Purpose: To evaluate the outcomes of large-angle exotropia by single-stage adjustable strabismus surgery (SSASS) under monitored conscious anesthesia. Methods: A prospective study was done in 33 patients above 14 years with ≥40 prism dipters (PD) of exotropia. All patients underwent SSASS under monitored conscious anesthesia (topical anesthesia plus intravenous sedation). For deviations of ≤55 PD, two horizontal rectus muscles, and for >55 PD, three rectus muscles were operated and a decision on adjustment/operatoring on an additional rectus muscle was taken after assessing the alignment. Monitored conscious anesthesia allowed us to check our results after surgery and plan further surgery/adjustment to achieve the desired alignment. Results: Mean preoperative deviation for distance was 52 ± 11.1 PD. The target alignment was achieved with the initial surgical plan in 10/21 patients with <55 PD exotropia and 4/12 patients with >55 PD exotropia, and one patient in each group needed adjustment. The remaining patients needed additional rectus muscle surgery. One patient with >55 PD exotropia needed both adjustment and additional rectus surgery. The success rate for distance correction was 85% at 6 months and 1 year. The overall success rate was 71% at 6 months. Percentage of patients with binocular single vision improved from 31% preoperatively to 78% by 6 months. Incidence of oculocardiac reflex was 6.1%. Conclusion: SSASS under monitored conscious anesthesia is a viable option for large-angle strabismus correction with good patient comfort and safety.

Key words: Large-angle strabismus, monitored conscious anesthesia, SSASS

Large-angle horizontal strabismus has been variably defined in the literature. Various studies have used a cut-off value of 40–60 PD to define large-angle strabismus.[1‑3] The management of large-angle strabismus is challenging. Two, three, and four muscle surgery have been tried by various authors.[1,4] Tables for strabismus correction, in general, are designed for two muscle surgery, and there are no large-scale studies validating the surgical dosage for three and four muscle surgery to the best of our knowledge. Reported approaches (for managing large-angle horizontal strabismus) include doing large surgeries on two horizontal rectus muscles,[5‑8] operating on three horizontal rectus muscles (putting all of them on adjustable),[4,9] recessing two horizontal rectus muscles in both eyes by a specified amount and adding a third or fourth rectus muscle based on surgical tables/dosing formulated by the author,[10] dividing a surgical amount of 18–19 mm into three rectus muscles, dividing the deviation by two to decide the surgical dosing for one eye and doing the same in the fellow eye.[11] Some authors have tried adjustable strabismus surgery,[4,14,10] while others have stuck to using fixed surgical dosages.[1,3,9] The success rate of surgery for large-angle horizontal strabismus has varied between 40% and 89% across studies.[1‑5]

Single-stage adjustable strabismus surgery (SSASS) under monitored conscious anesthesia has been reported to give good success rates for patients with comitant exotropia.[12‑14] We used this technique in our study patients. The surgery is done on two/three horizontal rectus muscles (depending on the measured deviation) with the recessed muscle placed on adjustable sutures under topical anesthesia supplemented with subconjunctival lignocaine, intravenous (i.v.) fentanyl, and midazolam.[15‑17] Further surgery/adjustment is done based on the correction achieved. The purpose of this study was to determine if this allows us to optimize the number of rectus muscles operated and achieve good motor alignment. To the best of our knowledge, there are no reported studies on the correction of large-angle strabismus with SSASS.

