AMERICAN ACADEMY OF OPHTHALMOLOGY®

Ophthalmic Technology Assessment

Adjustable Sutures in the Treatment of Strabismus

A Report by the American Academy of Ophthalmology

Gena Heidary, MD, PhD,[1] Vinay K. Aakalu, MD, MPH,[2] Gil Binenbaum, MD, MSCE,[3] Melinda Y. Chang, MD,[4] David G. Morrison, MD,[5] Deborah K. VanderVeen, MD,[1] Scott R. Lambert, MD,[6] Rupal H. Trivedi, MD, MSCR,[7] Jennifer A. Galvin, MD,[8] Stacy L. Pineles, MD[9]

Purpose: To review the scientific literature that evaluates the effectiveness of adjustable sutures in the management of strabismus for adult and pediatric patients.

Methods: Literature searches were performed in the PubMed database through April 2021 with no date limitations and were restricted to publications in English. The searches identified 551 relevant citations, of which 55 were reviewed in full text. Of these, 17 articles met the inclusion criteria and were assigned a level of evidence rating by the panel methodologist. The search included all randomized controlled studies regardless of study size and cohort studies of 100 or more patients comparing the adjustable versus nonadjustable suture technique, with a focus on motor alignment outcomes or reoperation rates.

Results: The literature search yielded no level I studies. Of the 17 articles that met the inclusion criteria, 11 were rated level II and 6 were rated level III. Among the 12 studies that focused on motor alignment outcomes, 4 small randomized clinical trials (RCTs) did not find a statistically significant difference between groups, although they were powered to detect only very large differences. Seven of 8 nonrandomized studies found a statistically significant difference in motor alignment success in favor of the adjustable suture technique, both overall and in certain subgroups of patients. Successful motor alignment was seen in both exotropia (in 3 studies that were not limited to children) and esotropia (in 1 study of adults and 2 of children). The majority of included studies that reported on reoperation rates found the rates to be lower in patients who underwent strabismus surgery with adjustable sutures, but this finding was not uniformly demonstrated.

Conclusions: Although there are no level I studies evaluating the effectiveness of adjustable sutures for strabismus surgery, the majority of nonrandomized studies that met the inclusion criteria for this assessment reported an advantage of the adjustable suture technique over the nonadjustable technique with respect to motor alignment outcomes. This finding was not uniformly demonstrated among all studies reviewed and warrants further investigation in the development and analysis of adjustable suture techniques. *Ophthalmology 2021;■:1–11 © 2021 by the American Academy of Ophthalmology*

The American Academy of Ophthalmology prepares Ophthalmic Technology Assessments to evaluate new and existing procedures, drugs, and diagnostic and screening tests. The goal of an Ophthalmic Technology Assessment is to review systematically the available research for clinical efficacy, effectiveness, and safety. After review by members of the Ophthalmic Technology Assessment Committee, other Academy committees, relevant subspecialty societies, and legal counsel, assessments are submitted to the Academy's Board of Trustees for consideration as official Academy statements. The purpose of this assessment by the Pediatric Ophthalmology/Strabismus Panel was to evaluate the scientific literature that examines the effectiveness of adjustable sutures in the management of strabismus for adult and pediatric patients.

Background

The adjustable suture technique involves the placement of a suture that may be repositioned postoperatively to modify the final position of a horizontal, vertical, or oblique extraocular muscle after strabismus surgery.[1] Adjustment for cooperative patients may occur immediately in the postanesthesia care unit or in an office-based setting. This technique allows the surgeon to refine the position of the

https://doi.org/10.1016/j.ophtha.2021.07.026
ISSN 0161-6420/21

extraocular muscle in the early postoperative period, thereby theoretically offering greater precision in surgical outcomes and reduction of long-term costs with respect to the reoperation rate. Despite more than 40 years of literature introducing and advancing the techniques of adjustable sutures for strabismus surgery,[2,3] universal adoption of adjustable suture techniques has not occurred within the field. This is partly because of the added complexity of the techniques and the conflicting interpretations of the effectiveness or necessity of this approach. Additionally, surgeons may be reluctant to incorporate adjustable suture techniques because of the additional surgical and postoperative investment of time and resources.[4,5]

Despite this uncertainty, there have been advances in the technique of adjustable suture placement that have expanded its use and applicability.[6] Modifications in the suture technique allow for the possibility of delayed suture adjustment within 1 week of surgery.[6] Further, there has been an evolution in the administration of sedation in children that has expanded the use of adjustable sutures in pediatric patients.

Historically, the use of the adjustable suture technique for children has been avoided because of a question of practicality and feasibility, but many studies have demonstrated that older children are able to undergo suture adjustment in a manner similar to adults without a need for further anesthesia.[7-9] In some surgical centers, suture adjustment with sedation is now being offered to children for whom an awake adjustment in the office may not be possible based on age or the ability to cooperate. Such protocols have further expanded the availability of adjustable sutures for pediatric patients.[10-14]

Description of the Treatment

The treatment under consideration for this assessment is the use of adjustable sutures for strabismus surgery. Various adjustable suture techniques were used during surgery. Refinement of surgical dosing using adjustable sutures was performed at the end of the procedure intraoperatively when topical or sub-Tenon's anesthesia was administered, in the immediate postoperative period in the postanesthesia care unit, or 1 or more days later. Adjustment may have occurred with or without sedation in an office/procedure room, recovery area after surgery, or operating room setting.

Questions for Assessment

The focus of this assessment was to address the following questions, with separate consideration given to adult and pediatric patients: (1) Do adjustable sutures improve motor alignment outcomes after strabismus surgery? (2) Are there etiologies of strabismus or strabismus types for which adjustable sutures are particularly effective with respect to motor alignment outcomes? (3) Do reoperation rates differ in cases when adjustable sutures are used versus nonadjustable sutures?

