

The effects of partial and full correction of refractive errors on sensorial and motor outcomes in children with refractive accommodative esotropia

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Abstract

Purpose To investigate the effects of partial and full correction of refractive errors on sensorial and motor outcomes in children with refractive accommodative esotropia (RAE).

Methods The records of pediatric cases with full RAE were reviewed; their first and last sensorial and motor findings were evaluated in two groups, classified as partial (Group 1) and full correction (Group 2) of refractive errors.

Results The mean age at first admission was 5.84 ± 3.62 years in Group 1 ($n = 35$) and 6.35 ± 3.26 years in Group 2 ($n = 46$) ($p = 0.335$). Mean change in best corrected visual acuity (BCVA) was 0.24 ± 0.17 logarithm of the minimum angle of resolution (logMAR) in Group 1 and 0.13 ± 0.16 logMAR in Group 2 ($p = 0.001$). Duration of deviation, baseline refraction and amount of reduced refraction showed significant effects on change in BCVA ($p < 0.05$). Significant correlation was determined between binocular vision (BOV), duration of

deviation and uncorrected baseline amount of deviation ($p < 0.05$). The baseline BOV rates were significantly high in fully corrected Group 2, and also were found to have increased in Group 1 ($p < 0.05$). Change in refraction was -0.09 ± 1.08 and $+0.35 \pm 0.76$ diopters in Groups 1 and 2, respectively ($p = 0.005$). Duration of deviation, baseline refraction and the amount of reduced refraction had significant effects on change in refraction ($p < 0.05$). Change in deviation without refractive correction was -0.74 ± 7.22 prism diopters in Group 1 and -3.24 ± 10.41 prism diopters in Group 2 ($p = 0.472$). Duration of follow-up and uncorrected baseline deviation showed significant effects on change in deviation ($p < 0.05$).

Conclusions Although the BOV rates and BCVA were initially high in fully corrected patients, they finally improved significantly in both the fully and partially corrected patients. Full hypermetropic correction may also cause an increase in the refractive error with a possible negative effect on emmetropization. The negative effect of the duration of deviation on BOV and BCVA demonstrates the significance of early treatment in RAE cases.

Keywords Binocular vision · Hypermetropia · Emmetropization · Refractive accommodative esotropia

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Introduction

Fully refractive accommodative esotropia (RAE) requiring no surgical intervention is one of the most common form of pediatric strabismus associated with varying degrees of hypermetropia [1, 2]. Since the pathogenesis is excessive accommodation and convergence due to uncorrected hypermetropia and blurred vision, the aim of treatment is to correct the deviation by full hypermetropic correction following cycloplegic refraction [3, 4]. Insufficient refractive correction may lead to an increase in deviation, which may deteriorate visual acuity and binocular functions. However, Park and Oh [5] observed that binocular functions were not adversely affected by reducing the tolerable hypermetropic refraction in RAE cases.

Besides the refractive errors and their appropriate correction, factors such as amblyopia, binocular vision (BOV), and the amount of deviation angle are also known to affect the disease course in RAE as in all strabismus cases. In this study, we aim to determine the clinical features of cases with RAE and to evaluate the effects of partial and full hypermetropic correction on treatment outcomes.

Patients and methods

The present study was carried out at the Strabismus Department of İzmir Atatürk Educating and Research Hospital in accordance with the Helsinki Declaration Principles, after obtaining the approval of the institutional ethics committee. The medical records of cases with RAE between January 1997 and March 2015 were retrospectively reviewed. Refractive accommodative esotropia was diagnosed when esotropia was eliminated or decreased to within 10 prism diopters (PD) at both near and distance with spectacle correction. Patients who had regular recorded findings of examinations and within 10 PD deviation angle with spectacles during at least 1 year follow-up period were included in the study. The partial correction group (Group 1) consisted of patients who could not tolerate full correction and whose esotropia decreased to within 10 PD with a symmetrical reduction of 1.00 diopters (D) or more than their cycloplegic refractive errors in both eyes. The full correction group (Group 2) consisted of patients who had received spectacles

less than 1.00 D of their cycloplegic refractive errors in both eyes.

Patients were excluded from the study when they had mental retardation and neurological disorder, failed to comply with the orthoptic assessment, suffered from significant inferior oblique hyperfunction (+ 2 and above), dissociative vertical deviation or nystagmus, high accommodative convergence/accommodation ratio, partial RAE, underwent surgery for strabismus or another ocular disorder, and anisometropia > 3 D.

