For Objective 3: Good Health and Well-Being
Eye Health Management

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Abstract

The "Specially Invited Major Report on Global Eye Health" published by The Lancet Global Health pointed out that 1.1 billion people have untreated vision impairment by 2020, this number will be increased to 1.8 billion in 2050. The incidence of vision abnormalities in China is rapidly expanding and tends to be younger. Vision problems seriously affect the healthy growth of children and adolescents, which have become a public health issue of increasing concern. According to the results of a joint survey conducted by the Ministry of Education and the Ministry of Health, the incidence of myopia in China exceeds 60%, ranking first in the world, which is a threat to the health of children and adolescents as well as the sustainability of social-economic development. Refractive error is the main cause of abnormal vision development in preschool children, it is also the most common cause of amblyopia and strabismus in children. This study will explore an efficient and convenient method of ophthalmology public health screening through cross-sectional screening of vision and refractive status for children and adolescents in China. For Kaleidos, a portable optometry device, the refractive status of adolescents and children will be tested, and the influencing factors by parents will be surveyed, obtain the original test data. To compare with the diagnosis of the medical optometrist and the screening results (gold standard), analyze the reliability and validity of the Kaleidos screening results to determine whether Kaleidos can correctly classify the tested population into the corresponding myopia category, the unconditional Logistic regression model is used to conduct a binary multi-factor analysis of related influencing factors after stepwise regression, the main influencing factors were screened out, and the correlation with the prevalence was analyzed. Accurate vision test data will help the World Health Organization and domestic health agencies to allocate the limited health resources when formulating effectively and reasonably eye health hygiene strategies. The research results can also be used as the basis for the evaluation of Kaleidos screening results, which can provide information on the reliability and validity of the optometry equipment for the field of eye health and blindness prevention, and provide a new screening method for eye health management in China. If the problem of preventable early vision loss in adolescents is solved, it will play an important role in realizing the Sustainable Development Goals (SDGs203) of China and the United Nations as a whole.

Keywords: Opthalmic public health, refractive errors, screening modalities, screening tools

Introduction

Myopia Screening Models Globally

Globally, more than 253 million people are visually impaired, among them, 217 million have moderate to severe vision impairment and 36 million are blind. Up to 81% of people who are blind or have moderate or severe vision impairment are aged 50 years and above [1] . More than 90% of the world's visually impaired people live in low- and middle-income countries. Except in the most developed countries, cataract remains the leading cause of blindness[2]. The prevalence of eye disease has increased steadily from 1990 to 2015, a trend which will continue at least until 2020. Vision loss is recognized as the third-most common impairment worldwide. The productivity loss due to visual impairment and the direct expense on education and recovery has been a huge burden on families, communities and the society. It has been estimated the global economic productivity loss for vision impairment would be reached to $110 billion in 2020 without any intervention.

In 1999, WHO and IAPB initiated Vision 2020—Right to Sight, aimed at alleviating avoidable blindness by 2020, in which many NGOs, professional institutions and eye care organizations have participated. The mission of Vision 2020 is to eliminate the key causes of avoidable blindness by promoting the design, development and implementation of sustainable national-level eye care programs by the end of 2020. The three core strategies of Vision 2020 are disease control in combination with primary health care; human resources development; and deployment of infrastructure and appropriate technology. The inclusion of equitable, sustainable and comprehensive models of eye care within national health care systems is considered as the best way to realize the goals of Vision 2020.

When we can prevent a disease, we should use effective methods to prevent it, which is the primary prevention of the disease. When a disease is not yet preventable, we should detect it and treat it early, which is the main content of secondary prevention. Disease screening refers to the systematic application of some tests, examinations, or other measures in a group of people to identify some asymptomatic, undetected patients who may have a certain disease, suspicious people, or people with a high risk of developing such a disease, which is an important method to detect. The main goals of epidemiological research are controlling the occurrence and prevalence of disease and reducing disability and death, and disease screening is also intended to achieve such goals. Performing disease screening is part of epidemiological studies of diseases and can determine the occurrence or natural course of some diseases. Disease screening allows early detection of patients for early diagnosis and early treatment. Through disease screening, it is possible to identify people at high risk of suffering from certain diseases and take measures to prevent diseases from an etiological point of view as early as possible. After early detection of the disease, follow-ups can be conducted to understand the natural history of the disease in the population or to take treatment measures and observe the efficacy.

Refractive error is an important visual problem in children, and there is a necessity and importance for screening. Many developed countries have established routine visual acuity and refractive error screening policies, both as part of the government health service system and as a separate operation for commercial purposes. In Sweden, vision screening is mandatory for preschool children and is repeated at ages 7 and 10 years. The European Association for Myopia Research has been established. It includes a working network that aims to combine the resources and insights of dozens of experts from seven European countries to develop regulations and policies that can be used to control the increasing development of myopia in children[1]. The American Association for Pediatric Ophthalmology and Strabismus (AAPOS) advocates screening children for visual impairment and refractive error. They encourage trained volunteers and optometrists to perform screenings and recommend pediatric ophthalmology professionals to manage pediatric eye diseases. At the 2005 AAPOS Annual Meeting, a workshop explored the topic of working intensely to make screenings for childhood vision and refractive errors mandatory in every state. In the United States, a system of childhood eye screening has been established, with specific programs and measures varying by state, such as in Ohio, where children receive biennial eye screenings in kindergarten. In the UK, although in those areas where screening for childhood eye disease is important, every student has the opportunity to receive a vision screening at school, mass screening of vision and refraction has been declining in some regions. Some scholars are skeptical about the effectiveness of screening, and one study analyzed the effect of screening after it was discontinued and found that most of the vision loss found with screening was mild. Many children with eye disease had already received treatments when they were screened [2].

