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RESEARCH ARTICLE

Anterior and Posterior Segment Manifestations of Pathological Myopia: A Clinical Study from Turkish Aegean Region

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Abstract:

Background and Objective:

Myopia is one of the most prevalent vision conditions caused by a mismatch between the refractive power and axial length of the eyeball. High myopia may have a degenerative disorder, including cornea, sclera, choroid, optic disc, vitreous, macula, and peripheral retina. Although there are few studies regarding clinical features of pathological myopia, especially in the far-eastern countries where myopia is common, but are no comprehensive data in our region. This study was aimed to demonstrate both anterior and posterior ocular segment manifestations of pathological myopia.

Methods:

One hundred forty eyes of 82 patients who met the pathological myopia criteria were enrolled in this prospective study. Measurements of Central Corneal Thickness (CCT), endothelial cell parameters, Anterior Chamber Depth (ACD), Axial Length (AL) and Subfoveal Choroidal Thickness (SFCT) were performed in all patients. Presence of posterior segment pathologies such as peripapillary atrophy, tilted disc, Lacquer's crack, foveoschisis, myopic maculopathy, Choroidal Neovascularization (CNV), and peripheral retinal degeneration was recorded.

Results:

The mean age was 54.1 ± 14.2 years. 43 (52.4%) of the patients were female. One hundred patients (71.4%) were phakic and 40 (28.6%) were pseudophakic. The mean CCT, corneal endothelial cell density, ACD, AL, and SFCT were 548.91 ± 43.44 µm, 2335.89 ± 374.38 cells/mm^2, 3.93 ± 0.79 mm, 28.75 ± 2.20 mm, and 94.56 ± 73.11 µm, respectively. Tilted disc, peripapillary atrophy and posterior staphyloma were detected in 89 (63.6%), 119 (85%) and 78 (55.7%) eyes, respectively. Normal fundus, tessellated fundus, diffuse chorioretinal atrophy, focal chorioretinal atrophy and macular atrophy were seen in 13 (9.3%), 59 (42%), 26 (18.6%), 14 (10%), and 28 (20%) eyes, respectively. Lacquer crack, CNV, and Fuchs spot were observed in 11 (7.9%), 39 (27.9%), and 47 (33.6%) eyes, respectively.

Conclusion:

This study reported clinical characteristics of eyes with pathological myopia in a retina specialty clinic at a tertiary referral center from the Turkish Aegean Region. Pathological myopia may affect both anterior and posterior ocular segments. However, posterior segment manifestations may be associated with lesions that threaten vision. Therefore, periodic follow-up in patients with pathological myopia is critical.

Keywords: Anterior chamber depth, Axial length, Myopic maculopathy, Optical coherence tomography, Pathological myopia, Posterior staphyloma.

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1. INTRODUCTION

Myopia, known as nearsightedness, is one of the most prevalent vision conditions caused by a mismatch between the refractive power and Axial Length (AL) of the eyeball and causes the images to focus in front of the retina [1 - 4]. Myopia separates into two groups called physiological and pathological, according to a degree of diopter (D). Pathologic group, a common eye disorder around the world, has myopia greater than 6.00 D. Prevalence studies indicate that pathological myopia occurs in approximately 12-15% of all myopic population, which corresponds to 2% of the general population. In addition, seventy percent of eyes with

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pathological myopia have a degenerative disorder in various ocular structures such as cornea, sclera, choroid, optic disc, vitreous, macula, and peripheral retina. However, impairments particularly affecting the posterior segment may cause vision impairment or threaten vision [1 - 3].

Although there are few studies regarding clinical features of pathological myopia, especially in the far-eastern countries where myopia is common, but there are no comprehensive data in our region. Therefore, we aimed to demonstrate anterior and posterior ocular segment manifestations in pathological myopic eyes.

2. MATERIALS AND METHODS

This prospective study included patients who met the pathological myopia criteria (refractive error > -6.0 D and AL > 26 mm) admitted to the Ophthalmology Clinic of Bozyaka Training and Research Hospital between January 2017 and June 2017. The study protocol was conducted following the principles of the Declaration of Helsinki and approved by the local ethics committee. An informed consent form was obtained from all included patients.

