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Evaluation of keratoconus patients with or without surgery by both sub-scales of “Keratoconus End-Points Assessment Questionnaire”

Betul Akbulut Yagci,¹ **Ozlem Ozkan**,² **Zeynep Ozbek**,³ **Canan Asli Utine**^{2,4,5}

¹Department of Ophthalmology, Aksaray University Education and Research Hospital, Aksaray, Türkiye

²Department of Ophthalmology, Dokuz Eylul University, Izmir, Türkiye

³Department of Ophthalmology, Dünyagöz Izmir Hospital, Izmir, Türkiye

⁴Izmir Biomedicine and Genome Center, Izmir, Türkiye

⁵Department of Ophthalmology, University of Naples Federico II, Naples, Italy

Abstract

Purpose: The purpose of the study was to evaluate the results of Keratoconus End-Points Assessment Questionnaire (KEPAQ) in patients who did or did not have any surgery for keratoconus.

Methods: This cross-sectional, single-center, observational study included 127 patients with keratoconus at the Cornea Service, Department of Ophthalmology, Dokuz Eylul University. Patients were classified as Group 1 (no ocular surgery) and Group 2 (any surgery for keratoconus). Best-corrected visual acuity (BCVA), spherical equivalent (SE), keratometry readings (Kmean), asphericity coefficient (Q value), and central corneal thickness values were recorded. Patients were asked to answer the questions of emotional (E) and functional (F) KEPAQ subscales.

Results: Group 1 consisted of 59 patients (46.5%), and Group 2 consisted of 68 patients (53.5%). In Group 2, 33 patients had cross-linking (CXL), 16 had intrastromal corneal ring segment (ICRS) implantation, 4 had both CXL and ICRS implantation, 5 had deep anterior lamellar keratoplasty (DALK), and 10 had penetrating keratoplasty (PK). KEPAQ-E scores were positively correlated with BCVA ($r=0.34$, $p<0.01$) and SE ($r=0.20$, $p=0.04$). KEPAQ-F scores were positively correlated only with BCVA ($r=0.25$, $p=0.01$). In Group 2, the worst E and F scores were found in patients who had ICRS implantation and PK, whereas the best E and F scores were obtained in patients who underwent DALK.

Conclusion: In this study, BCVA appeared to be the most important predictor of emotional and functional QoL, followed by SE. Other clinical parameters used to stage disease severity did not show any significant correlation with functional or emotional QoL measures.

Keywords: KEPAQ-E, KEPAQ-F, Keratoconus end-points assessment questionnaire, Keratoconus, Quality of life

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Correspondence: Canan Asli Utine, M.D. Department of Ophthalmology, Dokuz Eylul University, Izmir, Türkiye

E-mail: cananutine@gmail.com

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Keratoconus is the most common primary corneal ectasia worldwide. Since keratoconus causes a progressive decline in visual quality, affected individuals may have significant difficulty performing daily tasks.^[1] Therefore, it is often necessary to rehabilitate patients with optical aids and/or surgery.

Recently, patient-reported outcome measurements (PROMs) have gained significant importance as an effective way to gather information about the burden of disease from patients' perspectives.^[2] These instruments provide a reliable assessment of the subjective change in quality of life (QoL) patients experience due to the disease. This approach is fundamental because patient-directed visual disturbance is not necessarily related to factors the physician can directly measure. That visual change is highly subjective. Disease-specific PROMs are preferred as they provide much more information about the patient's current condition, suffering from a unique disease.^[2] Balparda *et al.*^[3] developed a keratoconus-specific "Keratoconus End-points Assessment Questionnaire" (KEPAQ), which has been tested and validated. KEPAQ measures both emotional well-being and functional compromise in keratoconus patients. Prior psychometric evaluation through Rasch analysis has demonstrated that KEPAQ is a robust and well-constructed instrument.^[4] However, an easy E&F classification system was recently created, and KEPAQ scores were divided into 1–4 on a scale of 5.^[5]

Herein, we aimed to evaluate the results of KEPAQ in patients who did or did not have any keratoconus surgery and assess whether the history of surgery makes any difference in the functional and emotional well-being of the patients.

