Original Article

Early and delayed suture adjustments after adjustable suture strabismus surgery: a randomized controlled trial

Ahmed Adel Abdelmonem [1], Ahmed Awadein [2], Mahmoud Mohamed M Genidy [1], Ahmed Shawkat Abdelhalim [1] and Sahar Torky A Abdelaziz [1]

[1] *Ophthalmology Department, Faculty of Medicine, Minia University, Minia, Egypt*
[2] *Ophthalmology Department, Faculty of Medicine, Cairo University, Cairo, Egypt*

ABSTRACT

Background: Adjustable sutures increase the success rate of strabismus surgery. However, the optimal timing of postoperative suture adjustment remains controversial. This trial was aimed at comparing the surgical outcomes and pain scores of early or 2 – 4 h and delayed or 24 h postoperative suture adjustment in adult patients undergoing strabismus surgery.

Methods: An open-label, prospective, randomized, comparative interventional study was performed in consecutive adult patients scheduled for eye muscle surgery. Patients were randomized into two groups: the early group, with suture adjustment 2 – 4 h postoperatively, and the delayed group, with suture adjustment 24 h postoperatively. Subjective pain scores during the adjustment were also analyzed. The angles of misalignment at 1 and 3 months and the success rate at 3 months postoperatively were compared.

Results: Forty-five (90%) patients completed the follow-up, including 23 (92%) in the early adjustment group and 22 (88%) in the delayed adjustment group, with a mean (standard deviation) age of 25.6 (9.5) years and a male-to-female ratio of 46.7:53.3. Thirty patients (66.7%) had exotropia, and 15 (33.3%) patients had esotropia. Both groups had comparable baseline characteristics (all $P > 0.05$). The mean pain scores during adjustment did not differ significantly between groups ($P > 0.05$). The postoperative angles of alignment were comparable between the groups before suture adjustment and at the 1- and 3-month follow-ups (all $P > 0.05$). The success rate in the early adjustment group was slightly higher (87.0% versus 63.6%), but the difference was not statistically significant ($P > 0.05$). The success rate was comparable between the groups in patients with esotropia or exotropia (both $P > 0.05$).

Conclusions: Although the early adjustment group had a slightly higher success rate, the difference was not significant. Both groups had comparable subjective pain scores during adjustment, final motor alignment, or success rate. Future clinical trials should be performed different time intervals for postoperative suture adjustment, and subjective and objective outcomes, such as diplopia and stereopsis, should be compared between patients with a first strabismus surgery and those who underwent reoperation. This could better resolve the persistent controversy related to the optimal time for suture adjustment.

KEYWORDS

comitant strabismus, squint, heterophoria, esotropias, exodeviation, ocular surgery, adjustable

Correspondence: Sahar Torky Abdelrazik Abdelaziz, Ophthalmology Department, Minia University hospital, Minia University, 98 Cornish El Nile Street, Minia, Egypt. Email: sahar.abdelrazek@mu.edu.eg. ORCID iD: https://orcid.org/0000-0003-2435-7701

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INTRODUCTION

Adjustable sutures have been used in eye muscle surgeries for several decades in an attempt to increase the success rate of strabismus surgeries [1-3]. Several techniques are recommended for adjustable sutures, including the sliding noose [4-6] and the slip-knot techniques [1].

While some studies described intraoperative adjustment as a one-stage procedure to reduce the time required [7-9], most used postoperative adjustment [3, 10]. Surgery is usually performed under general anesthesia, with adjustments performed later with topical anesthesia [11, 12].

In patients undergoing postoperative adjustment, the adjustment can be performed 2 – 4 h [10], after 24 h [11, 12], and up to a few days [13-15] postoperatively. The main concern with performing the adjustment early after surgery is the uncertainty of patient cooperation, particularly in patients with severe postoperative pain and ocular discomfort [16-19]. Furthermore, mechanical factors, tissue reactions, and the stability of muscle healing to the sclera following eye muscle surgery may influence the final alignment of the eye after the adjustment procedure [20].

Early adjustment allows the patient to be discharged on the day of surgery and ensures that no long sutures are left in the eye overnight, which could irritate the patient [11, 12]. Delayed adjustment allows for a more accurate alignment evaluation and adjustment. Because the muscle may begin to attach to the sclera, the procedure may become more painful and difficult [12].

This study was aimed at comparing the outcomes and challenges of early or 2 – 4 h and delayed or 24 h postoperative suture adjustment.

