

## Evaluation of single-stage adjustable strabismus surgery under conscious sedation

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**Purpose:** To evaluate the feasibility and stability of ocular alignment after single-stage adjustable strabismus surgery (SSASS) performed under topical anesthesia.

**Materials and Methods:** Forty-five patients of concomitant exodeviations were randomized into three groups of 15 cases each and were operated with three different techniques: Group I - conventional surgery, Group II - two-stage adjustable suture technique with suture adjustment performed 6h postoperatively and Group III- SSASS under topical anesthesia and intravenous conscious sedation with midazolam and fentanyl. Intraoperative suture adjustment was done by giving a cross target to the patient on the ceiling at the end of the procedure. Surgical results were compared among the three groups at three months follow-up. Intraoperative hemodynamic parameters and patients' experience of the surgery (by questionnaire) were also compared.

**Results:** Mean preoperative deviation for distance in Groups I, II, III was -41.67 prism diopter (pd)  $\pm$ 9.0, -38.93 pd  $\pm$ 11.05 and -41.87 pd  $\pm$ 8.91 ( $P=0.6$ ) respectively. At three months, mean correction achieved for distance was +31.87 pd  $\pm$ 11.71, +35.47 pd  $\pm$ 10.86 and +42.80 pd  $\pm$ 10.71 respectively which was significantly different between Group III and Group I ( $P=0.03$ ). Intraoperatively all hemodynamic parameters remained stable and comparable ( $P=0.5$ ) in all groups. Intraoperative pain ( $P<0.001$ ) and time taken for surgery ( $P<0.001$ ) was more in the SSASS group. Amount of exodrift was 10-12 pd, comparable in all three groups ( $P=0.5$ ).

**Conclusions:** SSASS, performed under topical anesthesia, is safe and has better outcomes than conventional recession-resection surgery for concomitant exodeviation. An overcorrection of about 10-12 pd is recommended to check the exodrift and achieve stable alignment.

**Key words:** Exodeviations, intermittent exotropia, intravenous anesthesia, single-stage adjustable strabismus surgery, topical strabismus surgery, two-stage adjustable suture surgery

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Precise ocular alignment is desirable in all strabismus surgeries. The surgical options in all cases are either conventional strabismus surgery of fixed amount based on standard algorithms or adjustable suture surgery wherein the adjustable recession is done along with nonadjustable resection.

The conventional surgery is planned preoperatively in the office room considering the patient's age, refraction, fusional ranges and the expectations of the patient from the surgical procedure. Once the surgery is done one cannot alter the results postoperatively, giving unpredictable results many times. Adjustable suture surgery was designed to eliminate this problem. Here the planning of the surgery is extended into the intraoperative period so that the final outcome can be altered even in the postoperative period. Adjustable suture surgery was described as early as 1885 in the United States but it was

re-introduced and made popular by Jampolsky in 1965.<sup>[1]</sup> Since then there has been a trend by some of the strabismologists to use it even in routine surgical procedures, as the use of adjustable sutures in strabismus surgery has increased the rate of surgical success.<sup>[2-4]</sup> Depending on the time of adjustment, it is called single-stage adjustable strabismus surgery (SSASS, the adjustment is done during the operative period itself) or two-stage adjustable strabismus surgery, (TSASS, surgery is done under local or general anesthesia followed by the adjustment 6 to 24 h later).

There has been very little data comparing adjustable suture surgery with conventional surgery. In fact, there is no prospective randomized study comparing the surgical results of the two types of adjustable suture surgery with conventional muscle recession-resection. Thus the aim of this study was to evaluate the feasibility and stability of ocular alignment after SSASS performed under topical anesthesia in comparison with two-stage adjustable and conventional strabismus surgery groups.

### Materials and Methods

This study was a prospective comparative pilot study approved by our institutional review board. A total of 45 cases (age above 15 years) of concomitant exodeviations with no oblique muscle overactions, cooperative for postoperative adjustment were enrolled in the study. Patients with vertical strabismus, dense

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amblyopia, eccentric fixation, significant cardiorespiratory or other systemic diseases were excluded. An informed consent was taken from all the patients. All the patients were evaluated preoperatively for strabismus angle measurement with prism bar cover test (PBCT), binocularity assessment on Bagolini striated glasses test (BSGT) and stereopsis measurement with TNO (The Netherlands Organization for applied scientific research) test. In addition, patients were evaluated for any systemic illness.