Description of Evidence

Literature searches in the PubMed database were restricted to publications in English and were performed through April 2021 with no date limitations. Search terms for this review included the following: *strabismus, esotropia, exotropia, hypertropia, diplopia, Graves, Graves/hyperthyroidism, thyroid myopathy, strabismus, squint, squint/amblyopia, adjustable, nonadjustable, conventional, suture techniques, "sutures"*[majr], sutures, "*strabismus/surgery*"[majr], "*oculomotor muscles/physiopathology*"[majr], "*oculomotor muscles/surgery*"[majr], "*extraocular muscle surgery.*"

The literature searches identified 551 citations, 55 of which were reviewed in full text for their relevance according to the questions for assessment. Articles not reviewed focused on strabismus outcomes unrelated to adjustable suture techniques, studies on technical modifications of the adjustable suture technique, and review articles. After full review, 17 articles were deemed to have met the following inclusion criteria: (1) The research was original; (2) the study was a comparative study examining outcomes between adjustable and nonadjustable sutures with a focus on motor alignment outcomes, specific etiologies for which an adjustable suture technique would be useful, or reoperation rates; and (3) the study was a randomized control trial (RCT) with no requirement for the number of patients or a cohort study with a minimum of 100 patients. The study committee set the minimum number of patients for the nonrandomized cohort studies in an effort to review studies more likely to be adequately powered to detect a difference between surgical techniques, if present. Excluded articles were noncomparative studies and studies that did not fulfill the minimum requirement of 100 patients.

The methodologist (V.K.A.) reviewed the 17 articles that met the inclusion criteria and assigned a level of evidence rating to each article according to the rating scale developed by the Oxford Centre for Evidence-Based Medicine and adopted by the American Academy of Ophthalmology.[15] A level I rating was assigned to well-designed and well-conducted RCTs, a level II rating was assigned to well-designed case control and cohort studies and lower-quality randomized studies, and a level III rating was assigned to comparative case series. There were no level I studies. Eleven articles, which included 4 RCTs, were assigned a level II rating, and the remaining 6 articles were assigned a level III rating.

Published Results

Motor Alignment Outcomes

Twelve articles evaluated the impact of incorporating the adjustable suture technique on motor alignment outcomes; 10 were rated level II, and 2 were rated level III. Four of the articles were small RCTs, and 8 of the articles were retrospective cohort studies. In the following sections, the RCTs are discussed first, followed by the retrospective cohort studies. When clearly delineated, the results are separated for

studies with mixed ages (summarized in Table 1) and studies focused specifically on pediatric patients (summarized in Table 2).

Adult Studies (>18 years) or Mixed-Age Studies

Level II Studies. The literature search identified 3 RCTs that compared outcomes in the adult-only or mixed pediatric and adult age groups. These are presented chronologically, followed by cohort studies in chronological order.

Altintas et al[16] compared motor alignment outcomes in a mixed-age cohort of patients undergoing strabismus surgery for a heterogeneous group of strabismus types. A total of 88 patients were enrolled, of whom 50 were treated using adjustable sutures and 38 with nonadjustable sutures. The mean age in the adjustable group was statistically older than in the nonadjustable group (33 vs. 11 years, respectively, $P = 0.015$). The methods of randomization were not consistently reported because patients with paralytic strabismus and reoperations were included in the adjustable suture cohort, yet no patients with paralytic strabismus and only 1 reoperation were included in the nonadjustable group. In the adjustable group, topical or sub-Tenon's anesthetic was used compared with topical or general anesthesia in the nonadjustable group. In the adjustable cohort, adjustment was performed at the end of the surgical procedure because surgery was not performed under general anesthesia. This occurred in 44% of the adjustable cohort. The primary outcome was motor alignment at 3 months, with motor success defined as $\leq$10 prism diopters (PD) in the primary position. The authors found that 73% (19/24) in the adjustable group had motor success compared with 82% (9/11) in the nonadjustable group ($P = 0.35$). The total number of patients reported for the 3-month measurements was less than the original number undergoing strabismus surgery, and this discrepancy is not explained. The results of this prospective study must be interpreted with caution. The groups were not matched with respect to age or strabismus type/etiology, and method of randomization was not clearly delineated. In addition, the 2 groups did not have a standard surgical protocol insofar as the 2 cohorts received distinctly different types of anesthesia. Specifically, the persistence of sub-Tenon's anesthetic in the adjustable cohort during the intraoperative adjustment, which has been shown to limit muscle function, may have adversely affected the accurate assessment of motor alignment and, subsequently, motor outcomes.[27] There may have been a selection bias for more complex strabismus to be included in the adjustable group that likely affected motor alignment success. Further, the authors did not provide a power analysis to calculate the minimum number of patients required to detect an effect. With these considerations in mind, the paper was rated level II.

Sharma et al[17] compared the nonadjustable suture technique with 2 different types of adjustable suture surgery in an RCT for patients with comitant exotropia. A total of 45 patients were randomized into 3 groups of 15: nonadjustable suture surgery, adjustable suture surgery 6 hours after completion of the operation, and single-stage intraoperative adjustment with conscious sedation. Patients were 15 years of age and older, and the mean ($\pm$ standard deviation) age for each group was 24 $\pm$ 10 years without adjustable sutures, 24 $\pm$ 11 years with traditional adjustable sutures, and 23 $\pm$ 4 years in patients undergoing single-stage/intraoperative adjustment ($P = 0.9$).[17] All surgeries were performed by the same surgeon. Exclusion criteria included vertical strabismus, dense amblyopia, and eccentric fixation. The primary outcome measure was motor alignment success defined as $\leq$8 PD at 3 months follow-up and was achieved in 67% in the intraoperative suture adjustment group, 80% in the traditional adjustment group, and 53% in the nonadjustable suture group. The difference in these outcomes was not addressed statistically. The group undergoing intraoperative suture adjustment had anesthesia under topical with conscious sedation compared with the nonadjustable and traditional postoperative adjustment group, which each had peribulbar anesthesia coupled with conscious sedation. Pain intraoperatively was significantly higher in the group undergoing the single-stage intraoperative adjustable technique ($P < 0.001$).