Materials and Methods

This cross-sectional, single-center, observational study included 127 patients with keratoconus at the Cornea Service, Department of Ophthalmology, Dokuz Eylul University Hospital. The protocol of this study was approved by the Institutional Ethical Committee (2021/20–58) and was conducted in accordance with the tenets of the Declaration of Helsinki.

Keratoconus was diagnosed based on the requirements of the global consensus on ectatic diseases,^[6] that is, the inclined appearance of posterior corneal elevations, an abnormal distribution of corneal thickness, corneal thinning, and an increase in corneal curvature. Patients at least 10 years of age were included in the study. The demographic data, including age, gender, underlying

systemic diseases, and past medical history, were recorded. Complete ophthalmological examination was performed, including best-corrected visual acuity (BCVA) in Snellen lines with spectacles or contact lens correction, slit-lamp biomicroscopy, air-puff tonometry, and dilated funduscopy. Refractive errors were tested under non-cycloplegic conditions via an auto-refractor (Nidek® ARK-510A autorefractor/keratometer, Japan), and spherical equivalent (SE) values were recorded. Average of steep and flat simulated keratometry readings (K_{mean}), asphericity coefficient (Q value), and central corneal thickness (CCT) measured with Scheimpflug corneal tomography (Pentacam®; Oculus Systems, Germany) were recorded. The BCVA, SE, Kmean, Q values, and CCT values of both eyes were averaged to yield one set of data per patient that would indicate the patient's overall status.

Patients were classified into Group 1 (patients who did not undergo any ocular surgery) and Group 2 (patients who underwent any keratoconus surgery). Group 2 was divided into subgroups based on the type of surgery performed: Collagen cross-linking (CXL), intrastromal corneal ring segment (ICRS) implantation, deep anterior lamellar keratoplasty (DALK), and penetrating keratoplasty (PK). All patients were reached by phone and asked to answer KEPAQ questions after receiving detailed information about the study.

The KEPAQ is a recently developed and validated self-administered keratoconus-specific scale questionnaire.^[4] It consists of two subscales and 16 questions in total. The first part of the scale (i.e., KEPAQ-E) consists of seven questions. This subscale assesses patients' emotional adjustment secondary to the disease (Table 1). The second subscale (i.e., KEPAQ-F) consists of nine questions about functional status secondary to keratoconus (Table 2). All questions are written clearly and briefly to determine how much the disease hinders patients in various situations. All questions use a corresponding scoring system: "Not at all"=3; "A little"=2; "Quite a bit"=1; "A lot"=0. The "Not applicable" option is also offered to patients who believe the problem is unrelated to any aspect of daily life.

Statistical Analysis

Patients' questionnaire results were recorded in the Excel file provided by Harvard Dataverse, as suggested by Balparda *et al.*,^[5] which is freely available from Harvard Dataverse at <https://dataverse.harvard.edu/api/access/datafile/4289090>. The Excel file used a linear transformation to convert the specified formulation to an associative scale between 0 and 100. Here, a higher score

Table 1. The subscale assesses patients' emotional adjustment secondary to the keratoconus

Question	Not at all	A little	Quite a bit	A lot	N/A
1. Do you feel your eye disease has affected your confidence to perform your daily tasks?	3	2	1	0	X
2. Do you feel your eye disease has affected your confidence to leave the house?	3	2	1	0	X
3. Do you feel your eye disease has affected your happiness in general?	3	2	1	0	X
4. Do you feel your eye disease has affected your confidence to go from one place to another?	3	2	1	0	X
5. Do you feel your eye disease has affected your self-esteem?	3	2	1	0	X
6. Do you feel your eye disease has affected your confidence about the future?	3	2	1	0	X
7. Do you feel your eye disease has caused your fear about the future?	3	2	1	0	X

Table 2. The subscale assesses patients' functional status secondary to the keratoconus (KEPAQ-F)