Patients were randomly divided into three groups of comparable age, sex, weight, and amount of deviation by draw of chits just before surgery. In Group I there were 15 patients operated with conventional non-adjustable suture surgery under peribulbar anesthesia and intramuscular (IM) premedication by pethidine and phenergan. In Group II there were 15 patients operated with TSASS under peribulbar anesthesia and IM premedication with pethidine and phenergan. In Group III there were 15 patients operated with SSASS under topical anesthesia with proparacaine (0.5%) and with conscious sedation provided with intravenous midazolam and fentanyl. All patients were explained the surgical procedure preoperatively and how to respond in case of pain (single hand squeeze) and nausea/vomiting (double hand squeeze). All patients were monitored intraoperatively for heart rate, continuous electrocardiogram (EKG), noninvasive blood pressure (NIBP) and oxygen saturation by pulse-oximeter. In addition the respiratory rate and finger-nail color of the patients were also monitored. All these parameters were recorded at baseline before giving topical anesthesia and IV sedation and then after instilling the topical anesthetic and IV sedation and subsequently every 15 min during the procedure.

In the non-adjustable group and in the TSASS group, regional anesthesia with peribulbar anesthesia was given using a mixture of 2% lignocaine and 0.5% bupivacaine and hyaluronidase (12.5 IU/ml) according to body weight.

In the SSASS group, surgery was done under conscious sedation. Topical anesthesia was established by instilling proparacaine 0.5% in the eye 5 min prior to conjunctival incision. In addition, the patients were maintained in a state of conscious sedation (Ramsay sedation score<sup>[5]</sup> 2-3 i.e. asleep but arousable to verbal command) using intravenous sedation with midazolam as a bolus of 0.5-1.0 mg (10-20 microgram/kg body weight) and fentanyl 0.5-1.0 microgram/kg body weight.

Hemodynamic parameters, pain and nausea/vomiting were assessed intraoperatively and postoperatively using pain and nausea/vomiting score<sup>[6]</sup> respectively. Persistent nausea or vomiting was treated with ondansetron (0.1 mg/kg) IV for the first 24 h. The frequency of oculocardiac reflex (defined as 20% decrease in heart rate from the baseline) during surgery was noted and treated with IV glycopyrrolate (10 microgram/kg) as and when needed. In addition we also got feedback from patients at the end of the procedure regarding the pain during operation and also when given the option of the three types of surgeries, whether they would like to undergo a similar operation in future.

**Surgical technique** - All the surgeries were performed by a single surgeon (PS). The amount of recession and resection was based on the published nomogram.<sup>[7]</sup> The fornix approach was used in the conventional (Group I) and SSASS group (Group III)

but for Group II, the limbal incision was made for the muscle to be adjusted, that is for the lateral rectus. Moreover, in the SSASS group, the procedure was slightly altered in that the resection was done prior to the recession so that intraoperative adjustment of the recessed muscle could be done at the end of the procedure. For intraoperative suture adjustment, a cross target was given to the patient on the ceiling (about seven feet away). In the TSASS group, suture adjustment was done 6 h postoperatively under topical anesthesia with patients fixing at target 10 feet away.

All patients were evaluated at one week, one month and at three months and were assessed for their strabismus angle correction (for near and distance) (primary outcome). The secondary outcomes were exodrift, binocular status, time taken to complete the surgery along with the parameters like hemodynamic stability, pain, nausea, and vomiting.

**Statistical analysis** - Data were recorded on an Excel spreadsheet. For data analysis, statistical software SPSS 10.0 was used. Chi square test was used for qualitative data like sex, type of deviation (intermittent vs. alternate), patients with BSV. The comparison for continuous data like age, weight, deviation, exodrift, stereopsis was done using the one way ANOVA (Kruskal-Wallis test) followed by Posthoc analysis (Bonferroni). In this study  $P < 0.05$  has been considered as statistically significant.

## Results

The age, sex, weight of the subjects in each group was comparable as shown in Table 1. Group I and Group III had seven cases of intermittent divergent squint (IDS) and eight cases of alternate divergent squint (ADS) while it was 11 and four cases respectively in Group II which were comparable. There was no significant difference in the refractive error in either of the groups and the refractive correction did not affect the deviation.