Patients with prominent corneal and/or lens opacity that could affect the fundus exam were excluded from the study. The detailed ophthalmological examination including auto-refractometer measurement (Canon RK-F1 Auto Ref-Keratometer, Tokyo, Japan), Best-Corrected Visual Acuity (BCVA) test (converted to log MAR), Intraocular Pressure (IOP) measurement with Goldmann applanation tonometer, anterior segment assessment with slit-lamp biomicroscopy, and dilated fundus exam was performed. The detailed fundus examination was performed using 90 D aspheric noncontact lens, Goldmann three-mirror lens and indirect ophthalmoscopy. AL and Anterior Chamber Depth (ACD) measurements were performed with optical biometry (IOL Master 500, Carl Zeiss Meditec, Germany). The specular microscope (CEM-530, NIDEK Co., Ltd., Gamagori, Japan) was used for Endothelial Cell Density (ECD) and Central Corneal Thickness (CCT) measurements. The measurements of a Central Macular Thickness (CMT) and Subfoveal Choroidal Thickness (SFCT) were performed with Spectral-Domain (SD) Optical Coherence Tomography (OCT) (version 1.7.0.0, Heidelberg Engineering, Heidelberg, Germany).

Manifestations of the posterior ocular segment associated with pathologic myopia, such as peripapillary atrophy, myopic maculopathy, and peripheral degenerative disorders, were recorded. Myopic maculopathy was divided into the following five categories; absence of myopic degenerative lesions (category 0), tessellated fundus appearance (category 1), diffuse chorioretinal atrophy (category 2), focal chorioretinal atrophy (category 3), and macular atrophy (category 4). Plus, lesions such as Lacquer cracks, myopic Choroidal Neovascularization (CNV) and Fuchs spot were noted [4]. OCT was used for several macular pathologies such as the presence of CNV, foveoschisis, Macular Hole (MH), Lamellar Hole (LH), and Epiretinal Membrane (ERM). The optic disc tilt ratio was estimated on optic disc photographs. It was calculated by dividing the shortest optic disc diameter into the longest diameter. A tilted optic disc was defined as an index of tilt less than 0.8.

2.1. Statistical Analyses

Statistical analysis was performed using SPSS Version 21.0 statistic software package (SPSS Inc., Chicago, IL). The Kolmogorov-Smirnov test determined normalization for each continuous variable. Data were expressed as means ± Standard Deviation (SD). Comparisons between groups were performed with analysis of the parametric test. A chi-square test was used to compare categorical data. An independent t-test was used for intergroup comparisons for standard distributed continuous variables. One way ANOVA test was used to compare clinical results between the three groups. Correlations between variables were determined using the Pearson correlation coefficient. A value of $p < 0.05$ was considered statistically significant.

3. RESULTS

One hundred forty eyes of 82 patients with high myopia were examined. The mean age was 54.1 ± 14.2 years (range from 19 to 80). Forty-three (52.4%) of the patients were female. One hundred (71.4%) eyes were phakic and 40 (28.6%) were pseudophakic.

A comparison of phakic and pseudophakic groups is shown in Table **1**. There were significant differences for ACD, ECD, and SE between the two groups ($p < 0.05$). In the phakic group analyzes, there was a negative correlation between SE and AL ($p < 0.001$, $r = -0.809$, Pearson correlation analysis). No correlation between AL and ECD ($p = 0.603$, $r = 0.053$, Pearson correlation analysis) was observed. In addition, no correlation was found between AL and CCT in both phakic and pseudophakic groups ($p = 0.962$, $r = 0.005$ and $p = 0.817$, $r = 0.020$, Pearson correlation analysis, respectively). However, a positive correlation was found between the corneal radius of curvature and AL ($p = 0.005$, $r = 0.28$, Pearson correlation analysis).

Table 1. Comparison of the pseudophakic and phakic eyes for anterior segment parameters.

–	Phakic Mean ±SD	Pseudophakic Mean ±SD	Total Mean ±SD	p
Number (%)	100 (71.4)	40 (28.6)	140 (%100)	
CCT (μm)	548.08 ± 45.54	551.0 ± 38.15	548.91 ± 43.44	>0.05
ACD (mm)	3.56 ± 0.38	4.87 ± 0.78	3.93 ± 0.79	**<0.05**
IOP (mmHg)	15.7 ± 3.0	16.8 ± 4.5	16.01 ± 3.6	>0.05

(Table 1) contd.....

