Changes in quality of life after laser in situ keratomileusis for myopia

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PURPOSE: To measure quality of life (QoL) outcome in prepresbyopic myopic patients having laser in situ keratomileusis (LASIK) refractive surgery using the Quality of Life Impact of Refractive Correction (QIRC) questionnaire and to compare the QoL of preoperative patients with a sample of spectacle and contact lens wearers not considering refractive surgery.

SETTING: Department of Optometry, University of Bradford, Bradford, and Ultralase, Leeds, West Yorkshire, United Kingdom.

METHODS: The validated QIRC questionnaire was prospectively completed by 66 patients before and 3 months after LASIK. Patients had myopia greater than 0.50 diopters (D) (range −0.75 to −10.50 D) and were aged 16 to 39 years. Patients were also directly asked to evaluate their QoL after surgery.

RESULTS: Overall QIRC scores improved after LASIK from a mean of 40.07 ± 4.30 (SD) to 53.09 ± 5.25 ($F_{1,130} = 172.65$, $P<.001$). Greater improvements occurred in women (53.83 ± 5.46) than in men (49.39 ± 5.94; $F_{1,64} = 9.37$, $P<.005$). Overall, 15 of the 20 questions (especially convenience, health concerns, and well-being questions) showed significantly improved scores ($P<.05$). Patients who "strongly agreed" (53.96 ± 4.91, n = 33) or "agreed" (51.78 ± 6.19, n = 23) had improved QoL and had significantly higher QIRC scores than those who "neither agreed nor disagreed" (44.36 ± 4.97, n = 5) or "strongly disagreed" (42.82, n = 1) ($F_{1,60} = 11.24$, $P<.001$). The matched group not contemplating LASIK scored 42.41 ± 3.89 on QIRC overall.

CONCLUSIONS: Large improvements in QIRC QoL scores were found after LASIK for myopia in the majority of patients, with greater improvements in women. A small number of patients (4.5%) had decreased QIRC QoL scores, and these were associated with complications. People presenting for LASIK scored measurably poorer than matched patients not contemplating refractive surgery.

Refractive error affects over 50% of the United Kingdom population (Optical Goods and Eyecare). While spectacles and contact lenses are the primary choice of refractive error correction among myopic patients, during the past decade, refractive surgery has gained interest even among successful contact lens wearers.[1] The outcome of refractive surgery has usually been characterized by objective standard clinical measures, such as postoperative uncorrected visual acuity and residual refractive error.[2] Although these measures provide important information, they do not necessarily correlate well with patients' postoperative subjective impressions and visual improvement.[3–5] The importance of patient-centered measurement using a measure of quality of life (QoL) for clinical research and practice has been widely recognized, and many QoL questionnaires have been developed.[6] Therefore, patient-based subjective assessment of refraction-related QoL and visual functioning have recently become increasingly used to assess the outcome of refractive surgery.[7,8]

Two validated questionnaires have been developed to assess health-related QoL in patients with refractive error and its correction: the Refractive Status and Vision Profile (RSVP)[7] and the National Eye Institute Refractive Quality of Life (NEI-RQL).[8] Both questionnaires have been shown to be sensitive to visual functioning and refractive error related QoL changes and have reported improved QoL following refractive surgery. Other studies have reported a high level of postrefractive satisfaction with refractive surgery patients,[5,9–11] but these results were determined with nonvalidated questionnaires.

The RSVP and the NEI-RQL instruments, however, use traditional Likert scoring[12] in which patients' response scores for a selected set of items are summed to derive the overall score. Likert scoring assumes the value of each item