Babu et al[18] evaluated motor alignment outcomes for the treatment of intermittent exotropia in adult patients aged more than 18 years. A total of 40 patients were enrolled and randomized into 2 equal groups of 20 for a mild- to moderate-angle exotropia between 15 and 40 PD. Mean age was 25 $\pm$ 4 years in the adjustable group and 25 $\pm$ 5 years in the nonadjustable group ($P = 0.5$). Both groups were treated using bilateral lateral rectus recessions. Adjustment was performed within 8 hours after surgery, and the proportion of patients requiring adjustment was not specified. The primary outcome measure was motor alignment success at 3 months, which was defined as <10 PD in the primary position. Successful motor alignment was achieved in 90% of patients using adjustable sutures and 85% using nonadjustable sutures, which did not differ significantly ($P = 0.316$). There were no intraoperative or postoperative complications reported for either group in the study. This level II study lacked a power analysis for setting its sample size.

Mireskandari et al[19] evaluated motor alignment outcomes in patients aged 12 years and older undergoing horizontal or vertical strabismus surgery. The study included 404 patients, 264 of whom underwent the adjustable suture technique and 140 underwent the nonadjustable suture technique. All surgery was performed by a single surgeon with the same surgical approach except for the placement of a bowtie adjustable suture. Patients were not randomized, and all patients were offered the adjustable suture technique. The decision on the surgical approach was based on patient preference. Assessment for suture adjustment was performed in the afternoon after morning surgery, and 29% of patients required suture adjustment. All adjustments were performed using topical anesthesia. The mean age of the group undergoing suture adjustment was significantly higher at 40 years compared with 22 years in the nonadjustable group ($P < 0.01$). The primary outcome measure was successful motor alignment, defined as $\leq$10 PD for horizontal surgery and <5 PD for vertical surgery. Overall, there was a modest benefit using adjustable sutures, with motor alignment success in 78% of patients

Table 1. Summary of Motor Alignment Outcomes Using Adjustable Versus Nonadjustable Sutures in Adult or Mixed-Age Patients

Author, Year	Level of Evidence; Design	Total No. of Patients	Age (yrs)	Strabismus Type	Minimum Length of Follow-up (mos)	Definition of Motor Success	Adjustable Sutures (% success)	Nonadjustable Sutures (% success)	P Value
Altintas et al, 2006[16]	Level II; RCT	88	Mixed adult and pediatric	All types horizontal and vertical	3	≤10 PD horizontal	73	81.9	0.348
Sharma et al, 2009[17]	Level II; RCT	45	Mixed adult and pediatric >15	Comitant exotropia	3	≤8 PD horizontal	80	53	Not reported
Babu et al, 2018[18]	Level II; RCT	40	Adult >18	Intermittent exotropia	3	<10 PD horizontal	90	85	0.316
Mireskandari et al, 2012[19]	Level II; cohort	404	Mixed adult and pediatric	Horizontal and vertical	6	≤10 PD horizontal	77.7	69.1	0.059
			≥12	Exotropia (primary)		<5 PD vertical	82.5	50	0.003
Zhang et al, 2012[20]	Level II; cohort	491	Adult	Horizontal and vertical	7 days to 12 wks, mean 33 days	≤10 PD horizontal	74.8	61.3	0.0016
				Primary		≤2 PD vertical	81.4	65	0.135
				Reoperation			65.7	42.4	0.0268
				Thyroid			74.1	76.7	0.82
Mireskandari et al, 2015[21]	Level II; cohort	353	Mixed adult and pediatric	Horizontal and vertical	4	≤10 PD horizontal	81	70.6	0.027
			≥12	Exotropia		<5 PD vertical	86.4	58.7	0.001
Vasconcelos et al, 2015 [22]	Level II; cohort	231	Age not reported	Exotropia	3	≤10 PD horizontal	50	21.7	0.05
Grace et al, 2017[23]	Level III; cohort	248	Adult	Adult onset esotropia	2	≤10 PD	88	75	<0.04
Liu et al, 2020[24]	Level III; cohort	184	Adult	Esotropia	2	<10 PD	57.1	62.7	0.58
				Exotropia			69.2	58.4	0.34

PD = prism diopters; RCT = randomized clinical trial.

Table 2. Summary of Motor Alignment Outcomes Using Adjustable Versus Nonadjustable Sutures in Pediatric Patients Only

Author, Year	Level of Evidence; Design	Total No. of Patients	Age (yrs)	Strabismus Type	Minimum Length of Follow-up (mos)	Definition of Motor Success	Adjustable Sutures (% Success)	Nonadjustable Sutures (% Success)	P Value
Kamal et al, 2016[25]	Level II; RCT	60	<12	Horizontal (all)	6	≤8 PD	86.67	73.33	0.197
				Esotropia			87	72	0.267
				Exotropia			85.7	75	1.0
Awadein et al, 2008[10]	Level II; cohort	298	≤10	Horizontal (all)	3	≤8 PD	79	64.5	<0.01
				Esotropia			78	62	0.025
				Exotropia			80	69	0.2
Kassem et al, 2018[26]	Level II; cohort	637	<15	Horizontal (all)	3	≤8 PD	77.7	64.6	0.003
				Primary			81	66	0.001
				Reoperation			69	57	0.41
				Esotropia (all)			77	62	0.014
				Exotropia (all)			80	66	0.086

using adjustable sutures versus 69% using nonadjustable sutures, but this did not reach statistical significance ($P = 0.059$).[19] Strabismus type was explored secondarily in a subgroup analysis. The adjustable suture technique was clinically advantageous in 83% of 146 patients undergoing primary surgery for an exotropia versus 50% of 85 patients using the nonadjustable technique ($P = 0.003$). There was not a statistically significant advantage between the techniques for esotropia, vertical surgery, or reoperation.[19] The authors performed a post hoc power analysis, which revealed that the cohorts for esotropia and vertical strabismus were too small to detect a 10% difference in motor success if present, thereby warranting further investigation for using adjustables for these types of strabismus. Using multiple regression analysis, the authors found that the presence of amblyopia, binocularity, and prior surgery did not adversely impact surgical outcomes. No adverse events were recorded for either group.[19]

