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The diagnostic accuracy of the IFLIP system for binocular visual function anomalies assessment

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Abstract. – OBJECTIVE: This study aimed to evaluate the diagnostic accuracy of the intelligent flipper (IFLIP) system in identifying binocular vision anomalies.

PATIENTS AND METHODS: This study comprised 70 participants aged 18 to 22. Participants underwent comprehensive eye assessments, including measurement of visual acuity, refraction, far and near cover test, stereopsis, and worth four dot test. The manual accommodation amplitude and facility, as well as the IFLIP system test, were also evaluated. The correlation between the indices of the IFLIP and manual accommodation tests was analyzed using multiple regression models, and the diagnostic ability of the IFLIP was characterized using Receiver Operating Curve (ROC) analysis. The significance level was 0.05.

RESULTS: The mean age of the 70 participants was 20.03±0.78 years. The mean manual and IFLIP accommodation facilities were 12.00±3.70 cycle per minute (CPM) and 10.01±2.77 CPM, respectively. No correlation was found between the indices of the IFLIP system and manual accommodative amplitude. However, the regression model showed that the contraction/relaxation ratio of the IFLIP system was positively correlated to the manual accommodation facility, and the average contraction time was negatively correlated with the manual accommodation facility. The ROC analysis proposed a cut-off of 10.15 CPM monocularly for the IFLIP accommodation facility assessment.

CONCLUSIONS: This study indicated that the parameters obtained by the IFLIP system and the manual accommodation facility were comparable, and the IFLIP system had good sensitivity and specificity in the assessment of the accommodation facility, thus may serve as a promising tool for screening and diagnosis of binocular visual function anomalies in clinical and community settings.

Key Words:
Accommodation facility, Binocular visual function anomalies, IFLIP system, Computer-based, Average contraction time, Average relaxation time.

Introduction

Binocular visual function anomalies are disorders affecting visual performance, particularly in near-task situations. Numerous studies[1-5] have indicated that binocular visual function anomalies are prevalent in young populations from various countries, including China. Among the binocular visual function anomalies, accommodative dysfunction was the most pervasive disorder[5]. In accommodation, the eye changes the refractive power to see clearly and comfortably from various distances[6]. The mechanism of accommodation involves the contraction or relaxation of the ciliary muscle, which modulates the curvature of the crystalline lens, leading to changes in its refractive power. As a result, when accommodation is contracted, objects at close distances can be visualized with greater clarity, while objects at greater distances can be more easily seen in a relaxed state of accommodation. Accommodation could be disrupted in many ways. These disruptions are categorized as accommodative insufficiency, accommodative excess, accommodative infacility, and ill-sustained accommodation[7]. Accommodative insufficiency is the most widely observed type of accommodative dysfunction.

Subjects with binocular visual function anomalies may present symptoms such as blurred vision, diplopia, watering, and headache, leading to a decline in academic performance in young populations[8]. These anomalies have also been shown to be closely associated with various ocular disorders, including anisometropia, amblyopia, strabismus, ocular fatigue, and presbyopia. Given the high incidence and negative impact of binocular visual function anomalies, it is essential to incorporate assessment for these anomalies as a standard component in both optometric clinical settings and community-based evaluations. The

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accommodation facility and amplitude can be assessed monocularly in evaluating binocular visual function anomalies. Previous research[9] suggested a positive correlation between the accommodation facility and accommodative amplitude and a negative correlation between the accommodation facility and negative relative accommodation. The correlation may highlight the significance of accommodation facility as an indirect indicator of other binocular visual function anomalies indices. Despite its importance, traditional manual methods of assessing the accommodation facility can be inconvenient and challenging to implement in routine optometric clinics or community screenings[10]. With the advent of digital and telecommunication technologies in eye care, there have been various applications of digital devices for measuring anatomical dimensions of the eye, automatically grading retinal diseases, and monitoring ocular diseases[11]. However, similar applications in evaluating binocular visual function anomalies have been limited. To our knowledge, only one study reported using a computer-based apparatus named "train your eyes" (TrYE) to detect binocular visual function anomalies[12].