–	Phakic Mean ±SD	Pseudophakic Mean ±SD	Total Mean ±SD	p
AL (mm)	28.37 ± 1.98	29.70 ± 2.44	28.75 ± 2.20	>0.05
BCVA (log MAR)	0.73 ± 0.59	0.79 ± 0.68	0.75 ± 0.61	>0.05
SE(D)	-12.01 ± 4.59	1.45 ± 2.43	-9.00 ± 6.29	**<0.05**
Astigmatism (D)	-1.57 ± 1.21	-1.55 ± 1.45	-1.56 ± 1.28	>0.05
ECD (cells/mm^2)	2437.77 ± 286.46	2081.18 ± 445.08	2335.89 ± 374.38	**<0.05**
Coefficient of variation	31.17 ± 6.26	31.30 ± 9.44	31.21 ± 7.27	>0.05
Hexagonal cell ratio	67.25% ± 5.48	69.35% ± 6.58	67.85% ± 5.87	>0.05
Radius of curvature (mm)	7.66 ± 0.29	7.63 ± 0.26	7.66 ± 0.28	>0.05

Abbreviations: CCT, central corneal thickness; ACD, anterior chamber depth; IOP, intraocular pressure; AL, axial length; BCVA, best corrected visual acuity; SE, spherical equivalent; ECD, endothelial cell density.

Eighty-nine eyes (63.6%) had tilted disc. The mean disc tilt ratio was 0.75 ± 0.11 and there was no correlation between AL and disc tilt ratio ($p = 0.068$, $r = -0.155$, Pearson correlation analysis). In addition, no correlation was found between the disc tilt ratio and total astigmatism ($p = 0.938$, $r = -0.008$, Pearson correlation analysis) and corneal radius of curvature ($p = 0.834$, $r = -0.21$, Pearson correlation analysis). Peripapillary atrophy was detected in 119 eyes (85%) and it was more often in the longer AL group ($p < 0.001$, Chi-square test). Seventy-eight eyes had posterior staphyloma which was more frequently in the longer AL group ($p < 0.001$, Chi-square test) (Table **2**). When patients were examined for myopic maculopathy; a total of 68 (48.6%) eyes had myopic maculopathy, which was more common in eyes with longer AL ($p <0.001$, Chi-square test) (Table **3**). C0, C1, C2, C3, and C4 were observed in 13 (9.3%), 59 (42%), 26 (18.6%), 14 (10%), and 28 (20%) eyes, respectively. Plus lesions, including Lacquer crack (11 eyes, 7.9%), CNV (39 eyes, 27.9%), and Fuchs spot (47 eyes, 33.6%) were encountered in 50 (35.7%) eyes (Table **4**). A total of 59 (42.1%) eyes had peripheral retinal degeneration. The incidence of peripheral lesions was more common in eyes with longer AL ($p < 0.001$, Chi-square test) (Table **4**). The most common peripheral degenerative lesions were Lattice degeneration (34 eyes, 24.3%) and retinal tears (9 eyes, 6.4%). The mean CMT was 250.04 ± 68.80 microns. There was no correlation between AL and CMT ($p = 0.389$, $r = 0.073$, Pearson correlation analysis). Mean SFCT was 94.56 ± 73.11 microns (phakic group: 113.77 ± 74.02 microns, pseudophakic group: 46.53 ± 42.77 microns). A negative correlation was found between SFCT and BCVA ($p < 0.001$, $r = -0.499$, Pearson correlation analysis). There was also a negative correlation between AL and SFCT ($p < 0.001$, $r = -0.553$, Pearson correlation analysis). The SFCT was found to be significantly thicker in eyes with CNV and posterior staphyloma ($p < 0.001$). The number of eyes with CNV was found in 39 (27.9%) eyes. Of these, 2 (1.4%) were in the active stage, 26 (18.6%) were in the atrophic stage, and 11 (7.9%) were in the scar stage. According to OCT findings, foveoschisis, MH, LH and ERM were found in 4 (2.9%), 5 (3.6%), 7 (1.4%) and 7 (5%) eyes, respectively.

Table 2. Tilted disc, peripapillary atrophy and posterior staphyloma incidence according to axial length (n = 140).