Refraction was evaluated by retinoscopy or the autorefractometer (Topcon KR-8100) 45 min after the instillation of cyclopentolate hydrochloride (cycloplegin 1%, Abdi İbrahim İlaç San ve Tic. AŞ, Turkey) 2 times at 5-min intervals. Refractive errors were calculated as spherical equivalent (spherical error plus half the cylindrical component). Anterior segment was assessed with slit-lamp biomicroscope, and fundus examination was performed with + 90 D indirect lens while the cycloplegic effect continued.

Best corrected visual acuity (BCVA) was determined with the Snellen chart letters or symbols and transformed to the logarithm of the minimum angle of resolution (logMAR) for statistical analysis. Amblyopia was defined as a BCVA less than 0.10 logMAR in one eye along with a difference of two or more rows between the two eyes. Occlusion therapy was recommended for children with amblyopia depending on patient age and amblyopia depth after 3 months wearing glasses, if necessary. Anisometropia was defined as a refractive error of more than 1.00 D between the two eyes.

Eye movements were examined at nine cardinal gaze positions. Deviation was measured in the primary position with and without correction for near (33 cm) and distance (6 m) with prism cover test or Krimsky test. Deviation angle at near fixation was used in data analysis. Binocular vision functions were evaluated using the Titmus and Worth 4-dot tests after hypermetropic correction with glasses. Stereopsis ≥ 100 s/arc and the presence of fusion were accepted as indicating BOV. The onset of deviation was determined by a family member's description. The duration of deviation was calculated as the interval between the onset of deviation and age at first presentation. The initial follow-up was performed at 3 months, and the regular follow-up was generally performed every 6 months.

Statistical analysis of data was carried out with the SPSS (Statistical Package for Scientific Studies, SPSS Inc., Chicago, IL, USA) version 22 statistical package program. Quantitative variables were reported as mean \pm standard deviation and range (minimum to maximum). Qualitative variables were expressed as frequency and percentage (%). The normal distribution of the data was assessed with the Kolmogorov–Smirnov test. The Mann–Whitney *U* test was used in the comparison of two independent groups with respect to quantitative data as the continuous variables were not normally distributed. Categorical data between groups were compared with Pearson Chi-square test. Statistical analysis of dependent quantitative variables within the groups were performed using the nonparametric Wilcoxon signed rank test. Binocular vision changes between the groups were evaluated with the McNemar test. Factors thought to be effective on visual acuity, BOV, refraction and the angle of deviation were evaluated by regression analysis. Variables were examined at the 95% confidence level, and $p < 0.05$ was considered significant.

Results

The 81 RAE cases matching the study criteria revealed by the retrospective review of patient charts were enrolled in the study. The partial correction group (Group 1) consisted of 35 patients, and the full correction group (Group 2) consisted of 46 patients. The patients' demographic characteristics are presented in Table 1.

Table 1 Demographic features of partial (Group 1) and full (Group 2) hypermetropic correction cases

Variables	Group 1 (<i>n</i> = 35)	Group 2 (<i>n</i> = 46)	<i>p</i> value
Female	13 (37%)	25 (54%)	0.124*
Male	22 (63%)	21 (46%)	
Family history	7 (20%)	10 (22%)	0.849*
Age of onset of deviation (year)	2.40 \pm 1.84 (0–7)	1.93 \pm 1.34 (0–6)	0.257**
Age at first admission (year)	5.84 \pm 3.62 (2–13)	6.35 \pm 3.26 (2–13)	0.335**
Duration of deviation (year)	3.44 \pm 4.19 (0–13)	4.42 \pm 3.46 (0.3–13)	0.142**
Follow-up (year)	3.58 \pm 2.82 (1–13.83)	4.34 \pm 3.74 (1–13.67)	0.514**

