

Standard Operating Procedure (SOP)

für die Durchführung eines orthoptischen Status bei Kindern mit
Esotropie

Auf den folgenden Seiten finden sie einen Auszug der Original-SOP, welche für die BISS Studie verwendet wurde.

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1 Examination Responsibilities

The objective measures for the “full orthoptic workup” at 12±1 months and 18±1 months are made by an orthoptist who is “blind” to the past intervention. During these examinations the orthoptist is instructed to reduce communication to a minimum. Patients (and their parents) are instructed not to mention in which study arm they have been prior to the examination. The orthoptist who examines patients at 12±1 months and at 18±1 months has not examined the patient prior to that date. The same orthoptist may examine the patient at both endpoints.

2 Correcting Refractive Errors

Some of the examinations require a correction of the refractive error. If a refractive error is corrected, it must be fully corrected, i.e. undercorrecting hypermetropia measured by cycloplegia (induced with either of the following: cyclopentolate, tropicamide, or atropin) by no more than 0.5 diopters if possible. A undercorrection of 1 diopter is accepted if a higher hyperopic correction is not accepted by the patient.

3 Non-recurrent Assessments

All of the following must be assessed once during or before the first full orthoptic workup. Some of the tests require cooperation and may not be possible in younger children.

3.1 Objective Refraction

- Cycloplegia with a subsequent objective refraction using retinoscopy and/or autorefractometer are performed
- Accommodative power is measured

3.2 Dilated eye examination

- The anterior segment, including cornea, anterior chamber, and lens is examined.
- The posterior pole including optic disc and macula is examined. The fundus periphery is examined as far as possible.

3.3 Prism correction/adaptation

If a decompensated esophoria is not ruled out as diagnosis a prism correction/adaptation is made. Prism adaptation consists of correction of the full strabismus angle measured at distance using prisms (Fresnel or prism blocks) for strabismus angles $\leq 25^\Delta$. Prism adaptation may not be possible with larger angles. Some time (often about 30 minutes) after prism correction the angle is again determined and prism correction is increased if an esophoria is found. This process is reiterated until prism correction results in stable (prism-corrected) orthophoria during at least 30 minutes since the last change of prisms. The entire process of prism adaptation must not be shorter than 4 hours. It may be made over days or weeks.

3.4 Saccades and smooth pursuit

A clinical measure of saccadic accuracy, saccadic velocity (horizontal and vertical), smooth pursuit, and VOR (vestibulo ocular reflex) cancellation is made if the child's age/cooperation allows it.

3.5 Pupils

Pupillary assessment with pupillary diameter in bright light and in the dim/dark is made. Presence of a relative afferent pupillary deficit (RAPD) is determined.

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3.6 Dominant eye

In case of unilateral esotropia or alternating esotropia with unilateral predominance, the predominantly fixating eye is considered the dominant eye. In cases with alternating esotropia with an unclear ocular dominance, the dominant eye is determined by having the patient fixating a distant object through an aperture formed with both hands. The fixating eye is considered the dominant eye. If this test fails, due to cooperation, a judgment of the dominant eye may be made based on the predominant side of the esotropia, squinting, or history.

3.7 History of strabismus onset

The following questions are addressed: When, at what age (in years and months), was strabismus noticed for the first time? When was strabismus objectively found for the first time? In cases of ambiguity family photographs are reviewed and ocular alignment is estimated based on corneal light reflex.

4 Recurrent Assessments

The following procedures should be made at each orthoptic workup. Some of the tests may not be feasible in younger children.

- History including head posture, double vision (hours per day), perceived ocular alignment (i.e. aligned vs not aligned, hours per day), presence of asthenopia (visually induced strain/headache, grade 1-10 and hours per day), wearing of glasses (hours per day).
- Current glasses are measured
- Head posture is described
- Distance visual acuity is measured at 4-5m using Landolt rings with a spacing of ≥ 35 minutes of arc using best optical correction. The optical correction used must be noted. If vision is below normal limits, a pinhole vision with best optical correction must be measured.
- Near visual acuity is measured at 40cm distance, again using best correction. Spacing for these optotypes is 2.6 minutes of arc.
- If Landolt rings cannot be used due to compliance/age Lea symbols or preferential looking tests may be used to determine visual acuity.
- Simultaneous prism cover test is made for the primary gaze at 4-5m and at 33cm with correction as described above.

In the case of a decompensating phoria, which may be compensated occasionally, the patient is asked to relax and to decompensate if easily possible, then the simultaneous prism covertest is used. If the patient is compensated throughout this measure the result of the simultaneous prism covertest is 0.