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represents equal difficulty, and it scores them equally. In addition, the linear response scale used for each item assumes uniform changes for that item. For example, in a Likert-scaled vision disability questionnaire such as the Activities of Daily Vision Scale (ADVS),[13] a response of "a little difficulty" (score of 4) is used to represent twice the level of ability as "extreme difficulty" (score of 2) which is similarly twice as good as "unable to perform the activity due to vision" (score of 1) for all items. This appears illogical, and Rasch analysis has been used to confirm that differently weighed items are required to provide a valid scale.[14] Similarly, Likert scales assume that all items are of equal difficulty. For example, in the ADVS questionnaire, an answer of "a little difficulty" to the question regarding visual difficulties "driving at night" scores the same as the "a little difficulty" with "driving during the day." Again, this is illogical and Rasch analysis has been used to confirm that driving at night is a more difficult task than driving during the day and can provide an appropriate weighting factor for each item.[14] This new approach to questionnaire development using modern psychometric methods, such as Rasch analysis,[15–18] to measure health outcomes has suggested improved validity in item inclusion and on assessment of item difficulty across person QoL.[14,19–21] Rasch analysis, by converting the categorical data into a linear scale, calculates item difficulty in relation to patient QoL and weighs overall item and person QoL scores respectively with an objective set of criteria.[15–18]

In an earlier study, we developed and validated the Quality of Life Impact of Refractive Correction (QIRC) questionnaire to measure the QoL of people who require a refractive correction (spectacles, contact lens, and post-refractive surgery).[22] Item identification and selection (647 items) were performed using an extensive literature review, professional advice, and lay focus groups. Item reduction was performed by focus groups and administration of a pilot questionnaire. The 90-item pilot questionnaire was administered across settings of optometry, contact lens, and refractive surgery to 306 patients (102 responses for each mode of refractive correction). Rasch analysis was used for item reduction, which resulted in a 20-item questionnaire. (available at www.optvissci.com). Rasch analysis of 312 questionnaires of patients from the 3 refractive correction modes and standard psychometric analysis showed that QIRC is a valid and reliable measure of self-reported QoL in patients with refractive error and its correction (person separation, 2.03; reliability, 0.80; root mean square measurement error, 3.25; mean square $\pm$ SD infit, 0.99 $\pm$ 0.38; outfit, 1.00 $\pm$ 0.39, item infit range 0.70 to 1.24, item outfit range 0.78 to 1.32; unrotated factor analysis principal factor loadings 0.40 to 0.76, Cronbach alpha 0.78, test–retest intraclass correlation coefficient 0.88, and coefficient of repeatability of $\pm$ 6.85 units).[22] Rasch analysis was used to estimate values on an interval scale for each item and for each patient. These values can be used in subsequent studies including this 1, in which we compared the QoL of prepresbyopic patients before and after laser in situ keratomileusis (LASIK) refractive surgery for myopia using QIRC. The role of sex and complications in outcomes were also evaluated. Patients were also asked directly about their perceived QoL gains; these results were compared with QIRC scores. In addition, QIRC scores of preoperative patients (spectacle and/or contact lens wearers) were compared with those in a sample of spectacle and contact lens wearers not considering refractive surgery.

PATIENTS AND METHODS

Study Population

Patients included in this study were prospectively recruited from refractive surgery clinics in London and Leeds (United Kingdom). Sixty-six consecutive patients who had LASIK for myopia in both eyes gave informed consent to participate in the preoperative and postoperative study. The study followed the tenets of the Declaration of Helsinki and was approved by the university's ethics committee. Exclusion criteria included ocular disease, ocular surgery (other than refractive), neurological or systemic disease, any medication that could alter visual function, and an inability to read and understand written English. Inclusion criteria included myopia greater than 0.50 diopter (D) spherical equivalent and age between 16 and 39 years (adult prepresbyopic age) as QIRC was developed for the prepresbyopic population.[22] The QIRC was administered to all patients before and 3 to 8 months after bilateral LASIK treatment.

Instrument

Patients were requested to complete QIRC before they had their refractive surgery consultation. Patients were also informed they would be asked to complete the questionnaire 3 months after the surgery. Quality of Life Impact of Refractive Correction consists of 20 items; these are listed in Table 1. Patients were required to

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Table 1. Comparison of scores from 66 myopic patients before and after LASIK refractive surgery.

