Are Cataract Surgery Consent Forms Readable by Patients with Impaired Vision?

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ABSTRACT

Introduction: Cataract surgery is one of the most frequently performed surgical procedures in the world that affects vision. In this study, we aimed to determine the extent to which cataract surgery consent forms are readable by patients.

Materials and Methods: The study data were evaluated retrospectively and 400 patients who underwent cataract surgery between 1.7.2023 and 31.12.2023 were randomly included in the study. The the patients' ages and gender, best corrected visual acuity levels according to the Snellen chart and the corresponding Jaeger near vision chart levels and the corresponding point size of the Jaeger chart were evaluated retrospectively.

Results: 32 individuals with best corrected visual acuity of 0.4-0.5 in the eye with good vision before surgery, 27 individuals with best corrected visual acuity of 0.51-0.64, 74 individuals with best corrected visual acuity of 0.64-0.81 and 67 individuals with vision better than 0.81 are expected to read a normal consent form written in a 12–15-point font size. Approximately 50% of patients had sufficient visual acuity to read a routine consent form, suggesting that the other 50% of the cases will have difficulty reading the consent forms in the current order even with the visual acuity of their better-seeing eyes.

Discussion: The determination by the physician planning the surgery whether the patients who need to undergo surgery due to conditions that directly affect vision, such as cataract, have visual acuity at a level that will allow them to read the consent form means providing one of the cornerstones of the concept of informed consent.

Conclusion: A significant portion of the patients cannot see the informed consent forms before cataract surgery due to their inadequate visual acuity.

Keywords: Cataract Extraction, consent Forms, informed Consent, visual Acuity

1. INTRODUCTION

An informed consent form plays a crucial role in the physician-patient relationship. Physicians have been obtaining consent from patients for centuries. For instance, a translated example of such a consent form from the Ottoman period indicates this historical practice. In 1640, a patient decided to undergo inguinal hernia surgery performed by a surgeon known as Hasan Beşe. The informed consent document, originally recorded in Ottoman Turkish and later translated into modern Turkish, reads as follows:

"I am currently suffering from a hernia. Since it is clearly known that many individuals have been cured of such illness through the treatment and intervention of Hasan Beşe, I have hired his services to treat this condition for a fee of two thousand akçes, which he accepted. I have paid and delivered the aforementioned amount to Hasan Beşe. If I do not recover from this illness and die by the will of Almighty God despite his treatment, let neither my heirs nor others cause harm to Hasan Beşe by claiming blood money or compensation."

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As the above declaration was duly confirmed by Hasan Beşe in accordance with legal procedure, this record was written upon request on the 2nd April, 1640 CE. [1,2]

As given in the example above, past consent forms have included statements that briefly state that all risks, including death, are accepted. The modern concept of patient consent originated in a decision made by the US Supreme Court in 1914 and became part of international law following World War II, with the principle that patient consent was mandatory before any invasive procedure was performed.[3,4] Modern consent forms should include a description of the disease, treatment methods and possible complications. Today, consent forms come to the forefront as a legal responsibility, especially for surgical procedures. [5,6] Developments in the field of health technology require the reorganization of the treatment relationship between doctors and patients in scientific, ethical and legal terms. In this sense, it is important that informed consent forms comply with certain standards.[7,8]

Many physicians typically print out consent forms on A4 paper in a 12–15-point font size and have patients sign them before the surgical procedure. Patients with normal visual acuity can typically read and understand a consent form written in this font, but a patient applying to the hospital for cataract surgery is expected to have visual acuity below normal. Therefore, there are difficulties to overcome in getting consent forms signed by people with visual acuity below normal, especially cataract patients.

Legal standards require that patients personally read the consent forms and sign each page separately after all necessary conditions are met. However, a study reported that a significant portion of the cases had their relatives sign the consent forms.[9] Except for cases where a guardian is present, informed consent forms must be signed by the person on whom the procedure will be performed. In light of all this, subjects must have sufficient visual acuity to be able to read and understand informed consent forms and to sign the page containing the text. Cataract surgery is among the most common surgical procedures across all medical specialties, with an estimated 3.7 million cases per year in the United States, 7 million in Europe, and 20 million worldwide. [10-12] Therefore, in this study, we aimed to determine the extent to which cataract surgery consent forms were readable by the patients.

