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Dose effect and stability of postoperative cyclodeviation after adjustable Harada-Ito surgery

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Abstract

Purpose: To report the dose-response relationship of adjustable Harada-Ito surgery, and postoperative stability of cyclodeviation.

Design: Retrospective cohort study

Methods: 20 patients underwent a unilateral adjustable Harada-Ito advancement of the anterior fibers of the superior oblique tendon, with or without resection. The surgical dose was calculated as resection plus advancement plus adjustment. Cyclodeviation was measured using double Maddox rods at pre- and postoperative time points. We assessed dose effect by calculating change in cyclodeviation from preoperatively to post-adjustment and evaluated the dose-response relationship by Spearman rank methods. Postoperative stability of cyclodeviation was assessed by comparing post-adjustment measurements with 1-day and 6-week measurements, and also 1- and 5-year measurements, when available.

Results: Change in cyclodeviation from preoperatively to post-adjustment ranged from 7° to 20° of incyclo effect. There was a dose effect of 1.3° per mm ($r_s=0.52$ $P=.019$). Postoperative incyclodeviation unwound a mean of $3.6^\circ \pm 2.5^\circ$ between post-adjustment and day 1. Overall change between post-adjustment and the 6-week window was $6.5^\circ \pm 2.9^\circ$ in an excyclo direction. Unwinding continued with a mean change of $0.2^\circ \pm 2.6^\circ$ between the 6-week and 1-year windows, and of $0.4^\circ \pm 2.1^\circ$ between 1-year and 5-years windows.

Conclusions: Adjustable Harada-Ito advancement of the anterior fibers of the superior oblique has a dose response of 1.3° per mm but its effect regresses over time. Based on our data, an immediate postoperative target incyclodeviation of 7° is reasonable.

INTRODUCTION

Torsional diplopia often requires surgical intervention. Symptomatic excyclodeviation is commonly corrected using the Harada-Ito procedure, which was first described by Harada and Ito in 1964,¹ and later modified by Fells.² Using adjustable sutures for this surgery,

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described by Metz and Lerner,³ allows the surgeon to adjust the measured amount of cyclodeviation to a desired immediate postoperative target angle. Previous authors⁴ have reported a postoperative goal (target angle) of 0° of cyclodeviation, but it is unknown whether this is the ideal target for long-term success, or if an initial overcorrection would result in better long-term alignment.

The aims of the present study were: (1) to report the dose-response relationship of unilateral adjustable Harada-Ito surgery, (2) to report longitudinal changes in cyclodeviation in patients who underwent an adjustable Harada-Ito procedure, and (3) to define an optimum immediate postoperative target angle.

METHODS

Institutional Review Board approval was obtained from the Institutional Review Board at the Mayo Clinic, Rochester, Minnesota. All procedures and data collection were conducted in a manner compliant with the Health Insurance Portability and Accountability Act and all research procedures adhered to the tenets of the Declaration of Helsinki.

Patients

The senior author's (JMH) surgical database was searched for patients who had undergone unilateral adjustable Harada-Ito surgery over a 20-year period (1996–2015). Patients that had simultaneous vertical rectus surgery on either eye, simultaneous other oblique muscle surgery on either eye, or previous superior oblique surgery on the operated eye were excluded. Patients with restrictive strabismus (e.g., Graves' ophthalmopathy) were also excluded. Simultaneous horizontal muscle surgery on either eye (n=8; 40%), previous superior oblique surgery on the other eye (n=3; 15%), and previous inferior oblique muscle surgery (n=1 on same eye, n=3 on other eye) were allowed.

All patients had torsional alignment measured in straight-ahead position using double Maddox rods. A detailed description of the measurement technique can be found in a previous publication.⁵ Patients unable to perform double Maddox rod testing, for reasons such as suppression, were excluded.