In a subsequent study, the same group explored whether adjustable sutures augmented the ability to achieve the target postsurgical alignment and subsequently improve long-term motor outcomes.[21] They studied 353 patients 12 years of age and older, using the same definition of motor success noted above. The adjustable suture technique was offered to every patient, and a decision to perform adjustable versus nonadjustable surgery was determined by patient preference. Overall success of surgery was higher with adjustable sutures versus nonadjustable sutures (81% vs. 71%; $P = 0.027$).[21] The primary predictor for surgical success was achievement of the desired target angle in the immediate postoperative period, which was more readily attained in patients with adjustable sutures than in patients with nonadjustable sutures (76% vs. 54%; $P < 0.0001$).[21] As in the prior study, a statistically significant advantage was noted for motor success in strabismus subtype analysis with respect to the impact of adjustable sutures on exotropia (86.4% adjustable vs. 58.7% nonadjustable; $P < 0.0001$) but not for esotropia or vertical deviations, with the caveat that the study was not adequately powered to detect a difference of 9% for the latter 2 strabismus types.[21]

Zhang et al[20] evaluated the use of adjustable sutures for adult patients undergoing horizontal or vertical strabismus surgery for a heterogeneous group of etiologies, including childhood strabismus, reoperation, thyroid, paretic, restrictive, and iatrogenic (e.g., after glaucoma shunt or scleral buckle). A total of 491 patients, including 305 with adjustable sutures and 186 with nonadjustable sutures, were studied. Patients were from 3 strabismus surgeons, 2 of whom performed adjustable suture surgery often and 1 of whom did not. Further detail on the selection of patients for adjustable suture surgery was not specified. Postoperative suture adjustment was performed on 82% of the adjustable suture group under topical anesthesia either the same day of strabismus surgery or the day after. The primary outcome measure was motor success defined as ≤10 PD for horizontal alignment and ≤2 PD for vertical alignment, with a minimum follow-up of 1 to 12 weeks. Motor alignment success was achieved in 75% of the adjustable patients versus 61% of the nonadjustable patients ($P = 0.0016$). The authors performed subgroup analysis to evaluate adults undergoing primary surgery, adults undergoing a reoperation, and adults with thyroid eye disease. If the patient was undergoing primary surgery as an adult with a history of childhood strabismus (90 patients), use of adjustable sutures conferred a motor alignment success in 81% versus 65% in patients with nonadjustable sutures, but this did not reach statistical significance ($P = 0.135$). For the 100 patients undergoing a reoperation after childhood strabismus, there was a significant benefit from using adjustable sutures, with a successful motor alignment outcome in 66% of patients undergoing adjustable surgery versus 42% undergoing nonadjustable surgery ($P = 0.0268$).[20] Among 57 patients undergoing surgery for thyroid orbitopathy, using adjustable sutures did not confer an advantage with respect to motor alignment outcomes (74% adjustable vs. 77% nonadjustable; $P = 0.82$).

Vasconcelos and Almeida[22] evaluated the impact of the adjustable suture technique in comitant horizontal strabismus surgical outcomes in a Brazilian cohort of 231 patients, in which 124 had nonadjustable and 107 had adjustable suture surgery. One of the authors participated in all of the surgeries. Charts selected for the study were identified using a probabilistic sampling of a pool of 1439 patients who had undergone the adjustable versus nonadjustable technique with a power calculation of a

minimum of 104 patients per group for a power of 90% and alpha of 5% to detect a difference in the success rate between the groups using a relative risk of 0.62. The demographics of the cohort with respect to patient age were not reported. Motor alignment success was defined as ≤10 PD. At 1 year postoperatively, surgical success was higher in the adjustable group for patients with extropia (9/18; 50% vs. 5/23; 21.7%; $P = 0.05$), but not for patients with esotropia, a finding similar to that of Mireskandari et al.[19,21]

Level III Studies. Grace et al[23] focused on motor outcomes comparing the adjustable with the nonadjustable suture technique in the setting of 248 patients with adult-onset esotropia (esotropia at ≥18 years of age). Of this cohort, 195 patients had adjustable sutures and 53 did not. The underlying etiologies for strabismus were heterogeneous. The most common diagnosis in this series was esotropia in the setting of 6th nerve palsy (36%), followed by thyroid orbitopathy (18%), age-related divergence insufficiency (15%), and breakdown of pre-existing esotropia (13%).[23] Although the primary focus was horizontal surgery outcomes, 10% of the cohort also underwent surgery for a vertical misalignment. Selection for the adjustable versus nonadjustable suture technique was at the discretion of the surgeon, and further details were not provided. Timing of the adjustment was not discussed, but 45% of the adjustable suture cohort required adjustment. The primary outcome measure was motor success defined as ≤10 PD for horizontal alignment. Motor alignment success was achieved in 88% of patients with adjustable sutures compared with 75% with fixed sutures ($P < 0.04$).

Liu et al[24] evaluated an adult cohort of 184 patients, 68 of whom had adjustable sutures and 116 did not. The primary outcome measure was horizontal motor alignment <10 PDs at 2 months' follow-up. One of 2 surgeons performed the surgery, and patients were stratified into the adjustable or nonadjustable cohort on the basis of preferred practice by the surgeon (i.e., comparing the time period when the surgeons preferred to use adjustable sutures to the period when they did not during the 14 years reviewed). Etiologies varied from childhood strabismus to cranial neuropathy and thyroid orbitopathy, and subgroup analysis was not performed. No significant difference was noted for patients with esotropia undergoing adjustable sutures (57.1%) versus nonadjustable sutures (62.7%; $P = 0.58$) or for patients with exotropia undergoing adjustable sutures (69.2%) versus nonadjustable sutures (58.4%; $P = 0.34$). This level III study was not powered to identify a difference between the 2 groups.

Pediatric-Specific Studies (<18 Years)

Level II Studies. The only RCT specifically focused on pediatric patients was by Kamal et al.[25] The authors evaluated the use of adjustable sutures in children aged less than 12 years who were undergoing primary horizontal strabismus surgery. A total of 60 children were enrolled and randomized to 2 groups of 30 with comparable mean ages, 3.5 ± 2.4 years in the adjustable group and 3.6 ± 2.6 years in the nonadjustable group. Patients with any form of restrictive strabismus, paralytic strabismus, Duane syndrome, myasthenia gravis, nystagmus, or reoperation were excluded. Adjustable sutures were only applied to recessed muscles in the adjustable suture group; no resected muscles had adjustable sutures placed. Children in the adjustable suture group were assessed within hours after surgery and underwent a sedated, propofol-based suture adjustment in the operating room when needed. Postoperatively, 33% of children required suture adjustment for undercorrection (17%) or overcorrection (17%). The primary outcome was motor alignment at 6 months, with motor success defined as ≤8 PD in the primary position. By 6 months, overall motor alignment success was achieved in 87% of children undergoing adjustable suture surgery and 73% of children undergoing nonadjustable suture surgery ($P = 0.197$). When analyzing for the specific type of strabismus, 87% of children with esotropia in the adjustable suture group had motor alignment success versus 72% of children in the nonadjustable suture group ($P = 0.267$). Children with exotropia similarly experienced a higher motor alignment success with adjustable sutures 86% versus 75% with nonadjustable sutures ($P = 0.197$). The differences were not statistically significant, but no power calculation was performed to determine the minimum number of patients needed to detect a statistically significant effect.