Question	Not at all	A little	Quite a bit	A lot	N/A
1. Do you feel your eye disease has affected your ability to play sports?	3	2	1	0	X
2. Do you feel your eye disease has affected your ability to see objects near you?	3	2	1	0	X
3. Do you feel your eye disease has affected your ability to perform your daily tasks?	3	2	1	0	X
4. Do you feel your eye disease has affected your ability to go to the movies?	3	2	1	0	X
5. Do you feel your eye disease has affected your ability to do your job?	3	2	1	0	X
6. Do you feel your eye disease has affected your ability to watch television?	3	2	1	0	X
7. Do you feel your eye disease has affected your ability to use the computer?	3	2	1	0	X
8. Do you feel your eye disease has affected your ability to read books?	3	2	1	0	X
9. Do you feel your eye disease has affected your ability to see objects that are faraway?	3	2	1	0	X

means having a better QoL. At the same time, the Excel file provides an easy E&F classification system by dividing KEPAQ scores on a 1–4 scale using Tukey's Hinges. E1 and F1 indicate better emotional and functional states, respectively; E4 and F4 indicate the worst emotional and functional states. This study used this approach to evaluate the E&F classification system with respect to the presence or absence of keratoconus surgery.

The Statistical Package for the Social Sciences (SPSS) software version 24 (IBM® SPSS® Statistics, USA) was used to analyze patient demographics and KEPAQ scores statistically. The Shapiro–Wilk test was used to assess the normality of the variables' distributions. Descriptive variables were addressed as means and standard deviations. The proportions of non-parametric variables between the groups were compared using the Chi-square test. Comparison of the parametric variables between groups was performed using an independent samples t-test when the data were normally distributed and a Mann–Whitney U test when the data were not normally distributed. Pearson correlation analysis was

used for normally distributed data, and Spearman's rank correlation analysis was used for data without normal distribution. $P < 0.05$ was defined as statistically significant.

Results

A total of 127 keratoconus patients were included in the study. Demographic data and baseline examinations of the groups were summarized in Table 3. Group 1 consisted of 59 patients (46.5%) who were followed up without surgery; Group 2 consisted of 68 patients (53.5%) who underwent surgery to rehabilitate keratoconus. Post-operative data of Group 2 patients are included in the demographic data. Groups were age and gender-matched. All demographic characteristics were statistically similar between the two groups ($p > 0.05$ for all), except for the Q value, which was significantly more negative in Group 1 than in Group 2 ($p < 0.05$). BCVA and Kmean values were distributed normally ($p > 0.05$ for all). All other parametric variables did not follow a normal distribution ($p < 0.05$ for all).

Table 3. Demographic data and examination results of Group 1 and Group 2

Characteristics	Group 1	Group 2	<i>p</i> *
	<i>n</i> (%)	Chi-square test	
Patient numbers	59 (46.5)	68 (53.5)	
Gender	F- 23 (39.0) M- 36 (61.0)	F- 25 (36.8) M- 43 (63.2)	0.80
Vernal keratoconjunctivitis	24 (40.7)	26 (38.2)	0.78
History of surgery	None (0)	CXL (33, 48.5) ICRS (16, 23.5) CXL+ICRS (4, 5.9) DALK (5, 7.4) PK (10, 14.7)	
	Mean $\pm$ SD (Range)		
Age (years)	29.42 $\pm$ 11.47 (14–64)	30.13 $\pm$ 10.9 (11–68)	0.72
Age at initial diagnosis (years)	22.82 $\pm$ 7.86 (10–45)	21.66 $\pm$ 7.84 (10–57)	0.41
Time from initial diagnosis (months)	19.09 $\pm$ 38.53 (0–168)	23.35 $\pm$ 42.65 (0–180)	0.60
BCVA	0.63 $\pm$ 0.26 (0.13–1)	0.59 $\pm$ 0.2 (0.1–1)	0.41
SE	–4.6 $\pm$ 3.87 (–18–1.75)	–3.96 $\pm$ 3.08 (–12.5–5.13)	0.30
CCT	473.24 $\pm$ 54.35 (296.5–573.5)	468.99 $\pm$ 53.66 (258–632.5)	0.67
K _{mean}	48.77 $\pm$ 5.05 (40.88–63.37)	47.65 $\pm$ 4.15 (40.6–69.25)	0.18
Q value	–0.9 $\pm$ 0.46 (–2.09–0.06)	–0.66 $\pm$ 0.5 (–2.3–0.51)	<0.008*
KEPAQ-E scores	70.13 $\pm$ 9.21 (36.15–76.78)	68.73 $\pm$ 11.32 (29.12–76.78)	0.45
KEPAQ-F scores	58.68 $\pm$ 15.3 (28.02–83.27)	57.94 $\pm$ 17.23 (22.99–83.27)	0.80