*Pearson Chi-square test

**Mann–Whitney *U* test

Visual acuity

At the initial examination of the cases, amblyopia was detected in 94% of Group 1 and 80% of Group 2 ($p = 0.103$). At the last examination, amblyopia was detected in 57% of Group 1 and 39% of Group 2 ($p = 0.122$). Baseline mean BCVA was 0.35 ± 0.23 (1.10–0.00) logMAR in Group 1 and 0.20 ± 0.19 (0.80–0.00) logMAR in Group 2 ($p = 0.001$). Final mean visual acuity was 0.11 ± 0.12 (0.52–0.00) logMAR in Group 1 and 0.07 ± 0.10 (0.40–0.00) logMAR in Group 2 ($p = 0.136$). Mean change in visual acuity was 0.24 ± 0.17 (0.70–0.00) logMAR and 0.13 ± 0.16 (0.58–0.05) logMAR in Group 1 and in Group 2, respectively ($p = 0.001$). Regression analysis of the factors effecting the change in visual acuity revealed that the duration of deviation ($p = 0.000$; 95.0% CI 0.013–0.030), the baseline refraction ($p = 0.037$; 95.0% CI 0.001–0.039) and the amount of reduced refraction ($p = 0.008$; 95.0% CI 0.012–0.079) had negative effect on visual acuity, whereas the other variables were insignificant ($p > 0.05$) (Table 2).

Binocular vision

Binocular vision was detected in 2 (6%) cases in Group 1 and in 11 (24%) in Group 2 at the initial examination. The baseline BOV rates were significantly higher in fully corrected Group 2 ($p = 0.027$). These numbers were 19 (54%) in Group 1 and 23 (50%) in Group 2, and no significant differences were detected between the two groups at the final examination ($p = 0.702$). Regression analysis revealed that the duration of deviation and baseline uncorrected deviation had negative effect on BOV with a value of 82.4% ($p = 0.028$; 95.0% CI 0.693–0.979) and 93.7%

Table 2 Factors affecting the increase in visual acuity (logMAR) of the patients with refractive accommodative esotropia

Variables	<i>B</i>	<i>SE</i>	<i>Beta</i>	<i>t</i>	<i>p</i> value	95.0% <i>CI</i>	
Duration of deviation (year)	0.021	0.004	0.521	4.926	0.000*	0.030	0.013
Follow-up (year)	− 0.001	0.006	− 0.021	− 0.189	0.850	− 0.012	0.010
Baseline refraction (D)	0.020	0.010	0.233	2.125	0.037*	0.001	0.039
Amount of reduced refraction (D)	0.046	0.017	0.292	2.709	0.008*	0.012	0.079
Uncorrected baseline deviation (PD)	0.000	0.002	0.011	0.099	0.922	− 0.003	0.003

Bold values were significant ($p < 0.05$)

B unstandardized coefficient, *SE* standard error of the regression coefficient, *Beta* standardized coefficient, *t* statistic test, *CI* confidence interval

*Duration of deviation, baseline refraction, amount of reduced refraction had negative effect on the increase of visual acuity (logMAR)

($p = 0.006$; 95.0% *CI* 0.894–0.982), respectively, whereas the other variables were insignificant ($p > 0.05$) (Table 3).

Refraction

Mean spherical equivalent refraction was $+ 6.21 \pm 1.91$ D ($+ 3.00/+ 10.00$ D) in Group 1 and $+ 4.57 \pm 1.67$ D ($+ 2.25/+ 9.25$ D) in Group 2 at initial examination ($p = 0.001$). The final examination values were $+ 6.12 \pm 1.99$ D ($+ 2.25/+ 9.88$ D) in Group 1 and $+ 4.92 \pm 1.70$ D ($+ 1.50/+ 10.25$ D) in Group 2 ($p = 0.003$). There was no significant difference between the initial and last examination values in Group 1 ($p = 0.295$), whereas a significant increase was determined in Group 2 ($p = 0.002$). Mean change in refraction was $- 0.09 \pm 1.08$ ($- 4.50/+ 1.88$) D and $+ 0.35 \pm 0.76$ ($- 2.13/+ 1.50$) D in Group 1 and in Group 2, respectively

($p = 0.005$). Regression analysis revealed that the duration of deviation ($p = 0.015$; 95.0% *CI* 0.013–0.117), the baseline refraction ($p = 0.014$; 95.0% *CI* 0.027–0.233) and the amount of reduced refraction ($p = 0.033$; 95.0% *CI* 0.016–0.391) had positive effect on the decrease of refraction while other variables showed no significant effect ($p > 0.05$) (Table 4).

