

**AUGMENTED MEDIAL RECTUS MUSCLE RECESSION VERSUS MEDIAL RECTUS
RECESSION WITH POSTERIOR SCLERAL FIXATION IN PARTIALLY
ACCOMMODATIVE ESOTROPIA**

FULL PROTOCOL

Principal investigator(s):

Hala Elhilali, MD, MD, Professor of Ophthalmology, Cairo University

Ahmed Awadein, MD, Professor of Ophthalmology, Cairo University

Clinical Trials Registration Number: NCT02413463

Submitted to Cairo University Ophthalmology Department Medical Research Approval Committee on December 10th, 2014

Final revision approved on January 10th, 2015

INTRODUCTION:

The initial treatment of partially accommodative esotropia (PAET) is correction of the full hyperopic error. Surgery is needed if there is residual esotropia \geq 12 prism diopters for distance and near, and/or if the patient is not attaining fusion ¹. A variety of surgical approaches have been proposed to decide the surgical target angle on which the amount of muscle surgery is based. These strategies include: the standard formula ², prism adaptation ³, and the enhanced ⁴ and the augmented surgical formulas ⁵.

However overcorrection might occur with augmented recession, and often requires reduction of hyperopic correction to maintain alignment. Such overcorrection might carry the risk of development of consecutive exotropia later on ^{6,7}.

Various methods have been described before to address variability in the angle of the deviation in esotropia including posterior scleral fixation ⁸, pulley fixation ⁹, slanting recession ¹⁰, combined recession-resection ¹¹ and Y-splitting of the medial rectus muscle ¹². While these modalities have been described before in the management of convergence excess esotropia because of their ability to reduce the variability in the angle especially for near, their value in PAET have not been adequately studied.

The aim of this study is to evaluate whether posterior scleral fixation sutures can adequately address the variability of the angle of deviation in children with PAET while minimizing the risk of postoperative overcorrection.

METHODS:

A prospective controlled interventional study will be performed on patients with partially accommodative esotropia. An informed consent for the surgery will be obtained from all patients. All patients' guardians will receive a thorough explanation of the study design and aims, and signed a written informed consent.

All patients will receive a full ophthalmological assessment including history taking, measurement of uncorrected and best-corrected visual acuity, cycloplegic refraction, anterior segment examination, as well as a dilated fundus examination.

In addition, all patients will have a detailed motor examination during the initial evaluation and at each follow-up period. The angle of misalignment will be measured by the prism and alternating cover tests for both distance and near with and without glasses. The angle of horizontal misalignment will also be measured in side gazes and in straight up and down gazes. Measurement of the angle of deviation in up and down gazes will be done by tilting the head, approximately 25 degrees down and up respectively, with the patient fixing on a distance target. The difference between the angles of horizontal misalignment in up and down gazes will be used to calculate the amount of pattern strabismus if present.

The ductions and versions in all cardinal directions of gaze will be analyzed before surgery and thereafter during the postoperative follow up visits. Underaction will be measured on a 4-point

scale ranging from -1 to -4. Similarly overaction will be measured on a 4-point scale ranging from +1 to +4.

In all patients cycloplegic refraction will be performed using cyclopentolate 1% eye drops instilled 3 times 10 minutes apart with the last time 30 minutes before refraction. Patients with hypermetropia with a spherical equivalent $\geq +1.5$ D will then be prescribed the full cycloplegic refraction and then re-evaluated with spectacles one month later. Patients who appear to have a partially accommodative esotropia defined as residual esotropia >8 PD for distance with spectacles will have repeat refraction using atropine 1% drops 3 times a day for 3 days before refraction.

After ensuring that full cycloplegic refraction was prescribed, patients will then be evaluated with glasses to identify those with partially accommodative esotropia without convergence excess. Patients will be included in the study if the residual distance angle with cycloplegic prescription was > 15 PD. Patients with convergence excess esotropia, defined as the angle of deviation with glasses for near exceeding that for distance by 15 PD or more will be excluded from the study.

Amblyopia will be defined as a difference of 0.3 logMAR in verbal children (3 lines on the standard logMAR visual acuity chart) or a strong unilateral fixation preference using an accommodative target in infants and preverbal children. All patients with amblyopia will be treated before surgery. In general amblyopia therapy was continued till there was no further improvement of visual acuity or fixation preference despite adequate compliance with therapy for an acceptable

duration. Amblyopia will be treated following the standard clinical practice using part-time occlusion and in concordance with the PEDIG guidelines ¹³. Anisometropia is defined as a difference in the spherical equivalent of both eyes by 1 D or more.

Patients with neurologic, ocular, or developmental disorders or follow-up less than 6 months will be excluded from the study. In addition, patients will be excluded if they showed oblique muscle dysfunction, vertical deviation, significant A or V patterns, paralytic or restrictive forms of strabismus, or had a history of prior eye muscle surgery.

The smallest angle of deviation is defined as the corrected angle for distance. The largest angle is defined as the angle for near measured without correction. The angle disparity is defined as the difference between the largest and smallest angles.