In this study, we introduced the IFLIP system to assess binocular visual function anomalies. Our objective was to investigate the correlation between the indices of the IFLIP and the parameters of manual visual function tests, as well as to assess the diagnostic accuracy of the IFLIP system. Through this analysis, we aimed to determine the potential for applying the IFLIP system in clinical and community settings.

Patients and Methods

Study Object

This study was conducted between May 2022 and December 2022. It was approved by the ethics committee of Chong Qing Medical and Pharmaceutical College, and it adhered to the tenets of the Declaration of Helsinki. All examinations took place at the Medical Technology Department of the college. The subjects were tested in a room with the illumination maintained at 300-800 LUX (Mini light meter UT383, UNI-T Inc., DongWan, Guangdong, China).

Subjects aged 18-22 years (20.03±0.78 years) were recruited by advertisement from Chong Qing Medical and Pharmaceutical College students. The exclusion criteria included best-corrected or uncorrected visual acuity less than 20/20, strabismus, amblyopia or any other diseases affecting accommodation and binocular vision, surgery, medications usage, stereopsis less than 400s/arc, failure in the Worth Four dot experiment, failed in either +2.00 D or -2.00 D lens of manual accommodation facility test, and no informed written consent.

A sample size of 70 subjects was included according to the primary measurement, considering 80% sensitivity and 10% precision[13].

Conventional Manual Visual Function Test

All subjects underwent a preliminary eye examination by well-trained optometrists: demographic data, best-corrected acuity at distance and near to determine whether amblyopia was, cover test at far and near to exclude strabismus, non-cycloplegic objective and subjective refraction, stereo acuity tests using the Random Dot stereo test (Vision Assessment Corp., Elk Grove Village, IL, USA), and Worth 4 dot test to exclude suppression.

The accommodative amplitude was examined by push-away test three times, and the mean of three trials was further analyzed. The subject was required to report sustained blurriness as a near vision chart was moved away from (2 cm/second) the eye. The inverse of distance (m) was calculated as the accommodative amplitude. A ±2.00 D manual flipper was applied to assess the accommodation facility while using the 20/30 letters at a distance of 40 cm as the fixation target. The accommodation facility was measured as cycles per minute (CPM). This study considered a monocular accommodation facility score of less than 11 CPM a "failure"[14].

The IFLIP Visual Function Test

In the IFLIP system (NengNeng Technology Corp., Sha Pingba District, Chongqing, China), an automated flipper and a tablet computer with a touch-screen interface would be connected by Bluetooth. The reading targets were displayed on the screen (10.1-inch, 1,920x1,200 pixels resolution), and the screen's luminance was kept constant and adjusted to 300-500 cd/m^2. All subjects were seated 40 cm before the screen during the test session. The subjects were required to view the 20/30 letter targets on the IFLIP screen through an automated flipper's lens (±2.00 D). Upon naming the character's direction, the subject pressed the control button on the handle of the automatic flipper, which caused the lens-well

plane of the flipper and the symbols on the screen to switch synchronously. The IFLIP system typically took a few cycles, not exceeding 6, to obtain the test results for a single session. Upon completion, the test results, including the average contraction time (the response time while reading after minus lenses), the average relaxation time (the response time while reading after plus lenses), the contraction/relaxation ratio (average contraction time divided by average relaxation time), and the accommodation facility calculated by computer-based algorithms would be displayed on the screen.

Statistical Analysis

The IFLIP and the conventional test results were analyzed with SPSS version 24.0 (IBM Corp., Armonk, NY, USA). The descriptive statistics of clinical measures were presented as the mean ± standard deviation (SD). Shapiro Wilk test was used for the normality test. The accommodation facility results were compared between the manual test and the IFLIP test by the Paired-sample *t*-test. Spearman's correlation was applied to explore the relationship between the indices of the IFLIP and conventional accommodative parameters. Multiple Linear Regression was operated for the relevant variables. ROC curves were plotted for the monocular accommodation facility of the IFLIP system. The $p<0.05$ was considered significant for all the tests. Considering the high correlation between the eyes, only data from the right eye were analyzed in this study.