METHODS

This open-label, prospective, randomized, comparative, interventional study was performed on consecutive adult patients scheduled for eye muscle surgery between December 2019 to September 2021. Age, sex, and previous treatment (prisms, patching, or surgery) were recorded. Patients aged > 14 years, with concomitant esotropia or exotropia > 15 prism diopters (PD) and adequate cooperation were included. We excluded uncooperative patients or those who had previous strabismus surgeries.

The Research Ethics Committee of the Faculty of Medicine, Minia University, approved the study protocol (approval number: 360: 12/2019). All local laws and principles of the Helsinki Declaration were followed during the research and data collection. This clinical trial was registered in the ClinicalTrials.gov Protocol Registration System (identifier NCT04617158). All participants provided written informed consent.

Complete ophthalmological assessment was performed, including full history-taking, slit-lamp biomicroscopy examination (LS Ophthalmic Slit Lamp; ChongQing Medical Sunkingdom Medical Instruments Co., Ltd., ChongQing, China), dilated fundus examination using a binocular indirect ophthalmoscope (Keeler Instruments, Inc., PA, USA) and + 20 diopter ancillary lens (VOLK Optical Inc., Mentor, Ohio, USA), cycloplegic refraction after installation of topical cyclopentolate eye drops 1% (Plegica 10 mg, EPCI Pharmaceutical, Egypt) thrice every 10 min, and measuring uncorrected and best-corrected distance visual acuity using Landolt's broken ring chart (auto chart projector ACP-1500; Stallion Medical Inc., San Diego, CA, USA).

Detailed orthoptic evaluation was performed. The prism and alternate cover tests were used to measure the angle of deviation in the primary position and in different gaze positions at 30 cm and 6 m with and without glasses, if present, and the target angle for surgery was midway between distant and near deviations. The Krimsky method was used in patients with poor fixation [21]. The ductions and versions in 6 cardinal positions of gaze of all patients were assessed [22].

Preoperative assessment was performed with the cotton bud test to check cooperation of the patient for postoperative suture adjustment. Patients who could withstand the examiner to gently manipulating the bulbar conjunctiva of the non-anesthetized eye with a cotton bud were considered to be good candidates for adjustable suture strabismus surgery.

All patients underwent surgery using a standardized general anesthesia protocol [23]. The procedure was performed with the fornix approach, and 6-0 absorbable Vicryl (6-0 Vicryl; Ethicon Inc., Somerville, NJ, USA) sutures were adjusted with the sliding noose technique [1].

Two surgeons (A.A. and A.A.A.) performed the surgeries. Both surgeons performed an almost equal number of surgeries with the same technique. The surgeons were blinded to the patient groups. The patients were randomized into 2 groups using a random number generator [24]: the early adjustment group, with adjustments 2 – 4 h postoperatively, and the delayed adjustment group, with adjustments approximately 24 h postoperatively. Only one muscle was used for adjustment in each patient. In general, adjustable 6-0 absorbable Vicryl (6.0 Vicryl; Ethicon Inc., Somerville, NJ, USA) sutures were predominantly used on the muscle to be recessed, as it is easier to pull forward a recessed muscle than to recess it further [25].

Adjustments were made in both groups with the same technique. Alignment of the patient was checked at both distance and near. For topical anesthesia, benoxinate hydrochloride 0.4% eye drops (Benox, Eipico, Cairo, Egypt) were instilled with the patient in the supine position. The assistant pulled the traction 6-0 absorbable Vicryl sutures to expose the muscle sutures. The surgeon then pulled the muscle sutures to expose the noose. The noose was then moved along the muscle sutures. The patient is then asked to look in the direction of the muscle to allow retraction of the muscle. Patient alignment was then checked, and further adjustments were made when required. When alignment was satisfactory, the muscle sutures were tied over the noose. The noose and muscle sutures were then removed. Traction sutures were then cut and removed after the patient was instructed to look in the direction of the muscle.

In patients with esotropia, the target endpoint for adjustment was orthotropia for distance and near. In patients with exotropia, the target endpoint for adjustment was esotropia/esophoria; 6 – 8 PD for distance, and orthophoria for near.

The patient was asked at the end of the adjustment procedure to rate the severity of pain during the procedure on a scale of 0 to 10, with 0 indicating no pain and 10 represents the most severe pain ever felt [26].

Eye alignments at 2 and 24 h postoperatively were noted and compared between the groups. The amount of drift in the first 24 h was analyzed. Ocular drift was calculated by subtracting the angle of deviation postoperatively from the angle of deviation at the time of adjustment [20].