Deviation angle

Baseline mean uncorrected deviation at near fixation was 26.23 ± 10.99 PD (12–55 PD) in Group 1 and 33.46 ± 12.53 PD (12–80 PD) in Group 2 ($p = 0.007$) while the mean uncorrected final deviation was 25.49 ± 11.80 PD (8–45 PD) in Group 1 and 30.22 ± 13.89 PD (6–80 PD) in Group 2 ($p = 0.134$). There was no significant decrease in these angles between the initial and final examinations

Table 3 Factors affecting the increase in binocular vision of the patients with refractive accommodative esotropia

Variables	<i>B</i>	<i>SE</i>	<i>Wald</i>	<i>df</i>	<i>p</i> value	<i>Exp (B)</i>	95.0% <i>CI</i>	
Duration of deviation (year)	− 0.194	0.088	4.857	1	0.028*	0.824	0.693	0.979
Follow-up (year)	− 0.075	0.072	1.062	1	0.303	0.928	0.805	1.070
Baseline refraction (D)	0.103	0.118	0.760	1	0.383	1.109	0.879	1.397
Amount of reduced refraction (D)	0.367	0.217	2.873	1	0.090	1.444	0.944	2.208
Uncorrected baseline deviation (PD)	− 0.065	0.024	7.510	1	0.006*	0.937	0.894	0.982

Bold values were significant ($p < 0.05$)

B unstandardized coefficient, *SE* standard error of the regression coefficient, *Wald* statistic test, *df* degree of freedom, *Exp (B)* odds ratio, *CI* confidence interval

*Duration of deviation, uncorrected baseline deviation had negative effect on the increase of binocular vision

Table 4 Factors affecting the decrease in refraction of the patients with refractive accommodative esotropia

Variables	<i>B</i>	<i>SE</i>	<i>Beta</i>	<i>t</i>	<i>p</i> value	95.0% CI	
Duration of deviation (year)	0.065	0.026	0.297	2.512	0.015*	0.013	0.117
Follow-up (year)	0.000	0.031	0.002	0.013	0.989	– 0.060	0.061
Baseline refraction (D)	0.130	0.052	0.272	2.513	0.014*	0.027	0.233
Amount of reduced refraction (D)	0.204	0.094	0.237	2.164	0.033*	0.016	0.391
Uncorrected baseline deviation (PD)	– 0.016	0.008	– 0.210	– 1.909	0.060	– 0.032	0.001

Bold values were significant ($p < 0.05$)

B unstandardized coefficient, *SE* standard error of the regression coefficient, *Beta* standardized coefficient, *t* statistic test, *CI* confidence interval

*Duration of deviation, baseline refraction, amount of reduced refraction had positive effect on the decrease of refraction

of Group 1 ($p = 0.314$), whereas a significant decrease was found in Group 2 ($p = 0.038$). Mean change in deviation was -0.74 ± 7.22 ($-27/+15$) PD and -3.24 ± 10.41 ($-10/+42$) PD in Group 1 and in Group 2, respectively ($p = 0.472$). Regression analysis revealed that the follow-up duration ($p = 0.001$; 95.0% CI 0.398–1.527) and the deviation angle without correction at baseline ($p = 0.023$; 95.0% CI 0.026–0.351) had positive effect on the decrease of deviation whereas the other variables were insignificant ($p > 0.05$) (Table 5).

Discussion

The initial age at which strabismus appears varies between the day after birth and 8.5 years in RAE cases, in which hypermetropic refraction errors are corrected with glasses [2, 6–10]. The lowest age limit in the literature was reported by Guclu et al. [9] and Cho et al. [10], and the upper age limit by Mulvihill

et al. [2]. The rate of a positive family history ranges between 14.3 and 24% [7, 9].

In accordance with the literature, our mean age of onset of strabismus for Group 1 (partial correction) and Group 2 (full correction) was 2.4 and 1.93 years, the lower age limit was immediately after birth and the upper age limit 7 and 6 years, and the rate of positive family history was 20 and 22%, respectively. However, considering that the time of onset of strabismus may be influenced by subjective interpretations of the parents, it is probable that gaze positions were misinterpreted as deviation in the early postpartum period when visual reflexes have not yet developed adequately. The duration of strabismus was much longer than 10.8 months in the study conducted by Uretmen et al. [6] where all cases were from the same geographic region, namely 3.74 years in Group 1 and 4.55 years in Group 2, suggesting that lower socio-cultural and economical level may lead to delayed application to an ophthalmologist.