Mean preoperative deviation [Table 1] for distance in prism diopters (pd) in the three groups was comparable ( $P=0.6$ ) as well as for near (pd) ( $P=0.7$ ) respectively. Postoperatively at three months, mean correction (pd) achieved for distance is shown in Table 2. The correction achieved was comparable in conventional versus TSASS group ( $P= 1.0$ ) and also between TSASS and SSASS ( $P= 0.2$ ). There was significant difference in mean correction achieved between conventional and SSASS at three months ( $P= 0.03$ ). Mean correction (pd) achieved for near is shown in Table 2, which was not significantly different among the three groups ( $P=0.095$ ). Group III had percentage mean correction of 102% at the end of three months, whereas patients in Group II and Group I had 91% and 76% mean correction respectively compared to their baseline deviation. Mean final distance deviation achieved at the end of three months was +0.93 pd +9.22 (esodeviation) in the SSASS group compared to -3.47pd +6.61 (exodeviation) in the TSASS group and -9.80 pd +9.01 (exodeviation) in the conventional group.

The mean exodrift in the three groups for distance and near was similar with no significant difference ( $P=0.5$  and  $0.8$  for distance and near respectively) [Table 2, Fig. 1]. There was further mean exodrift of -1.27 pd in Group I and -2.00 pd each in both Group II and Group III between three and six months for distance. Exodrift for near showed similar changes after

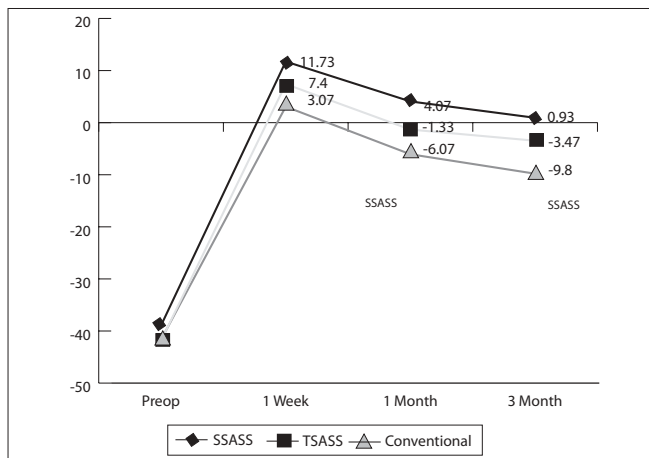
**Table 1: Preoperative parameters in the three groups**

Parameters	Group I	Group II	Group III	P value
Age (Mean±SD) (in years)	24±9.49	23.53±10.82	22.8±4.06	0.9
Sex (Male:Female)	11:4	9:6	12:3	0.4
Weight (Mean ± SD) (Kg)	64.87±17.04	65.80±23.73	60.87±17.15	0.7
Intermittent:Alternate (XT)	7:8	11:4	7:8	0.5
Deviations (Mean ± SD) (pd)				
Distance	-41.67±9.0	-38.93±11.05	-41.87±8.91	0.6
Near	-42.07±8.85	-39.67±9.35	-42.07±8.85	0.7

**Table 2: Postoperative results at three months in the three groups**

Parameters	Group I Mean ± SD	Group II Mean ± SD	Group III Mean ± SD	P value
Distance correction achieved (in pd), Mean±SD	+31.87±11.71	+35.47±10.86	+42.80±10.71	0.03 (Group I vs. III) 95% Confidence intervals (-0.65 to 22.51)*
Near correction achieved (in pd), Mean±SD	+32.4±11.75	+33.73±12.03	+41.27±11.42	0.095
Exodrift (at distance, in pd) Mean±SD	-12.87±7.81	-10.87±5.11	-10.80±5.21	0.58
Exodrift (at near, in pd) Mean±SD	-12.33±8.68	-11.27±8.09	-10.73±5.66	0.85
Cases with BSV (distance) preop vs. postop	1 vs.9	4 vs.15	0 vs.13	0.01 (among all groups)
Stereopsis (in arc sec), Mean±SD	224± 230.68	112±131.97	140±164.58	0.221

BSV: Binocular single vision, done with Bagolini striated glasses test for distance. \*The difference in mean correction at distance and confidence interval of mean correction between Group I and II was 3.6 pd and -8.1 to 15.25, and between Group II and III was 7.33 pd and -3.81 to 18.47.