Item	Mean ± SD		*P* Value*
	Preoperative	Postoperative	
1. Driving in glare conditions	47.23 ± 12.57	48.86 ± 11.27	.439
2. Eyes feeling tired or strained	47.79 ± 9.96	50.14 ± 9.84	.177
3. Unable to use non-Rx sunglasses	36.11 ± 13.30	56.71 ± 0.00	<.001
4. Having to think about…before doing	34.22 ± 8.60	59.02 ± 7.26	<.001
5. Not being able see on waking	36.63 ± 11.34	57.92 ± 5.59	<.001
6. Unaided vision for swimming	37.37 ± 10.10	63.15 ± 4.88	<.001
7. Trouble with spectacles…for gym…	33.99 ± 12.58	55.17 ± 0.00	<.001
8. The initial and ongoing cost to buy	41.20 ± 10.58	57.81 ± 10.88	<.001
9. The cost of unscheduled maintenance	41.37 ± 12.22	53.34 ± 10.75	<.001
10. Increasingly reliant upon	36.94 ± 7.34	62.10 ± 8.01	<.001
11. Vision not as being as good as could	35.64 ± 4.48	56.69 ± 11.16	<.001
12. Medical complications from	42.40 ± 13.03	48.85 ± 11.47	<.05
13. UV protection	41.66 ± 10.11	49.70 ± 12.00	<.001
14. That you have looked your best	39.40 ± 12.75	50.22 ± 13.79	<.001
15. Think others see you the way want	42.53 ± 12.42	51.26 ± 14.06	<.001
16. Complimented/flattered	42.54 ± 9.51	51.06 ± 13.41	<.001
17. Confident	44.99 ± 14.58	50.27 ± 15.61	.052
18. Happy	45.67 ± 10.96	49.28 ± 12.69	.089
19. Able to do things you want to	35.23 ± 12.65	47.32 ± 14.61	<.001
20. Eager to try new things	38.40 ± 14.80	42.95 ± 14.49	.086
Total QIRC score in each group	40.07 ± 4.30	53.09 ± 5.25	<.001

Rx = prescription; UV = ultraviolet
*Analysis of variance

answer all questions on a 5-point response scale with evenly spaced descriptors.[23] For questions regarding visual function, symptoms, convenience, and concerns, the positive adjectival descriptor was assigned to the lowest rating scale; for the remaining questions regarding well-being, the positive adjectival descriptor was assigned to the highest rating scale. Patients were asked to grade questions 14 to 20 concerning well-being in relation to their refractive correction and the instructions to the relevant questions included: "We are now interested in the effect that your optical correction (refractive surgery, plus possible spectacles and/or contact lenses) have had on the way you have been feeling. The effect on your feelings may be obvious (eg, you may feel that you look better without spectacles) or it may be indirect (eg, you may feel more confident after refractive surgery because you feel that you look better)." Patients were requested to answer QIRC for when they were wearing spectacles (S), contact lenses (C), or none (N). Therefore, for those patients who wore more than 1 type of correction, multiple answers were provided. Rating scores for patients wearing both spectacles and contact lenses were taken from their predominantly used refractive correction.

An additional question asked patients postoperatively to grade on a 5-point agreement scale from strongly agree to strongly disagree whether their QoL had improved due to refractive surgery.

Laser in situ keratomileusis was performed under topical anaesthesia using the Technolas 217 (V2 9997; Bausch & Lomb) excimer laser and the Hansatome microkeratome (Bausch & Lomb Surgical). In all eyes, the corneal flap was 160 μm thick and, where possible, 9.5 mm in diameter, otherwise 8.5 mm in diameter; the optical zone was at least 6.0 mm, increased to 0.5 mm greater than the scotopic pupil for pupils over 5.5 mm.

Statistical Analysis

The preoperative and postoperative scale responses were assigned from weighed Rasch scores of 312 patients (104 of each correction mode: spectacles, contact lenses, and postrefractive surgery patients) from the original validation study.[22] The sample used in the validation study was shown to be representative of the U.K. population of patients using refractive correction. A higher score on the QIRC scale represents better QoL. For statistical analysis, the response polarity of items 14 through 20 was reversed so positive responses represented higher scores and negative responses represented lower scores.