Axial length (mm)	N	Tilted disc		Peripapillary Atrophy		Posterior Staphyloma	
		n (%)	p value	n (%)	p value	n (%)	p value
26.00- 27.50	47	30(63.8)	0.330*	30(63.8)	<0.001*	9(19.1)	<0.001*
27.51- 29.50	48	27(56.2)		45(93.7)		27(56.2)	
>29.51	45	32(71.1)		44(97.8)		42(93.3)	
Total	140	89(63.6)		119(85.0)		78(55.7)	

*Chi-quare test.

Table 3. Distribution of myopic maculopathy stages according to axial length (n = 140).

Axial Length (mm)	N	Category 0 (C0)		Category 1 (C1)		Category 2 (C2)		Category 3 (C3)		Category 4 (C4)	
		n (%)	p value	n (%)	p value	n (%)	p value	n (%)	p value	n (%)	p value
26.00- 27.50	47	11 (23.4)	Reference	29 (61.7)	0.059*	3 (6.4)	<0.001*	3 (6.4)	<0.002*	1 (2.1)	<0.001*
27.51- 29.50	48	2 (4.2)		23 (47.9)		11 (22.9)		4 (8.3)		8 (16.7)	
>29.51	45	0 (0.0)		7 (15.5)		12 (26.7)		7 (15.5)		19 (42.3)	
Total	140	13 (9.3)		59 (42.1)		26 (18.6)		14 (10.0)		28 (20.0)	

Abbreviations: CO, normal fundus; C1, tesellated fundus; C2, diffuse chorioretinal atrophy; C3, focal chorioretinal atrophy; C4, macular atrophy.

Table 4. Relationship between axial length and presence of myopic maculopathy, plus lesion, and peripheral lesion (n = 140).

Axial length (mm)	N	Myopic maculopathy		Plus lesion		Peripheral lesion	
		n (%)	p value	n (%)	p value	n (%)	p value
26.00- 27.50	47	7 (14.9)	<0.001*	5 (10.6)	<0.001*	11 (23.4)	<0.001*
27.51- 29.50	48	23 (47.9)		15 (31.2)		19 (39.5)	
>29.51	45	38 (84.4)		30 (66.6)		29 (64.4)	
Total	140	68 (48.6)		50 (35.7)		59 (42.1)	

*Chi-quare test.

4. DISCUSSION

In pathologic myopia, which is referred to earlier as malignant or degenerative myopia; the glob progressively extends in the anterior-posterior direction. Secondary changes can occur in the glob due to the mechanical stretching of the eye structures. As a result of these changes, the patients may encounter with visual problems. In this study, we aimed to demonstrate both anterior and posterior ocular segment manifestations at the same time.

4.1. Anterior Segment Considerations

The corneal endothelium is a cell layer that cannot renew itself, has metabolic activity and protects corneal transparency and has a hexagonal structure. The density and morphology of these cells can be assessed by specular microscopy. Some researchers examined changes in this cell layer associated with pathological myopia. Delshad *et al*. [5] reported that there was a significant decrease in ECD and hexagonal structure in high myopic eyes. Similar results were also found by Urban *et al*. [6] and Chang *et al*. [7]. However, we did not find any association between AL and ECD.

CCT can be especially important in myopic eyes in cases where it is necessary, such as follow-up of glaucoma and ocular laser surgery to correct refractive errors. The effects of refractive changes on CCT in myopic patients have demonstrated conflicting results. While some studies [8] have reported no association between CCT and myopia, other studies [7, 8] have been demonstrated increased corneal scarring as myopia progresses. In a study comparing pathologic myopia and emmetropic eyes, no difference was found regarding as CCT between two groups [9]. Pedersen *et al*. [10] compared 57 emmetrops with 48 high myopia patients. They found that there was no correlation between CCT and AL. Similarly, we did not find a significant correlation between AL and CCT. On the other hand, Wang *et al*. [11] reported that CCT was thicker in patients with high myopia.

Previous studies investigating corneal curvature in high myopic patients have reported a positive correlation between corneal curvature and AL, which is similar to our findings [12, 13]. ACD is defined as the distance between the posterior aspect of the cornea and the anterior aspect of the lens and has great importance for phacoemulsification surgery. In myopic eyes, the changes in AL can affect the ACD. Hosny *et al*. [14] stated that there was an important relationship between ACD and AL in healthy eyes. Chung *et al*. [15] found a positive correlation between ACD and AL in mild myopic eyes, but did not observe in high myopic eyes. In contrast with these studies, we did not find any correlation between AL and ACD.