Although vision screening programs have been introduced to developing countries, most children still do not receive eye examinations. They usually have little access to health services, especially in rural areas. School vision screening is becoming more common in India, especially in urban areas [3]. Despite the high prevalence of myopia, many Southeast Asian countries other than India have not established appropriate screening measures for refractive error and vision in children.

Although the visual acuity scale method is widely used as a visual acuity screening tool, the development of screening thresholds has not been fully standardized. In China, naked distance visual acuity has long been used as a monitoring indicator. However, there are certain defects in naked distance visual acuity as a monitoring indicator because it is not only affected by eye refraction but also by eye nerve adjustment ability and is related to individual mental and psychological factors. Therefore, the weak distance vision is often not equivalent to myopic refraction, and the severity of visual refraction cannot be estimated based on nor can it be based on the degree of vision loss. There is a large body of research literature on low visual acuity in primary and secondary school students in China, but there is little conferment in survey methods. Moreover, the survey methods are not uniform, and the results are poorly comparable [4-5]. Currently, there is no standardized screening system for childhood eye diseases in China. In the southern urban areas of China, 9.6% of children aged 5-15 years old have correctable visual acuity loss, 95% of which is due to uncorrected refractive errors. Although ciliary muscle paralysis detection shadowing is the basis for clinical diagnosis of refractive error and prescription of wear lenses, it is a time-consuming and interventional examination method that is not suitable for mass level screening [6]. Computerized automated optometry is small, light, portable, and quick to operate, which is suitable for screening at the large-scale population level. Screening children's refractive errors with this computerized automated optometry aligns with the screening principles of simplicity, speed, and ease of acceptance. Domestic and foreign scholars have also studied the evaluation of the accuracy of computerized automated optometry. Pesudovs et al. compared the consistency of two automated optometry devices, NIDEKARF.700A and TOPCONKR-8000, with subjective optometry and found that the difference was not statistically significant. Allen et al. applied NIDEKARF.600A to compare the repeatability of the refractive state of healthy adult eyes with subjective optometry and found that the NIDEKAR series of optometers had good repeatability and high consistency with subjective optometry [7]. Cordonmer et al. screened 897 children for high myopia using a Retinomax handheld automated optometer with a non-ciliary muscle paralysis method. The results showed that using +1.5 D as the positive diagnostic threshold yielded good specificity (94.6%), sensitivity (70.2%), and positive predictive value (78.6%) [8]. They concluded that non-ciliary muscle paralysis automated optometry for refraction is an effective and feasible method for screening children for hyperopia, provided that the positive threshold for screening is adjusted accordingly. Several studies have reported that students with abnormal visual acuity are about twice as likely to be recommended for further testing with glasses compared to those without glasses. This result further suggests that students who wear glasses should also participate in vision screening at school [9]. The key point of successful correction of childhood eye disease is early detection and early treatment to avoid missing the critical period of visual development. Therefore, screening is undoubtedly an essential tool for the early detection of refractive errors [10]. Nicola et al. found that if screening is for detection and treatment of amblyopia, the target population should focus on preschool children; if screening is for detection and correction of refractive errors, a more appropriate screening program is for optometrists to screen school-age children. Myopia is most likely to occur and develop during elementary school, especially at 8 to 12 years. Therefore, screening at this age is considered necessary [11].

Human Resources for Myopia Screening in Low Resource Settings

Compared with health supervision, disease prevention and control, etc, there are large differences in the number, educational background and age of grassroots vision screening practitioners in rural China. The overall grass-roots vision screening team has the phenomenon of "two lows and one high", that is, low educational background, low professional title, high age, and lack of professional talents. Personnel engaged in primary vision screening should not only possess certain professional abilities, but also have practical experience. Most of the staff engaged in vision screening at the grass-roots level are those who do not have clinical practice skills or whose qualifications do not meet the requirements of practice.