Table 5 Factors affecting the decrease in deviation of the patients with refractive accommodative esotropia

Variables	<i>B</i>	<i>SE</i>	<i>Beta</i>	<i>t</i>	<i>p</i> value	95.0% CI	
Duration of deviation (year)	– 0.058	0.283	– 0.025	– 0.203	0.840	– 0.624	0.508
Follow-up (year)	0.963	0.284	0.357	3.392	0.001*	0.398	1.527
Baseline refraction (D)	0.205	0.534	0.043	0.384	0.702	– 0.857	1.267
Amount of reduced refraction (D)	– 0.710	0.960	– 0.083	– 0.739	0.462	– 2.620	1.201
Uncorrected baseline deviation (PD)	0.189	0.082	0.252	2.315	0.023*	0.026	0.351

Bold values were significant ($p < 0.05$)

B unstandardized coefficient, *SE* standard error of the regression coefficient, *Beta* standardized coefficient, *t* statistic test, *CI* Confidence interval

*Follow-up duration, uncorrected baseline deviation had positive effect on the decrease of deviation

The most important parameters in strabismus examination are determining the visual acuity and amblyopia so that the age-appropriate treatment for amblyopia can be started. Since the onset of deviation is rather late and easily corrected by glasses in RAE cases, it is suggested that the amblyopia is usually not too deep in these cases and responds well to amblyopia treatment with a normal final visual acuity [2]. The highest rates of amblyopia at the initial and final examinations have been reported as 82 and 23%, respectively, in different studies [2, 6, 7]. As for BCVA at the last follow-up examination, Uretmen et al. [6] found 0.00 logMAR in both eyes in 71.8% of the cases, and Lambert and Lynn [11] reported 0.22 logMAR or better in the right eyes of 90% and in the left eyes of 88% of cases.

There was no statistically significant difference between the groups in terms of the amblyopia rates at the initial and final examinations. We can explain higher levels of amblyopia in our cases by rather the older age of initial examination and the longer duration of strabismus compared to most other studies. Regression analysis revealed that optimal success at desired levels may not be achieved in amblyopia treatment of those children with a delay in treatment and prolonged strabismus, high hypermetropic refractive error and incomplete correction of refractive error. Our mean initial BCVA values were 0.35 logMAR and 0.20 logMAR in Group 1 and Group 2, changing to 0.11 logMAR and 0.07 logMAR, respectively, at least 1-year follow-up which indicated a better visual acuity in full hypermetropic correction as expected. Furthermore, Group 2 patients had significantly lower hypermetropia that could have promoted better visual outcomes.

Strabismus generally occurs during the non-critical period in RAE cases, allowing the development of BOV [2, 8]. A relationship between the age at strabismus onset and duration of strabismus and the development of stereopsis has been reported in some publications with others reporting no such relationship [6, 7]. Fawcett and Birch [8] stated that the duration of strabismus was the most important risk factor for BOV and that abnormal BOV was 4.6 times more common when strabismus was not corrected within 4 months. Berk et al. [7] reported that 24.2% of RAE cases had stereopsis at 100–40 s/arc and 73.5% had fusion with the Worth 4-dot test, but age at onset of strabismus and age of treatment had no effect on the outcome of

stereoacuity. Uretmen et al. [6] reported that 50% of RAE cases had abnormal BOV despite successful optical parallelism and that abnormal BOV levels are caused by a congenital deficit and short-term fixed deviations that distort stereopsis. They concluded that orthotropia did not guarantee BOV.

In this study, the presence of fusion in addition to stereopsis of 100 s/arc and over, which is taken as the basis for BOV, was determined in 6 and 24% at the initial examination while 54 and 50% at the final examination of Group 1 of Group 2 cases, respectively. A negative correlation detected between the duration of strabismus, the baseline deviation angle without glasses and the change in BOV support the other reports demonstrating the importance of early correction in RAE cases regarding BOV development [8, 9, 12]. Because, as pointed out by Wilson et al. [13] the presence of BOV is one of the important factors ensuring the parallelism in eyes of RAE cases as in all strabismus cases.