Results

Demographic Characteristics

In all, 70 students with their consent were included, out of which the mean age was 20.03±0.09 years (the median age was 20 years). The sample comprises 12 (17.1%) males and 58 (82.9%) females. There were no significant differences ($p=0.332$) in gender. Therefore, the data were pooled (Table I).

The Shapiro-Wilk test showed that the average contraction and relaxation times data distribution with the IFLIP system assessments were nonnormal ($p<0.001$). The Paired Sample *t*-test showed a significant difference between manual accommodation facility assessments and the IFLIP system assessments ($p<0.001$) in the accommodation facility. The accommodation facility of the IFLIP system assessments (10.01±2.77 CPM) was significantly worse than Conventional manual assessments (12.00±3.70 CPM). In this study, the average relaxation time was longer than the average contraction time (Median: 3.31 fs *vs.* 2.64 s; Mean±SD: 3.75±1.79 *vs.* 2.79±0.70), which corresponded to the contraction/relaxation ratio of the IFLIP (0.85±0.29).

Association Between the Indices from the IFLIP System and Conventional Accommodative Parameters

Given that the time data with the IFLIP were nonnormal, Spearman's correlation test was used to analyze correlations between the indices of the manual accommodative assessment and the IFLIP test. Spearman's correlation test showed significant correlations between the indices from the IFLIP system and conventional manual accommodation facility except for accommodative amplitude (Table II). The manual accommodation facility was positively correlated with the accommodation facility of the IFLIP ($r_s=0.738$, $p<0.001$) and the contraction/relaxation ratio ($r_s=0.611$, $p<0.001$). Meanwhile, the manual accommodation facility was negatively correlated with the average contraction time ($r_s=-0.331$, $p=0.005$) and the average relaxation time ($r_s=-0.750$, $p<0.001$).

Furthermore, the parameters of the IFLIP, which were highly correlated to the manual ac-

Table I. Descriptive statistics of clinical measures.

Clinical measures (right eye)	Mean ± SD	Skew	Normality test
Accommodation Facility (manual) (cycle per minute)	12.00 ± 3.70	0.08	$p = 0.551$
The mean amplitude of accommodation (D)	13.39 ± 2.45	0.59	$p = 0.067$
Accommodation Facility (IFLIP) (cycle per minute)	10.01 ± 2.77	0.02	$p = 0.230$
The average contraction time (IFLIP) (second)	2.79 ± 0.70	1.58	$p < 0.001$*
The average relaxation time (IFLIP) (second)	3.75 ± 1.79	1.54	$p < 0.001$*
The contraction/relaxation ratio (IFLIP)	0.85 ± 0.29	0.20	$p = 0.384$

*$p < 0.05$.

Table II. Correlations between the indices of the IFLIP system and monocular accommodative parameters.

Clinical measures (right eye)	Accommodation facility (the IFLIP system)		The average contraction time (the IFLIP system)		The average relaxation time (the IFLIP system)		The contraction/ relaxation ratio (the IFLIP system)	
	r_s	*p*	r_s	*p*	r_s	*p*	r_s	*p*
Accommodation facility (manual)	0.738	< 0.001*	-0.331	0.005*	-0.750	< 0.001*	0.611	< 0.001*
The mean amplitude of accommodation (D)	-0.139	0.250	0.079	0.517	0.121	0.320	-0.110	0.364

*$p < 0.05$; r_s: Spearman coefficient.

commodation facility, were analyzed in a multiple linear regression model. In this model, the manual accommodation facility was correlated with the contraction/relaxation ratio (B=8.543, p=0.003). Meanwhile, the manual accommodation facility had a significant association with the average contraction time, such that each 1-unit decrease in the average contraction time increased the manual accommodation facility by 2.629 units (Table III).

ROC Curve for Sensitivity and Specificity for the IFLIP System in Accommodation Facility Assessment

In our study, we employed the diagnostic categorization of "fail" or "pass" based on conventional manual assessment for the monocular accommodation facility test[14]. Out of 70 subjects, 27 (38.57%) were determined to have failed the test with less than 11 CPM monocular. An area under the curve (AUC) of 0.882 (p<0.001) in the ROC analysis indicated that the IFLIP system had a high level of accuracy for the monocular accommodation facility test. The cut-off point for determining a failure in the test was determined to be 10.15 CPM using the IFLIP system (Figure 1).