Data were collected at the following time points: immediate preoperative, pre-adjustment, immediate post-adjustment, one day postoperatively, and at the 6-week window (21 days to 5 months postoperatively). Where available, data at the 1-year window (>5 months to 2 years postoperatively) and at the 5-year window (>2 years to 7 years postoperatively) were also included. For the 6-week window, 1-year window, and 5-year window, the visit closest to the designated time point within the pre-specified window was used. In the case of a reoperation, the last available examination before reoperation was carried forward and used as the outcome for the following time point (n=1). If there was an additional examination later in the previous window, but no examination in current window, the last examination was carried forward to the next time point to provide the longest available follow-up (n=2). Abduction deficits were estimated preoperatively and at 6 weeks postoperatively on a scale of 0, -trace, -1, -2, -3, -4, and -5.⁶

Surgery

All patients underwent the modified Harada-Ito procedure, described by Fells,² using an adjustable suture technique, described by Metz and Lerner (Figure 1).³ The anterior fibers of the superior oblique were isolated on the temporal side of the superior rectus and longitudinally split (typically for 15 mm). The proportion of the tendon split anteriorly was chosen based on whether or not a vertical effect was desired, and ranged from one quarter to three quarters of the width of the tendon. The distal end of the tendon was then imbricated using 6–0 Vicryl with or without a resection. A resection was performed when a larger amount of torsional correction was desired. Greater amounts of resection were performed in more recent years as the post-adjustment target evolved to 7° of incyclodeviation at post-adjustment. Scleral bites were then taken 8mm back from the superior pole of the insertion of the lateral rectus, from which the tendon was hung back (0 to 10mm, median 5mm) (Figure 1). A sliding noose was used to allow further advancement or recession at the time of adjustment. If adjusted, the noose was slid up or down and the amount of advancement or recession was estimated in increments of 0.5mm. To avoid large over- or undercorrections, intraoperative monitoring of the torsional alignment⁷ was used in more recent years of the study. Our rationale for using both intraoperative monitoring and postoperative adjustment was that intraoperative monitoring does not allow fine tuning of the alignment to the nearest 1–2° and does not account for muscle tone in the awake patient. The adjustment was performed postoperatively on the same day as surgery ranging from 1 to 8 hours after surgery. Early in the study period, the post-adjustment target was a small incyclodeviation in straight-ahead position, but over several years, the target became more specifically defined as 7° of incyclodeviation.

Analysis

The surgical dose was calculated by adding the amount of resection, amount of advancement, and amount of adjustment. The amount of advancement was calculated by subtracting the distance between the distal end of the advanced tendon and the superior border of the lateral rectus muscle, from 13 mm. This 13-mm value represents the typical distance from the original superior oblique insertion to the superior edge of the lateral rectus muscle belly and was calculated based on measurements made on a model eye and informal in vivo measurements. For example, a tendon set at 3 mm from the superior edge of the lateral rectus, was considered to have been advanced 10 mm. The calculated dose for each patient is given in the Supplemental Table (Supplemental Materials at AJO.com).

Spearman rank correlation coefficients were used to evaluate the dose-response relationships (change in torsional alignment from preoperatively to immediately post-adjustment versus the surgical dose). The dose effect was calculated as a mean change per mm of surgical dose. The amount of unwinding was analyzed by calculating mean change in torsional alignment between postoperative time points (immediately post-adjustment, day 1, 6-week, 1-year, and 5-year windows) (Supplemental Materials at AJO.com).

The number of patients demonstrating recurrence of excyclodeviation was also analyzed. A recurrence was defined as more than 5 degrees of excyclodeviation measured using double Maddox rods in the straight-ahead position.

RESULTS

We identified 20 patients (mean age 63 years, range 24 to 87 years) who had undergone unilateral adjustable Harada-Ito surgery. Four patients (20%) were females and 19 (95%) self-identified as white. The causes of exocyclodeviation were fourth nerve palsy (acquired $n=12$, decompensated congenital $n=2$), sensory exocyclodeviation ($n=2$), and other ($n=4$). All included patients had symptoms of torsional diplopia and were unable to fuse without correction of the cyclodeviation preoperatively. The mean torsional alignment at the preoperative examination was 9.0° of exocyclodeviation (range 5° to 17°). Twelve patients (60%) underwent Harada-Ito surgery on the right eye, and 7 (35%) had simultaneous resection of the tendon. Eight patients (40%) underwent an adjustment (Supplemental Materials at AJO.com).

Dose Effect of Harada-Ito Surgery

Mean surgical dose was 10.9 mm (range 6.0 to 16.0 mm), and mean change in torsional alignment from preoperatively to immediately post-adjustment was 13.3° in the incyclo direction (range 7° to 20°). There was a positive relationship between dose and effect of surgery ($r_s=0.52$, $P=.019$), with a mean of $1.3^\circ \pm 0.3^\circ$ (95% confidence interval 1.1° to 1.4°) of induced incyclodeviation per milli meter of surgery. Inspection of scatter plot (Figure 2) shows that, resection of the tendon, or proportion of tendon advanced did not differentially affect the amount of induced incyclodeviation.