Topical antibiotic Tobramycin 0.3% eye drops (Tobrin; EIPICO, Cairo, Egypt) was prescribed postoperatively, and patients were followed-up after 1 week, 1 month, and 3 months. The final postoperative alignment of the eyes 3 months postoperatively was compared in both study groups. Successful outocme was defined as alignment within 8 – 10 PD for patients with esotropia and within 5 PD for those with exotropia at the last follow-up [27]. A masked observer performed the measurements at the last follow-up. Intraoperative and postoperative complications were recorded.

Statistical analyses were performed using the Statistical Package for Social Sciences (SPSS) for Windows (Version 22; SPSS Inc., IBM Corp., Armonk, NY, USA). Data distribution were tested with the Shapiro – Wilk test. Data from the two groups were compared using the independent-samples *t*-test and Mann – Whitney U test for continuous variables and Fisher's exact test for categorical variables. Variables are expressed as mean, standard deviation (SD), and range or numbers (percentages). A P-value < 0.05 was considered to indicate statistical significance.

RESULTS

A total of 75 patients with strabismus were assessed for eligibility. After excluding 20 patients who did not meet the inclusion criteria, three patients who declined to participate, and two patients who were uncooperative during the cotton bud test and were excluded. Thus, a total of 50 patients were included, including 25 patients in each group. After two patients in the early group and three patients in the delayed group were lost to follow-up, 23 (92%) patients in the early group and 22 (88%) patients in the delayed group completed the follow-up period and were included for the analysis (Figure 1).

The participants included 21 (46.7%) men and 24 (53.3%) women, with a mean (SD) age of 25.6 (9.5) years. Of the 45 included patients, 30 patients (66.7%) had exotropia, and 15 patients (33.3%) had esotropia (Table 1).

In most patients (n = 32, 71.1%), surgery was performed on two muscles, with adjustable sutures placed on one muscle. Adjustment was required in a total of 19 patients (42.2%) patients, including 11 in the early adjustment group and eight in the delayed adjustment group ($P > 0.05$) (Table 2). The amount of adjustment required or the pain score during adjustment did not differ significantly between the groups (both $P > 0.05$) (Table 2).

In both groups, the mean angle of deviation at 2 h postoperatively was close to orthophoria, with no statistically significant difference between the two groups ($P > 0.05$). In the group that underwent postoperative adjustment after 24 h, the change in the angle after 24 h was not statistically significant ($P > 0.05$) (Table 3). Most patients showed no change in the angle during the first 24 h.

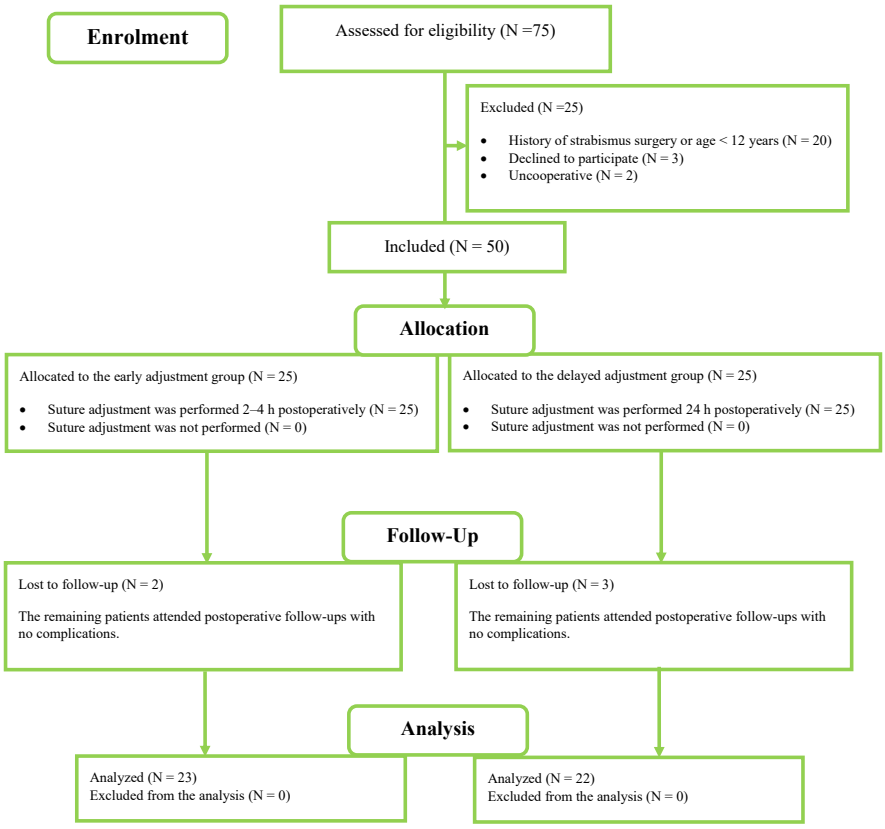

Figure 1. CONSORT flow diagram for study participants' allocation to the early or delayed adjustment group for suture adjustment after strabismus surgery. Abbreviations: N, number of patients.