Discussion

The conventional manual assessment of the accommodation facility was troublesome and time-consuming for many children. The procedure is prone to various sources of variability, including inter-subject differences in reaction time, inconsistencies in the flipper placement, and subjectivity in the tester's criteria for evaluating and recording results. The IFLIP system offers a solution to these challenges by automating the flipping process, thereby reducing the impact of individual differences in hand-eye coordination. Additionally, the system standardizes the test procedure by fixing the distance between the lenses of the automated flipper and the front surface of the cornea or glasses plane, thereby reducing measurement error. The objective calculation of results through computer algorithms further enhances the validity of the test results. In a single test, the IFLIP system can display the results on the screen in seconds, typically within 1 minute. It represents a significant time saving compared to the conventional method, which can take a minimum of 1 minute per test. Using computer software (TrYE) for visual functions has also been demonstrated to be time-saving in the literature. Our study observed that the IFLIP

Table III. The IFLIP system's accommodative indices were associated with the manual accommodation facility in the Multiple Linear Regression Model

Clinical measures (right eye)	Unstandardized coefficients (B)	Standardized coefficients (Beta)	*p*-value
Accommodation Facility (Manual)			
The contraction/relaxation ratio (the IFLIP system)	8.543	0.685	0.003*
The average contraction time (the IFLIP system)	-2.629	0.856	0.003*
The average relaxation time (the IFLIP system)	0.107	0.510	0.835

*$p < 0.05$.

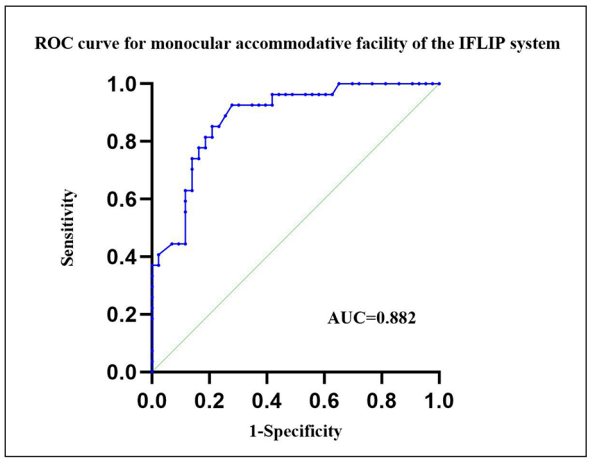

Figure 1. ROC analysis for monocular accommodation facility.

system produced a lower average accommodation facility (10.01±2.77 CPM) than the conventional assessment (12.00±3.70 CPM).

Similarly, the monocular accommodation facility median based on computer software (TrYE) was lower than that of manual assessment (2CPM *vs.* 6CPM). Two possible factors can explain the observed discrepancy. Firstly, using the IFLIP system may have minimized the likelihood of personal measurement errors during manual assessments. Secondly, the accommodation facility may increase with testing time. The IFLIP system, which typically requires less than one minute per test session, may have shortened the testing time, resulting in lower accommodation facility values in this study.

The results of the IFLIP system will be promptly displayed upon completion of the test with new parameters. Our study found a strong correlation between the manual accommodation facility and various parameters of the IFLIP system, including the accommodation facility, the average contraction time, the average relaxation time, and the contraction/relaxation ratio. The accommodation facility is a parameter for evaluating the stamina and dynamics of the accommodative response. It has been observed that a shorter average contraction (relaxation) time is associated with a higher accommodation facility, which may explain the negative correlation found between the manual accommodation facility and the average contraction (relaxation) time. Our Multiple Linear Regression Model findings also supported the observed relationship between the manual accommodation facility and the average contraction time. The results suggested that the accommodation facility might be more sensitive to the average contraction time in young individuals. The correlation analysis indicated that an increase in the manual accommodation facility was associated with an increase in the accommodation facility and the contraction/relaxation ratio of the IFLIP system. The positive relationship between the manual accommodation facility and the contraction/relaxation ratio of the IFLIP system was also confirmed in the Multiple Linear Regression Model, implying that a higher contraction/relaxation ratio of the IFLIP system is correlated with a higher accommodation facility in young populations. The highly correlated relationship between the parameters of the IFLIP and the manual assessment indicated that the IFLIP system might be a potential tool with new assessment parameters for binocular visual function anomalies instead of the manual accommodation facility test.