BCVA: Best corrected visual acuity; CCT: Central corneal thickness; CXL: Collagen cross-linking; DALK: Deep anterior lamellar keratoplasty; F: Female; ICRS: Intrastromal corneal ring segment; K_{mean}: Mean keratometry; n: number of patients; M: Male; PK: Penetrating keratoplasty; SD: Standard deviation; SE: Spherical equivalent; Q value: Asphericity coefficient. **p*<0.05 statistically significant.

In Group 2, 22/33 patients underwent bilateral CXL surgery, whereas 11/33 underwent unilateral CXL. Likewise, 6/16 had bilateral ICRS implantation surgery, whereas 10/16 had unilateral ICRS implantation. All four patients with both CXL and ICRS implantation were operated on in one eye only. Five eyes of 5 patients underwent DALK, 15 eyes of 10 patients underwent PK, and 1 PK patient was re-

grafted in 1 eye. No surgical eyes had any intraoperative or post-operative complications. In the operated eyes, pre-operative BCVA was 0.32 $\pm$ 0.21, which improved to 0.59 $\pm$ 0.2 at the last follow-up (*p*<0.001).

Correlations between patient demographics and KEPAQ E/F scores were analyzed across all included patients. KEPAQ E scores were positively correlated with BCVA (*r*=0.34, *P*<0.01) and SE (*r*=0.20, *p*=0.04). KEPAQ F scores were positively correlated with BCVA (*r*=0.25, *p*=0.01) but not with SE (*r*=0.17, *p*=0.06). Both KEPAQ E and F scores were positively correlated with BCVA in better-seeing eyes (*r*=0.35, *p*<0.001; *r*=0.27, *p*<0.01, respectively) and BCVA in worse-seeing eyes (*r*=0.24, *p*<0.01; *r*=0.19, *p*=0.04, respectively).

The correlation analyses were also performed separately for both groups. In Groups 1 and 2, KEPAQ E and KEPAQ F scores were strongly positively correlated with each other (*r*=0.71, *p*<0.01 for both). On the other hand, in Group 2, KEPAQ E scores were negatively correlated with time from diagnosis (*r*=–0.27, *p*=0.04) and Kmean (*r*=–0.31, *p*=0.01); positively correlated with pre-operative and post-operative BCVA (*r*=0.43, *p*<0.01; *r*=0.38, *p*<0.01, respectively). KEPAQ F scores were negatively correlated with Kmean (*r*=–0.35, *p*=0.01); positively correlated with SE (*r*=0.35, *p*=0.01), pre-operative and post-operative BCVA (*r*=0.28, *p*=0.01; *r*=0.48, *p*<0.01, respectively).

The correlations between the KEPAQ E/F scores and the BCVA in the better-seeing and worse-seeing eyes were studied separately in Groups 1 and 2. In Group 1, only the positive correlation between KEPAQ E scores and BCVA in better-seeing eyes was significant (*r*=0.33, *p*=0.01). In Group 2, KEPAQ E scores were positively correlated with BCVA in better-seeing eyes (*r*=0.37, *p*<0.01) and BCVA in worse-seeing eyes (*r*=0.25, *p*=0.04). Similarly, KEPAQ F scores were positively correlated with BCVA in better-seeing eyes (*r*=0.46, *p*<0.001) and BCVA in worse-seeing eyes (*r*=0.33, *p*<0.01).

KEPAQ E and F classification data in both groups are summarized in Figure 1. The differences in the number of patients with E1, F1, E4, and F4 scores between the two groups were not statistically significant (*p*>0.05 for all). In the subgroup of patients with E4 and/or F4 scores in both groups (*n*=13), no significant differences were found between the age, age at diagnosis, time from diagnosis, BCVA, SE, CCT, Kmean, and Q values of the patients (*p*>0.05 for all).

In surgical subgroups of Group 2, KEPAQ E&F classification score results are summarized in Figure 2.