Methods

This was a prospective interventional study conducted in a tertiary eye care hospital in South India from August 2017 to May 2019. Patients with large-angle exotropia of ≥40 PD and above 14 years of age were included in the study. Patients with significant vertical deviations, and neurological problems...
precluding cooperation were excluded. The study adhered to the tenets of the Declaration of Helsinki and was approved by the institution’s ethics committee. All patients underwent a comprehensive preoperative evaluation that included vision, cycloplegic refraction, ocular deviation measured in relevant gazes for distance (primary, 25-degree upgaze, and 35-degree downgaze, side gazes) and near (Krimsky test was done in cases with poor fixation), binocular single vision status (BSV) with the Bagolini striated glasses, and stereopsis with the Randot stereo test. The presence of an X response (without any central scotoma) was taken as evidence of binocularity. An improvement (from preoperative to a postoperative review at one month or more) from gross stereopsis/absent stereopsis to any level of stereopsis better than 400 s of arc or improvement two levels or more (if the preoperative stereopsis was better than 400 s of arc), e.g., 100 s of arc preoperative to 50 s postoperative was considered significant. Ocular deviations in patients with intermittent exotropia were measured after 45 min of patch. All patients were operated on by the second author under anesthetist supervision. Monitored conscious anesthesia was achieved with intravenous fentanyl (0.5–4.0 µg/kg) and Midazolam (10–20 µg/kg).[12] All patients were premedicated with i.v. glycopyrrolate and ondansetron. Patients were maintained in a verbally arousable but painless state (Ramsay sedation score: 2–3).[18] Lignocaine jelly (2%) was placed in the conjunctival fornix of the eye to be operated on first 5 min before surgery, and topical proparacaine 0.5% was instilled before surgical asepsis. Patients were instructed to respond in case of pain/discomfort and nausea. Supplemental i.v. fentanyl/midazolam was given and a drop of proparacaine was instilled whenever the patient reported pain/discomfort. Further, 1 cc of lignocaine 2% mixed with adrenaline was injected subconjunctivally near the limbus in all cases prior to commencement, before the second/third muscle, and whenever the patient reported pain. A drop of topical proparacaine was instilled in the conjunctival sac and 25–50 µg of i.v. fentanyl and 0.5–1 mg of i.v. midazolam were administered before hooking the muscles (in addition to subconjunctival lignocaine). Further, i.v. medication and subconjunctival lignocaine were given based on patient requirement and before operating on oblique muscles.

The patient’s vitals were monitored throughout the surgery. Should there be a drop in pulse rate >20% from the baseline, the hooked extraocular muscle was released. The procedure was resumed after the pulse rate stabilized [Video 1].

For resections, the rectus muscle was secured with 6-0 Vicryl® sutures and placed on a hangback suture at the insertion. Resections were done by a standard technique. Every effort was made to minimize traction on the extraocular muscles.

If the ocular deviation was between 40 and 55 PD, two horizontal rectus muscles were operated. For deviations of >55 PD, three rectus muscles [2 Lateral rectus (LR) + 1 medial rectus (MR) or 2 MR + 1 LR surgery] was initially done with the recessed muscle(s) on adjustable suture. Our surgical dosing was modeled on Yang et al.’s table[21] with one important difference. Yang et al.[21] operated on 3 horizontal recti for deviations between 40 and 55 PD and 4 horizontal recti for horizontal deviations of >55 PD. As we used SSASS on all our study patients, we performed less surgery initially and added more when needed. This allowed us to optimize the number of muscles operated. For patients with sensory strabismus, only the eye with poor vision was operated upon. When there was a discrepancy between the distance and near deviations, the surgical dosage was planned for the smaller deviation and then adjusted in the event of residual deviation. After completion of surgery based on the initial plan, the patient was made to sit up. We removed the speculum and sterile drape, wiped off the blood, and washed the cornea with BSS before getting the patients to sit up. The extraocular movements were evaluated. If more than 2- limitation on a scale of 1 to 4[19] was noted in any direction or if the patient failed to cooperate, the evaluation and adjustment were postponed to the next surgery day. The alignment was assessed by fixing on a Snellen letter chart placed 3.5 m away for distance fixation and at 33 cm for near fixation (with the optical correction if any). For patients requiring optical correction, the glasses were wiped with isopropyl alcohol and then with lens cleaning solution using sterile cotton before asking the patient to wear them. The surgical area was again painted with povidone-iodine, and a sterile adhesive drape was applied before further surgery/adjustment. Residual deviations were corrected by further recessing the recessed muscle or by operating on an additional muscle. Pattern strabismus (A/V patterns) was corrected either by recessing the oblique muscles (when there was overerelevation/overdepression in adduction) or by vertical shift of the horizontal rectus muscles in other patients. The target angle was an alignment of 4–6 PD esotropia for patients with exotropia. On completion of surgery, the anesthesia staff requested the patient to rate his/her pain on a scale of 0–10 with 0 implying no pain, 1–3 implying mild pain, 4–6 as moderate pain, and 7–10 referring to severe pain.[20] A note was made of postoperative nausea and vomiting for the first 24 h after surgery. A subjective surgeon comfort based on patient cooperation during surgery was also noted on a scale of 1–10. Postoperatively patients were placed on a tapering regime of topical loteprednol for 10 days, moxifloxacin eye drops for 5 days, and artificial tears for 6 weeks. The ocular deviations were measured on postoperative day 1, 1 month, 3 months, and 6 monthly thereafter. For non-normally-distributed quantitative parameters, Wilcoxon signed t-test and Mann–Whitney u test were used, and for categorical outcomes, Chi-square test/Fisher’s Exact test was used. P < 0.05 was considered statistically significant.