It should be noted that the median of the average relaxation time was higher than that of the average contraction time, and the Mean±SD of the contraction/relaxation ratio of the IFLIP was 0.85±0.29. It means that most subjects gained more relaxation time than average contraction time, so the accommodation imbalance, especially unrelaxed accommodation, would be one hidden issue for the young population. The new assessment parameters of the IFLIP may disclose visual function anomalies in other ways.

Otherwise, decreased accommodation amplitude with age would cause reduced accommodative facility, according to previous studies[15-17]. However, all the indices of the IFLIP system were not correlated to the mean accommodation amplitude in our study. That may be because we adopted a young population as the study cohort, and the distribution of the accommodative amplitude of this study group was normal and centered (18D-22D). Therefore, we could not find a similar relationship in this study.

The ROC curve analysis in this study showed good sensitivity and specificity for the accommodation facility (AUC=0.882, $p<0.001$), the cut-off point for the monocular accommodation facility test of the IFLIP was about 10 CPM which was approached to 11 CPM in manual accommodation facility assessment. In the study of computer-based software (TrYE), 3.5 CPM was the cut-off point for the monocular accommodation facility, which was significantly smaller than 11 CPM in the manual accommodation facility

assessment. However, the test reliability of the TrYE was not disclosed during the study, and the AUC of TrYE was lower than that of IFLIP in our study (0.794 *vs.* 0.882). The study shows that the IFLIP system can test accommodation facilities, which can be tried as a screening tool for binocular visual function anomalies[18-20]. In addition to the accommodation facility test, the IFLIP system can be used for vision therapy to address binocular vision function anomalies. The IFLIP system generates data that can be uploaded to a cloud database, making it an ideal solution in today's fast-paced society, where there is limited time available for clinic visits. The IFLIP system has the potential to facilitate remote assessment and monitoring, providing greater convenience for patients and practitioners[21,22].

Limitations

There were also limitations in this study. Firstly, the study population consisted of students within a specific age range. All individuals had normal accommodative amplitude, which may explain the absence of a statistical correlation between the monocular accommodative amplitude and the facility. The second limitation is the small sample size; the average contraction (relaxation) time was not equally distributed. The third limitation is that the relationship between the indices of the IFLIP and parameters of binocular visual function such as Negative relative accommodation, Positive relative accommodation, accommodative response, accommodative convergence to accommodation (AC/A) ratio, phoria, convergence amplitude, fusional vergence, and vergence facility were not discussed in the present study[21]. It is necessary to examine the relationship between the indices of the IFLIP system and various binocular vision parameters in more extensive, diverse populations, including children and adults over 35 (the onset of early-onset presbyopia)[22]. Further research will bring a more comprehensive understanding of the clinical applications of the IFLIP system.

Conclusions

In this study, we presented an IFLIP system for binocular visual function anomalies assessment. Its indices were highly correlated with that of the conventional accommodation facility assessments. The IFLIP system also displayed excellent sensitivity and specificity in assessing binocular visual function anomalies. Based on these results, the IFLIP system has the potential to serve as an effective screening and diagnostic tool for binocular visual function anomalies.

Conflict of Interest

The Authors declare that they have no conflict of interests.

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Ethics Approval

All tests in this study followed the ethical standards of Chongqing Medical and Pharmaceutical College (Approval No. KYLLSC20220528049) and the Helsinki Declaration.

Informed Consent

All the subjects recruited in the study were required to give informed consent.

Availability of Data and Materials

The data supporting this study's findings are available from the corresponding author (Jingying Wang) upon reasonable request.

Authors' Contribution

Jingying Wang designed the study and wrote the manuscript, Xiaorong Chen performed the relevant clinical measures, Shan Peng did the collection the data, and Ling Zhu analyzed the data.

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