Outcomes of the Harada–Ito Procedure

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ABSTRACT
Purpose: Fell’s modification of the Harada–Ito (HI) procedure is often used to tackle subjective torsion usually following superior oblique palsy. There is limited published data on the longer-term outcomes and the effect on horizontal incomitance of the procedure. The purpose of this study is to report on the medium to long-term outcomes of the HI procedure.

Materials and methods: A retrospective review of 20 patients who had all undergone a single surgeon modified HI procedure to correct subjective torsion was undertaken. Follow-up data were analyzed in relation to stability of torsion measurements, the effect on vertical incomitance of horizontal deviation and the final treatment outcome.

Results: There was a significant reduction in median maximum torsion from preoperative to immediately post-op (p < .01) and there remained a significant difference in maximum torsion from preoperative measurement at both the 3-month (p = .02), and 12-twelve month (p = .01) follow-up. HI had a significant effect on associated V-pattern esotropia (p < .05).

Conclusion: The HI procedure is effective in eliminating subjective torsion initially and reducing incomitant horizontal deviation; however, regression toward preoperative torsion measurement occurs after time.

Subjective torsional diplopia is often associated with superior oblique (SO) palsy, particularly acquired and bilateral palsies. The Harada–Ito (HI) procedure first described in 1964 and then later modified by Fells has demonstrated positive statistical and clinical postoperative results. Postoperative follow-up times are often limited to under 1 year and some report a regression of postoperative torsion measurements back toward the preoperative level over time. Due to the position of action of the SO muscle and its horizontal action (abduction), there is also often an associated V-eso pattern, which is usually exacerbated in bilateral palsies and there are few reports as to the effect of the HI procedure on this incomitance. Furthermore, reports regarding the additional conservative treatment that may be required in order to alleviate any residual symptoms of torsion postoperatively are limited.

The aim of this study is to determine the success of the HI procedure on subjective torsion, determine the stability of corrected torsion over time and assess the effect of the procedure on vertical incomitance of horizontal deviation.

Materials and methods
This was a retrospective chart review with local ethical approval undertaken between April 2019 and June 2020. Patients were identified from case notes at a single clinical site. All patients were under the care of one ophthalmologist and had undergone the same surgical technique of Fell’s modification HI. A data-collection sheet was produced recording etiological factor, age when HI was performed, patient’s symptoms/main complaint, deviation in the primary position, stereoacuity, measurement in the nine positions of gaze using the Major Amblyoscope (synoptophore) for horizontal, vertical and cyclovertical deviation and additional treatments employed to eliminate residual symptoms. For synoptophore measurement, Maddox slides commensurate with the visual acuity of the weaker eye were used to measure all elements of the deviation, the vertical deviation was measured (objectively) in prism diopters and horizontal deviation (objectively) and subjective torsion in degrees as per normal clinical practice. Data was recorded immediately preoperatively, immediately postoperatively (IPO), 3 months (3PO), 6 months (6PO), 12 months (12PO), 18 months (18PO), 24 months (24PO), and greater than 24 months (>24PO) postoperatively.

Subjective torsion was recorded from the measurement in the primary position and in the position that yielded the maximum amount of torsion to analyze the effect of HI and to assess the stability of torsion at each follow-up event. Subjective excyclotorsion was recorded as a positive number and incyclotorsion was recorded as

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a negative number. The effect of the HI on associated vertical incomitance of horizontal deviation was determined by recording the angle of horizontal deviation in direct elevation and direct depression. Confirmation of vertical incomitance of horizontal deviation was via calculating the difference in horizontal deviation between direct depression and direct elevation. The final or additional treatment solution (or most recent treatment if the patient was still under review) given to patients in order to alleviate residual symptoms following HI surgery was also recorded.

**Exclusion criteria**

Patients were excluded if they were diagnosed with a restrictive or mechanical etiology or if they had undergone any strabismus surgery prior to the initial HI procedure.

**Results**

Twenty patient records that met the criteria were available for review, patient characteristics are outlined in Table 1. All 20 of the cohort who underwent HI had SO palsy as the cause, all of these were acquired, the majority 80% (n = 16) had bilateral palsy and trauma was the most common cause of SO palsy. Diagnosis of unilateral or bilateral palsy was made based on the features identified in the full orthoptic assessment, for example, amount of torsion in the primary position and depression, reversal of vertical deviation on lateral gaze and presence of V-pattern. The decision to perform unilateral or bilateral surgery was made by the ophthalmologist based on the combination of these findings and clinical experience. Four underwent unilateral procedures and 16 had bilateral procedures. In all cases, the maximum torsion measurements were in either direct depression, laevo-depression, or dextro-depression depending on whether the patient had a bilateral, right or left SO palsy.