Table 1. Comparison of demographic and baseline characteristics between the study groups

Variables		Early adjustment group (n = 23)	Delayed adjustment group (n = 22)	*P*-value
Age (y), Mean ± SD (Range)		25.1 ± 8.7 (16 to 45)	26.1 ± 10.3 (14 to 55)	0.712
Sex (Male / Female), n (%)		14 (60.9) / 9 (39.1)	7 (31.8) / 15 (68.2)	0.076
Type of deviation	**Esotropia**	10 (43.5)	5 (22.7)	0.208
	Exotropia	13 (56.5)	17 (77.3)	
Preoperative angle of deviation (PD), Mean ± SD (Range)		37 ± 15 (13 to 75)	36 ± 14 (30 to 75)	0.768

Abbreviations: n, number of patients; y, years; SD, standard deviation; %, percentage; PD, prism diopters. Note: The early adjustment group included patients who received suture adjustments 2 – 4 h after strabismus surgery; The delayed adjustment group included patients who received suture adjustments approximately 24 h after strabismus surgery.

Table 2. Comparison of intraoperative characteristics and pain scores during adjustment between the study groups

Variables	Early adjustment group (n = 23)	Delayed adjustment group (n = 22)	*P*-value
Operated muscles (n), Mean ± SD (Range)	2.1 ± 0.4 (1 to 3)	2.3 ± 0.8 (2 to 4)	0.187
Patients who required adjustments, n (%)	11 (47.8)	8 (36.4)	0.550
Amount of adjustment (mm), Mean ± SD (Range)	1.3 ± 2.2 (0 to 9)	1.4 ± 2.4 (0 to 8)	0.452
Pain during adjustment (score), Mean ± SD (Range)	2.2 ± 2.2 (0 to 8)	2.8 ± 2.8 (0 to 8)	0.213

Abbreviations: n, number of patients; %, percentage; SD, standard deviation; mm, millimeters. Note: The early adjustment group included patients who received suture adjustments 2 – 4 h after strabismus surgery; The delayed adjustment group included patients who received suture adjustments approximately 24 h after strabismus surgery.

Table 3. Comparison of changes in the alignment between study groups

Variables		Early adjustment group (n = 23)	Delayed adjustment group (n = 22)	*P*-value
Postoperative angle of deviation 2 h postoperatively and before any adjustments (PD), Mean ± SD (Range)		2 ± 8 (- 20 to 16)	0 ± 9 (- 20 to 15)	0.311
Postoperative angle of deviation 24 h postoperatively and before delayed adjustment in the delayed group (PD), Mean ± SD (Range)		1 ± 3 (- 5 to 10)	0 ± 9 (- 20 to 15)	0.824
Postoperative angle of deviation 1 month postoperatively(PD), Mean ± SD (Range)		2 ± 5 (- 3 to 15)	4 ± 7 (- 10 to 25)	0.221
Postoperative angle of deviation 3 months postoperatively(PD), Mean ± SD (Range)		2 ± 5 (- 3 to 15)	2 ± 9 (- 15 to 25)	0.454
Success rate at 3 months postoperatively, n (%)	Total	20 (87.0)	14 (63.6)	0.091
	Esotropia	8 (80.0)	3 (60.0)	0.518
	Exotropia	12 (92.3)	11 (64.7)	0.117

Abbreviations: n, number; PD, prism diopters; SD, standard deviation; %, percentage. Note: The minus sign denotes exotropia or exophoria, and the plus sign denotes esotropia or esophoria; The early adjustment group included patients who received suture adjustments 2 – 4 h after strabismus surgery; The delayed adjustment group included patients who received suture adjustments approximately 24 h after strabismus surgery; Success rate,successful outocme was defined as alignment within 8 – 10 PD for patients with esotropia and within 5 PD for those with exotropia at the last follow-up.

The change in the mean postoperative angle in either group from 1 to 3 months after surgery was not statistically significant (both $P > 0.05$). The success rate at the 3-month follow-up was slightly higher in the early adjustment group (87.0% versus 63.6%). However, the difference in the success rate did not reach statistical significance ($P > 0.05$), and the success rate was comparable between the groups in patients with esotropia or exotropia (both $P > 0.05$) (Table 3).

DISCUSSION

In the present study, despite a slightly higher success rate in the early adjustment group than in the delayed adjustment group, the difference was not statistically significant. We found a comparable subjective pain scores during adjustment in both groups.