**Figure 1:** Showing exodrift for distance deviation at various point of time in three different groups

three months with further mean exodrift of -1.64 pd in Group I, -0.57 pd in Group II and -2.6 pd in Group III.

Surgical success of the procedure is indicated by the alignment achieved at the desired follow-up period. In this study there were eight patients (53%) each in Group III (SSASS) and Group II (TSASS) who were within 4 pd deviation range at three months follow-up, however, there were only three patients (20%) who matched this criterion in Group I (conventional). If the criterion for success is taken as 8 pd, then there were 10 patients (67%) in Group III, 12 patients (80%) in Group II and eight patients (53%) in Group I who matched this criterion for success.

Time taken to complete the surgery (intraoperative time for recession and resection) was maximum in Group III (44.8 min +8.80,  $P < 0.001$  Group I vs. III) followed by Group II (40.13 min +8.12  $P = 0.016$  Group I vs. II). Group I took minimum time (32 min +5.28). There was no significant difference in surgical time between Group II and Group III.

At the follow-up period of three months, there were 13 patients in Group I, 10 patients in Group II and five patients in Group III who were having residual or consecutive squint. Of these patients there was one patient each in Group III (10 pd esodeviation) and Group II (18 pd exodeviation) and three patients in Group I (all had exodeviation > 15 pd) who had significant residual strabismus.

Binocular single vision for distance significantly improved in all the three groups compared to the preoperative state ( $P = 0.01$ ) [Table 2]. Regarding stereopsis, preoperatively all the groups had comparable stereopsis ( $P = 0.06$ ). There were five patients in Group I (mean 160 arc sec.), eight patients in Group II (84 arc sec) and four patients in Group III (mean 40 arc sec) who had any amount of stereopsis checked on TNO stereopsis chart. Postoperatively at three months, there were eight patients in Group I (mean 224 arc sec), 12 patients in Group II (112 arc sec) and 10 patients in Group III (140 arc sec) who had stereopsis, which was not statistically significant among the three groups as shown in Table 2 ( $P = 0.221$ ).

All the cases in the SSASS group and two cases in the TSASS group complained of diplopia in the immediate postoperative period. But none of them were given any prismatic correction and all the patients were relieved of the diplopia by the second follow-up at one month.

Hemodynamic parameters - All the hemodynamic parameters, heart rate, respiration rate and blood pressure changes remained stable and comparable among the three groups at all time points beginning at baseline to 2 h postoperatively except the systolic BP at 15 min intraoperatively, which showed significant drop in Group II and Group I compared to Group III ( $P=0.03$ ). This can be explained by a significantly higher incidence 73.34% (11/15) of oculocardiac reflex (OCR) in the SSASS group compared to the other groups, of which three required medical therapy (IV glycopyrrolate). Oxygen saturation and finger nail color remained stable and comparable in all the three groups.

Patients in Group III experienced more intraoperative pain compared to patients in the other two groups ( $P<0.001$ ). All patients in Group III experienced pain (five mild, 10 moderate) while six in Group II (five mild, one moderate) and one patient in Group I experienced mild pain. Incidence of nausea (one vs. three vs. one) and vomiting (three vs. two vs. two) was comparable in the three groups. Postoperative pain (nine vs. 11 vs. zero) was significantly less in Group III ( $P<0.001$ ).

## Discussion

When comparing the mean postoperative outcome in the three groups, the surgical results of SSASS (Group III) were significantly better compared to conventional recession and resection (Group I) ( $P=0.03$ ) at three months follow-up. The major factor contributing to the better results in SSASS is more than the usual amount of overcorrection (~11 pd esodeviation) that happened on table. This was not deliberate. At the time of adjustment (intraoperative) we attributed the limitation of abduction to temporary paresis of the lateral rectus muscle due to topical anesthesia used to relieve the pain, and so ended up leaving more esodeviation. On the first postoperative follow-up at Day 7, most of the patients of this group had more than 10 pd esodeviation. In retrospect we attribute this esodeviation at the end of the surgery not to paresis but possibly to central sag of muscle belly which was more in the SSASS group patients due to early reinnervation (recovery from anesthesia) of the muscle that gives an over-recession effect resulting in more esodeviation at the first follow-up. In the TSASS group, suture adjustment was done after 6 h in the postoperative period and by that time enough adhesions<sup>[8]</sup> would be formed preventing the sagging of the muscle belly and thus controlled adjustment was achieved in the TSASS group. In the conventional and TSASS groups we had achieved 5-7 pd of esodeviation only, as reinnervation becomes effective only after the local anesthesia wears off, that is, after 4-5 h. This overcorrection was to check the postoperative exodrift as also suggested by Choi *et al.*<sup>[9]</sup> who reported better long-term stability of the surgical outcome in cases of intermittent exotropias with intentional overcorrection and postoperative use of Fresnel prisms.