4.2. Posterior Segment Considerations

Several vitreoretinal disorders including vitreous degeneration, posterior vitreous detachment, peripapillary atrophy, lattice degeneration, tilted disc, retinal pigment epithelium (RPE) atrophy, posterior staphyloma, Lacquer cracks and Fuch's spot can be seen in pathological myopia. Chang *et al*. [16] reported that posterior staphyloma (23%), chorioretinal atrophy (19.3%), and lacquer cracks (1.8%) were more common myopia-related macular findings. They also reported that the most common optic disc findings were peripapillary atrophy (81.2%), and tilted disc (57.4%). In contrast with this study, Chen *et al*. [17] showed that the most common myopic maculopathy finding was lacquer cracks (29.1%). Koh *et al*. [18] reported that the most common retinal findings were peripapillary atrophy (98.3%), tilted disc (22%), posterior staphyloma (32%) and chorioretinal atrophy (8.3%). Different studies have been indicated that the frequency of posterior staphyloma, chorioretinal atrophy, CNV and tilted disc were 90.0%, 60.9%, 11.3% and 57.4%, respectively [19 - 21]. Likewise, in our study, the rate of peripapillary atrophy was similar to literature. However, the rate of posterior staphyloma was higher than the previous literature.

Macular degeneration in patients with pathological myopia typically progresses slowly over the years, but the loss of visual acuity may begin earlier than expected. Pathological myopia is the second common cause of secondary CNV. It is usually seen in adult patients younger than 50 years and consists of approximately 62% of CNV cases caused by pathological myopia [22]. Myopic CNV usually appears small circular and grayish color and settles near the macula or optic disc. More than 70% of these lesions are classical type and 65% are subfoveal. However, occult type and pigment epithelial detachment are rarely seen [23]. Fundus fluorescein angiography (FFA) and OCT are complementary ancillary tests in both diagnosis and classification. OCT demonstrates the presence of subretinal fluid in the active phase.

On the other hand, FFA presents hyperfluorescence in early periods but shows leakage in late periods. Myopia-associated CNV rate reported to be 5-11% in different studies [2, 24, 25]. In contrast to previous studies, a higher CNV ratio (27.9%) was found in our research.

As is known, one of the earliest changes in pathological myopia occurs in the choroidal layer. With Enhanced Depth Imaging-OCT (EDI-OCT), choroidal tissue can be displayed more effectively and the changes that may occur can be

interpreted in detailed. In a study conducted by Gupta *et al*. [26] who compared pathological myopia and emmetropic eyes, the SFCT was found significantly thinner in pathological myopic eyes. Similarly, Wang *et al*. [27] reported thinner SFCT in myopic eyes. In subgroup analysis, they also reported that the choroidal thickness in eyes with CNV was thinner than eyes without CNV. [27]. Similarly, in a study conducted by El Matri *et al*. [28], high myopia eyes with and without CNV were compared and the mean SFCT was found to be significantly thinner in the eyes with CNV. In addition, a negative correlation was demonstrated between AL and SFCT. [28] Also, they found that every 1 mm increase in AL, which is corresponding an 8.4 μm decrease in SFCT. However, in another study conducted on 120 eyes, this rate was found as 25.9 μm [29]. Hsu *et al*. [30] reported that the SFCT was thinner in patients with myopic maculopathy than in non-maculopathic patients. Similar to previous studies, we showed thinner SFCT in patients with myopic maculopathy.

The tilted disc is a common finding in myopic population. The optic disc is seen as being tilted and rotated around its axes. It may cause myopia, astigmatism, visual field defect, and colored vision problem. Although the tilted disc is not progressive, it may be misdiagnosed as optic disc edema and glaucoma [31]. Two hypotheses regarding its formation have been proposed. First, it is associated with impaired closure of congenital embryonic optic fissure [31, 32]. Second is that it results from the progressive prolongation of the globe [33]. In a population-based SCORM (Singapore Cohort of Risk Factors for Myopia) study, tilted disc was detected in 37% of eyes. They also reported that eyes with tilted disc had higher myopic and astigmatic, and longer AL [34]. In our study, only high myopia patients were included and the rate of tilted disc was higher than SCORM study (63.6% *vs*. 37%). In addition, no correlation was found among tilted disc and AL, astigmatism and corneal curvature. Similarly, Moghadas *et al*. [35] did not find a difference in biometric parameters between eyes with and without tilted disc in the patients with pathological myopia.

