia; XT = exotropia.

Table 4. Percentage of Success for Patients in the Entire Cohort

	Success Rate (%)		
	Exotropia	*Esotropia*	*Hypertropia/Hypotropia*
Gender			
Male	83.5	75.5	87.5
Female	70.6	75.6	58.3
P	0.03	0.99	0.13
Operation			
Primary	67.1	73	58.3
Reoperation	79.5	78.4	87.5
P	0.04	0.45	0.13
Amblyopia			
Present	76.3	80	100
Not present	75	73.4	62.1
P	0.83	0.4	0.19
Binocularity			
Binocular	75	78.4	58.3
Not binocular	77.1	72.2	87.5
P	0.43	0.45	0.13
Diagnosis			
Mechanical/neurologic	45.5	68.2	50
Other	76.9	76.9	85.7
P	0.018	0.38	0.035

Discussion

There are no randomized controlled trials comparing the success rates of AS and NAS surgery.[4] Carruthers et al[9] conducted a comparison between ASs and botulinum toxin injection, which highlighted the problems of performing prospective randomized trials in strabismus surgery. They had 80% refusal rate, and at the end of their 2.5-year funding period, they had recruited only 30 of the 150 required patients. Therefore, our understanding of the relative efficacy of AS and NAS procedures comprises a number of retrospective case series. Herein is presented the largest series comparing successful alignment after AS and NAS surgery using the same hang-back surgical technique for both groups.

In this series, the overall higher success rate of AS over NAS sutures came close to, but did not reach, significance (77.7% vs. 69.1%; $P = 0.059$). However, the difference was significant in patients with exotropia ($P = 0.011$) and was highly significant in exotropic patients undergoing primary strabismus surgery ($P = 0.003$; OR, 4.71). This is interesting in that one of the main indications for AS surgery

Table 5. Univariate Analysis for Likelihood of Success

Factor	P	Odds Ratio (95% Confidence Interval)
Male gender	0.026	1.8 (1.1–3)
Amblyopia	0.39	1.3 (0.7–2.1)
Binocularity	0.60	0.9 (0.6–1.4)
No mechanical/neurogenic strabismus	0.004	2.5 (1.3–4.6)
Strabismus type	0.40	1.7 (0.6–3.5)
Reoperation	0.01	1.8 (1.1–2.9)
Strabismus angle	0.70	1.0 (0.98–1.01)
Age	0.86	1.0 (0.98–1.01)

Table 6. Multiple Regression Analysis on Factors That Influence Surgical Success

Factor	P	Odds Ratio (95% Confidence Interval)
Male gender	0.024	1.82 (1.1–3.1)
No mechanical/neurogenic strabismus	0.030	2.1 (1.1–4)
Reoperation	0.067	1.8 (0.97–2.6)

traditionally has included patients who had undergone previous surgery.[3,8,10] However, in the present series, although AS surgery in primary exotropia had a higher success rate than NAS surgery, this advantage was not present among patients with exotropia undergoing repeat surgery. A statistically significant difference in favor of AS was not evident in esotropic patients, whether primary or repeat surgeries. Therefore, in the overall results, multivariate analysis did not identify previous surgery as a statistically significant factor in determining success ($P = 0.067$). This result is indicative of the usefulness of AS in all primary exotropia surgery, if the patient is a suitable candidate for AS.

Wisnicki et al[6] studied 290 patients undergoing AS surgery, and they reported a 10% lower reoperation rate in patients having AS compared with those having NAS. In the AS patients specifically, they found that the reoperation rate for primary surgery (8.6%) was slightly lower than in those who underwent repeat surgery (11.5%), although this was not significant. Tripathi et al[5] reported on 443 patients with demographics similar to those of the current patients. They found that AS cases had a lower reoperation rate (8.51%) than NAS cases (27.15%), but they reported no difference between primary and repeat surgery. They did not give any breakdown of their results according to strabismus type. Both of these studies chose reoperation rates as their main outcome measure. The authors believe that reoperation rates are not the best criterion for reporting success in this context. Patients can require or decline reoperations for various reasons, not all of which are the result of a failure to align them in primary position. Furthermore, in the authors' experience, some patients decide not to undergo repeat surgery even if their postoperative deviation is not in the target angle. For example, they may be satisfied with their cosmetic result, or they simply may not opt to undergo another intervention. Thus, an alignment criterion was chosen, not reoperation rates, as the main outcome measure.

Bishop and Doran[11] retrospectively reported on 52 case-matched patients with nonthyroid incomitant strabismus and found no difference between AS and NAS surgery (81% vs. 88% success, respectively). Their definition of success also included meeting surgical aims and not necessarily alignment criteria. Furthermore, their small numbers could not differentiate between success in exotropia and esotropia. Park et al[12] reported on 54 patients with sensory exotropia, and they did not find a difference in success between AS and NAS surgery. However, their success criterion was alignment within 15 PD of orthophoria, with only 3 months of follow-up. The current patient numbers are much larger and criteria for success tighter than both above series, which may explain the statistically significant results in the exotropic patients.