Current Situation Regarding Myopia Screening in China

According to statistics, the annual loss of GDP due to refractive errors in the world can reach 202 billion US dollars [12]. The world still needs a large number of optometrists and optometry technicians to meet the untreated refractive problems worldwide. The prevention and control of abnormal vision in children and adolescents has become a destiny issue related to national rejuvenation and the future of the country, a crisis issue related to national physical health, and a public issue that the people expect. In August 2018, the Ministry of Education and other eight departments jointly researched and formulated the implementation plan for the comprehensive prevention and control of children's myopia, and the "Comprehensive Prevention and Control of Myopia in Children and Adolescents Implementation Plan" was issued. Among the goals of the plan, our country is required to control the myopia rate of 6-year-old children to about 3% by 2030, and requires medical and health institutions to establish children's vision health care files, strictly implement the national basic health service requirements for eye care and vision examinations for children aged 0-6, realize early monitoring, early detection, and early treatment, and achieve annual coverage of eye care and vision examinations rate exceeds 90% for children aged 0-6 in our country by 2019 [13]. The United States Preventive Services Task Force (USPSTF) also requires all children to undergo at least one vision screening between the ages of 3 and 5 [14]. Traditionally, the commonly used refraction methods in China are retinoscopy after cycloplegia and automatic refractometers on desktop computers (such as Topcon, Nidek, etc.). In the process of pediatric ophthalmology examination, the cooperation of children is very important. Many clinical examinations often fail because children do not cooperate, which may delay the diagnosis and treatment of some children with amblyopia. Among the traditional methods of refraction examination, retinoscopy is time-consuming and requires high levels of cooperation for children and professional skills of examiners. It is difficult for those without professional training to master in a short period of time. The Topcon computer refractometer also requires the good cooperation of children to obtain relatively stable and accurate results. In addition, the desktop refractor is large in size and difficult to transport. It requires a special examination room, which is inconvenient and not suitable for extensive, large-area refractive screening. An ideal screening model for children at high risk of amblyopia should be able to screen children who may have high risk factors for amblyopia from children with low vision through rapid testing, examination or other measures [15]. At present, various types of vision screeners are constantly on the rise. Because of their simple inspection methods, no need for mydriasis, and high reliability of results, they have been widely used around the world [16-18]; The screening instrument can only analyze the refractive status of children, and the screening age group is not comprehensive. There are few studies on simultaneous vision screening, pupil and interpupillary distance investigation, and gaze position status of children aged 0.6-6; The Kaleidos used in this study can not only analyze the refractive status of children, but also has a quick and simple operation. The examiner can master it without professional training. Because the instrument is far away from the child during the examination, and there are sounds and a circle of rotating bright spots, children are easy to cooperate with. In addition, it is easy to carry and reliable in inspection results. It is now widely used in children's vision screening and eye care. It can also simultaneously detect children's interpupillary distance, pupil size, gaze position and other parameters. Pupil size is closely related to visual quality, it determines the amount of external light entering the retina, can reduce the chromatic aberration caused by the cornea and lens, and can increase the depth of vision, etc. [19-23]; It has been found that pupil size in children with amblyopia is larger than that in normal non-amblyopic children [24-26]. At present, the prevalence of refractive errors in children is high. The main way to correct myopia in our country is to wear frame glasses. When optometry and fitting frame glasses, the eye position plays a guiding role when the optometrist gives the prescription for optometry. The purpose of the measurement is to make the optical center distance of the lens consistent with the pupillary distance of both eyes, and to avoid the prism effect of the lens. Therefore, the measurement of pupil, interpupillary distance, and eye position is also crucial in children's vision screening[27].

Study Aims

To discuss more efficient and convenient ophthalmic public health screening methods. Comparing the screening results of portable barrel optometry equipment (Kaleidos) with the diagnostic results of medical optometrists (Gold Standard), analyze the reliability and validity of the Kaleidos screening results to determine whether Kaleidos can correctly categorize into the corresponding myopia category.

A total of 4 data collections were completed in this study. They were: 232 cases of data were collected in Zhangwu County, Fuxin City on April 26, 2019; 114 cases of data were collected in Xinmin City on May 16, 2019; 113 cases of data were collected in Shenyang He Eye Specialist Hospital from 29th July 2019 to August 13th 2019; 127 cases of data were collected in Zhuanghe City on November 8 2019, and total 529 cases were valid.

Materials and Methods

Study Objectives

The study subjects were students in grades 1 to 3 (aged 6-10) who enrolled in the primary schools and were designated to participate in this study, excluding students in the other grades or students aged 6-10 who did not obtain an informed consent.

Methods and Analysis

Screening Method Evaluation

The eyes of the eligible subjects will be examined, followed by non-cycloplegic computerized optometry, non-cycloplegic autorefraction and lens insertion refraction, Kaleidos (Fig 4.1) refraction and retinoscopy optometry under the ciliary muscles paralyzed in chronological sequence.

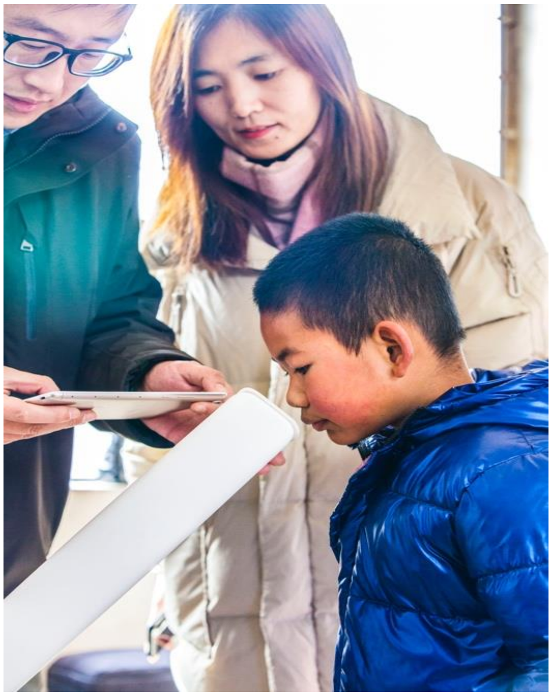


Illustration of the Use of Kaleidos

Kaleidos Being Used at Rural Community Setting

In the project, retinoscopy optometry after cycloplegia (known as mydriasis optometry) was selected as the gold standard in the screening evaluation process, The gold standard optometry result was used as the only standard for refractive error results; and the optometry results by Kaleidos (Fig 4.2) were compared with the gold standard results to analyze the validity and reliability of screening methods.

