

DOI: 10.14744/eer.2023.93063 Eur Eye Res 2023;3(3):132–138



ORIGINAL ARTICLE

A tertiary hospital study on standard versus simplified consent forms for cataract surgery: Is there a perceptible or imperceptible influence on surgery decision-making?

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Abstract

Purpose: The aim of the study was to investigate the standard versus simplified consent forms (CFs) for cataract surgery to see if there was a difference that influenced patients' surgery decisions.

Methods: Four hundred patients scheduled for elective cataract surgery at a tertiary hospital between March 1, 2022, and June 30, 2022, were investigated. Patients signed the CFs on the day of surgery, either independently or with the assistance of a companion. Demographic data were collected, including age, gender, educational level, prior surgery, and whether or not they were alone.

Results: The simplified CFs were far more likely to be read than the standard CFs, and the reading rate increased significantly with educational level (P < 0.001). No significant influential difference existed in the CF reading between patients reading independently and those assisted by companions (P = 0.139). The simplified CFs influenced surgery-related patients' decisions the most (P < 0.001).

Conclusion: In the CFs, a relatively simple, easily readable, and comprehensible language appears to have a significant perceptible, or at least imperceptible, influence on patients' surgery decisions.

Keywords: Cataract surgery; consent forms; decision; educational level; influence; readability.

Informed consent is a fundamental ethical component in both clinical research and treatment procedures. In the informed consent process, basic information is provided for the patients to whom the procedure will be performed. Thus, patients can make informed decisions about participating in research or surgical intervention based on rational data. Many patients regard consent forms (CF) as merely a part of a procedure, which is why they are not sufficiently clear. Signing a CF to legally save the situation does not mean that all ethical obligations have been met. This is due to the fact that the CF should be simple enough for the signer to comprehend.^[1,2]

Cite this article as: Ay IE, Akdogan M, Oral AY, Erogul O, Dogan M, Gobeka HH. A tertiary hospital study on standard versus simplified consent forms for cataract surgery: Is there a perceptible or imperceptible influence on surgery decision-making? Eur Eye Res 2023;3:132-138.

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Submitted Date: 16.03.2023 Revised Date: 20.03.2023 Accepted Date: 08.05.2023



Although the CF importance has always been emphasized in clinical research and pretreatment interventions, its effectiveness and validity have long been contested. The literature has debated whether the signers are competent in this regard, whether they fully understand the issue, and whether they consent to the procedure. [3] Further, appropriate patient selection, pre-operative risk counseling, and informed consent after explaining all risks and obtaining the patient's consent have all been reported to reduce medicolegal risks. [4] The possibility that patients will be unable to adequately assess the risks before consenting to participate in a study or have a procedure performed on them is a major source of concern.

Furthermore, as the population ages, the number of people requiring cataract surgery grows year after year. Cataract surgery is performed on approximately 3.7 million people in the United States, 7 million in Europe, and 20 million people worldwide each year. [5] Given the lower level of education, particularly in developing countries, it is also critical that the CFs be written in a readable and understandable manner. [6] The term readability refers to a written text's comprehensibility based on the education level of the patient signing the forms, and the CFs should be written accordingly. [7]

Therefore, our study, which was conducted at a tertiary hospital, was designed to assess the standard versus simplified CFs for cataract surgery and determine whether there could be an influence on patients' surgery decision-making.

Materials and Methods

Study Design and Participants

The study included 400 patients who had previously been examined at a tertiary hospital's ophthalmology clinic and decided to have elective cataract surgery between March 1, 2022, and June 30, 2022. Patients who were included in the study during one eye surgery but returned for the other eye surgery were not included in the study again.

Ethical Declaration

This study, which was carried out in accordance with the Helsinki Declaration, was approved by the Afyonkarahisar University Clinical Research Ethics Committee with the approval date and number: 2022/154. All patients were informed about the study, and those who wished to participate signed the CFs when they arrived at the hospital on the day of surgery. In situations where companions were present, their closeness to the patient was assessed. Those

who came with their son or daughter (children), spouse, or other relatives were divided into subgroups, and the education level of the companions was taken into account when reading the CFs instead of the patient.