**Subjective torsion**

Maximum torsion measurements for all patients along with median (IQR) at each follow-up point has been collated in Table 2. There was a significant reduction in median maximum torsion from pre-operative (17.0° IQR 11.2–19.6) to IPO measurement (6.0° IQR –8.6–9.6) (Wicoxon Ranked Test, p < .01, n = 20). There remained a significant difference in maximum torsion from preoperative measurement at both the 3-month (5.5° IQR 0.0–3.5, p = .02, n = 12) and the 12-month (6.5° IQR 0.0–15.2, p = .01, n = 14) follow-up appointments.

Median subjective torsion in the primary position (Table 3) was affected in a similar fashion, with a significant reduction from preoperative (8.0° IQR 5.6–10.2) to IPO measurement (2.0° IQR –1.5–3.6, p = .02, n = 18) and 12PO follow-up (1.0° IQR 0.0–3.5, p = .03, n = 14).

Statistical analysis was not performed for data-collection points between 3 and 12 months or beyond twelve-month due to the small number of patients who had had both maximum and primary position torsion measurements documented; individual patient measurements as well as overall medians are available in Tables 2 and 3.

Graphs 1 and 2 illustrate the overall pattern of the effect of the HI procedure on maximum (Graph 1) and primary position (Graph 2) torsion across each of the patient follow-up episodes. In Graph 1 the initial significant drop can be seen between pre-op and IPO; a further slight drop in the median maximum torsion can be seen at the 6th-month follow-up, followed by a steady increase in the amount of median maximum torsion at 18-, 24-, and greater than 24-month follow-up.

For primary position subjective torsion illustrated in Graph 2, median torsion measurements remain relatively stable from IPO to beyond 24 months.

**Vertical incomitance of horizontal deviation**

The presence of vertical incomitance of horizontal deviation was identified by calculating the difference in horizontal deviation between depression and elevation.
Eight of the cohort had confirmed vertical incomitance of horizontal deviation (a difference of 7° in horizontal deviation from depression to elevation) (Table 4), all eight were V-pattern esotropia deviations. V-pattern data was available for these eight patients at IPO and 3 months postoperatively. Ten patients (50%) also complained of noticeable horizontal and vertical diplopia as a preoperative symptom. This is commensurate with eight of the cohort having a true V-eso pattern. A further seven patients had a V-eso tendency (an increase in horizontal deviation from depression to elevation less than 7°), meaning that 75% of the cohort overall had vertical incomitance of horizontal deviation to some extent even if not reaching the threshold to be considered as having a ‘true’ V pattern.

Median (IQR) difference preoperatively was 11.5° (11.0–14.2) and this had fallen significantly to 3.5° (1.0–6.6, p < .05) at the IPO follow-up and remained significantly lower at the 3-month follow-up (6.0°, IQR 4.5–7.0; p < .05).

**Additional/final follow-up treatment solution**

The final treatment required to alleviate any residual symptoms for all 20 patients recorded at their final
follow-up appointment is collated in Table 5. Seven patients had demonstrable stereopsis measured (150 second of arc or better: patients 1, 7, 13, 14, and 16–18). Spearman’s Ranked correlation revealed no influence ($p > .05$) on the final treatment outcome by either etiology of the SO palsy, the preoperative maximum subjective torsion measurement, preoperative primary position subjective torsion measurements, or pre-HI symptoms.
Table 5. Final follow-up treatment given to all patients.

| Patient | Outcome | Deviation in primary position |
|---------|---------|-----------------------------|
| 1       | OCL     | Latent                      |
| 2       | U       | Latent                      |
| 3       | Prism   | Latent                      |
| 4       | SO      | Latent                      |
| 5       | None**  | Latent                      |
| 6       | OCL     | Latent                      |
| 7       | OCL     | Latent                      |
| 8       | OCL     | Manifest                    |
| 9       | Prism   | Latent                      |
| 10      | None    | Latent                      |
| 11      | OCL     | Manifest                    |
| 12      | None    | Latent                      |
| 13      | None    | Latent                      |
| 14      | None    | Latent                      |
| 15      | None    | Latent                      |
| 16      | None    | Latent                      |
| 17      | None    | Latent                      |
| 18      | None*   | Latent                      |
| 19      | None    | Latent                      |
| 20      | None*   | Latent                      |

OCL = occlusive contact lens, SO = sector occlusion. *Diplopia in extreme depression only. **Still under review.