In addition to 1 RCT, 2 retrospective cohort studies were identified that focused on motor alignment outcomes in the pediatric age group specifically. Awadein et al[10] reported 1 of the first comparative large cohort studies examining motor alignment outcomes in children. They examined 396 children aged 10 years of age or less undergoing horizontal strabismus surgery. In this cohort, 298 children had adjustable suture surgery and 98 children had nonadjustable suture surgery with a single surgeon.[10] The study included results over a 15-year study period, during which time the surgeon performed nonadjustable suture strabismus surgery for the first 4 years in the majority of patients and exclusively adjustable suture strabismus surgery for all patients regardless of age for the remaining 11 years of the study.[10] The mean age was 4.7 ± 2.5 years in the adjustable group and 4.2 ± 2.4 years in the nonadjustable group (difference in mean age, $P = 0.2$). As anticipated, the mean age of children who underwent a nonsedated suture adjustment was older at 6.5 years versus those who underwent intravenous propofol suture adjustment at 4.2 years ($P < 0.001$). The primary outcome was motor alignment success at 3 months, which was defined as ≤8 PD in the primary position. For the entire cohort, there was a higher rate of motor success for patients who underwent adjustable suture surgery, with 79% success among 236 patients versus 65% success among the 63 patients in the nonadjustable group ($P < 0.01$). This difference remained statistically significant when stratified by primary surgery ($P = 0.01$) versus reoperation ($P = 0.04$). However, when the authors compared using adjustable sutures for the strabismus type (i.e., esotropia or exotropia), the adjustable suture technique showed a statistically significant advantage for esotropia, with 78% success among 131 patients in the adjustable group versus 62% success among 41 patients in the nonadjustable group ($P = 0.025$). This advantage was not seen for exotropia, where there was an 80% success among

105 patients in the adjustable group versus 69% success among 22 patients in the nonadjustable group ($P = 0.2$). Although there was an 11% improvement in motor alignment success in the exotropic group with adjustable sutures, the authors suggest that the study was not powered to evaluate this effectively given the small number of patients with extropia who were in the nonadjustable suture group. No complications were reported in the setting of adjustable sutures.

Kassem et al[26] provided a follow-up study to Awadein et al[10] from the same institution and same strabismus surgeon in an effort to further determine the efficacy of adjustable sutures in children. The study added 8 additional years compared with the earlier study and expanded the inclusion criteria to consider children who were 15 years of age and younger. There likely is an overlap with the cohort from the prior study, but it is unclear what proportion of that cohort was reanalyzed in this updated work. To address the concern from the prior study that the exotropia group with nonadjustable sutures was underpowered,[10] the authors extended their analysis to include patients from an earlier time period when the strabismus surgeon was not routinely performing the adjustable suture technique in children. Selection of cases was as described above. Before 1994, the majority of cases were performed using nonadjustable sutures, and after 1994, cases were performed exclusively using adjustable sutures. A total of 637 patients were included in the study; 521 patients had adjustable suture surgery, and 116 patients had nonadjustable suture surgery. Children who had adjustable sutures were older, with a median age of 5.1 years (range, 0.3−15.7 years) compared with those who had nonadjustable sutures at a median age of 3.8 (range, 0.5−10.6 years; $P < 0.0001$). The primary outcome measure was motor alignment success at 3 to 6 months postoperatively, defined as ≤8 PD in the primary position. The proportion with successful motor alignment was higher in 405 patients who underwent adjustable surgery (78%) compared with 74 patients who underwent nonadjustable surgery (65%; $P = 0.003$), particularly if this was the primary surgery (307 adjustable, 81% vs. 61 nonadjustable, 66%; $P = 0.001$). For reoperations, the motor alignment success appeared to have a 12% improvement using adjustable sutures, with 69% success among 98 patients in the adjustable group versus 57% success among 13 patients in the nonadjustable group, but this was not statistically significant ($P = 0.41$). As noted in the prior study,[10] this effect was present in esotropic patients, with 77% success among 222 patients in the adjustable group versus 62% success among 41 patients in the nonadjustable group ($P = 0.014$). Motor alignment success was higher in the adjustable suture technique group among patients with exotropia, but the difference was not statistically significant (183 adjustable, 80% vs. 33 nonadjustable, 66%; $P = 0.086$). The authors cited the smaller sample size of the nonadjustable suture group of patients with exotropia as limiting their power to detect a difference. However, when the authors examined those children who underwent primary surgery for exotropia, a statistically significant improvement of 85% was noted in the 126 children in the adjustable suture group versus 69% success in the 27 patients in the nonadjustable group ($P = 0.032$). No complications were reported in the setting of adjustable sutures. In addition to motor alignment success, the authors compared reoperation rates between patients undergoing adjustable versus nonadjustable suture surgery; that analysis is discussed below.

Level III Studies. There were no level III studies that focused specifically on motor alignment outcomes in children.