Regarding whether or not surgery induced an abduction deficit, the range of preoperative limitation was 0 to -1 and postoperative limitation was from 0 to -1 , and only changed in 7 patients (4 worse and 3 better, overall median change = 0 with a maximum worsening from 0 to -1 and a maximum improvement from -1 to 0).

Unwinding of Cyclodeviation After Harada-Ito Surgery

The mean exocyclodrift from immediately post-adjustment to day 1 postoperatively was $3.6^\circ \pm 2.5^\circ$ (range 0° to 11°). From postoperative day 1 to week 6 window, there was an additional mean exocyclodrift of $2.9^\circ \pm 2.4^\circ$ (range 5° exocyclodrift to 4° incyclodrift), whereas from the 6-week to 1-year window ($n=13$) the mean change was only $0.2^\circ \pm 2.6^\circ$ exocyclodrift (range 5° exocyclodrift to 4° incyclodrift). Similarly, for the 7 patients that had a 5-year window follow-up, the mean change from year 1 to year 5 was only $0.4^\circ \pm 2.1^\circ$ (range 3° exocyclodrift to 2° incyclodrift) (Figure 3) (Supplemental Materials at AJO.com).

At 1 year, there was a moderate relationship between incyclodeviation postadjustment and exocyclodrift from post-adjustment to the 1-year window ($r_s=0.62$, $P=.023$, Figure 4).

Recurrence of Exocyclodeviation Postoperatively

At the postoperative 6-week window, 2 patients (10%) had recurrence of exocyclodeviation (6° and 7°) both of whom had 14° of exocyclodeviation preoperatively (17° and 14°). One of the 2 patients went on to have additional surgery and the other was lost to follow-up. At the 1-year window, one additional patient (1 of 13, 8%) had recurrence to 7° of exocyclodeviation (13° exocyclodeviation preoperatively), and went on to have additional surgery.

DISCUSSION

In the present study evaluating dose-response relationship of unilateral adjustable Harada-Ito surgery, we found an effect of 1.3° of excyclodeviation corrected per millimeter of surgery. Regarding postoperative stability of the cyclodeviation, we found unwinding (reduction of induced incyclodeviation or increasing excyclodeviation) occurring mostly between post-adjustment and 6-week window postoperatively (mean 6.5°) with slight further unwinding occurring by 5 years.

We are not aware of previous studies evaluating the dose-response relationship of the Fells' modification of the Harada-Ito procedure. Harada and Ito, in their original publication, reported a dose-response relationship of 3° correction per millimeter of advancement.¹ Harada and Ito imbricated the tendon 5 mm behind the insertion and plicated the tendon, doubling the anterior fibers of the superior oblique, which likely explains why they found approximately double the dose effect we now report. An additional difference between our technique and that of Harada and Ito is the use of a more anterior insertion site in the original Harada-Ito procedure. Other authors reported the dose-response relationship of other superior oblique tendon strengthening procedures. Simonsz and colleagues⁸ studied the immediate dose-response relationship of superior oblique tendon resection and found approximately 1° of effect per millimeter resected. Steffen and Kolling⁹ reported the torsional effect of superior oblique tendon tuck and found a mean of 1° of induced incycloeffect per millimeter of surgery. Each of these studies is consistent with our findings.

We also studied postoperative stability of the cyclodeviation to evaluate the occurrence and magnitude of unwinding of the induced incyclodeviation or recurrence of excyclodeviation. Nishimura and colleagues reported no significant change in cyclodeviation from day 1 to 2 months postoperatively, but a significant change of 3.8° from 2 months to 12 months.⁴ In contrast, we found that most of the change occurred early in the postoperative time period (mean change 3.6° by day 1 and 2.9° between 1 day postoperatively and the 6-week window). There were methodological differences between studies: Nishimura et al⁴ adjusted patients at postoperative day 1 while we adjusted the same day, and Nishimura et al⁴ used an immediate post-adjustment goal (target angle) of 0° cyclodeviation whereas we aimed for incyclodeviation (most recently 7° incyclodeviation). In addition, Repka mentioned the unwinding effect of the Harada-Ito procedure in 2004 but no data were reported.¹⁰ Von Noorden reported partial recurrence of excyclodeviation after a Harada-Ito procedure, which he attributed to loosening of the suture,¹¹ but this may in fact have been the same unwinding effect reported by us and others. It is also possible that regression of the cyclodeviation may be more using Vicryl suture than when using mersilene sutures, but all our cases and Nishimura and colleagues' cases were performed using Vicryl sutures.

