DOI 10.1007/s10527-018-9825-9
Biomedical Engineering, Vol. 52, No. 4, November, 2018, pp. 257-262. Translated from Meditsinskaya Tekhnika, Vol. 52, No. 4, Jul.-Aug., 2018, pp. 29-32.
Original article submitted May 14, 2018.

Assessment of Visual Acuity after Implantation of Gradient Multifocal Lenses

T. A. Morozova[1]* and G. I. Rozhkova[2]

The aims of the present work were to analyze existing methods of testing visual acuity and to undertake a comparative study of visual acuity at different distances after implantation of multifocal gradient intraocular lenses using modified ETDRS tables with Russian letters and the decimal system. The study data did not identify any statistically significant differences between measures of visual acuity obtained using the logarithmic and decimal systems. Use of ETDRS tables with Russian letters allows the procedure to be standardized for multinational clinical trials and exchange of databases.

Multifocal intraocular lenses (IOL) of the "premium" class are currently widely used in ophthalmological practice [1-6]. Many clinical trials have been performed in a variety of countries after implantation of multifocal IOL [1-4, 6]. On this background, the question of standardizing clinical investigations is relevant in terms of appropriate comparative analysis [4].

One basic and obligatory measure of the state of the visual functions required for objective comparison of results obtained by different investigators is visual acuity [7]. There are various methods for assessing visual acuity, though the most widely used are tables; different countries traditionally use their own tables. It is long since standards for testing visual acuity in Russia have been reviewed. Historically, Sivtsev and Golovin tables have been used. Sivtsev tables have 12 rows of upper-case letters and seven letters of the Russian alphabet are used: Ш, Б, М, Н, К, Ы, and И. Golovin tables contain 12 rows of Landolt rings (four versions with different gap locations: top, bottom, right, and left). Automated projection systems later came into use with optotypes in the form of letters, numbers, Landolt rings, and other figures.

The term "visual acuity" was introduced in the middle of the 19th century by Donders, who defined this concept and suggested measuring visual acuity in relative units, by comparing the visual ability of a subject with an arbitrary "standard eye" with a resolving ability corresponding to one arc minute (1′) [8].

The history of the development of the scientific approach to testing the quality of vision in most European countries started in 1843, when the German ophthalmologist Küchler raised the question of the need for standardization of studies of visual ability and suggested using tables containing rows of printed letters of different sizes for this purpose. To exclude the influences of possible memory of the letters on vision test results using these tables, Küchler created three interchangeable tables with identical size gradations but different sets of letters. Then, in 1854, the Viennese oculist Eger improved the Küchler tables and published them in German, French, English, and other languages. He used scripts which at that time were used in the Viennese state typography. In 1862, the Dutch ophthalmologist Snellen, a pupil of Donders, published in Utrecht the first tables not using typographical scripts but specially designed alphabetic symbols with simplified characteristics [9]. Snellen called these special signs "optotypes." In 1888, Landolt introduced optotypes consisting of rings with gaps (now known as Landolt rings) into practice, which were subsequently recommended as the international standard. Among the nonalphabetic optotypes apart from Landolt rings, so-called "tumbling E"s have also received wide use. These were proposed in 1978 by Taylor, using the then current table design principles (Tumbling E Chart [8]) for testing visual acuity in illiterate people. The rows of these tables con-

---

[1] Institute of Medical-Biological Problems, Russian Academy of Sciences, Moscow, Russia; E-mail: TatianaMorozovaMD@gmail.com
[2] Institute for Information Transmission Problems named after A. A. Kharkevich, Russian Academy of Sciences, Moscow, Russia.
* To whom correspondence should be addressed.

sist of symbols resembling the letter E written in squares with four different orientations.

The International Standardization Organization has developed standards for testing visual acuity, recommending the use of tables with Landolt rings [10-12]. Despite these recommendations, clinical practice abroad has until recently made wide use of letter-based Snellen tables.