Results

A total of 33 patients with a median age of 23 years (range: 15–69 years) met the study criteria. Ten patients had intermittent exotropia. The number of rectus muscles operated and the percentage of patients who needed adjustment and additional rectus muscle surgery for deviation of <55 PD and >55 PD are given separately in Table 1. Six patients also had surgery on the inferior oblique, and five patients needed superior oblique weakening procedures for pattern exotropia. Three patients had sensory exotropia and were operated on the eye with poor vision. The average amount of surgery was 20.3 ± 5.7 mm (average recession: 13.1 ± 4.5 mm), and we got a dose-response of 2.8 ± 0.7 PD/mm. The mode of number of muscles (rectus + obliques) operated was 3 (range: 2–5).

The median pain score was 2. Two patients reported severe pain and four had moderate pain. Seven patients had no pain throughout the surgery and the remaining experienced
mild pain. In all patients, the pain was intermittent and occurred during hooking of the extraocular muscles and subsided with supplemental anesthesia. The pain score was not substantially different in patients who underwent surgery on oblique muscles ($P = 0.09$). Only one patient had vomiting in the postoperative period. The mean duration of surgery was $1.3 \pm 0.4$ h ($0.7–2.30$ h). The surgeon’s comfort during the procedure was high (median score was 9; range: 5–10). Two patients needed further adjustment/additional muscle surgery after 3 days as alignment could not be assessed after the initial surgical plan. One patient needed repeated injection of fentanyl and midazolam for pain relief. He was too drowsy to cooperate for assessment. In another patient, repeated use of subconjunctival lignocaine in the right eye made a reliable assessment of deviation difficult (restricted ocular motility more than 2–). The second eye surgery was done three days later in both the patients. The other patients were satisfactorily managed with the preplanned dose of intravenous fentanyl and midazolam as mentioned in the methods section. The initial surgical plan was effective in achieving the target angle in fourteen patients and the remaining needed adjustment/further surgery [Table 1]. Representative patients are shown in Figs. 1a–c and 2a–d. The post-op first-day deviation in primary gaze was not significantly different from the deviation obtained at the end of surgery (excluding the two patients who had deferred adjustment) and hence it is unlikely that lignocaine affected the primary gaze deviation. Asymptomatic ocularcardiac reflex occurred in two patients (6.1%) and subsided on temporarily releasing the hooked muscle. Drop in heart rate was 20% and 22% respectively in those two patients. None of the other patients had significant variations in heart rate. No patient had clinically significant variation in oxygen saturation or blood pressure. All surgeries were done under anesthetist supervision and the pulse and SpO2 were monitored continuously by anesthesia staff. No other intra/postoperative complications were noted in any of the other patients.

The mean deviation preoperatively and at various visits postoperatively is given in Table 2. The mean correction achieved for distance was $52.7 \pm 12$ PD for exotropia. The postoperative alignment significantly improved compared to preoperative deviation ($P < 0.001$). The mean pattern deviation (difference between up gaze and down gaze deviation) was $26.4 \pm 9$ PD preoperatively, which significantly reduced to zero at POD 1 and $8.1 \pm 8.6$ at 3 months and $8.7 \pm 8$ PD at 6 months ($P < 0.05$). The mean correction of pattern strabismus attained at 1 month was $20.3 \pm 9.2$ and at 3 months was $18 \pm 11.9$ PD ($P < 0.05$).