Reoperation Rates

Six articles focused on the impact of the adjustable suture technique on reoperation rates in patients who underwent strabismus surgery. The assumption in these articles is that reoperation implies surgical failure, and none of these articles considered whether additional surgery was planned, such as in a staged procedure for complex strabismus. Two of these studies were rated level II, and 4 were rated level III. The results are summarized in Table 3. Four of the 6

Table 3. Summary of Reoperation Rates Using Adjustable Versus Nonadjustable Sutures

Author, Year	Level of Evidence; Design	Total No. of Patients	Age	Minimum Length of Follow-up (mos)	Adjustable Sutures (% reoperation)	Nonadjustable Sutures (% reoperation)	*P* Value
Kassem et al, 2018[26]	Level II; cohort	637	<15	3	15	21	0.033
Christensen et al, 2018[28]	Level II; cross-sectional	10010	<65	12	5.5	7.3	0.29
Tripathi et al, 2012[32]	Level III; cohort	443	≥13	12	8.51	27.15	<0.005
Leffler et al, 2015[29]	Level III; cross-sectional	6178	<65	12	5.8 horizontal	7.8	0.02
					15.2 vertical	10.4	0.05 did not reach significance after controlling for patient age
Leffler et al, 2016[30]	Level III; cross-sectional	1446 H 654 V	<65	Varied	4.1 horizontal 4.1 vertical	7.1 8.3	0.047 0.07
Leffler et al, 2016[31]	Level III; cross-sectional	829	<18	12	9.6	7.4	0.18

H = horizontal strabismus surgery; V = vertical strabismus surgery.

studies originated from the group of Leffler and colleagues, with a focus on reoperation rates using large national databases; 3 of these papers examined adult patients, and the fourth, discussed below, examined pediatric patients.[28-31]

Level II Studies. Kassem et al[26] (discussed above in the "Motor Alignment Outcomes" section) focused on pediatric patients aged 15 years and less undergoing horizontal strabismus surgery. Reoperations occurred between 6 months and 10 years after the primary surgery, and there was a statistically significant lower rate of reoperation that occurred among those patients who underwent adjustable suture placement (15%) compared with the nonadjustable group (21%, $P = 0.033$).

Christensen and colleagues[28] used a fee-for-service Medicare database to analyze whether reoperation rates among adults undergoing strabismus surgery were influenced by the geographic region, availability of adjustable suture surgery, and type of ophthalmology practice. In multivariable analysis, there was no benefit of adjustable suture surgery over nonadjustable surgery with regard to the reoperation rate. There was no association between the use of adjustable sutures and the reoperation rate in patients undergoing horizontal surgery (5971 patients, odds ratio [OR], 0.86; $P = 0.29$), vertical surgery (2840 patients, OR, 0.98; $P = 0.93$), and surgery with known restrictive disease (1199 patients, OR, 0.86; $P = 0.61$). Interestingly, the claims data revealed that the majority of providers who billed for the adjustable suture technique were located in the Northeast, Florida, or on the West Coast (45% compared with other geographic regions in the United States 8%, $P < 0.001$).[28]

Level III Studies. Tripathi et al[32] evaluated reoperation rates for 443 patients between the ages of 13 and 78 years, comparing adjustable and nonadjustable techniques for a heterogeneous group of strabismus types. All patients were given the option for adjustable sutures, and selection for adjustable versus nonadjustable was at the patient's discretion. In this cohort, there was a marked difference in the reoperation rate in those undergoing adjustable (9%) versus nonadjustable suture surgery (27%; $P < 0.005$). The majority of patients in the nonadjustable group underwent reoperation for an undercorrection (84%).

In addition to the recent article by Christensen and colleagues,[28] 3 additional articles[29-31] from Leffler evaluated reoperation rates using claims data. The earliest of these articles evaluated the reoperation rate at the 1-year follow-up of 6178 adult patients undergoing strabismus surgery with adjustable or nonadjustable sutures.[29] The study spanned a 5-year period. For horizontal strabismus surgery, the adjustable suture technique was associated with a lower rate of reoperation (5.8% adjustable vs. 7.8% nonadjustable; $P = 0.02$). In contrast, for vertical strabismus surgery, the adjustable suture technique was associated with a higher rate of reoperation (15% adjustable vs. 10% nonadjustable; $P = 0.05$).

In a second study, Leffler and Pariyadath[30] examined the rate of reoperation for a sample of Medicare beneficiaries in a 1-year period and compared a group for whom adjustable sutures were available versus a group for whom those sutures were not available.[30] This study was rated level III because of the study design and assumptions made based only on billing codes to determine the availability of the adjustable suture technique. In a 1-year period, reoperations occurred at a rate of 4.1% when the adjustable suture technique was used compared with a higher rate of 7.1% ($P = 0.047$) when the surgeon did not perform adjustable surgery for horizontal strabismus. Likewise, the rate of reoperation was lower for vertical strabismus when the adjustable suture technique was used (4.1% vs. 8.3%; $P = 0.07$).[30] Interestingly, the authors found that 74% of surgeons used the conventional suture technique and the minority used the adjustable suture technique.

With respect to children specifically, Leffler and colleagues[31] examined a national insurance database that was specific for patients aged less than 18 years to evaluate reoperation rates within the first year after strabismus surgery. In this study, the cohort of children who had undergone reoperation included 829 patients among 11 115 total cases of pediatric strabismus surgery for a reoperation rate of 7.7%. The majority of patients undergoing a reoperation procedure had nonadjustable sutures (804 nonadjustable vs. 25 adjustable). Younger age was associated with a higher reoperation rate, as might be anticipated. When comparing outcomes with adjustable sutures versus fixed sutures, the authors found that 9.6% (25/260) of children receiving adjustable sutures had reoperations compared with 7.4% receiving fixed sutures (804/10,806; $P = 0.18$). When analyzing this in a multivariate analysis and excluding superior oblique surgery, for which the adjustable suture technique was not used, the association between adjustable suture use and reoperation was not significant (OR, 1.47; confidence interval, 0.91−2.36; $P = 0.11$).[31]

Complications

There have been no studies to date that provide complication rates associated with the placement of adjustable sutures. Considerations include the possibility of increased inflammation surrounding additional suture material, the potential for the adjustable slip knot to loosen, and the potential complications during suture adjustment such as a vasovagal reaction when manipulating the adjustable suture during a nonsedated procedure. Further concerns regarding additional sedation for pediatric patients remain to be evaluated and were beyond the scope of the articles included for this assessment. In the literature cited in this assessment, there were no reports of complications from the placement of adjustable sutures or from modified techniques for adjustment such as sedation in children.