1. Validity evaluation: indexes include sensitivity, specificity, Youden index (YI) and likelihood ratio (LR).

Table 1. 1 Classification of Screening Results

Methods	Gold Standard	
	Patients	Non-patients
Positive	True Positive（TP）	False Positive（FP）
Negative	False Negative（FN）	True Negative（TN）
Total	C1	C2

(1) Sensitivity: known as TP rate, the percentage of patients with the disease and diagnosed as positive by the screening method, reflecting the ability of the screening method to find the patient.

$$\text{Sensitivity} = \frac{TP}{TP + FN} \times 100\%$$

(2) Specificity: known as TN rate, the percentage of patients without disease and diagnosed as negative by the screening method, reflecting the ability of the screening method to identify non-patients.

$$\text{Specificity} = \frac{TN}{FP + TN} \times 100\%$$

(3) YI: screening method can discover the real patients and non-patients.

$$\text{YI} = (\text{Sensitivity} + \text{Specificity}) - 1$$

(4) LR: comprehensive indicators of sensitivity and specificity, including positive LR and negative LR.

$$+LR = \frac{TP}{TN} = \frac{\text{Sensitivity}}{1-\text{Specificity}}$$

$$-LR = \frac{TN}{TP} = \frac{1-\text{Sensitivity}}{\text{Specificity}}$$

2. Reliability evaluation: to evaluate the consistency of the results under different detection methods, the Kappa value was used as an index to evaluate the degree of consistency.

$$\text{Kappa} = \frac{P_A - P_E}{1 - P_E}$$

P_A is the actual observed consistency rate, P_E is the expected consistency rate, the consistency of the results checked by different methods is caused by chance.

Consistency Analysis

Using different examination methods to observe subjects requires evaluating the consistency of repeated tests, if the consistency is low, it indicates that the reliability of tested results is affected by the inconsistent of repeated test results; if the consistency is high, it indicates that the repeated test results are reliable.

In the actual test, it is difficult to avoid the inconsistency of results caused by repeated examination, Kappa is used to evaluate its consistency:

Table 1.2 Consistency Evaluation by Kappa

Method 1	Method 2			Total
	Level 1	Level 2	Level 3	
Level 1	a1	a2	a3	Na1
Level 2	b1	b2	b3	Na2
Level 3	c1	c2	c3	Na3
Total	Nc1	Nc2	Nc3	N

$$Kappa = \frac{P_A - P_E}{1 - P_E}$$

$$P_A = \frac{\sum A}{N}$$

In the formula, A is the actual value observed by different examination methods, a1, b2 and c3 in the table.

$$P_E = \frac{\sum E}{N}$$

P_E is the expected consistency rate, the consistency rate of the two examination results by chance, referred to as the expected rate.

In the formula, E is the expected value, taking a1 in the table as an example, its corresponding Ea1 is Na1*Nc1/N.

The Kappa value is between -1 and +1, Kappa=+1, indicating that the results of the two tests are completely consistent; Kappa=-1, indicating that the results of the two tests are completely inconsistent; Kappa=0, indicating that the results of the two observations are occurred by chance.

U test for Kappa value: the Kappa value calculated according to the actual data is a sample statistic with sampling error. Whether the calculated Kappa value comes from the population with a total Kappa value of zero requires hypothesis testing to calculate the U value:

$$U = \frac{Kappa}{S_K}$$

In the formula, S_K is the standard error of Kappa value, and the formula is:

$$S_K = \frac{\sqrt{P_E + P_E^{2} - \frac{\sum N_a N_c \left(N_a + N_c\right)}{N^3}}}{\left(1 - P_E\right)\sqrt{N}}$$

Method of Examination

The examination methods used in the project include computerized optometry, lens insertion optometry, mydriatic refraction and Kaleidos refractive error detection.

Kaleidos is a portable binocular refractometer and vision analyzer that can measure both eyes under real-life conditions. It combines high technology to fully detect refractive errors, eye deformities and eyesight defective by testing the target refraction in the range of -15D to +15D. There are no special requirements for the use of Kaleidos photorefractometer. Only need to put patients' head on the top of tube of Kaleidos, look at the red light in the tube for 3-5 seconds, save the data directly to the tablet or mobile phone, and a complete vision test report will be displayed, which can be shared with collaborators, colleagues and patients.

After test by Kaleidos, an experienced ophthalmologist examined the conjunctiva, cornea, anterior segment, iris, pupil morphology, intraocular pressure, and fundus conditions using a portable slit lamp and a direct ophthalmoscopy.

Definition of Myopia

The result of retinoscopy optometry after cycloplegia (gold standard):

any eye with spherical equivalent (SE) power >-0.5D is classified as normal or hyperopic;

any eye with SE power ≤ -0.5D & > -3.0D is classified as mild myopia;

any eye with SE power ≤-3.0D & >-6.0D is classified as moderate myopia;

any eye with SE power ≤-6.0D is classified as high myopia.