Demographics and Consenting Process

Aside from demographic characteristics such as age, gender, and educational level, patients were asked whether they came for surgery independently or with a companion. The patients were also asked if they had previously undergone cataract surgery. Initially, a medical secretary distributed standard cataract surgery CFs to patients and, if necessary, companions, under the supervision of an experienced ophthalmologist (IEA). This was followed by a detailed control to determine whether the patients/companions read the standard CF, confirming after they signed it by asking if they completely read it, and finally recording the results.

The patients/companions were then given simplified cataract surgery CFs. Again, after signing the CF, they were asked if they had read it completely. Those who did not read the simplified CF were also questioned as to why they did not. Responses were recorded for analysis. Based on the simplified CF reading, patients were grouped into three: (a) Those who went ahead with the surgery decision, (b) those who wanted more information about the procedure, and (c) those who gave up on the surgery outright. The evaluation was then conducted in conjunction with the collected demographic data.

Determining CF Readability Levels

The readability formulas of Atesman[8] and Bezirci and Yilmaz, [9] whose validity and reliability have been proven in Turkish, were used to evaluate the standard CF, which is routinely used before cataract surgery in our ophthalmology department. This form was determined to be readable with 16 years of education and at the undergraduate level (≥16 years) using the Bezirci and Yilmaz and Atesman readability formulas, respectively. On the other hand, using the same formulas revealed that a new simplified CF designed specifically for our study was readable with 8 years and 9–10 years of education, respectively.

Statistical Analysis

Predictive Analytics Software Statistics version 18 (IBM Inc., Armonk, New York, USA) was used for statistical analysis. Categorical variables were represented as percentages and frequencies in the descriptive statistics results, while continuous variables were represented as mean and standard deviation. In independent groups, the Chi-square, Fisher-

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Freeman-Halton exact test, and linear by linear chi-square were used to compare categorical variables; in dependent groups, the McNemarBowker test was used. The Multinomial Logistic Regression test was used to evaluate variables that had statistically significant differences after statistical analysis. The results of the logistic regression were presented as odds ratios and 95% confidence intervals (95% CI). The statistical significance level was set at P < 0.05. The actual α value of the study was 0.036, and the power of the study was 100%, according to the post hoc power analysis.

Results

Demographics, Educational Level, and Surgery Consenting

The female-to-male ratio among the 400 cataract surgery candidates was 189:211. The patients' mean age was 68.51 \pm 10.24 years, with 271 (67.75%) being over 65. 256 patients (64%) reported having cataract surgery for the 1st time, while 144 (36%) had previously had surgery from other hospitals. As far as educational level was concerned, the majority of the patients (82.25%) had a primary school education. The CF was read and signed by 34.25% of patients alone, 45% by their children, 10.75% by their spouses, and 10% by other relatives. Again, the majority of those who read the CF (58.25%) had only a primary school education (Table 1).

The CF Reading Rate

The standard CF was not read by 77.75% of the participants, while only 13.7% and 8.5% read it completely and partially, respectively. The simplified CF, on the other hand, was read completely by 49.25%, partially by 25.50%, and not at all by 25.25%. The simplified CF was statistically significantly more likely to be read than the standard CF used routinely in clinical practice (P < 0.001) (Table 2).

The Simplified CF Reading Rate by Education Level

Analysis of the simplified CF reading by educational level

Table I.Analysis of education level and cataract surgery consenting

Parameters	n (%)
Patients' education level	
Illiterate	11 (2.75)
Literate	8 (2)
Primary school	329 (82.25)
High school	34 (8.50)
University	18 (4.50)
Participant reading the consent form	
Independent reading by a patient	137 (34.25)
Children (son or daughter)	180 (45)
Spouse	43 (10.75)
Other relatives (grandchild, caregiver, etc.)	40 (10)
Education level of a participant reading the consent form	
Primary school	233 (58.25)
High school	91 (22.75)
University	76 (19)

n: Number of participants; %: Percent.

revealed relatively comparable percentages among those with primary school education, that is, 33.05% completely read, 32.19% partially read, and 34.76% did not read at all. The majority of high school graduates, 61.54%, read the simplified CF completely. University graduates were the group with the highest percentage of participants who read the simplified CF completely (84.21%). The rate of simplified CF reading increased significantly with education level (P < 0.001) (Table 3).