Conclusions

Both adjustable and nonadjustable suture techniques resulted in successful motor alignment outcomes in the

majority of cases. Although the majority of studies that met the inclusion criteria for this assessment reported advantages of adjustable suture techniques over nonadjustable techniques, the overall magnitudes and significance of these advantages are yet to be determined, and they warrant further investigation in the development and analysis of adjustable suture techniques. The range of reported benefit varied greatly and reflects the heterogeneity of the studies collated for this assessment with respect to strabismus type, methodology of study, surgical technique, age at time of surgery, and outcome measures. This assessment highlights the need for standardization with respect to methods of study randomization, surgical technique, and metrics of surgical success for future investigations.

According to claims data, use of the adjustable suture technique appears to be more prevalent on the East and West coasts, consistent with the lack of universal adoption of the technique. Factors that may play in the decision to offer adjustable sutures include lack of training or comfort with the technique, additional logistics of suture adjustment, and considerations of extra sedation events for pediatric patients. Another factor that may be an impediment to the adoption of the adjustable suture technique is the continued absence of large, well-controlled RCTs to evaluate the method. The panel sought to strengthen its review by including small RCTs and more robust studies of only comparative studies with at least 100 patients and a nonadjustable group as the control group.

Future Research

This assessment did not identify any level I evidence to support using adjustable sutures, which highlights the need for well-designed, adequately powered future work. With respect to this topic, it may not be feasible to enroll patients in a large, multicenter RCT comparing surgical techniques given surgeon preference, which often is influenced by prior training and personal experience, and the absence of standardization of postoperative assessment to guide decisions and dosing of suture adjustment. Nevertheless, small RCTs and larger retrospective studies evaluated in this assessment suggest a possible advantage in using adjustable suture techniques. Future studies, with a clearly delineated method for randomization, are warranted that not only focus on strabismus types for which these are most effective but also specify details about the method of suture adjustment. Understanding the algorithm for performing an adjustment, the surgical target angle for the adjustment, and the impact on immediate and long-term alignment would be informative and may facilitate in refinement of surgical nomograms. Defining surgical success in relation to strabismus type, beyond PDs from orthotropia, is important because overcorrections in some forms of strabismus may be more symptomatic postoperatively than undercorrections (e.g., in the treatment of exotropia). Evaluating the role of adjustables in complex multiple-muscle procedures is warranted. To expand our understanding of the role of adjustable sutures in pediatric patients, future studies should focus on the use of adjustable sutures in children. This should be weighed within the context of the logistical and other costs of performing adjustable suture surgery. Furthermore, use of goal-directed metrics, such as the development of binocularity or elimination of diplopia coupled with an assessment of patient satisfaction, may expand our understanding of the impact of this technique on outcomes beyond the traditional metrics of motor success and reoperation rate.[33,34]

Footnotes and Disclosures

Originally received: July 22, 2021.
Final revision: July 22, 2021.
Accepted: July 22, 2021.
Available online: ■■■. Manuscript no. D-21-01477.

[1] Department of Ophthalmology, Boston Children's Hospital, Harvard Medical School, Boston, Massachusetts.

[2] Illinois Eye and Ear Infirmary, University of Illinois College of Medicine at Chicago, Chicago, Illinois.

[3] Department of Ophthalmology, Children's Hospital of Philadelphia, Philadelphia, Pennsylvania.

[4] Children's Hospital of Los Angeles, Keck School of Medicine, University of Southern California, Los Angeles, California.

[5] Vanderbilt Eye Institute, Vanderbilt University Medical Center, Nashville, Tennessee.

[6] Department of Ophthalmology, Stanford University School of Medicine, Palo Alto, California.

[7] Storm Eye Institute, Department of Ophthalmology, Medical University of South Carolina, Charleston, South Carolina.

[8] Eye Physicians and Surgeons PC, Department of Ophthalmology and Visual Science, Yale School of Medicine, New Haven, Connecticut.

[9] Jules Stein Eye Institute, Los Angeles, California.

Disclosure(s):
All authors have completed and submitted the ICMJE disclosures form.

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

Funded without commercial support by the American Academy of Ophthalmology.

Prepared by the Ophthalmic Technology Assessment Committee Pediatric Ophthalmology/Strabismus Panel and approved by the American Academy of Ophthalmology's Board of Trustees June 18, 2021.

HUMAN SUBJECTS: No human subjects were included in this study. The requirement for informed consent was waived because of the retrospective nature of the study. All research adhered to the tenets of the Declaration of Helsinki.

No animal subjects were used in this study.

Author Contributions:

Conception and design: Heidary, Aakalu, Binenbaum, Chang, Morrison, VanderVeen, Lambert, Trivedi, Galvin, Pineles

Data collection: Heidary, Aakalu, Binenbaum, Chang, Morrison, VanderVeen, Lambert, Trivedi, Galvin, Pineles

Analysis and interpretation: Heidary, Aakalu, Binenbaum, Chang, Morrison, VanderVeen, Lambert, Trivedi, Galvin, Pineles

Obtained funding: N/A

Overall responsibility: Heidary, Aakalu, Binenbaum, Chang, Morrison, VanderVeen, Lambert, Trivedi, Galvin, Pineles

Abbreviations and Acronyms:
OR = odds ratio; **PD** = prism diopters; **RCT** = randomized clinical trial.

Key words:
strabismus, esotropia, exotropia, hypertropia, diplopia, Graves, hyperthyroidism, thyroid myopathy, squint, amblyopia, oculomotor muscles, extraocular muscle surgery, adjustable sutures

Correspondence: Andre Ambrus, MLIS, American Academy of Ophthalmology, Quality and Data Science, PO Box 7424, San Francisco, CA 94120-7424. E-mail: aambrus@aao.org.