Discussion

Torsion

There is a clear overall reduction in maximum subjective torsion at the IPO follow-up from preoperative measurement (6.0° IQR −8.6–9.6 vs. 17.0° IQR 11.2–19.6, p < .01) illustrated by Table 2 and Graph 1. This is with the exception of one patient who measured a large (10°) increase in subjective torsion at this stage (Table 2, patient 3). Preoperatively, this patient had no features of a bilateral palsy, and therefore underwent unilateral surgery which subsequently revealed the presence of a contralateral SO underaction which was retrospectively deemed preoperatively asymmetric. This was subsequently resolved with a further contralateral HI procedure. Patient 10 (Table 2) had a negligible (1°) increase in torsion at the IPO follow-up, however, this did not require additional surgical intervention and the patient was binocular and did not require any additional conservative intervention at the final follow-up. The significant reduction in torsion post-operatively is in agreement with earlier studies that report favorable results following HI surgery. Following the IPO measurement there is initial further drop in median torsion at the 3PO and 6PO measurement (5.5° IQR 0.0–3.5, 4.0° IQR −4.2–6.6, respectively) which indicates that early in the postoperative stages there is good stability of maximum torsion.

However, median maximum torsion measurements then begins to increase at the 12, 24, and >24PO follow-up visits. This is in again agreement with an earlier report of a regression of postoperative torsion toward the preoperative measurement. Statistical analysis was not indicated at every follow-up due to a limited number of patients having measurements at every follow-up point. Although torsion does not increase for all patients, there is a pattern of increasing torsion for at least some who have undergone the HI procedure. At the 12PO follow-up, maximum torsion measurements are available for almost three quarters of the cohort and after an initial continuous drop in torsion; the median torsion for these 14 patients is slightly more than the IPO median. The median continues to rise for the eight patients with data available at 18PO (n = 14) to almost double that of the IPO 11° IQR 5.0–11.0 vs. 6.0° IQR −8.6–9.6) and then to almost match the preoperative median at the >24PO (n = 5) (16° IQR, 2.5–19.0 vs. 17° 11.2–19.6). Although it may be suggested that those patients still requiring review and measurement of torsion at the 18, 24, and >24PO would inevitably have higher levels, this does not detract from the fact that for at least some patients, there is a significant regression of torsion back to preoperative levels following the HI procedure. Nevertheless, for this group overall, the HI procedure had reduced maximum subjective torsion to more than 50% of the preoperative measurement at least the 12PO visit. Another way of determining the success of the HI procedure besides the final measures of torsion is assessing whether patients required any additional intervention in order to control or alleviate subjective torsion this will be discussed in more detail later.

There is also a significant drop in torsion in the primary position from pre-op to IPO (n = 18) (8.0° IQR 5.6–10.2 vs. 2.0° IQR −1.5–3.6; p = .02). Two patients did not have torsion measured in the primary position at the IPO follow-up and so were removed from this analysis. As with maximum torsion, there is then a further slight drop in measured torsion at 3PO and although there is slight fluctuation, median torsion remains reasonably stable (within 1°) of the IPO up to the >24PO. However, the median primary torsion at >24PO is almost half the amount recorded pre-operatively. This therefore suggests that although the effect is smaller than in maximum torsion, there remains a pattern of regression back toward preoperative levels following the HI procedure.

Nishimura and Rosenbaum suggest that the reduction in the effect of HI over time may be due to the procedure not incorporating concurrent weakening of the SO direct antagonist, resulting in an inevitable regression over time and cite other modification that may reduce this effect such as the use of adjustable sutures. Others have suggested that this inevitable regression of torsion may be due to weakening of the sclera suture. Perhaps modifications such as these or others warrant further prospective exploration in relation to long-term stability of HI and subjective torsion post-HI.
One interesting observation from the data is that six of the cohort presented with a reversal in the orientation of maximum subjective torsion (from excyclotorsion to incyclotorsion) at the IPO follow-up. Overcorrection following HI is something that has been described previously.\textsuperscript{12} Only one patient had persistent incyclotorsion (patient 11), three did not require any additional active treatment for torsion and three required an occlusive contact lens to alleviate problematic subjective torsion. This suggests that an initial overcorrection of torsion does not then prevent or diminish the gradual regression back toward the preoperative measurement, nor does it result in a better overall outcome with respect to binocularity.