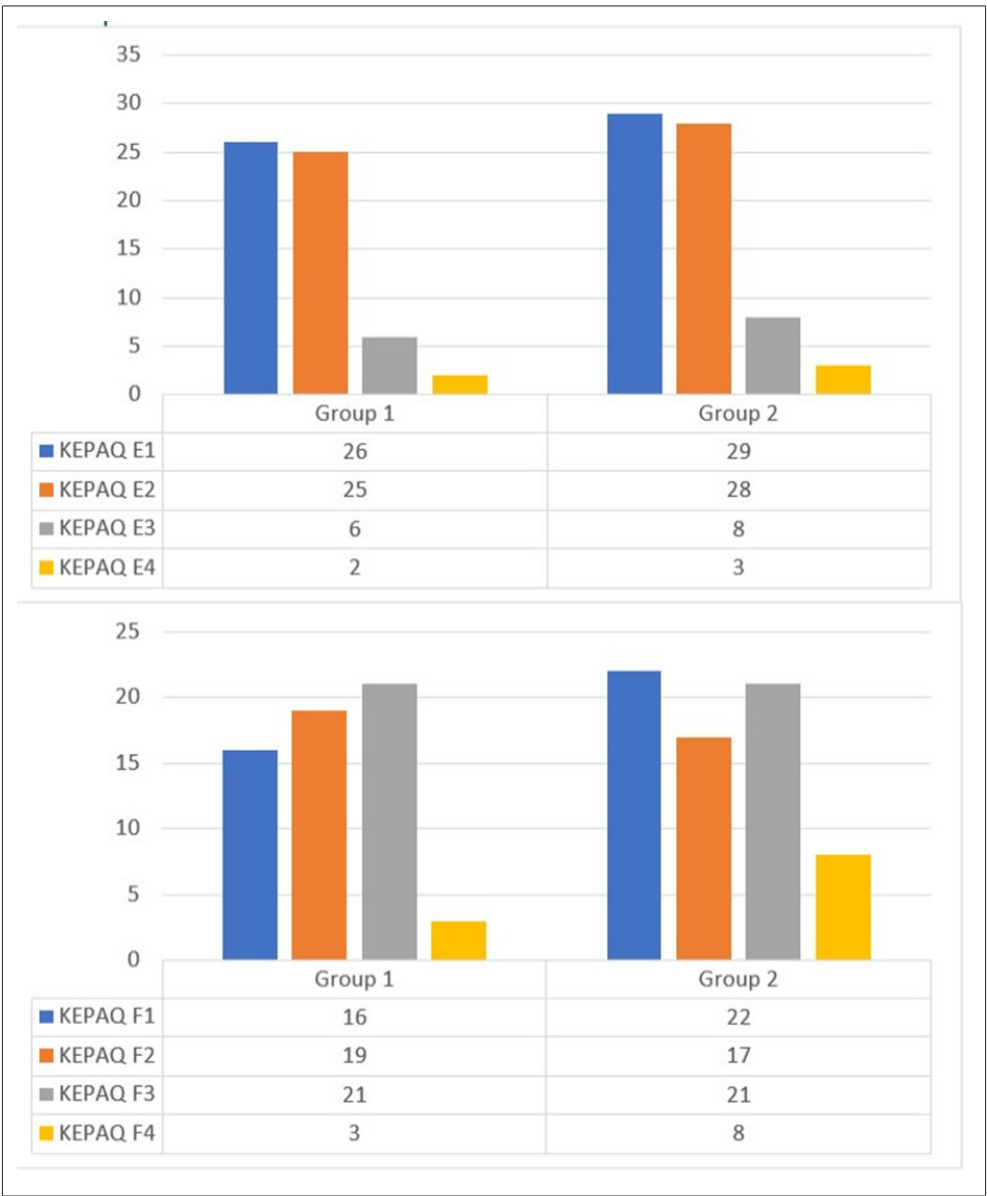


Fig. 1. Keratoconus end-points assessment questionnaire (KEPAQ) E and F classification data in both groups. This figure displays how the KEPAQ scores were distributed among patients who underwent and did not undergo any surgical procedure. (Group 1: Non-surgical keratoconus patients, Group 2: Surgically treated keratoconus patients). Emotional adjustment worsens progressively from score E1 to E4, and functional status from F1 to F4. (Materials and Methods for the calculation methodology)

The order of surgical procedures that yielded the poorest to better E scores was PK or ICRS surgery, CXL, DALK, or combined CXL and ICRS implantation. The order of surgical procedures that yielded the poorest to the best F scores was ICRS surgery, CXL, PK, combined CXL, and ICRS surgery or DALK.