References

1. Goldenberg-Cohen N, Tarczy-Hornoch K, Klink DF, Guyton DL. Postoperative adjustable surgery of the superior oblique tendon. *Strabismus*. 2005;13:5−10.
2. Jampolsky A. Strabismus reoperation techniques. *Trans Sect Ophthalmol Am Acad Ophthalmol Otolaryngol*. 1975;79:704−717.
3. Rosenbaum AL, Metz HS, Carlson M, Jampolsky AJ. Adjustable rectus muscle recession surgery. A follow-up study. *Arch Ophthalmol*. 1977;95:817−820.
4. Vasconcelos GC, Guyton DL. Adjustable sutures in strabismus surgery: why surgeons either love them or hate them after three decades. *Arq Bras Oftalmol*. 2014;77:5−6.
5. Gawecki M. Adjustable versus nonadjustable sutures in strabismus surgery-who benefits the most? *J Clin Med*. 2020;9.
6. Nihalani BR, Whitman MC, Salgado CM, et al. Short tag noose technique for optional and late suture adjustment in strabismus surgery. *Arch Ophthalmol*. 2009;127:1584−1590.
7. Chan TK, Rosenbaum AL, Hall L. The results of adjustable suture technique in paediatric strabismus surgery. *Eye (Lond)*. 1999;13(Pt 4):567−570.
8. Dawson E, Bentley C, Lee J. Adjustable squint surgery in children. *Strabismus*. 2001;9:221−224.
9. Mokashi A, Stead RE, Stokes J. Paediatric adjustable strabismus surgery. *Eye (Lond)*. 2012;26:1024−1025. author reply 1025-1026.
10. Awadein A, Sharma M, Bazemore MG, et al. Adjustable suture strabismus surgery in infants and children. *J AAPOS*. 2008;12:585−590.
11. Engel JM, Rousta ST. Adjustable sutures in children using a modified technique. *J AAPOS*. 2004;8:243−248.
12. Hakim OM, El-Hag YG, Haikal MA. Releasable adjustable suture technique for children. *J AAPOS*. 2005;9:386−390.
13. Tsai CB. Adjustable suture strabismus surgery in pediatric patients using pull-string technique. *Taiwan J Ophthalmol*. 2017;7:38−43.
14. Phanphruk W, Alkharashi M, Bilge A, Hunter DG. Sedated suture adjustment in children undergoing adjustable suture strabismus surgery. *J AAPOS*. 2017;21:196−200.
15. Howick J, Chalmers I, Glasziou P, et al. The 2011 Oxford CEBM levels of evidence (introductory document). Oxford Centre for Evidence-Based Medicine. https://www.cebm.ox.ac.uk/resources/levels-of-evidence/explanation-of-the-2011-ocebm-levels-of-evidence.
16. Altintas AG, Turker C, Levent GG, et al. Competitive analysis of intraoperative adjustable suture with conventional suture technique in strabismus surgery. *Ann Ophthalmol (Skokie)*. 2006;38:297−303.
17. Sharma P, Julka A, Gadia R, et al. Evaluation of single-stage adjustable strabismus surgery under conscious sedation. *Indian J Ophthalmol*. 2009;57:121−125.
18. Babu S, Goel Y, Chaudhary RB, et al. Comparison of adjustable sutures versus nonadjustable sutures in intermittent exotropia. *Eur J Ophthalmol*. 2018;28:264−267.
19. Mireskandari K, Cotesta M, Schofield J, Kraft SP. Utility of adjustable sutures in primary strabismus surgery and reoperations. *Ophthalmology*. 2012;119:629−633.
20. Zhang MS, Hutchinson AK, Drack AV, et al. Improved ocular alignment with adjustable sutures in adults undergoing strabismus surgery. *Ophthalmology*. 2012;119:396−402.
21. Mireskandari K, Schofield J, Cotesta M, et al. Achieving postoperative target range increases success of strabismus surgery in adults: a case for adjustable sutures? *Br J Ophthalmol*. 2015;99:1697−1701.
22. Vasconcelos GC, Almeida HC. Adjustable versus non-adjustable suture techniques for concomitant horizontal strabismus: a comparative study. *Arq Bras Oftalmol*. 2015;78:352−355.
23. Grace SF, Cavuoto KM, Shi W, Capo H. Surgical treatment of adult-onset esotropia: characteristics and outcomes. *J Pediatr Ophthalmol Strabismus*. 2017;54:104−111.
24. Liu D, Kumar A, Shieh D, et al. One-month postoperative horizontal strabismus surgery outcomes using adjustable and nonadjustable sutures. *J Binocul Vis Ocul Motil*. 2020;70:94−97.
25. Kamal AM, Abozeid D, Seif Y, Hassan M. A comparative study of adjustable and non-adjustable sutures in primary horizontal muscle surgery in children. *Eye (Lond)*. 2016;30:1447−1451.
26. Kassem A, Xue G, Gandhi NB, et al. Adjustable suture strabismus surgery in infants and children: a 19-year experience. *J AAPOS*. 2018;22:174−178 e171.
27. Brown DR, Pacheco EM, Repka MX. Recovery of extraocular muscle function after adjustable suture strabismus surgery under local anesthesia. *J Pediatr Ophthalmol Strabismus*. 1992;29:16−20.
28. Christensen MR, Pierson K, Leffler CT. Reoperation following strabismus surgery among medicare beneficiaries: associations with geographic region, academic affiliation, surgeon volume, and adjustable suture technique. *Indian J Ophthalmol*. 2018;66:1149−1153.
29. Leffler CT, Vaziri K, Cavuoto KM, et al. Strabismus surgery reoperation rates with adjustable and conventional sutures. *Am J Ophthalmol*. 2015;160:385−390 e384.
30. Leffler CT, Pariyadath A. Strabismus surgery among Medicare beneficiaries: Imputed rates of reoperation in the same calendar year. *Digit J Ophthalmol*. 2016;22:6−11.

31. Leffler CT, Vaziri K, Schwartz SG, et al. Rates of reoperation and abnormal binocularity following strabismus surgery in children. *Am J Ophthalmol*. 2016;162:159−166 e159.
32. Tripathi A, Haslett R, Marsh IB. Strabismus surgery: adjustable sutures-good for all? *Eye (Lond)*. 2003;17:739−742.
33. Ehrenberg M, Nihalani BR, Melvin P, et al. Goal-determined metrics to assess outcomes of esotropia surgery. *J AAPOS*. 2014;18:211−216.
34. Hatt SR, Leske DA, Liebermann L, Holmes JM. Incorporating health-related quality of life into the assessment of outcome following strabismus surgery. *Am J Ophthalmol*. 2016;164:1−5.