With time it has become apparent that these have a number of drawbacks, which should be eliminated. In particular, the structure of Snellen tables does not follow consistent rules: the numbers of letters in different rows are different, the distances between letters are not proportional to their sizes, the rows are not balanced in terms of the total probability that all the letters within them would be recognized, the letter size increments from row to row do not provide for consistent measurement accuracy at different parts of the working range of visual acuities. These and other disadvantages have the result that Snellen tables do not provide reliable measures of visual acuity or consistent conclusions when results from different studies are compared.

In 1982, Ferris et al. proposed standardization of the method for measuring visual acuity using their Early Treatment Diabetic Retinopathy Study (ETDRS) tables [13, 14]. These tables contain optotypes in the form of Sloan letters, with a proportional design and a uniform coefficient of decreasing size from the upper rows to the lower (1.2589-fold) corresponding to a step of 0.1 in the *LogMAR* system (the logarithm of the Minimum Angle of Resolution). The creators regarded the fact that the set of optotypes excludes the letters which are the easiest and most difficult to read, as well as particular combinations of letters giving identical recognition difficulty in each row, as an important characteristic of these tables. ETDRS tables subsequently entered wide use in clinical and scientific studies and were approved as a standard by the Vision Committee of the American Academies of Sciences – National Research Council [15].

In relation to the use of logarithmic scales for optotype sizes in the structure of the tables, it was recommended that visual acuity should be expressed in logarithmic units. Using the proposed logarithmic scale, higher visual acuity corresponds to smaller values, the best have negative values, and the arbitrary normal corresponds to a value of zero, which makes the analysis process difficult [16].

ETDRS tables were initially developed to assess changes in visual acuity after panretinal laser photocoagulation in patients with diabetic retinopathy. The result of these studies was that the potential of obtaining sufficiently accurate and reliable values was demonstrated, after which these tables also came into use for measuring visual acuity in cataract and refraction surgery.

Standard ETDRS tables include 10 Sloan optotypes, which are letters of the English alphabet.

For patients using the Greek alphabet, the Cyrillic alphabet, and the alphabets of Central Europe, the letters C, D, R, N, V, S, and Z in analogous ETDRS tables are replaced by E, P, B, X, Y, A, and T, respectively [15]. As different systems of units are currently used for assessment of visual acuity, tables for reference levels usually show two or three values in parallel (in the *LogMAR* system, in decimals, as Snellen fractions). Furthermore, there are conversion tables whereby visual acuity measurements in one system can be expressed in units of another.

To provide for assessment of the results of clinical trials conducted in the Russian Federation using international standards and to eliminate problems when specialists from different countries interact during performance of international projects, there is a need to create Russian versions of the ETDRS tables.

Collaborative work between the Academician S. N. Fyodorov Eye Microsurgery CSTS, the Research Center of the University of Crete (UoC), and Precision Vision Inc., a leader in the development and manufacture of ETDRS tables, led to the creation of modified ETDRS tables with specially developed optotypes based on the Cyrillic alphabet [4, 15]. The introduction of analogs of ETDRS tables with letters from the Russian alphabet will not only avoid the hindrances to comparing results from clinical and statistical studies performed in different countries, but will also provide for exchange of databases between specialists in different ophthalmology centers.

Aims

To conduct comparative clinical investigations of visual acuity after implantation of multifocal IOL with gradient optics using a variety of measurement methods and to assess the possibility of standardizing studies of visual acuity using different methods.

Materials and Methods

A study of visual acuity over time was conducted in 41 patients (12 men, 29 women), mean age 66.4 ± 5.15 years, with monocular implantation of multifocal gradient IOL after ultrasound phacoemulsification of cataract performed using standard methods.

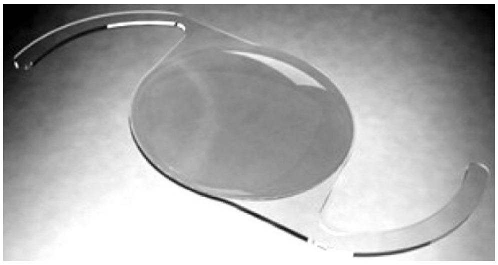

Fig. 1. A new-generation Gradiol (Reper-NN., Nizhny Novgorod) multifocal intraocular lens with gradient optics.