2. MATERIALS AND METHODS

The study data were evaluated retrospectively. In our retrospective study, informed patient consent form was not obtained. The research was designed as a cross-sectional study. Permission for the study was obtained from the Afyonkarahisar Health Sciences University Clinical Research Ethics Committee (2023/6-268). For the study, 400 patients whose visual acuity was measured at the ideal distance using the Snellen chart in the ophthalmology outpatient clinic and who underwent cataract surgery between July 1, 2023 and December 31, 2023 by specialist doctors (M.D, H.H.G, İ.E.A) with at least five years of experience in their field were randomly included in the study. Patients undergoing surgery in one eye were included. Those scheduled for second-eye surgery within the same period were excluded to avoid duplication. Patients who did not have preoperative best corrected visual acuity data in their files, patients who were unable to evaluate their own consent form due to mental illnesses such as Down Syndrome and Alzheimer's, and patients under the age of 18 were excluded from the study.

Patients' ages, gender, best corrected visual acuity levels according to the Snellen chart and the corresponding Jaeger near vision chart levels and the corresponding point size of the Jaeger chart were evaluated retrospectively. Since the visual acuity values of 0.13 and 0.25 were not measured on the Snellen chart used, the J14 and J10 areas were excluded from the analysis. A vision level of 0.3 measured on the Snellen chart was evaluated as J7, corresponding to 0.32 on the Jaeger chart; a vision level of 0.5 on the Snellen chart was evaluated as J3, corresponding to 0.51 on the Jaeger chart; and a vision level of 0.64 on the Snellen chart was evaluated as J1, corresponding to the total data of patients with vision of 0.6 and 0.7 on the same chart. Cases with visual acuity levels of 0.81 and above on the Snellen chart were accepted as J0. The close chart prepared by Eğrilmez et al. in accordance with international standards was used as the close chart. The point levels corresponding to the appropriate J value on the Jaeger chart were also a guide for the study.[13] (Photograph 1).

Continuous data are shown as mean, median, maximum and minimum standard deviation. Grouped data are presented as percentage frequencies. The relationship between the data is shown with the scatter plot.

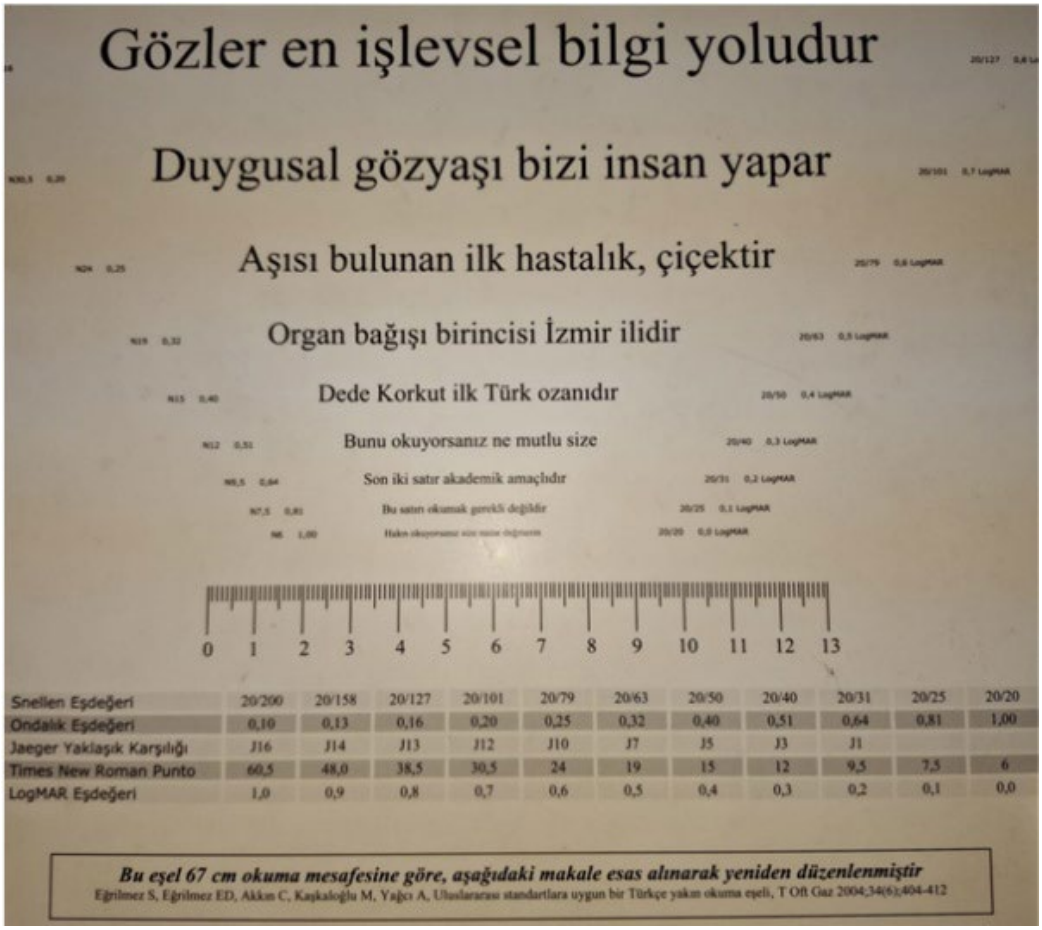

Photo 1. *Turkish close-range chart prepared by Sait Eğrilmez and his colleagues in accordance with international standards. The chart shows the Jaeger (J) values corresponding to best corrected visual acuity and the point sizes of the written text.*