The visual acuity provided as a result of the refractive correction is considered the main factor controlling the process of emmetropization [14, 15]. Many studies investigating the effects of partial and full correction on emmetropization have indicated a low probability of emmetropization in RAE patients with full hypermetropic correction whereas partial hypermetropic correction could allow emmetropization [10, 14, 16–18]. Yang et al. [19] pointed out that the reduced amount of refraction was the only factor associated with the reduction of hypermetropia and underlined that full correction would inhibit emmetropization. Demirkılınc et al. [20] found no significant difference between the final values of fully and partially corrected RAE cases and argued that reduced hypermetropia might not be important in refractive changes, supporting Ingram et al. [15] who claimed that an inherent problem in these children could disturb the process of emmetropization.

As for within-group analysis, Group 1 cases, where the upper age limit was relatively high, displayed no significant difference for refractive error values between the initial and the final examinations in this study, whereas Group 2 cases displayed significantly increased hypermetropia. In addition, the refraction change of -0.09 D and $+0.35$ D, respectively, in Groups 1 and 2 showed a statistically significant difference. Our regression analysis results show that the duration of deviation is influential in the amount of

refraction along with the baseline high levels of hypermetropia, as pointed out by Park et al. [16] and also that full correction may cause an increase in the refractive error with a possible negative effect on emmetropization, as stated by Yang et al. [19].

In RAE cases, the deviation angles near and distance are similar although the deviation at near fixation is known to be higher [7]. The mean deviations at near and distance were reported as 28.7 PD and 23.2 PD, respectively, by Mulvihill et al. [2] and 34.0 PD and 30.9 PD, respectively, by Cho et al. [10]. In the cases monitored after gradually reducing the refractive error, Lambert et al. [21] demonstrated that the deviation could be controlled without glasses in 60% of the cases with a baseline refractive error of + 1.50 to + 5.00 D. MacEwen et al. [22] noticed that strabismus below 10 PD could be achieved in only half of the cases with RAE who had reductions up to – 2.0 D, and Park et al. [5] emphasized that reduction was safe up to – 1.50 D. Hutcheson et al. [17] stated that the correction may be related to the possible increase in divergence amplitudes. Furthermore, Kim and Kim [23] reported that stereoacuity obtained by early refractive correction, rather than the amount of refraction is important in decreasing and controlling deviation.

In the present study, where cases having partial correction with a mean reduction of – 2.0 D were compared with fully corrected cases with a deviation below 10 PD, we found that the deviation angle at the initial and final examinations was, respectively, 26.23 PD and 25.49 PD for Group 1, 33.46 PD and 30.22 PD for Group 2 with no statistically significant difference between the two groups in terms of the change in deviation at near without glasses. We can explain the reduction in strabismus among the full correction cases with better BOV function, which is a significant factor in ensuring parallelism of the eyes, as pointed out by Wilson et al. [13] and with the less amount of hypermetropia in this group, similar to the cases of Lambert et al. [21]. The relationship between the duration of follow-up, the amount of deviation at baseline and the change in deviation indicates that the patients could control the deviation better over time and that this control was more prominent when the angle of deviation was greater at the beginning.

Our study has a number of limitations. Firstly, it was a retrospective study and we only enrolled subjects who had partially and fully corrected

strabismus within 10 PD. Secondly, stereoacuity examination was not performed using the random-dot stereotest and refraction was determined either by retinoscopy or the autorefractometer. Thirdly, the study has a relatively small sample size which can affect some statistical conclusions and included relatively older children as well. Therefore, further prospective and controlled studies with larger sample sizes evaluating the effects of partial and full correction and the amount of safe undercorrection are needed.

Despite all these limitations, our results show the importance of early treatment and appropriate refractive correction in RAE cases because of the negative influence of the duration of deviation on visual acuity, BOV and refractive change. Although the visual acuity and BOV rates were initially high in fully corrected patients, they finally improved significantly in both fully and partially corrected patients. In addition, while full hypermetropic correction leads to a better visual acuity, it may cause an increase in the refractive error with a possible negative effect on emmetropization.

Compliance with ethical standards

Conflict of interest All authors have no affiliations with or involvement in any organization or entity with any financial interest in the subject matter or materials discussed in this manuscript.

Ethical approval The present study was carried out in accordance with the Helsinki Declaration Principles, after obtaining the approval of the institutional ethics committee.

Informed consent For this type of study, formal consent is not required.

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