The optical part of the multifocal IOL with gradient optics (Fig. 1) contains internal and external components, made using a combination of modifications of the optical material – oligourethane methacrylates with different refractive indexes, 1.4795 and 1.520. The diameter of the optical part of the IOL was 6 mm and the total diameter of the lens (with two haptic elements) was 12 mm. The gain in optical strength between the components was by 3.5 diopters.

The quality of vision was studied monocularly at different distances assessing visual acuity at a long distance (4 m), a close distance (33 cm), and an intermediate distance (66 cm) at different post-operative time points: one day, one month, and three months.

Measurement of visual acuity used the following methods: 1) modified ETDRS tables with optotypes based on the Russian alphabet [for distances of 33 and 66 cm (Fig. 2) and 4 m]; 2) a Topcon (ACP-8) CV-5000 computerized phoropter (Topcon Corporation, Japan) with standard optotypes (for a distance of 4 m); 3) Russian tables with text fragments in selected scripts of different sizes for determination of visual acuity at near distance.

Modified ETDRS tables had a proportional design with a step in size change from row to row of 0.1 *LogMAR* and giving visual acuity on the logarithmic *LogMAR* scale and decimal units. Tables used a set of 10 letters of the Russian alphabet: A, B, E, K, M, H, O, P, T, and X.

Cords attached to the table ensure clearly defined distances (33 and 66 cm) for investigation of visual acuity at close and intermediate distances respectively.

Visual acuity in the *LogMAR* system is defined on the basis of the value printed by the last row fully read without errors and –0.02 is added for each correctly read letter from the row below. The constant value of the increment per row throughout the table is determined by the constant difference between rows (–0.1 *LogMAR*) and the identical number of letters per row (5).

Fig. 2. An ETDRS table in Russian for testing visual acuity at close (33 cm) and intermediate (66 cm) distances.

An obligatory requirement in studies of visual acuity is a defined level of illumination of the test location. Background illumination affects the level of adaptation of the retina. According to the ANSI (American National Standards Institute) standard, the mean illumination of the room should be 258 Lx. This requirement is odd: from the physiological point of view, precision to three decimal places is meaningless, while from the technical point of view this is unrealistic, if only because even using the same room and the light source in the working cabinet, the third decimal place in the mean illumination level will depend on the lightness of clothing and the positions of people and objects. In this study, the mean illumination of the location was about 250 Lx; it was monitored using a Yu116 portable photoelectric light meter.

Results

The results of the study of the dynamics of increased visual acuity after surgery are presented in Table 1.

One day after surgery, the functioning of the visual system was quite high (Table 1).

Measurements made at one and three months (the time at which neural adaptation is complete) after surgery showed improvements in visual acuity for long distance, close distance, and intermediate distance (Table 1).

Statistical analysis of the data showed that in most cases there were no statistically significant differences between visual acuities measured using different methods (see Methods section) in identical conditions (time after surgery, observation distance) in terms of the significance criterion *p*.

Conclusions and Discussion

The comparative study of the dynamics of improvements in visual acuity in patients after implantation of multifocal IOL using different measurement methods showed that all means tested gave close results with good agreement between them. In most cases, statistical analysis showed no significant difference between measures of visual acuity obtained using Russified printed ETDRS tables, a Topcon (ACP-8) CV-5000 phoropter (symbol projector), and Russian tables for near distance as tradi-

TABLE 1. Measures of Visual Acuity for Different Distances (4 m, 66 cm, and 33 cm) in Patients after Implantation of Multifocal Gradient IOL at One Day, One Month, and Three Months after Surgery