3. RESULTS

400 patients were included in the study. Of the cases included in the study, 221 (55.3%) were female and 179 (44.7%) were male, and the mean age of all cases was determined as 67.5±9.5; the youngest case was 38 and the oldest case was 92 years old. In eyes that underwent cataract surgery, the best corrected visual acuity before surgery was determined to be 0.16±0.15 according to the Snellen chart, and the best corrected visual acuity in the eyes with good vision was determined to be 0.49±0.31.(Table 1). Good vision eyes were concentrated within the 0.0–0.6 range on the x-axis and the eyes with poor vision are concentrated in the 0-0.2 region on the y-axis (Figure 1).

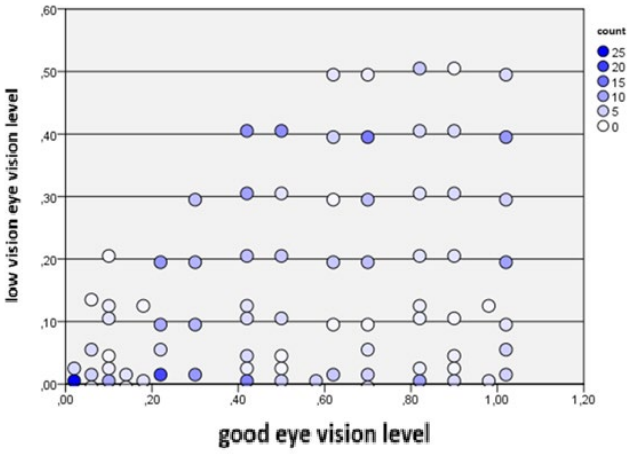

Figure 1. *Distribution of subjects' eyes with good vision and eyes with poor vision*

When all cases were evaluated, it was determined that the visual acuity of the poorer-seeing eye according to the Snellen chart was not more than 0.5 in any case (Figure 2).

The point range of 12-15, which is the point level frequently used in daily life, corresponds to the J3-J5 level of near vision for the Jaeger chart. The best corrected visual acuity required to read the point range in question must be greater than 0.4-0.5. Thirty-two people with visual acuity between 0.4 and 0.5, 27 people with visual acuity between 0.51 and 0.64, 74 people with visual acuity between 0.64 and 0.81, and 67 people with vision better than 0.81 are expected to read a normal consent form written in a 12–15-point font size. When we add up all these figures, suggesting that while 200 cases (50%) are expected to read a routine consent form, the other 50% of the cases will have difficulty reading the consent forms in the current order, even with the visual acuity of their better-seeing eyes. (Table 2).

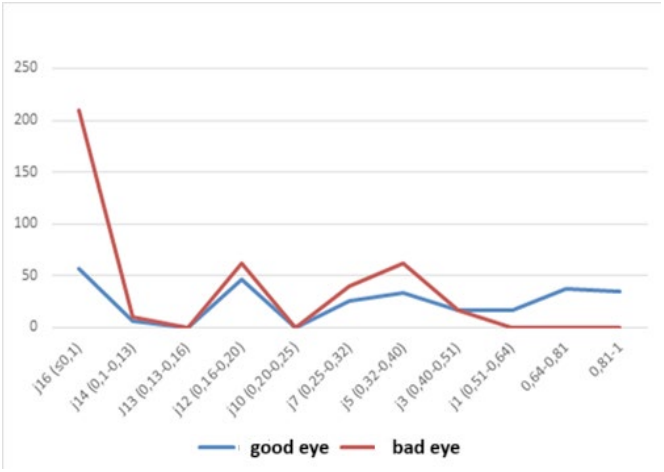

Figure 2. *Distribution of visual acuity in the eyes of the subjects with good vision and those with low vision*

Table 1. *Distribution of age and visual acuity levels of patients who underwent cataract surgery*

	Mean	Median	Standart Deviation	Minimum	Maximum
Age	67,50	69,00	9,53	38	92
Good eye vision level	0,49	0,45	0,31	0,0016*	1,00
Low vision eye vision level	0,16	0,10	0,15	0,0016*	0,50

*A visual acuity level of 0.0016 corresponds to perceptual positive visual acuity.