According to the classification standards of true and false myopia formulated by the Chinese Ophthalmological Society in 1986, the gold standard for pseudo-myopia is that the patient with far vision is lower than normal and near vision is normal. After using atropine, myopia disappeared and the result showed normal or mild hyperopia as pseudo-myopia. The myopia diopter is not reduced or the degree of reduction is less than 0.5DS which is true myopia; myopia diopter was significantly reduced (>0.5DS), but those who did not return to normal were mixed myopia.

Kaleidos test results for normal or hyperopia, mild myopia, moderate myopia, high myopia is the same as the gold standard results.

Diagnosis of pseudomyopia by Kaleidos: Kaleidos can only detect the spherical refractive information of the subjects, and has no function of detecting pseudomyopia without pupil dilation.

Data Analysis

Analysis of Gold Standard Alternative Methods

The data analysis of this project needs to use the gold standard to classify the research subjects, dividing the population into patients and non-patients. The results could be divided into positive and negative, and the effect of screening was evaluated based on the above data.

In the actual work of eye screening, subjects usually undergo computerized optometry or lens insertion optometry first. After the above test, the results show that for the patient with myopia, dilated pupil test is carried out after the consent of subjects with myopia. According to the previous data rules, more than 95% of the people who participated in dilated pupil tests were ametropia patients diagnosed by the gold standard. The number of non-patients who received the gold standard test was less than 5%, which resulted in the inability to obtain negative diagnostic data during the final evaluation of the screening, so it was impossible to evaluate most of the indicators of the authenticity of the screening results.

Based on the above situation, in order to ensure the integrity of screening effect evaluation, attempted to explore alternative methods to the gold standard, conducted reasonable analysis on the alternative methods, and evaluated the consistency of the examination results between the alternative methods and the gold standard. The examination results of the screening method in this project are compared with the alternative method to obtain the most realistic evaluation results.

The selection of alternative methods should be based on the principle that it does not excessively increase the difficulty of actual screening or eye health examination, and computerized optometry and lens insertion optometry are preferred.

Data Analysis of Gold Standard Alternative Method

During the analysis of the gold standard alternative method, we selected 150 subjects under their consent, collected each persons' data of computerized optometry, lens insertion optometry, and retinoscopy optometry under the ciliary muscles paralyzed. There are three optometry test results, excluding the incomplete data from the above data, a total of 95-98 cases used for analysis.

Consistency Analysis of Test Results by Computerized Optometry and Gold Standard

Referring to the definition of myopia, the test results by computerized optometry and gold standard were classified as normal, mild myopia, moderate myopia and high myopia. A total of 98 cases of valid data from the consistency analysis of computerized optometry and gold standard test results, the analysis was carried out using the method of rank data consistency analysis as follows:

Table 1.3 Consistency Analysis of Test Results

Computerized optometry	Gold standard				Total
	Normal	Mild	Moderate	Severe	
Normal	1	0	0	0	1
Mild	4	78	0	0	82
Moderate	0	4	9	0	13
High	0	0	0	2	2
Total	5	82	9	2	98

P_A is 0.918, P_E was 0.713, and the calculated Kappa value was 0.72. At this time, Kappa value was a sample statistic, and there was a sampling error. U test was needed, the statistic u was 9.31, and gold standard test results $U_{0.01}$=2.58, P<0.01. It can be considered that the computerized optometry results were consistent with the gold standard test results, referred to the definition of Kappa value:

0.0-0.20 extremely low consistency (slight);

0.21-0.40 general consistency (fair);

0.41-0.60 moderate consistency;

0.61-0.80 high degree of consistency (substantial);

0.81-1 is almost perfect.

In this case, the Kappa value was 0.72, and the 95% confidence interval (CI) was (0.56, 0.87), which could be considered highly consistent.

Consistency Analysis of the Test Results by Lens Insertion Optometry and Gold Standard

A total of 95 cases with valid data were obtained from the test results of the lens insertion optometry and gold standard. The results of the consistency analysis according to the rank data were as follows:

Table 1.4 Consistency Analysis of Test Results

Insertion optometry	Mydriasis test				Total
	Normal	Mild	Moderate	High	
Normal	0	0	0	0	0
Mild	4	75	0	0	79
Moderate	0	6	8	0	14
High	0	0	0	2	2
Total	4	81	8	2	95

P_A was 0.895, P_E was 0.722, and Kappa value was 0.62. Then the U test was performed, and the calculated statistic u was 7.86, U0.01=2.58, P<0.01. It could be considered that there was consistency and high consistency between the insertion optometry and the mydriasis test, and the 95% CI was (0.47 , 0.78).

Determination of Gold Standard Alternative Method

According to consistency analysis of test results of the above computerized optometry, lens insertion optometry and the gold standard, the conclusions were all high consistent. Therefore, computerized optometry and insertion optometry used as an alternative methods to the gold standard in this project.