Mean distance deviation achieved at the end of three months was almost orthotropia in the SSASS group (0.93 pd) compared to exodeviation in the TSASS group (3.47 pd) and conventional group (9.80 pd). While one patient in the SSASS group might require reoperation at the end of three months for the 10 pd esodeviation (overcorrection) left at six months follow-up, there was one patient in the TSASS group (deviation of 18 pd exodeviation) and three patients in the conventional group (deviation of 16, 18 and 35 pd exodeviation) at three months follow-up who might need reoperation. Wisnicki *et al.*<sup>[10]</sup> noted

similar reoperation rates following adjustable suture surgery in their case series.

The timing of postoperative adjustment in TSASS is debatable, although most strabismologists consider adjustment within 24 h.<sup>[8,11]</sup> We adjusted the muscle after about 6 h postoperatively. About 27% muscles required postoperative suture adjustment which is comparable to the other studies.<sup>[12-15]</sup>

A study by Eino and Kraft<sup>[16]</sup> showed exodrift of 7 pd in primary and 3 pd in reoperations in exotropias. Exodrift that occurred between three to six months when compared with exodrift over three months showed minimal changes (1-2 pd). Therefore three months follow-up may be sufficient as maximal exodrift occurred within the first three months.

As SSASS required patient's cooperation and suture adjustment on table, amount of time taken to complete the surgery became significantly more. SSASS took the maximum time and conventional group took least time, similar to the observation by Klyve *et al.*<sup>[17]</sup>

There was no significant difference in the hemodynamic parameters recorded throughout the procedure in all the three groups. All the hemodynamic parameters were stable and no incidence of complications was noted with any of the procedures except higher OCR in the SSASS group.<sup>[18-20]</sup> Eustis *et al.*<sup>[19]</sup> have reported similar incidence (65%) of OCR in strabismus surgery done under topical anesthesia.

SSASS is a safe procedure. Its safety has been documented previously<sup>[8,19,21-24]</sup> and is further strengthened by our study. Patient satisfaction was good at the end of the procedure. No patient had any regrets about the technique of surgery or anesthesia given to them. The advantage of conscious sedation anesthesia is that the patient remains in a state of light sedation but is arousable to verbal commands, which is helpful particularly during the adjustment phase of the surgery. Carruthers *et al.*<sup>[25]</sup> concluded that conscious sedation is a safe and effective alternative to general anesthesia for adjustable suture repair of horizontal misalignment in adult patients. Topical anesthesia with conscious sedation (IV midazolam and fentanyl) is a viable anesthetic technique and is free from the complications associated with peribulbar anesthesia like globe perforation, intravascular local anesthetic injection. It provides the advantage of patient's cooperation for suture adjustment in SSASS which helps in getting better surgical results, faster recovery and better postoperative pain relief.<sup>[26]</sup> The incidence of postoperative nausea/vomiting is also low and comparable with the peribulbar block group.

The overcorrection up to (~12 pd) produced better results in terms of motor alignment in Group III than Group I. Though SSASS has the disadvantage of longer surgery, more intraoperative pain and a much higher incidence of OCR, considering the better surgical outcome and the stability of the results obtained, this technique can be done under monitoring. Combination of fentanyl and midazolam can cause respiratory depression therefore respiratory rate and oxygen saturation need to be monitored during the surgery.

To conclude, SSASS under topical anesthesia with IV sedation is a reasonably acceptable technique but requires monitoring. In the presence of monitored anesthesia care in an institutional practice SSASS may be a recommended procedure for better surgical outcome without significant complications.

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