Six-month follow-up data were available for 26 patients and one-year data for 20 patients. At any visit, an alignment in primary position within 10 prism diopeters (PD) was considered as a surgical success. The success rates at various visits in patients who were orthotropic/overcorrected and undercorrected are given in Fig. 3. Patients who met success criteria at 3 months constituted 70% of the lost to follow-up cases at 6 months and 1 year. Success rate for distance correction was 85% at 6 months and 1 year. Success rates at various follow-up visits are given in Table 2. Patients who were orthotropic/overcorrected on the first postoperative day had better outcomes compared to patients who were undercorrected [Fig. 3]. The mean exotropic drift was $3.6 \pm 2.5$ PD in the study group. Twelve patients developed an exotropic drift and eight patients had an esotropic drift over six months review. Three patients complained of intermittent diplopia on the first postoperative day. This subsided by the first month review. No patient had ocular motility restriction of more than 1 (on a scale of 1 to 4) by the third-month review. No patient requested a second surgery for the residual deviation.
Preoperatively only 9 patients (31%) had fusion with gross stereopsis in two of them. There were 3 patients with poor vision in one eye and they were excluded from the analysis. Patients with BSV (fusion) increased to 78% by 6 months, and 83% by one year \( (P < 0.05) \). 67% patients had measurable stereopsis by 6 months. Stereopsis better than 100 arc seconds was attained in 37.5% patients by 6 months and 47% patients by one year. The difference was not statistically significant \( (P = 0.12) \).
larger preoperative angles of deviation were associated with a greater chance of undercorrection. The use of adjustable strabismus surgery was associated with greater success rates (63% compared with 33% for traditional suture surgery at the last review).

Putting all the aforementioned studies in perspective [Table 3] and considering our results presented in Table 2, there is no denying that the management of large-angle strabismus is challenging. There is a great variation in the surgical results obtained. In our series, 47.6% patients with deviations of <55 PD (n = 21) needed surgery on third rectus muscle and 50% patients with deviations of >55 PD (n = 12) needed surgery on four rectus muscles. Two muscle surgery may therefore be inadequate for deviations between 40 and 55 PD in many instances. We found that placing recessed muscles on adjustable sutures was of help in achieving a good initial alignment and found the need to use them in three of our patients. As the surgery was done under topical anesthesia with monitored conscious anesthesia, the decision to operate on a third muscle in the same sitting was easy. Again the decision for more surgery could be easily made without moving the patient out of the operating room. As mentioned earlier, only two patients had a deferred adjustment and further surgery as a two-staged procedure. A result similar to ours was reported by Currie et al. in a series of 26 patients with large-angle exotropia. Two, three, and four muscle procedures were used with adjustable sutures in 23/26 patients. The criteria for choosing the number of muscles, surgical dosing, type of anesthesia, and the timing of adjustment were not specified by the authors. Hong Li et al. reported on the management of very large-angle exotropia with three muscle surgery under topical anesthesia and all three muscles were placed on adjustable sutures (single-stage adjustment) after supramaximal surgery and obtained 83% success. We believe that having an Anesthetist on standby and administering intravenous analgesia/sedation (in addition to topical anesthesia) eases the surgery. A review of current literature on the treatment of large-angle horizontal strabismus can be found in Table 3. We supplemented intravenous