Patients will be randomly allocated using a random table to one of two groups. In one group bilateral augmented MR muscle recession will be performed (augmented group). In the other group bilateral MR muscle recession combined with posterior scleral fixation sutures will be performed (Faden group).

The surgeries will be performed by one of two surgeons (HE, AA) using the same surgical technique. In both groups the medial rectus muscle will be exposed and hooked through a limbal approach. The muscle will then secured with 6-0 polyglactin (Vicryl, Ethicon, Somerville, NJ) sutures.

In the augmented group, the medial rectus muscles will be recessed using standard tables ¹⁴ with the surgical dose targeting the average of the largest and smallest angles.

In the Faden group, medial rectus muscle recession will be performed as described above with the surgical dose targeting the smallest pre-operative angle. The muscle will then fixated to the sclera using 6/0 polyester sutures placed in a mattress like with the anterior and the posterior sutures passing through both the edge of muscle and the sclera 12 mm and 14 mm from the muscle insertion, respectively.

Patients will be followed up at 1 week, 1 month, 3 months and 6 months after surgery. The distance and near angles of deviation, with and without glasses, and the angle disparity will be measured at each follow up visit and the ductions and versions were assessed in all patients.

Patients will be considered to have successful outcome if both the distance and near angles with spectacles were less than 8 PD esotropia/phoria. Patients who develop any exophoria/tropia, or in whom hyperopic correction needed to be reduced for treatment of a consecutive exotropia will be considered to be unsuccessful ^{6, 7, 15}. In addition, patients will be further subdivided into 2 groups according to the preoperative angle disparity into those with angle disparity 20 PD or less and those with angle disparity more than 20 PD. The success rate in each subgroup will be calculated.

For categorical variables (e.g., gender), percent distribution will be used. For continuous variables (e.g. age, angle of deviation), mean, range and standard deviation were used. Comparisons between the two groups will be done using t-test for independent samples for continuous variables

and chi square test for categorical variables. Statistical analysis will be performed with SPSS for Windows (SPSS Inc., Chicago, IL).

SAMPLE SIZE:

An estimation of sample size was performed considering a study power of 0.8 with an alpha error of 0.05 aiming to detect a difference of 5 Δ in the postoperative angle disparity between the 2 groups, assuming a postoperative standard deviation of 6 Δ⁹. Based on this estimation, a total of 24 eyes were found to be adequate in each group, and considering a 25% dropout during the follow-up, recruitment of 30 study subjects in each group will be targeted

EXPECTED START DATE: 1 January 2015

EXPECTED COMPLETION DATE: 31 December 2016

REFERENCES:

1. von Noorden G. Binocular vision and ocular motility (5th ed), St. Louis: Mosby. 1996: 307-308.
2. Parks M.. Concomitant esodeviations. In: Parks M.. Ocular Motility and Strabismus, Hagerstown: Harper & Row 1975: 99-111.

3. Prism Adaptation Study Research Group. (1990). Efficacy of prism adaptation in the surgical management of acquired esotropia. *Arch Ophthalmol* 1990; 108: 1248-55.
4. Jotterand VH, Isenberg SJ. (1988). Enhancing surgery for acquired esotropia. *Ophthalmic Surg* 1988; 19(4): 263-266.
5. Wright KW, Bruce-Lyle L. (1993). Augmented surgery for esotropia with high hypermetropia. *J Pediatr Ophthalmol Strabismus* 1993; 30: 167-170
6. Kushner B. Partly accommodative esotropia: Should we overcorrect and cut the plus? *Arch Ophthalmology* 1996; 113: 1530-34.
7. Kushner BJ, Fisher M. Is alignment within 8 prism diopters of orthophoria a successful outcome for infantile esotropia surgery? *Arch Ophthalmol* 1996; 114: 176-180.
8. Akar S, Gokyigit B, Sayin N et al. Medial rectus Faden operation with and without recession for partially accommodative esotropia with a high accommodative convergence to accommodation ratio. *Br J Ophthalmol* 2013; 97(1): 83-87.
9. Fouad HM , Abdelhakim MA, Awadein A , Elhilali H. Comparison between medial rectus pulley fixation and augmented recession in children with convergence excess and variable-angle infantile esotropia. *J AAPOS* 2016; 20 (5): 405-409.
10. Gharabaghi D & Zanjani LK. Comparison of results of medial rectus using augmentation, Faden procedure, & slanted recession in treatment of high accommodative convergence/ accommodation ratio esotropia. *J Pediatr Ophthalmol Strabismus* 2006;43:91-94.
11. Somer D ,Gul Cinar F, Oral B ,Ornek F. Combined recession and resection surgery in the management of convergence excess esotropia with different levels of AC/A ratio. *J AAPOS* 2017; 21 (1):7.e1-7.e7
12. Hoerantner R, Priglinger S, Haslwanter T. Reduction of ocular muscle torque by splitting of the rectus muscle II: Technique and results. *Br J Ophthalmol* 2004;88:1409–1413.

13. Gunton KB. Advances in amblyopia: What have we learned from PEDIG trials? *Pediatrics* 2013;131:540-47.
14. Wright KW. *Color atlas of strabismus surgery: Strategies and techniques* (3rd ed), Springer, Berlin 2007: 3:32-41.