Logistic Regression Analysis of Simplified CFs by Education Level

Patients wishing to have cataract surgery for the 1st time and those wishing to have cataract surgery for the 2nd time had statistically non-significantly comparable rates

Table 2. Standard versus simplified CF reading frequency distribution

Simplified CF Didn't read, n (%)	Standard CF					
	Partially read, n (%)	Completely read, n (%)	Total, n (%)			
Didn't read	101 (32.48)	I (2.94)	0 (0)	102 (25.50)	<0.001	
Partially read	94 (30.22)	7 (20.59)	0 (0)	101 (25.25)		
Completely read	116 (37.30)	26 (76.47)	55 (100)	197 (49.25)		
Total	311 (100)	34 (100)	55 (100)	400 (100)		

CF: Consent form; %: Percent; n: Number of participants.

Table 3. The simplified CF reading frequency distribution

Education level Didn't read, n (%)	Simplified CF					
	Partially read, n (%)	Completely read, n (%)	Total n (%)			
Primary school	81 (34.76)	75 (32.19)	77 (33.05)	233 (58.25)	<0.001	
High school	15 (16.48)	20 (21.98)	56 (61.54)	91 (22.75)		
University	6 (7.89)	6 (7.89)	64 (84.21)	76 (19)		
Total	102 (25.50)	101 (25.25)	197 (49.25)	400 (100)		

CF: Consent form; %: Percent; n: Number of participants.

of reading standard and simplified CFs (P = 0.372 and P = 0.570, respectively). The subgroup analysis of patients who were assisted by companions in reading and signing the CFs revealed that there was no statistically significant influential difference in CF reading between patients who read independently and those who were assisted by companions (P = 0.139).

Retrospective analysis of the factors influencing CF reading revealed that 20 (5%) patients who consented for surgery without reading both forms reported being unable to read the CFs due to vision problems that prevented them from having better near vision. Hence, an inability to read the CFs was determined to be an absolute risk. Following the exclusion of 20 patients, a multinomial logistic regression analysis was performed between education levels.

Analysis of complete CF reading level based on university graduates indicated that the risk of not reading the CFs increased 8.84 times in primary school graduates (P < 0.001), but did not create a statistically significant difference in

high school graduates (P = 0.112). The analysis of partially CF reading levels revealed that having a primary school education increased the risk of not reading the CF by 10.36 times (P < 0.001); however, having a high school education increased the risk by only 3.89 times (P = 0.007) (Table 4).

Influence of the Simplified CF Reading Level on Surgery Decision-making

Aside from 102 (25.50%) patients who did not read the simplified CF, 101 (25.25%) patients read it only partially. When these patients were asked open-ended questions about why they did not read the CF completely, 19 (9.36%) stated, "I trust my doctor," 20 (9.85%) stated, "I have difficulty seeing too close to read the CF," and 43 (21.18%) stated, "I will have surgery anyway." Furthermore, 121 patients (59.61%) stated, "I do not want to read the CF." While 76.14% of 197 patients approved the surgery after completely reading the simplified CF, 21.32% asked additional questions to the attending physician before surgery approval, and 2.54% gave up on surgery. Those who read the standard

Table 4. Multi-nominal logistic regression analysis of the simplified CFs by education level