**Vertical incompitance of horizontal strabismus**

Its action of abduction means that a palsy of the SO muscle can result in a V-eso pattern and a significant V-eso pattern is often a differentiating characteristic between unilateral and bilateral palsies. All patients in this cohort presented with an eso deviation in the primary position and this increased in depression relative to elevation in 15 patients. There was a true V-eso pattern measured in eight of the patients (Table 4) and we analyzed the effect of the HI procedure on the V-pattern postoperatively in these patients. There was a significant reduction in the V pattern in this cohort IPO which persisted at the 3PO ($P = .01$) for those eight with a V-eso pattern. Furthermore, there appears to be the start of regression toward preoperative values following the initial reduction in V-eso size over time with median difference from elevation to depression increasing between the IPO (3.5° IQR, 1.0–6.6) and 3PO (6.0°, IQR 4.5–7.0) follow-up. This mirrors what happens to torsion measurements postoperatively which may indicate that the HI procedure is having a direct impact on the V-eso pattern and oblique dysfunction may play more of a significant role in the presence of vertical incompitance of horizontal deviation. The role of oblique dysfunction in the presence of vertical incompitance of horizontal deviation has been discussed within the literature previously.\textsuperscript{13,14} Kushner\textsuperscript{14} postulated that oblique dysfunction resulting in the cyclorotated eye’s new position causes a change in the force vectors of the recti muscles which contributed to but was not the primary cause of this. As the HI procedure isolates the fibers responsible for the cyclovertical action of the superior oblique, one might expect that the V pattern not be significantly affected by this surgery, which is not the case in this cohort. The effect on the V pattern following HI intervention in this group at least demonstrates that oblique dysfunction does have a role in the presence of vertical incompitance of horizontal deviation.

Vertial incompitance of horizontal deviation was not recorded in these patients beyond 3PO and therefore was not available for further analysis; it would be interesting to evaluate the progression of the pattern over a longer follow-up time. However, the fact that the pattern has not been recorded at subsequent clinical visits in these patients may suggest that it was not clinically significant enough to cause patients any symptoms.

**Additional/final follow-up treatment solution**

Measurement of subjective torsion postoperatively provides information about whether the procedure has significantly reduced the amount of torsion and how stable that is over a given follow-up time. However, another important measure of the success of a surgical treatment is what intervention, if any, patients required to resolve residual symptoms of torsion postoperatively (Table 5). As highlighted earlier, the five patients who had follow-up data for >24PO may be expected to have higher levels of torsion and one could therefore assume that they may need further intervention in order to resolve problematic torsion. Although four of these patients did demonstrate a regression in their torsion measurements, three of them (patients 4, 5, and 12) were binocular in the primary position at the >24PO follow-up with patient 4 only requiring sector occlusion for symptoms in extreme gaze. The remaining two patients (6 and 8) did require an occlusive contact lens for persistent problematic torsion. These outcomes indicate that merely because a patient is under review for longer following HI surgery this does not mean that this is always due to persistent torsion, as half of those with the longer follow-up (24PO or >24PO) had comfortable binocular vision with no problematic torsion.

Spearman’s Ranked correlation revealed no influence ($p > .05$) from maximum or primary position torsion on whether patients in this cohort would then require additional treatment in order to alleviate residual subjective torsion post-operatively. This suggests that a greater or lesser amount of torsion preoperatively is not predictive of the final or additional treatment required following HI surgery. Although the six patients with the least amount of maximum torsion preoperatively, did have resolution of their subjective torsion at their final follow-up with only one (patient 13) having diplopia in extreme gaze. The five with the greatest maximum torsion measurements preoperatively had a more mixed result with respect to final/additional treatment; two of these patients ultimately required an occlusive contact lens...
to alleviate residual torsion; however, two patients had resolution with no additional intervention (patients 5 and 12), and the final patient (4) only required sector occlusion. Patient seven, who had a maximum torsion measurement of −8° (a reversal of orientation of subjective torsion), no torsion in the primary position and was binocular, opted for an occlusive contact lens as they were unable to cope with the small amount of residual subjective torsion in depression. These examples demonstrate that the additional/final interventions required for these patients are variable and one cannot predict an outcome purely based on severity of symptoms pre-operatively or in fact postoperatively.

The authors acknowledge the limitations of this study, its retrospective nature, and the fact that additional surgeries were carried out on some following HI intervention. Fourteen of the cohort had follow-up surgery to the HI procedure for horizontal and/or vertical deviations. The most common additional intervention was inferior rectus Faden (eight), followed by five horizontal muscle surgeries, two contralateral HI and one superior oblique tuck. These additional interventions may well have had an effect on subjective torsion; however, the number, type and timing of these subsequent surgical intervention was varied based on individual patient need making it difficult to incorporate into statistical analysis.

Conclusion

The results from this study demonstrate that the HI procedure produces generally favorable outcomes with respect to resolving problematic subjective torsion in the short to medium term. It also appears to have an added beneficial effect in reducing vertical incomitance of horizontal deviation. Many patients do require further intervention such as additional surgical procedures or conservative intervention but with respect to torsion, the majority of the cohort had this element of their symptoms alleviated following the HI intervention. Longer follow-up times on a greater number of patients prospectively would be useful in order to evaluate the longer-term stability of torsion following HI intervention.

Disclosure statement

The authors have no conflicting interests to declare.

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