- Alternate prism covertest for 5 gaze positions (straight-, right-, left-, up-, and downgaze) at 4-5m. This test is made without optical correction.
- Alternate prism covertest in primary position at 4-5m without optical correction and with optical correction is determined.
- Alternate prism covertest at 33cm in primary gaze is made (1) without optical correction, (2) with optical correction for distance and (3) with +3.0 diopter in addition to the optical correction for distance.
- Motility is determined in all diagnostic gaze directions using a subjective scale [--, -, (-), ((-))]] and a measure of the pupillary dislocation in mm.

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4.1 Quantitative tests of binocular vision

All binocular tests required to determine the highest level of binocular vision (defined in 4.1.1.) are made. At least the binocular tests required for the level above and the level below a given level of stereovision must be used. For example, a patient with level 4 of binocular vision must be tested for level 5 AND level 3.

- Bagolini striated glasses (positive, negative, no response)
- Pencil-Test using two vertical pencils (positive, negative, no response)
- Titmus Housefly (positive, negative, no response)
- Titmus Test circles 1-9 (800", 400", 200", 140", 100", 80", 60", 50", 40", none, no response)
- Lang Test (Lang I : 1200", 600", 550" and Lang II: 600", 400", 200", none, no response)
- TNO Test plates V, VI, VII (480" & 240", 120" & 60", none, no response)

4.1.1 Levels of binocular vision

Levels of binocular vision are defined as described below. Level ≥ 1 is considered as binocular vision. Level 0 is defined as 'absent binocular vision'.

Level 0 Both Bagolini- and pencil tests are negative

Level 1 Bagolini- or pencil test is positive

Level 2 Both Bagolini- and Housefly-tests are positive, but no Titmus circle is recognized

Level 3 at least Titmus circles 800" to 140" are recognized

Level 4 at least Titmus circles 100" to 40" are recognized

Level 5 either all figures of the Lang Test or TNO Test plate V (480" & 240") are recognized

Level 6 TNO plates VI or VII (120" & 60") are recognized.

4.2 Assessment of examiner unblinding

The full orthoptic workup at 12 ± 1 months and at 18 ± 1 months ends with a response of the orthoptist to the following questions:

Does the examining orthoptist think that the patient was in the Botox arm or in the surgical treatment arm?

When and how was this found out?

5 GUIDELINES ORTHOPTIC WORKUP

The following procedures may be made.

5.1 Additional stereotests

If available the following two stereotest should be applied:

- Butterfly-Test
- Worth-4-dot-test
- Presence of binocular vision shown with the synoptophor (either stereovision, fusion or simultaneous perception)

5.2 Glasses

Glasses (subtracting no more than 1.0 diopters of spherical equivalent (D), preferably 0.5 D or less, from retinoscopy in cycloplegia values) are prescribed in case of:

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Spheric equivalent > 1.5 D

Anisometropia > 1.0 D

Astigmatism after age two: > 1.5 D or > 1.0 D when oblique, or against the rule

Astigmatism before age two: > 2.0 D or > 1.5 D when oblique, or against the rule

Less correction may be prescribed if a visual benefit is likely.

In cases of accommodative convergence excess progressive glasses or bifocals are prescribed if the near angle of strabismus can be reduced and/or binocular vision at near can be improved.

5.3 Marlow diagnostic occlusion

In cases of large discrepancies between the strabismus angles measured before and after prism adaptation a diagnostic occlusion may be made in order to determine the phoric strabismus angle. Marlow occlusion should be made during at least 4 hours, if possible 24 hours before measuring the angle.

5.4 Indications for prism adaptation

Prism adaptation may be made in any type of strabismus. It is particularly advised in cases with decompensated esophoria, large far-near-incomitance to determine whether the far-near-incomitance is less with prism correction and it is advised in cases with apparent variability of strabismus angles.

5.5 Accommodative power

If possible, the push-up method is used for determining accommodative power. For this the subjects initially view an accommodative target at a distance of approximately 0.5m wearing the full refractive correction. Then the target is slowly moved toward the patient who is instructed to keep the target as clear as possible and to report when it first becomes "blurry". The endpoint is the first slight sustained blur, which can no longer be cleared. Then the distance from the target to the spectacle plane is measured with a millimeter ruler and converted into diopters of accommodation using the table below.

cm	Diopter of accommodation
7	14
8	12
9	11
10	10
11	9.1
12	8.3
13	7.7
14	7.1
15	6.7
16	6.3
17	5.9
18	5.6
19	5.3
20	5
22	4.5
25	4
30	3.3
35	2.9

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40	2.5
45	2.2
50	2