| Author          | Sample size | Study type   | Large-angle strabismus definition | Adjustable | Anesthesia                  | Success       | No. of recti | Surgical dosing mentioned |
|-----------------|-------------|--------------|-----------------------------------|------------|-----------------------------|---------------|--------------|--------------------------|
| Schwartz et al. | 22          | Retrospective | >40 PD                            | No         | Not mentioned               | 77%           | 2            | Yes                      |
| Livir-Rallatos et al. | 63        | Retrospective | >35 PD                            | No         | Not mentioned               | ≤50 PD - 71%  | 2            | Yes                      |
| Currie et al.   | 26          | Retrospective | >45 PD                            | Yes        | Not mentioned               | 77%           | 2/3/4        | No                       |
| Millán et al.   | 92          | Retrospective | >40 PD                            | No         | LA + 5 mg Diazepam oral     | >15 PD residual in all cases >65 PD | 2            | Yes                      |
| Thomas et al.   | 50          | Retrospective | >50 PD                            | No         | LA/GA                       | 60% (esotropia) | 2/3        | Yes                      |
| Lau et al.      | 24          | Prospective   | >60 PD                            | No         | GA                          | 75%           | 3            | Yes                      |
| Chang et al.    | 4           | Prospective   | >75 PD                            | Yes        | GA                          | Cosmetically acceptable in all cases-4/4 had good alignment | 2            | No                       |
| Camuglia et al. | 51          | Infantile exotropia | >60 PD                         | Not mentioned | GA                          | 95.7% at 6 months | 3            | Yes                      |
| Li et al.       | 23          | Infantile exotropia | >120 PD                         | *yes       | TA alone                    | 82.6%         | 3            | Yes                      |
| John H Chen et al. | 47        | Exotropia    | > 40 PD                           | *Yes       | Not mentioned               | 42% (3 muscle) | 3/4        | Yes                      |
| Min Yang et al. | 40          | Intermittent exotropia | >60 PD                          | Not mentioned | GA                          | 77.5%         | 2/3        | No                       |
| Elkamshousy et al. | 64       | Retrospective | >60 PD                            | No         | Not mentioned               | 77%           | 2            | Yes                      |
| Cifuentes et al. | 28         | Retrospective | >30 PD                            | Yes        | Monitored conscious anesthesia and TA/LA | 85% (distance) | 3            | Yes                      |
| Our study       | 33          | Prospective   | >40 PD                            | In some cases Yes (SSASS) | Monitored conscious anesthesia and TA/LA | 85% (distance) | 3            | Yes                      |

LA - local anesthesia, GA - general anesthesia, TA - topical anesthesia SSASS - single-stage adjustable strabismus surgery PD - prism diopters
medications with liberal use of topical proparacaine and subconjunctival lignocaine (irrigated near the limbus). This affected ocular motility and precluded same-day adjustment in only one patient. We titrated subconjunctival lignocaine dosage based on the patient’s requirements. It may be argued that this may influence ocular motility or the primary position deviation. We believe that this was unlikely. The injection was given near the limbus away from the muscle. Also, ocular motility limitation was never more than 1 in any patient. It is difficult to say if limitation (when present) was due to the effect of recession or local anesthetic agent. Whenever we noted a greater restriction (as in the patient mentioned above), we deferred single-stage adjustment. The first postoperative day alignment was not significantly different from that obtained at the end of surgery.

We report an overall success rate of 71% at 6 months. We also observed a better success rate in patients who were orthotrophic/overcorrected on the first postoperative day [Fig. 3]. None of our patients needed a re-surgery, and all our patients were satisfied with the cosmetic outcome. It would therefore be reasonable to recommend the routine use of adjustable sutures in large-angle horizontal strabismus given the highly variable response to surgery. SSASS may provide additional advantages of minimizing patient visits to the operating room especially if there is a large undercorrection that cannot be remedied by adjustment alone. Sedation under intravenous fentanyl and midazolam allows the patient to be maintained in a verbally arousable but painless state.\[18\] This allows adjustment and additional surgery (where needed) to be done in the same sitting with good patient comfort and cooperation. The patients must however be counseled about the rare possibility of having to reschedule the adjustment to a later time in the event of drowsiness or globe hypokinesia. The use of conscious sedation in comitant exotropia was first reported by Sharma et al.\[12\] The authors concluded that it was a safe procedure and provided better results than conventional strabismus surgery. They reported a 73.34% incidence of oculo-cardiac reflex. The low incidence of this complication in our series was likely due to routine premedication with intravenous glycopyrrolate. The limitations of our study include small sample size and limited follow-up.

**Conclusion**

To sum up, SSASS under monitored conscious anesthesia is a viable option in treating large-angle exotropia. The operating surgeon may make an initial plan and add an additional muscle or adjust depending on the results achieved. Its role needs further evaluation in a larger series of patients.

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**Conflicts of interest**

There are no conflicts of interest.

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