Pathological myopia and prolonged AL are known to be closely related to peripheral retinal degenerations and retinal detachment [36]. Lattice degeneration, pavement degeneration, and white-without-pressure are the most common peripheral retinal degenerations associated with pathological myopia. Burton TC. [37] reported that this risk is increased 200-fold in cases with pathological myopia and lattice degeneration. In a study conducted on patients with asymptomatic pathologic myopia, peripheral retinal lesions were seen in 56.1% of the patients [38]. Similarly, in another study conducted by Cheng *et al*. [39] on pathologic myopia in pediatric patients, this rate was found to be 61.7%. Different studies have stated that the rate of lattice degeneration in pathological myopia varies between 3% and 10.7% [40]. However, this rate was higher in our review (42.1%) and Celorio *et al*'s study [41] (33.0%) than in previous studies. Racial and environmental factors may be responsible for higher rates of the tilted disc, posterior staphyloma, lattice degeneration and CNV in the population with pathological myopia in our region.

Pathological myopia may also lead to many complications such as cataract, Rhegmatogenous Retinal Detachment (RRD), and secondary glaucoma [42 - 44]. The link between cataract formation and high myopia was investigated by the Blue Mountains Eye Study and the Beaver Dam study [43, 44]. In these studies, myopia was associated with posterior polar cataract [43], posterior subcapsular cataract [43] and nuclear cataract [44]. In addition, significant visual field defects were defined in highly myopic eyes [45]. High myopia is known to be a risk factor for RRD and half of the patients with RRD are estimated to be myopia patients [46]. Myopia has also been described in association with systemic disorders such as Marfan, Ehler Danlos, Stickler, and Wagner syndrome and diabetes mellitus (DM) [47, 48]. Several studies have reported the association of Type 2 DM with myopia. In a study conducted by Ganesan *et al*. [48] on patients with Type 2 DM, the prevalence of myopia and high myopia was reported as 19.9% and 1.9%, respectively.

Prevention of the onset of myopia or the progression of low myopia to high myopia is of extreme importance to prevent the ocular complications of myopia. Early detection and treatment of possible ocular complications associated with high myopia are crucial to reducing morbidity. Therefore, patients should be informed in detail about complications associated with high myopia. In addition, the ophthalmologist can advise that patients with high myopia can check their own visual acuity and visual field with the same target in the same distance, and wear protective glasses during the sports. An ophthalmologist may also facilitate the screening with the regular control of intraocular pressure, central and peripheral retina and optic nerve. Furthermore, detailed fundus examination before cataract or refractive surgery is of great importance in these patients. Treatment of risky lesions before surgery may prevent postoperative complications and legally protect the physician.

This study has several limitations. First, our study design was cross-sectional and we could only present our observations. However, we could not document the progression of the lesions. Second, our study had limited statistical power to detect small differences due to the relatively small sample size. Third, we did not include the control group in the study. Therefore, we could not compare the parameters such as AL, CCT, ECD, ACD, and CMT between myopic eyes and non-myopic eyes. Fourth, the calculation of average SFCT was carried out manually due to the lack of automatic software. The objective automated measurements were better to yield convincing results and conclusions. However, we were measured the SFCT by two independently two blinded clinicians to remove the bias. Finally, the adult-based design may not be truly representative of the entire population.

CONCLUSION

In conclusion, our study clearly shows that pathological myopia may affect both anterior and posterior ocular segments. However, posterior ocular segment changes are the most important cause of vision loss in high myopic patients. Therefore, patients should be informed about the potential risks associated with myopia. In addition, periodic follow-up is essential for both the early diagnosis and treatment of possible asymptomatic ocular findings. This Turkish community-based

study has reported the clinical characteristics of patients with pathological myopia and compared with the previous studies. We consider that the data may be useful in assessing the global or local status of pathological myopia.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The ethics committee of the Center of Ophthalmology approved the study.

HUMAN AND ANIMAL RIGHTS

No animals were used in this research. All human research procedures followed were in accordance with the ethical standards of the committee responsible for human experimentation (institutional and national), and with the Helsinki Declaration of 1975, as revised in 2013.

CONSENT FOR PUBLICATION

An informed written consent was obtained from all the patients when they were enrolled.

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None.

CONFLICT OF INTEREST

The authors declare no conflict of interest, financial or otherwise.

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