The adjustment rate of 28.8% is lower than the 44% previously reported from the authors' center.[13] Indeed, most series have reported from 45% to 70% adjustment rates.[5,11,14–16] The reduced adjustment rates compared with historic data may be explained by increasing experience leading to better ability to judge the surgical numbers and muscle positions. Also, many early series deliberately overcorrected a recessed muscle because it was easier to advance it on AS rather than recess it further. Adjustment rates as low as 6.9% have been reported recently.[17]

We also identified male gender and mechanical and neurogenic strabismus as significant factors in determining surgical success on multivariate analysis. Surgery for exotropia and vertical deviations was more successful in men, whereas no difference existed for esotropia. Although complex strabismus is well recognized as having poorer surgical outcomes,[18,19] previous studies have not identified gender as a predictor for surgical outcome.[5,20] There is no obvious explanation for this difference between the genders in the present cohort. Other factors such as age, strabismus type and angle, presence of amblyopia, and preoperative binocularity did not affect surgical success. Isenberg and Abdarbashi[21] reported the presence of stereopsis to be associated with undercorrection drift in the postoperative period in patients undergoing AS surgery. Their study did not look at this factor in determining a successful outcome. In the current patients, we did not identify binocularity as a determinate of successful outcome. Other authors reported a high rate of sensory fusion gained by patients after strabismus surgery.[19]

This was a retrospective chart review and therefore suffers from the shortfalls of such research. Bias and loss to follow-up are experienced in large tertiary referral centers such as the authors', where more complicated patients are seen who may not travel long distances for follow-up. However, the large number of patients undergoing the same surgical technique for AS and NAS surgery by a single surgeon does allow good statistical comparison between the 2 groups. Although the patients themselves selected whether they underwent AS or NAS procedures, the 2 groups ended up having a very similar demographic profile in terms of gender distribution, strabismus type, angle of deviation, presence of amblyopia, binocularity, and percentage who had undergone prior surgery. Thus, the authors believed that the statistical analysis was able to answer important questions in an area without randomized studies.

The mean age of the AS group was higher than that of the NAS group. This finding reflects the fact that patients who decline AS generally are younger adults. In the authors' opinion, this difference should not be a factor that confounds the results. After a patient reaches the age of visual maturity (older than 9 years), most authors place him or her under the diagnostic umbrella of adult strabismus, with no differentiation of younger versus older adults.[19] Whether a patient is in the third or fifth decade of life, the nature of a chronic strabismus disorder is relatively similar and should not affect the response to surgery.

The results for esotropia and hypertropia were not supportive of an advantage of AS or NAS surgery. Using the data from this study, a power calculation was performed to test if the numbers were able to demonstrate such a difference. To show a 10% difference in success rates with 80% power, 342 patients were required in each group for esotropia and 393 patients were required for vertical deviation. The numbers clearly were too few to answer this important question, and further randomized studies are required. A study design that excludes neurologic and mechanical causes for strabismus may require fewer numbers to determine whether AS surgery is beneficial in primary and repeat surgery. Nevertheless, despite the recruitment difficulties encountered by Carruthers et al[9] mentioned above, a multicenter trial needs to be performed to achieve the numbers needed to put the controversy of AS to rest. Variation in AS technique and timing of measurement and adjustment varies widely between surgeons and needs to be addressed by such a study. Finally, a truly unbiased clinical trial is difficult because patients who are averse to the manipulation required for AS may opt out of a randomized study if there is a chance of being in the AS group, hence creating bias. All of these difficulties aside, the strabismus community needs the kind of large, multicenter, prospective, randomized trials that have benefited many other aspects of ophthalmology.

In conclusion, these results suggest that primary surgery for exotropia in adults is more successful using AS surgery. This supports the belief of many strabismus surgeons that AS surgery should be performed on most suitable patients and not just in complex strabismus and repeat surgery. Also, no impact on success rates for patients with amblyopia or lack of binocularity was demonstrated. Further studies are required to demonstrate effectiveness of AS surgery for esotropia and vertical deviation.

Acknowledgment. The authors thank Derek Stephens for biostatistical expertise and help in analyzing the data.

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Footnotes and Financial Disclosures

Originally received: March 1, 2011.
Final revision: July 21, 2011.
Accepted: August 11, 2011.
Available online: November 23, 2011. Manuscript no. 2011-355.

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Presented in part at: the Canadian Orthoptic Society Annual Meeting, June 2009, Toronto, Canada; the World Congress of Pediatric Ophthalmology & Strabismus, September 2009, Barcelona, Spain; and the International Strabismological Association, September 2010, Istanbul, Turkey.

Financial Disclosure(s):
The author(s) have no proprietary or commercial interest in any materials discussed in this article.

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