Discussion

Clinicians and researchers have realized that the success of management in ophthalmologic

conditions goes far beyond measurable variables such as BCVA, SE, keratometry readings, or Q values of asphericity.^[7] As vision is inherently a subjective process, it is imperative for the ophthalmologist to examine the patient’s perceptions. Kandel *et al.* ^[8] had previously stated that the impact of keratoconus on QoL may be disproportionate to clinical measures such as BCVA. Furthermore, some relationship has been demonstrated between corneal distortion and emotional distress.^[9]

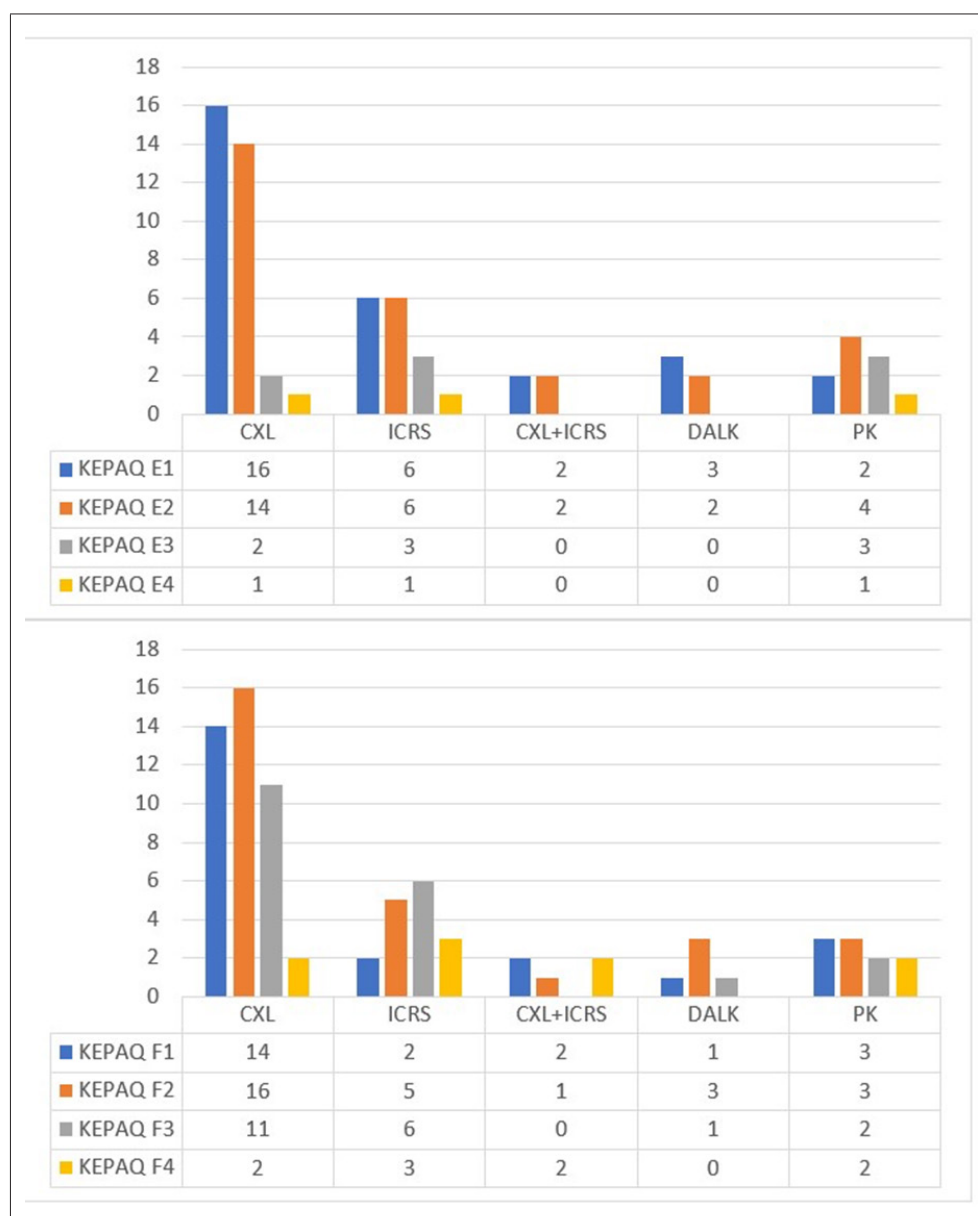


Fig. 2. In surgical subgroups of Group 2, keratoconus end-points assessment questionnaire (KEPAQ) E&F classification score results. This figure displays how the KEPAQ scores were distributed among patients who underwent different surgical procedures. (CXL: Collagen cross-linking, ICRS: Intrastromal corneal ring segment, DALK: Deep anterior lamellar keratoplasty, PK: Penetrating keratoplasty). Emotional adjustment worsens progressively from score E1 to E4, and functional status from F1 to F4. (Materials and Methods for the calculation methodology)

The World Health Organization defines the QoL as “the perception of an individual about their position in life in the context of culture and value systems in which they live, and in relation to his objectives, expectations, standards, and concerns.” QoL is expected to be challenging to measure by the medical sciences, and ophthalmology is no exception.^[10] To date, the best way of measuring QoL in patients has been through using PROMs,^[11] i.e., validated and standardized tools that

directly question the patient’s subjective experiences in their daily lives. While general PROMs can be helpful under certain circumstances,^[12] disease-specific PROMs will provide more insight into the burden on overall QoL from the patient’s perspective.^[11]

At present, only two keratoconus-specific scales have been validated. The first is the Keratoconus Outcomes Research Questionnaire (KORQ), designed by Khadka *et al.*^[13] and recently studied by Kandel *et al.*^[14] KORQ

exhibits many psychometric analyses. However, it completely ignores the emotional compromise caused by the illness. It has been emphasized that ectatic diseases affect emotionally, and keratoconus patients have a higher than normal prevalence of mental health-related diseases, especially clinical depression.^[8,15,16]