We found a moderate relationship between incyclodeviation post-adjustment and change from post-adjustment to 1-year postoperatively, which suggests that the procedure is somewhat self-adjusting, but even cases with no or very little incyclodeviation post adjustment tended to drift to an excyclodeviation (Figure 4), suggesting that there may be merit in an immediate overcorrection.

Unwinding of the relative incyclodeviation after Harada-Ito surgery is likely to be due to a combination of mechanical stretching of the operated muscle and tendon, and sensory adaptation. Measurements of cyclodeviation made using the double Maddox rod test cannot distinguish between these two distinct components. It would be beneficial to make objective measurements of globe position using, for example, fundus photographs, in addition to subjective testing using double Maddox rods or synoptophore, to better understand the relative contributions of motor and sensory components to the measured change in cyclodeviation. Nevertheless, monocular fundus photographs do not represent the relative binocular torsional alignment of the eyes and newer techniques, such as the simultaneous binocular scanning laser ophthalmoscope, are needed.

There continues to be a lack of consensus regarding whether there is any merit to using adjustable sutures for the Harada-Ito procedure. Marsh and colleagues¹² suggested adjustable sutures were not needed when performing Harada-Ito surgery. Their outcome data (4 to 29 months postoperatively) showed a number of patients with residual or recurrent excyclotropia, which suggests there may be a role for optimizing the immediate postoperative torsional alignment using adjustable sutures. Nevertheless, despite using adjustable sutures, we also had 3 patients with recurrent excyclodeviation (defined as more than 5°) which suggests that the achieved immediate post-adjustment torsional alignment (0°, 1°incyclo and 7°incyclo) may not have been optimal. These patients with recurrence also had large preoperative excyclodeviations (17°, 14°, and 13° excyclo) and likely weaker residual function of the superior oblique muscle, suggesting that a larger postoperative target torsional alignment or even bilateral surgery might have been beneficial. An incyclo target angle of greater than 7° may in fact be optimal in some patients.

Our present study has several limitations. Not all patients had more than 6 weeks follow-up and the patients who returned during the 1-year and 5-year windows may not have been representative of the entire cohort. In addition, our calculated dose required assumptions to be made regarding the distance from the original superior oblique insertion to the superior edge of the lateral rectus, because the actual distance was not measured. In future studies, measurements should be made with a curved ruler at the time of surgery on the surface of the globe. We used a method of estimation for judging the amount of advancement or recession at the time of adjustment, which might be directly measured in future studies. A further limitation is that our study did not address diplopia frequency, due to the lack of diplopia data in patients seen early in the study period before we started to routinely use a standardized, patient-reported Diplopia Questionnaire.¹³ Additional limitations were the change of surgical strategy during the course of the study and the non-standardized follow-up.

In summary, the unilateral adjustable Harada-Ito procedure induces a mean 1.3° of incycloeffect per millimeter of surgery. This effect unwinds over time, with most of the change (6° to 7°) occurring in the first postoperative year. Based on our study, an initial overcorrection to 7° of incyclodeviation is a reasonable target for a unilateral adjustable Harada-Ito procedure when adjusting the same day as surgery, acknowledging that in some cases the target overcorrection may need to be greater.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.
Illustration of the adjustable Harada-Ito procedure.

Figure 2.

Change in cyclodeviation preoperatively to immediately post-adjustment in relation to the total surgical dose. Filled points indicate Harada-Ito advancement combined with resection of the anterior fibers of the superior oblique tendon. Unfilled points indicate no resection. The line is plotted with the assumption of zero effect with zero surgery and has a slope of 1.3° per millimeter based on the calculated mean change. Resection per se did not appear to affect the amount of change per mm of surgery, nor did the width of the advanced tendon.

Figure 3.

Cyclodeviation measured in degrees using the double Maddox rod test at preoperative and postoperative timepoints, following unilateral Harada-Ito surgery. Bold figures represent mean changes between timepoints.

Figure 4.
Change in excyclodeviation from post-adjustment to the 1-year window in relation to the post-adjustment incyclodeviation