Visual acuity after surgery	Measurement system	Time after surgery					
		1 day	*p*	1 month	*p*	3 months	*p*
Far distance without correction	LogMAR	0.162 ± 0.06	$p < 0.175$	0.106 ± 0.04	$p < 0.327$	0.151 ± 0.05	$p < 0.002$
	Decimal	0.750 ± 0.18		0.800 ± 0.10		0.740 ± 0.19	
	Converted value	0.140 ± 0.11		0.100 ± 0.05		0.150 ± 0.12	
Far distance with correction	LogMAR	0.081 ± 0.04	$p < 0.298$	0.088 ± 0.04	$p < 0.922$	0.058 ± 0.05	$p < 0.000$
	Decimal	0.830 ± 0.11		0.850 ± 0.08		0.900 ± 0.12	
	Converted value	0.080 ± 0.06		0.080 ± 0.04		0.050 ± 0.06	
Intermediate distance without correction	LogMAR	0.217 ± 0.07	$p < 0.412$	0.291 ± 0.04	$p < 0.882$	0.230 ± 0.08	$p < 0.047$
	Decimal	0.670 ± 0.23		0.560 ± 0.11		0.660 ± 0.19	
	Converted value	0.200 ± 0.13		0.270 ± 0.08		0.220 ± 0.10	
Near distance without correction	LogMAR	0.400 ± 0.04	$p < 0.64$	0.330 ± 0.04	$p < 0.825$	0.266 ± 0.05	$p < 0.001$
	Decimal	0.430 ± 0.09		0.500 ± 0.10		0.560 ± 0.12	
	Converted value	0.380 ± 0.09		0.310 ± 0.09		0.260 ± 0.08	
Near distance with correction	LogMAR	0.290 ± 0.06	$p < 0.104$	0.226 ± 0.05	$p < 0$	0.082 ± 0.04	$p < 0.000$
	Decimal	0.570 ± 0.18		0.700 ± 0.13		0.860 ± 0.09	
	Converted value	0.270 ± 0.16		0.220 ± 0.09		0.070 ± 0.04	

Note: *p* for the significance of differences calculated between data obtained in the *LogMAR* system and the decimal scale (after conversion of V_D to V_L using a conversion table) for different distances.

tionally used in Russian clinics. The absence of differences can in part be explained by a circumstance hindering the detection of advantages and disadvantages of the methods under comparison: the measured visual acuity values mainly fell into the midpart of the working range, while the methods used gave significant differences in terms of measurement precision only for extreme values of visual acuity (very low and very high).

The main measurement range required for working with such patients is 0.4-1.0 on the decimal scale and 0.4-0.0 on the logarithmic scale. Within these ranges, all visual acuity measurement methods used in this study provided good measurement accuracy (with errors of 10-15%), so it is not surprising that no statistically significant differences were found between data recorded using different methods.

As an obligatory requirement for assessment of the quality of vision in patients with multifocal IOL is determination of visual acuity at different distances, the most convenient methods are currently the use of russified ETDRS tables, as the set of these tables (for 33 and 66 cm and 4 m) covers the required distances, their structure corresponds to contemporary standards, the measurement protocol is clearly described, and visual acuity is given in both the logarithmic and decimal systems.

Studies of visual acuity using the *LogMAR* system and the decimal scale provide the opportunity to assess functional results and the dynamics of visual functions in patients after surgery for cataract and implantation of multifocal IOL (with gradient optics).

The use of modified ETDRS tables with optotypes in Russian letters allows qualitatively comparable analysis to be conducted in clinical studies of multifocal IOL of different construction, performed by non-Russian investigators, without additional computation or use of conversion tables. Measurement of visual acuity on the background of multifocal correction significantly broadens the spectrum of studies: visual acuities at close, far, and intermediate distances are measured without correction and with correction, and visual acuity is also often tested with correction for far distance. Analysis of the results of multifocal correction dictates special requirements for visual acuity measurement methods: they must be reliable and standardized.

The significance levels of data obtained using the decimal scale and the *LogMAR* system were comparable.

The ability to increase the accuracy of the results by adding the "cost" of letters correctly recognized in the row following the last completely read row is regarded as a specific advantage of ETDRS tables. However, analogous interpolation approaches can be used with virtually any tables and measurement units. Theoretically, there is nothing preventing use of the method of calculating visual acuity in the *LogMAR* system considering each optotype for the decimal scale, which we will do in our future investigations and recommend for wide use, as this method allows study reliability to be increased. Theoretically, the same aim can be achieved by decreasing the step for changes in size from row to row by up to 10%, as such steps correspond to sufficient accuracy for assessment and are actually achievable using measurement tables. In ETDRS tables, the step is very large – 26% – so there is a requirement for interpolation increases in visual acuity measurement accuracy.