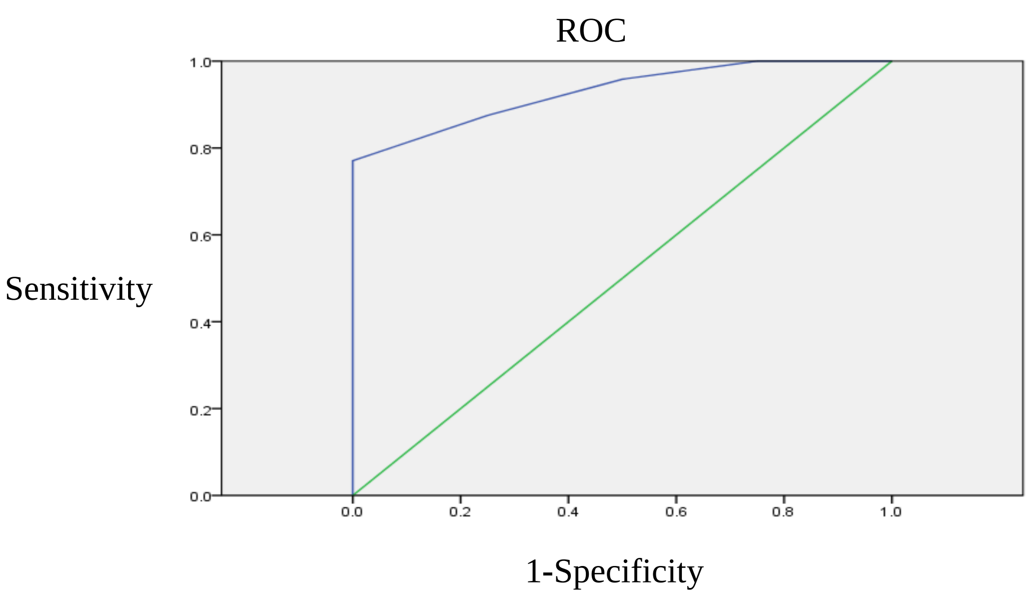
According to the conventional results of diopter detection, the accuracy of lens insertion optometry was higher than that of computerized optometry, and the consistency of lens insertion optometry and gold standard detection was higher than that of computerized optometry and gold standard in this test. However, the results of this test showed the opposite result. The reason was that in the experiment of exploring alternative methods, computerized optometry was used for all subjects tested after mydriasis, the data of computerized optometry before mydriasis were more close to the results of mydriasis detection, the final result shown was that the consistency of the two was higher, and there was a possibility of bias.

In the analysis of project, it was necessary to clarify which method to use for the detection of the subject after mydriasis. The gold standard alternative method needed to use the same method, so that the alternative method was more consistent and more qualified as an alternative method to the gold standard. At the same time, it was necessary to consider the actual situation of the project implementation. If the consistency of computerized optometry and lens insertion optometry was not much different from the gold standard test results, a more easier method should be selected as an alternative method.

Receiver Operating Characteristic (ROC)

Drawing the ROC Curve

In the process of drawing the ROC curve, 56 cases of valid data were used, and the result of the lens insertion refraction test was used as the standard for myopia. Non-myopia was defined as 0, and myopia was defined as 1. The value of the left and right eyes of the Kaleidos detection result, the data closest to the left side of the coordinate axis was used as variable data. Considering that the software for drawing the ROC curve does not recognize negative values, a value is added to all variable data to ensure that all variable data become positive values after conversion, and the conversion value was +4.5. Finally, when considering the best critical value, it needs to be converted again to get the real value. The ROC curve is as follows:



Square Under the ROC Curve

Variables: Kaleidos

Square	Standard error[a]	Sig.[b]	95% CI	
			Lower limit	Higher limit
.930	.036	.000	.860	1.000

Variable: Statistics can be biased.
a. nonparametric assumptions
b. null hypothesis： actual square = 0.5

The square under the ROC curve was 0.930, and the standard error of the square was 0.036. The Kaleidos test results were significant for myopia (P=0.000<0.05), and the 95% CI of the curve square was (0.86, 1.00), excluding 0.5 , the conclusion is consistent with the P value.

Best Screening/Diagnostic Critical Value

The ROC coordinates are as follows:

Coordinates of a curve

Test result variable:Kaleidos

If Positive is less than or equal to[a]	Sensitivity	1-Specificity
-1.0000	.000	.000
.1250	.021	.000
.6250	.042	.000
1.1250	.063	.000
1.3750	.104	.000
1.8750	.125	.000
2.3750	.188	.000
2.6250	.208	.000
2.8750	.250	.000
3.1250	.333	.000
3.3750	.500	.000
3.6250	.667	.000
3.8750	.771	.000
4.1250	.875	.250
4.3750	.958	.500
4.7500	.979	.625
5.2500	1.000	.750
5.6250	1.000	.875
6.7500	1.000	1.000

a. The minimum limit value is the minimum observed test value-1, and the maximum limit value is the maximum observed test value +1. All other limits are the average values of two adjacent observational tests.