			SE	Wald	P	OR	95% CI for OR	
Simplified CF	Educational level	В					Lower bound	Upper bound
Read	Reference category							
Didn't read								
Education level of the	Intercept	-2.35 I	0.427	30.289	<0.001			
person reading the CF	Primary education	2.180	0.460	22.479	<0.001	8.842	3.591	21.770
	High school education	0.847	0.533	2.524	0.112	2.333	0.820	6.636
	University	Reference	e category					
Partially read								
Education level of the	Intercept	-2.35 I	0.427	30.289	<0.001			
person reading the CF	Primary education	2.338	0.457	26.153	<0.001	10.362	4.229	25.387
	High school education	1.358	0.501	7.347	0.007	3.889	1.457	10.383
	University	Reference	ce category					

CF: Consent form; SE: Standard error, OR: Odds ratio; CI: Confidence intervals.

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Table 5. Influence of	ot a simbilitied CF re	ading level on surgic	ai decision-making	of the patients

Final decision	Simplified CF				
	Didn't read, n (%)	Partially read, n (%)	Completely read, n (%)	Total, n (%)	
Gave up on surgery	0 (0)	0 (0)	5 (2.54)	5 (1.25)	<0.001
Asked additional questions	0 (0)	0 (0)	42 (21.32)	46 (11.50)	
Direct approved the surgery	102 (100)	101 (100)	150 (76.14)	349 (87.25)	
Total	102 (100)	101 (100)	197 (100)	400 (100)	

CF: Consent form; %: Percent; n: Number of participants.

CF, as well as those who signed it without reading stated that they consented to the surgery. The simplified CF has a statistically significant influence on the patients' surgery decision-making when compared to the standard CF (P < 0.001) (Table 5).

Discussion

Our study assessed the standard versus simplified CFs for cataract surgery to determine whether there could be a significant influence on surgery decision-making among patients, 67.75% of whom were over the age of 65. The majority of patients (64%) underwent cataract surgery for the 1st time. Over 80% of patients had only a primary school education, and this group was found to be the most likely to read the CFs. In this context, the simplified CF was significantly more likely to be read than the standard CF used frequently in ophthalmology clinics. Furthermore, when compared to the standard CFs, the simplified CFs had a significant influence on the patients' decision-making regarding surgery. This fundamentally implies that relatively simplified and thus easily readable and understandable language in the CFs could have a significant perceptible, if not imperceptible, influence on patients' surgery decisionmaking, allowing for a clinically transparent and rapid consenting process.

Numerous studies on informed consent for cataract surgery have been conducted over the years. Kikuchi et al.[10] found that the majority of patients did not comprehend the preoperative information provided, highlighting the importance of including both patients and family members in the consenting process. Despite this, our study found no influential difference in CF reading between patients who read independently and those who were aided by companions. Morgan and Schwab^[11] investigated patients' recall of the CFs 1 day after cataract surgery. Despite the fact that all patients thought the pre-operative explanation was adequate, only 37% of the information from the previous day could be recalled. Furthermore,

while Kiss et al.^[12] reported that 76% of patients believed cataract surgery was risk-free, Cheung and Sandramouli^[13] revealed that cataract patients were under-informed about the risks of the surgery, with 48% believing the surgery was completely risk-free, rising to 80% in those planning a second cataract surgery. This also suggests an inadequacy of general CFs routinely used in clinical practices and calls for this medicolegally sensitive pre-operative information process to be improved not only with the inclusion of relatively readable CFs, but also comprehensible for the vast majority of patients.

There have been reports of patients becoming increasingly concerned that the surgery could be unsuccessful and that they could go blind as a result of surgery-related complications.[14-16] Scanlan et al. reported that allowing people to take a copy of their CFs home helped them remember the risks after surgery.[17] Given that patients' anxiety levels may be high just before cataract surgery, it may be more ethical to provide CFs ahead of time and allow them enough time to read these forms at home. Patients in our study, on the other hand, were given cataract CFs when they arrived for surgery. Given the patients' psychological preparation for the surgery until then, the percentage of CFs read could have been influenced. Learning about the risks of surgery on the same day may also make patients' decision to forego surgery more difficult. Furthermore, it is recommended that patients be competent to give consent, that adequate information be provided for the respective procedure, and that patients not be pressed for consenting before surgery.[18,19] Essentially, patients who consented on the day of surgery may feel relatively pressed.