Assessment of visual acuity at intermediate distance is currently possible only using ETDRS tables with decimal or logarithmic scales, because of the lack of other tables and optotypes.

In addition, the reliability of studies of visual acuity at near distance on the decimal scale is decreased because of the lack of accurate control of the measurement distance (33 cm).

The proposed method of verifying visual acuity using modified ETDRS tables now provides for standardization of this procedure for multinational clinical trials.

The authors would like to thank T. Z. Kerimov and E. N. Kruttsova for technical assistance.

REFERENCES

1. Morozova, T. A., Pokrovskii, D. F., Medvedev, I. B., and Kerimov, T. Z., "Current aspects of multifocal intraocular correction," Vestn. Ross. Akad. Med. Nauk, **72**, No. 4, 268-275 (2017).
2. Morozova, T. A. and Kerimov, T. Z., "Current approaches to the analysis of dysphotopsia, assessment of subjective satisfaction, and independence from spectacles on the background of multifocal intraocular correction. A review," Vestn. Ross. Akad. Med. Nauk, **72**, No. 4, 355-364 (2017).
3. Malyugin, B. E., Takhtaev, Yu. V., Morozova, T. A., and Pozdeeva, N. A., "Results of a multicenter trial of the implantation of third-generation multifocal gradient IOL (Gradiol-3)," Oftal'mo-khirurgiya, No. 2, 36-40 (2012).
4. Malyugin, B. E., Morozova, T. A., and Fomina, O. V., "Studies of visual acuity in patients after implantation of multifocal intraocular lenses," Sovrem. Tekhnol. Oftal'mol., **8**, No. 4, 163 (2015).
5. Morozova, T. A., Intraocular Correction of Aphakia with Multifocal Lenses with Gradient Optics. A Clinical-Theoretical Study: Dissertation for Master's Degree in Medical Sciences, Moscow (2006).
6. Vries, N. E. and Nuijts, R. M., "Multifocal intraocular lenses in cataract surgery: Literature review of benefits and side effects," J. Cataract Refract. Surg., **39**, No. 2, 268-278 (2013).
7. Walker, H. K., Hall, W. D., and Hurst, J. W., Clinical Methods: The History, Physical, and Laboratory Examinations, Butterworths, Boston (1990), 3rd edition.
8. Colenbrander, A., "The historical evolution of visual acuity measurement," Visual Impairment Research, **10**, No. 2-3, 57-66 (2008).

9. Snellen, H., Test-Types for the Determination of the Acuteness of Vision, P. W. van de Weijer, Utrecht (1862).
10. ISO 5725-2:1994 Accuracy (Trueness and Precision) of Measurement Methods and Results. Basic Methods for the Determination of Repeatability and Reproducibility of a Standard Measurement Method.
11. ISO 8597:1994 Ophthalmic Optics. Visual Acuity Testing. Standard Optotype and its Presentation.
12. ISO 8596:2009 Ophthalmic Optics. Visual Acuity Testing. Standard Optotype and its Presentation.
13. Ferris, F. L., 3rd, Kassoff A., Bresnick, G. H., and Bailey, I., “New visual acuity charts for clinical research,” Am. J. Ophthalmol., **94**, 91-96 (1982).
14. Ferris, F. L., 3rd and Bailey, I., “Standardizing the measurement of visual acuity for clinical research studies: Guidelines from the Eye Care Technology Forum,” Ophthalmology, **103**, 181-182 (1996).
15. Plainis, S., Tzatzala, P., Orphanos, Y., and Tsilimbaris, M. K., “A modified ETDRS visual acuity chart for European-wide use,” Optometry and Vision Science, **84**, No. 7, 647-653 (2007).
16. Rozhkova, G. I., Gracheva, M. A., and Lebedev, D. S., “Optimization of test signs and tables for measurement of visual acuity,” in: Proceedings of the Scientific Conference of Ophthalmologists “Neva Horizons 2014” [in Russian], St. Petersburg (2014), pp. 563-567.