Balparda *et al.*^[3] previously developed, tested, and validated the “Keratoconus End-points Evaluation Questionnaire” to adequately measure both functional and emotional evaluation. KEPAQ is a recently developed, robust, unidimensional, well-designed disease-specific PROM designed to provide the clinician reliability of emotional and functional reconciliation from the patient’s perspective (KEPAQ-E and KEPAQ-F, respectively).^[3] KEPAQ is robust in its concept and the epidemiological and mathematical creation and validation process. In addition, the KEPAQ is shorter than the KORQ,^[13] so its application in daily practice can be simpler and faster without compromising the test’s psychometric properties. The main difference between KORQ and KEPAQ is that the KEPAQ also has a sub-scale to measure emotional affect and distress secondary to keratoconus,^[4] as the progressive nature of the disease and the possible need for keratoplasty may cause anxiety.^[8]

Our study used the latest proposed, easily understandable, and implemented KEPAQ E&F classification scores by Balparda *et al.*^[5], which standardized the linear transformation to report KEPAQ results. This classification method has standardized the calculation, and the current status of patients with keratoconus can be better captured.^[5]

Tan *et al.*^[17] demonstrated that BCVA in the better eye was most strongly correlated with reading and mobility scores as measured by the Visual Impairment Questionnaire (IVI), a non-disease-specific PROM. In comparison, visual acuity in the worse eye was significantly associated with emotional scores.^[17] Balparda *et al.*^[9] reported that none of the better eye’s topographical elevations, visual acuity, and corneal thickness correlated with KEPAQ scores on either subscale. However, in the worse eye, A (Anterior elevation), B (Posterior elevation), and D (Distance visual acuity) were significantly correlated with KEPAQ scores on both subscales. The only criterion that did not show correlation behavior was C (Corneal thickness).^[9] These data showed that corneal distortion and visual function in the worse eye are associated with emotional distress and subjective functional handicap in keratoconus patients.