Table 2. *Distribution of near vision levels of subjects with good and low vision according to the Jaeger near chart and the corresponding point level.*

Best corrected visual acuity range	The range of near visual acuity corresponding to the Jaeger (J) chart	Font size required for near vision	Distribution of cases according to best corrected visual acuity of the good eye		Distribution of cases according to best corrected visual acuity of the low vision eye	
			n	%	n	%
<0,1	J16	>60,5	58	14,5	210	52,50
0,1-0,13	J14-J13	48-38,5	6	1,5	10	2,50
0,16-0,20	J13-J12	38,5-30,5	47	11,8	62	15,50
0,25-0,32	J10-J7	24-19	34	8,5	40	10,00
0,32-0,40	J7-J5	19-15	55	13,8	62	15,50
0,40-0,51	J5-J3	15-12	32	8,0	16	4,00
0,51-0,64	J3-J1	12-9,5	27	6,8	0	0,00
0,64-0,81	J1-J0	9,5-7,5	74	18,5	0	0,00
0,81-1	J0	7,5-6	67	16,8	0	0,00
Total			400	100,00	400	100,00

4. DISCUSSION

The use of consent forms in medicine dates back centuries, but the structure of consent forms is changing and developing with new views in medicine and ethics. A good consent form must be written in understandable language, and the definition of "readability" is used to determine at what level of education a written text in medicine is understandable. For example, it has been previously published that surgical consent forms written in Turkish used in the field of ophthalmology require 11-12 years of training.[14] Similarly, in another study conducted with consent forms of patients scheduled for intravitreal injection, it was determined that patients generally signed the consent forms without reading them, but consent forms written in simpler language were read at a higher rate.[15]

More critical than linguistic readability is the optical accessibility of the forms. It is that they are first and foremost optically readable, meaning that the visual acuity of the person reading the form must be sufficient to read the consent form. Particularly in the field of ophthalmology, the physician planning the surgery should determine whether patients who need surgery due to conditions that directly affect vision, such as cataracts, have visual acuity at a level that will allow them to read the consent form, which is one of the cornerstones of the concept of informed consent. For a good consent form, the patient must have the cognitive ability to understand the consent form or, in the case of a disease such as Alzheimer's, the person in the position of guardian must have these characteristics, the person reading the consent form must have sufficient visual acuity, and the consent form must be clear of technical terms and written in descriptive and simple language.

The cataract surgery consent form used in our clinic is written on paper in a font size between 12 and 15. It is known to everyone that many texts that are usually submitted for signature are written in a font size between 12 and 15 in daily life. To be able to read a text written in 12-15 point size, best corrected visual acuity must be at least 0.4-0.5. Among the cases included in our study, 200 cases (50%) had at least 0.4-0.5 best corrected visual acuity in their better-seeing eye, so it is expected that these cases will be able to see a standard consent form generally written in a 12–15-point font size. This means that half of the subjects were unable to see the text of the standard consent form, even when the visual acuity in their eyes was taken into account. Moreover, some of the subjects who are expected to be able to see the standard consent form may not be illiterate or the consent form may not have been written in accordance with the education level of the patients in question.

In addition to all this, in countries where there is no habit of reading, many people see such texts as a procedure to be passed over and choose to sign the consent form without reading it, even if they come across a text that they can actually read and understand. In fact, a study conducted in this field found that 88% of patients found cataract surgery consent forms necessary, but only 4% read them.[16] Moreover, considering that even in an ideal informed consent process, patients cannot remember a significant portion of the information given due to reasons such as surgical anxiety and that they define cataract surgery as risk-free, the importance of studies in this area is remarkable.[17]

Video-supported information can be provided and consent can be obtained before surgical interventions that reduce visual acuity, such as cataracts. The results obtained in cases where video information was given before cataract surgery were found to be beneficial for the patients, and it was determined that the patients understood the information given to them better.[18] Considering the increasing technological possibilities, obtaining consent forms with the help of audio and visual content for cases whose vision is affected, especially in the field of ophthalmology, should become more and more common.

5. STUDY LIMITATIONS

An important limitation of our study is that it was designed retrospectively and the patients' near vision levels were estimated based on the Jaeger equivalent in terms of their visual acuity. A study conducted directly before cataract surgery using a close-up chart and the consent form itself in the form of real-life data could provide much more meaningful data. A more comprehensive study can be designed by adding data such as the education levels of the subjects, the level of education for which the text is readable, and the number of those who skipped reading the consent text despite having the vision to read it.

6. CONCLUSION

A significant portion of patients cannot see the informed consent forms before cataract surgery because their visual acuity is not at a sufficient level. Informed consent forms should be written in appropriate font sizes, and if necessary, audio and visual consent should be obtained. We recommend the use of large-font or video-assisted consent tools in all preoperative settings where visual acuity may be compromised.

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