The Coordinate Information is Calculated by YI:

Test result variable:Kaleidos

If positive is less than or equal to[a]	Sensitivity	1-Specificity	YI
-1	0	0	0
0.125	0.021	0	0.021
0.625	0.042	0	0.042
1.125	0.063	0	0.063
1.375	0.104	0	0.104

1.875	0.125	0	0.125
2.375	0.188	0	0.188
2.625	0.208	0	0.208
2.875	0.25	0	0.25
3.125	0.333	0	0.333
3.375	0.5	0	0.5
3.625	0.667	0	0.667
3.875	0.771	0	0.771
4.125	0.875	0.25	0.625
4.375	0.958	0.5	0.458
4.75	0.979	0.625	0.354
5.25	1	0.75	0.25
5.625	1	0.875	0.125
6.75	1	1	0

It can be seen from the results that when the variable is 3.875, the YI is the largest, the corresponding sensitivity is 0.771, the specificity is 1, and the detection variable value of Kaleidos is 3.875. Considering that we converted the data before, the variable value at this time is -4.5, resulting in the actual best critical value of -0.625. The actual test result of Kaleidos is not a continuous variable. Based on the actual test result, the value -0.5, which is the closest value to -0.625, can be selected as the best critical value. The -0.5 here is consistent with the critical value of the golden standard for determining myopia ≤-0.5D (≤-0.5D is classified as myopia).

Results

total of 529 valid data were collected. Computerized optometry was selected as an alternative to the gold standard, and the Kaleidos test results were compared and analyzed by computerized optometry. The data are as follows:

Table 4.5 Kaleidos Screening Method Data Collation

Kaleidos	Computerized optometry		Total
	Myopia	Non-myopia	
Positive	260	112	372
Negative	47	110	157
Total	307	222	529

Validity Evaluation

Sensitivity

$$\text{Sensitivity} = \frac{TP}{TP+FN} \times 100\% = \frac{260}{307} \times 100\% = 84.69\%$$

Specificity

$$\text{Specificity} = \frac{TN}{FP+TN} \times 100\% = \frac{110}{222} \times 100\% = 49.55\%$$

YI

$$YI = (\text{Sensitivity} + \text{Specificity}) - 1 = 84.69\% + 49.55\% - 1 = 0.34$$

LR

$$+LR = \frac{TP}{FP} = \frac{\text{Sensitivity}}{1-\text{Specificity}} = \frac{84.69\%}{1-49.55\%} = 1.67$$

$$-LR = \frac{FN}{TN} = \frac{1-\text{Sensitivity}}{\text{Specificity}} = \frac{1-84.69\%}{49.55\%} = 0.31$$

Reliability Evaluation

Kappa value

According to the results of the gold standard alternative method analysis, computerized optometry as the gold standard, and combined all the data collected so far for comparative analysis. The valid data were as follows:

Table 4.6 Computerized Optometry Test Result

City	Computerized optometry test results				
	Normal	Mild	Moderate	Severe	Total
Zhangwu	106	84	7	1	198
Xinmin	47	56	3	0	106
Shenyang	3	90	14	3	110
Zhuanghe	66	43	6	0	115

Total	222	273	30	4	529

The Kaleidos classification results were as follows：

Table 4.7 Kaleidos Test Results

City	Kaleidos test results				Total
	Normal	Mild	Moderate	Severe	
Zhangwu	64	129	5	0	198
Xinmin	40	63	3	0	106
Shenyang	3	83	21	3	110
Zhuanghe	45	69	1	0	115
Total	152	344	30	3	529

The Consistency Analysis Results were as Follows：

Table 4.8 Consistency Analysis of the Test Results by Kaleidos and Computerized Optometry

Kaleidos test results	Computerized optometry test results				Total
	Normal	Mild	Moderate	Severe	
Normal	110	38	4	0	152
Mild	112	226	5	1	344
Moderate	0	9	21	0	30
Severe	0	0	0	3	3
Total	222	273	30	4	529

The P_A was 0.681 and the P_E was 0.459, resulting in a calculated Kappa value of 0.41. The U test was performed on the Kappa value of the sample, and the calculated statistic u was 11.56, U0.01=2.58, P<0.01. It can be considered that the results of the insertion optometry and the results of the mydriasis test are consistent, and it is judged as moderate consistency, 95% CI was (0.34, 0.48).

Data Collection Analysis

The Kaleidos test results are used to analyze the detection of refractive errors in different regions. The data analysis is as follows:

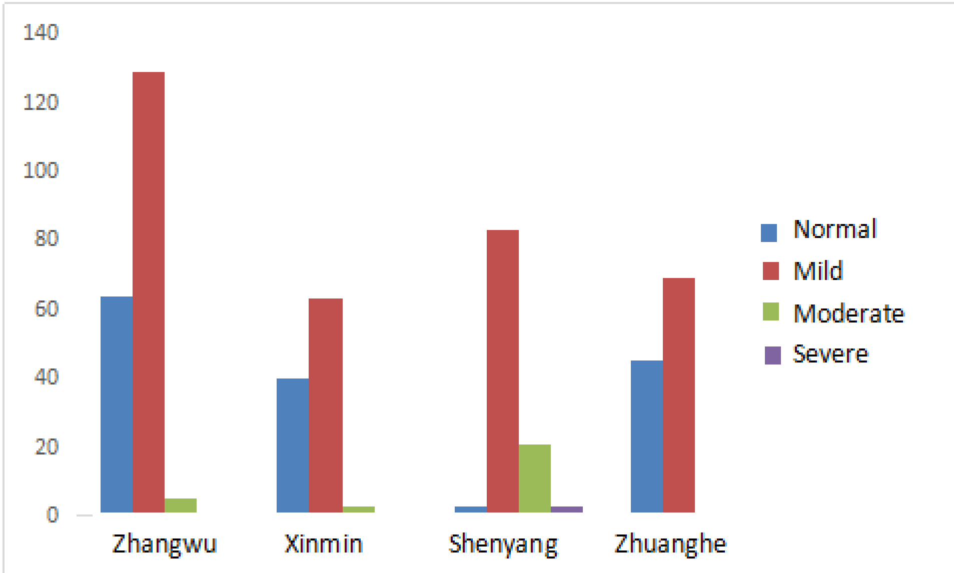


Figure 1. 3 Detection of refractive errors in different regions

The detection rates of refractive errors by region are as follows:

Table 1.9 Detection Rates of Refractive Errors by Region

City	Zhangwu	Xinmin	Shenyang	Zhuanghe
Detection rates	67.7%	62.3%	97.3%	60.9%

The detection rate of hyperopia by region is as follows:

Table 1.10 Detection Rate of Hyperopia by Region

City	Zhangwu	Xinmin	Shenyang	Zhuanghe
Detection rates	12.1%	14.2%	2.7%	8.7%

The detection rate of refractive error and hyperopia, except for the abnormal detection rate of Myopia Treatment Center of Shenyang He Eye Specialist Hospital, the detection rate in other areas is relatively stable: the detection rate of refractive error is about 65%, and the detection rate of hyperopia is about 10%. The reason for the abnormal detection rate of Myopia Treatment Center of Shenyang He Eye Specialist Hospital is that most of the people who have a vision test detected by other ways, and there are different degrees of abnormal visual acuity, which has a selection bias.

Discussion

From the results of the detection rate of refractive errors and hyperopia, it can be seen that, except for the abnormal detection rate of Shenyang He Eye Specialist Hospital, the detection rates of other areas are relatively stable: the detection rates of refractive errors are all about 65%, the detection rates of hyperopia are about 10%.

Like other countries, China is grappling with the coronavirus disease 2019 (COVID-19) lockdown and has prepared for work from home in every possible field. There is also no denying that our children will be staying at home for longer periods of time and that they will be taught their lessons in a virtual environment for a period of time in the future. A significant difficulty would be that children would be deprived of both appropriate and regular physical activities as well as the safe and productive classroom contact that is so critical to their physical and mental well-being. [28] In addition to the general implications on the health of the kid, it is crucial for eye care professionals to remember that children will be spending more time inside and participating in less outside activities, both of which are recognized risk factors for the beginning of myopia. Children will also spend an increasing amount of time with digital gadgets in the not too distant future. The influence of digital gadgets extends well beyond eye health, and it is now more vital than ever to raise public awareness of the potential harm that these devices might do to the developing visual apparatus of children and adolescents. There is a predicted increase in myopic refractive error, which will affect about 50 percent of the world's population by 2050. [29] If proper precautions are not taken during the home confinement period, the present lockdown may expedite this forecast even more. The phrase quarantine myopia is beginning to make its way into debates and discussions in the field of optometry and vision care. There has been an increase in concern over limits on community eye health initiatives, as well as travel restrictions that make it more difficult to get eye care. However, now is a better time than ever to monitor children who are at risk for myopia as well as those who have already been diagnosed with myopia, particularly progressive myopia, and to take preventative measures. It is suggested by the outcomes of this present research that Kaleidos, because of its remote operating capability as well as its high sensitivity and specificity, might be utilized to monitor myopia in youngsters. Although the ability to work remotely and hygienically is essential for monitoring myopia in the COVID-19 era, this proposed recommendation adheres to the fact that it is not only necessary but also beneficial to raise awareness among practitioners about the needs of myopic children, as well as the general public and all stakeholders[28].

Summary of Implications for Further Work

In summary, the prospects of using smart medical platforms for remote eye disease screening mode have been unanimously optimistic by researchers who believe that smart screening platforms can be competent for eye disease screening. Many researchers believe that this model will allow more people to enjoy safe, effective, convenient and inexpensive eye disease screening services for the general population and also can reduce the workload of medical workers and improve the quality and efficiency of their diagnosis and treatment. For medical institutions and medical systems, they can increase the scope of their service radiation and help medical resources go to the community to change the imbalance of medical resource distribution. The development of this technology is new and it is still being developed and improved. Although its model accuracy is very high, the stability still needs to be further tested in practice. However, in the face of the increasingly serious eye health problems and the foreseeable increase number of patients with eye diseases worldwide. The medical and health system will inevitably be under greater pressure. The development and application of smart medicine will give us the new solution and its remarkable superiority has showed us that smart medical treatment will be the new direction of China's medical and health development.

Conclusion

In conclusion, in present study, the refraction measured from Kaleidos a portable autorefractor was shown to have a strong ability to detect myopia compared to traditional Topcon autorefractor and cycloplegic refraction. The performance of Kaleidos in detecting individual refractive error was good, as expressed by ROC curves. These findings suggested that Kaleidos could be a very useful tool for large-scale population screening in Chinese population due to its portability and remote operational usability.

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