In this study, we evaluated KEPAQ scores with respect to BCVA, SE, CCT, Kmean, and Q values in surgery and no-surgery groups. While BCVA and SE values were correlated with emotional distress, only BCVA was correlated with functional compromise. This finding indicates that a low visual acuity yields functional and emotional compromise. However, the high refractive error also affects emotional well-being, possibly regarding self-esteem and confidence. The functional and emotional status of the patients was strongly correlated, as expected. Since most keratoconus patients are young, patients with low vision might have reduced functionality compared to peers and fear and anxiety with their progressive disease. Therefore, in our daily routines, it is far more critical to evaluate visual quality as a whole, that is, visual acuity, general visual, and mental comfort. Remarkably, neither functional nor emotional QoL was correlated with the current age, age at diagnosis, time from diagnosis, CCT, Q value, or Kmean values.

The correlation analyses in patients who did or did not undergo ocular surgery yielded that KEPAQ E and KEPAQ F scores were strongly correlated. In addition, in patients who had undergone any surgical intervention for keratoconus, both emotional and functional measures were poorer with increased disease duration and higher keratometry readings. They were increasingly better with higher pre-operative and post-operative visual acuities, but were not affected by the amount of change in visual acuity by the surgery. Unlike in the whole group of patients, SE of refractive error was correlated with functional compromise but not emotional distress.

In patients without surgery, emotional well-being was correlated with the BCVA in better-seeing eyes. BCVA in worse-seeing eyes was not correlated with emotional well-being, and BCVA in neither eye was correlated with functional well-being in this group of patients. On the other hand, both emotional and functional QoL data correlated with BCVA in better-seeing and worse-seeing eyes in patients who underwent any surgical intervention.

The distribution of E and F classification scores was similar in the surgery and no-surgery groups. In the severely reduced QoL patients (i.e., E4 and F4), there were no differences in BCVA, SE, CCT, Kmean, and Q values between the groups. One might conclude that patients experience similar emotional and functional QoL levels once the clinical parameters are similar. However,

correlations of those particular clinical parameters with KEPAQ E and F scores could not be identified. Only due to having had significant eye surgery, patients might also experience emotional and functional distress.

The surgical procedures that yielded the poorest E and F scores included ICRS implantation. In contrast, the best E and F scores were obtained in patients who underwent DALK, which can be another reason to prefer DALK over PK in keratoconus. PK patients reported moderate functional and poorest emotional well-being, possibly related to the invasiveness of PK. Surgical subgroups are relatively small, making subgroup comparisons less reliable.

This study is the first to use the E&F classification results in real life, in a cohort of various stages of keratoconus and treatment procedures. The main limitation of this study is having no pre-operative KEPAQ scores, as this study was not designed as a prospective study, but as a cross-sectional, observational study. Other limitations include a low number of patients in each surgical subgroup, as only patients whose phone calls could be reached were included, preventing interpretation of the effects of different types of surgeries. Age-specific evaluation of the results could also provide more insight into emotional and functional reconciliation from the patient's perspective. However, the sample size of this cross-sectional cohort was not high enough to make more groups and to evaluate patients with or without a history of surgery in age groups. Prospective studies with extensive and homogeneous series with respect to age and surgical intervention types could draw more accurate conclusions about factors affecting patients' QoL.

Conclusion

KEPAQ is a well-designed disease-specific questionnaire that measures the functional and emotional impact on QoL due to keratoconus. In this study, visual acuity was the most consistent indicator of functional and emotional well-being, particularly in patients who underwent surgery, followed by SE of refraction. Worst QoL patients had similar clinical characteristics in both surgery and no-surgery groups. However, clinical parameters commonly used to stage the disease severity did not correlate significantly with the functional or emotional QoL measures. The surgical procedures that yielded the poorest E and F scores included ICRS implantation and PK, whereas the best E and F scores were obtained

in patients who underwent DALK. Further evaluations might improve the clinical evaluation and rehabilitation of patients with keratoconus.

Ethics Committee Approval: This study was approved by The Ethical Committee of Dokuz Eylul University (2021/20–58).

Informed Consent: Written informed consents were obtained from patients who participated in this study.

Conflict of Interest: The authors declare that there is no conflict of interest.

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