In the Shukla et al.^[20] study, patients were divided into four groups before cataract surgery. While the first group received oral information, the second group received both an informative brochure and verbal information at the second grade education level. The third group received an informative brochure based on the eighth grade education level in addition to oral information. Aside from verbal in-

formation, the final group watched an informative video about cataracts produced by the American Academy of Ophthalmology. The group that received a brochure tailored to the second grade educational level and was informed through video had a better understanding of the risks of cataract surgery. A second surgery and a higher level of education, on the other hand, were not associated with a significant difference. In our study, regarding the CF reading rate, despite the fact that the second surgery was ineffective, as education level increased, so did the rate of CFs read. The ineffectiveness of the educational level in the preceding study could be attributed to the fact that the informative brochures and videos produced for the second grade level appealed to patients of all educational levels. Indeed, studies have highlighted the importance of education level in understanding informed CFs before cataract surgery.^[21]

In general, the patient's signature on the CF may have legally relieved the physician of certain medicolegal responsibilities. However, simply signing the CF for a procedure without being fully informed does not mean that all of the medicolegal responsibilities have been fulfilled. As a result, more in-depth research on CFs may be worthwhile to ensure that patients understand the recommended procedures. With technological advancements, it has been reported that obtaining a video-assisted CF before cataract surgery both increases patient satisfaction and shortens the consenting period. We are unwavering in our belief that CFs written in a more readable style will aid the patient's information processing before a particular surgery.

In comparison to other studies in the literature, our study has a significant advantage in that it included a significantly larger number of participants. Besides, it is worth noting that 5% of the cataract patients in our study lacked adequate vision to read the CFs and did not have a companion. In fact, it is not difficult to predict that patients' visual acuity will be poor, especially in the case of ocular surgeries. That being so, if necessary, the CFs written in relatively larger fonts can be used in this condition, and the written CF text may also be presented as an audio recording for normal hearing patients.

Participants in the Ruiss et al.^[24] study who received computer-based training during the informed consent process had more information about the procedure than the placebo group and expressed a desire to use such a system in future surgeries. No correlation, however, was found between age, computer usage habits, and their responses regarding the use of computer-based education. As a con-

sequence, the use of computer-assisted training to obtain informed CFs in accordance with ethical criteria may be revisited in the future.

Conclusion

Our findings highlight the importance of a simple and readable CF format for a critical interventional procedure like cataract surgery, which affects millions of people globally and is performed millions of times each year. Given the relatively low educational level, particularly in developing countries, CFs should be written in a simple and understandable language that allows for a clinically transparent, easy, and rapid consenting process. Further technological innovations, such as video and sound systems, may be implemented wherever necessary to provide patients with more clear and comprehensible pre-operative information.

Ethics Committee Approval: This study was approved by Afyonkarahisar Health Sciences University of Medicine Ethics Committee (15.04.2022; 2022/5).

Peer-review: Externally peer-reviewed.

Authorship Contributions: Concept: İ.E.A., A.Y.O., M.D., H.H.G.; Design: İ.E.A., M.A., A.Y.O., M.D., H.H.G.; Supervision: İ.E.A., A.Y.O., M.D.; Resource: İ.E.A., Ö.E., M.D., H.H.G.; Materials: İ.E.A., A.Y.O., M.D.; Data Collection and/or Processing: İ.E.A., M.A., H.H.G.; Analysis and/or Interpretation: İ.E.A., A.Y.O., Ö.E., M.D., H.H.G.; Literature Search: İ.E.A., Ö.E., H.H.G.; Writing: İ.E.A., H.H.G.; Critical Reviews: İ.E.A., A.Y.O., M.D., H.H.G.

Conflict of Interest: None declared.

Financial Disclosure: The authors declared that this study received no financial support.

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