Adjustable sutures have been used after strabismus surgery for over 40 years, but their use for eye muscle surgery has not been universal [1-3]. This is due to the complexity, competing interpretations of the effectiveness or necessity of this approach, and the fact that more time and resources are required [3, 10]. Regardless of this uncertainty, advancements in the adjustable suture technique have increased its use and applications [6, 7, 13, 14].

The present study was aimed at determining the optimal timing of adjustment after strabismus surgery. At the end of the 3-month follow-up, the early adjustment group had a slightly higher success rate without statistical significance, with a comparable mean postoperative angle difference between the groups. This postoperative adjustment has the advantage of modulating the position of the extraocular muscle in the early postoperative period, allowing for better surgical outcomes while lowering costs and reoperation rates [28-30]. However, in the current study delaying suture adjustment did not significantly affect the success rate.

Delaying the adjustment procedure, if possible, provides more angle stability and a better chance of evaluating the surgical outcome [13, 31]. Bleik and Karam compared simultaneous prism cover test measurements taken immediately after the patients were fully conscious of those taken 24 h later and discovered a significant change in postoperative alignment in 84% of patients during the first 24 h. During the first 24 h, the average drift in the alignment was 7.2 PD [20]. However, in the current study, we were unable to detect such a large drift in most patients. This may be explained by the fact that Bleik and Karam [20] evaluated patients immediately after they regained consciousness, while we evaluated patients a bit later, 2 – 4 h postoperatively.

Delaying the adjustment procedure may result in some muscle attachment to the sclera and surrounding tissues, increasing the difficulty of the adjustment [32, 33]. Using a rabbit model, slow-releasing tranilast [32] or paclitaxel [33] in polytetrafluoroethylene/polylactide-co-glycolide laminate reduced adhesion and allowed delayed suture adjustment for up to 5 weeks postoperatively. Several attempts have been made to postpone the adjustment beyond 24 h, either by refining the surgical technique [13–15] or by minimizing early adhesion between the muscle and the sclera using mitomycin C [34, 35], 5-fluoruracil [35, 36], polyurethane with sustained release dexamethasone, silicone sheets [31], suramin, genistein, and collagen matrix [37], slow-releasing paclitaxel [33],

polytetrafluoroethylene [36], viscoat [34], or SurgiWrap® [38]. Although we did not use such interventions in the present study, delaying suture adjustment did not significantly affect the success rate.

In the present series, the postoperative alignment at 3 months did not differ significantly between the two groups. Spierer compared the final postoperative alignment of patients who received adjustment within the first 8 h to those who received adjustment after 24 h in a retrospective study and found no statistically significant difference between the two groups [11]. Similarly, Velez et al. found no difference in final alignment between those who underwent early adjustment and those who underwent late adjustment [12]. However, in Velez et al.'s study, one surgeon performed early adjustment, and the other surgeon adopted the late adjustment. Moreover, the study was non-randomized, and the patient groups had different baseline characteristics [12]. However, in the present open-label, prospective, randomized, comparative, interventional study groups were comparable in terms of age, sex ratio, type of deviation, and preoperative angle of deviation.

During the adjustment procedure, both adjustment groups were equally associated with mild to moderate pain, with no significant difference in mean pain scores (2.2 in early adjustment group versus 2.8 in delayed adjustment group). This finding is compatible with that of Velez et al.'s study [12], which showed that the time of adjustment did not affect pain scores or adjustment difficulties.

In this study, variability was avoided by using a fixed technique for suture adjustment and a randomized clinical trial design. However, it has limitations, including a small number of patients and a short follow-up period. More research with a large sample size and a long follow-up period is required to verify the present findings. Furthermore, we propose conducting future clinical trials with different time intervals for postoperative suture adjustment and comparing subjective and objective outcomes, such as diplopia and stereopsis, between patients who underwent first strabismus surgery and those who underwent reoperation to better clarify the persistent controversy related to the optimal time for suture adjustment after strabismus surgery.

CONCLUSIONS

The pain score, final motor alignment, or success rate did not differ significantly between same-day and next-day suture adjustments. Nonetheless, our success rate in the early adjustment group was only slightly higher. Further research with a large sample size and a long follow-up period is required to verify the present findings.

ETHICAL DECLARATIONS

Ethical approval: The Research Ethics Committee of the Faculty of Medicine, Minia University, approved the study protocol (approval number: 360: 12/2019). All local laws and principles of the Helsinki Declaration were followed during the research and data collection. This clinical trial was registered in the ClinicalTrials.gov Protocol Registration System (identifier NCT04617158). All participants provided written informed consent.
Conflict of interest: None.

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