The main outcome measure was the overall QIRC score. However, we also tested the significance of differences on each of the 20 questions to determine which questions were contributing to overall differences. One-way analysis of variance was used for significance examination with Sheffé post-hoc significance testing and the statistical results were considered significant at $P \leq .05$. All statistical analyses were performed using SPSS for Windows (SPSS 11.0).

RESULTS

The demographic characteristics in the study population are shown in Table 2. The respondents included 40 women and 26 men with a mean age of 30.2 years ± 4.5 (SD) (range 21 to 39 years). Prior to surgery, more than half of the patients were predominantly spectacle wearers (60%) and 40% were predominantly contact lens

Table 2. Demographic characteristics in 66 patients having LASIK refractive surgery. Socioeconomic status was determined using the Market Research Society occupation groupings for the household chief income earner (Occupation groupings, A Job Dictionary, London, The Market Research Society, 2003).

Characteristic	Result
Mean age, y ± SD (range)	30.2 ± 4.5 (21–39)
Sex (% women)	61
Socioeconomic status	3.4 ± 0.6
Race (%)	
White	91
Asian	3
Black	3
Mixed	0
Other	3
Refractive error (%)	
Low (−0.50 D to <−3.00 D)	53
Moderate (−3.00 D to −6.00 D)	38
High (>−6.00 D)	9

wearers. The mean preoperative refractive error was −3.36 ± 1.86 D (range −0.75 to −10.25 D) in the right eye and −3.34 ± 1.74 D (range −1.00 to −10.50 D) in the left eye. All patients had refractive surgery in both eyes, and the postoperative QIRC data were collected at least 3 months after LASIK (mean 4.25 ± 1.50 months; range 3 to 8 months).

Overall QIRC scores improved after LASIK surgery from a mean of 40.07 ± 4.30 to 53.09 ± 5.25 ($F_{1,64}$ = 172.646, P<.001). Data were also analyzed from each item separately. The effect size (change divided by preoperative SD) was 13.05/4.30 = 3.03 units and the responsiveness statistic (change divided by retest SD) was 13.05/3.49[22] = 3.74 units. Fifteen of the 20 items showed statistically significant changes in QIRC scores after refractive surgery (Table 1). Patients reported improved QoL on items associated with all 5 convenience issues (P<.001), both economic issues (P<.001), all 4 health concern items (P<.05), and 4 of 7 items in the well-being domain (P<.001) (Figure 1).

Before surgery, women reported significantly worse overall QoL (mean 39.06 ± 4.54) than men (mean 41.68 ± 3.51; $F_{1,64}$ = 6.26, P<.05). There were also significant differences between women and men for individual questions. Women reported worse QIRC scores on items related to using nonprescription sunglasses (P<.05), seeing on waking (P<.05), seeing when exercising (P<.05), confidence (P<.05), and ability to do things you want to (P<.05). Overall, women reported a better overall QIRC score after refractive surgery than men (mean 53.83 ± 5.46 compared with 49.39 ± 5.94; $F_{1,64}$ = 9.37, P<.005). Postoperatively, women reported better QoL on items regarding having to think about their eyes before doing things (P<.05), concerned about their vision not being as good as it could be (P<.05), looking their best (P<.05), being complimented/flattered (P<.001), feeling happy (P<.05), and being eager to try new things (P<.05).

Patients were asked to rate their QoL improvement after refractive surgery on a 5-point scale of agreement (strongly agree, agree, neither agree nor disagree, disagree, and strongly disagree). There was no significant difference in the overall QIRC score between patients who strongly agreed (mean 53.96 ± 4.91, n = 33) or agreed (mean 51.78 ± 6.19, n = 23) their QoL had improved after refractive surgery (P = .344). However, these patients had significantly higher ($F_{1,60}$ = 11.24, P<.001) QIRC scores than those who neither agreed nor disagreed (mean 44.36 ± 4.97, n = 5) or strongly disagreed (42.82, n = 1).

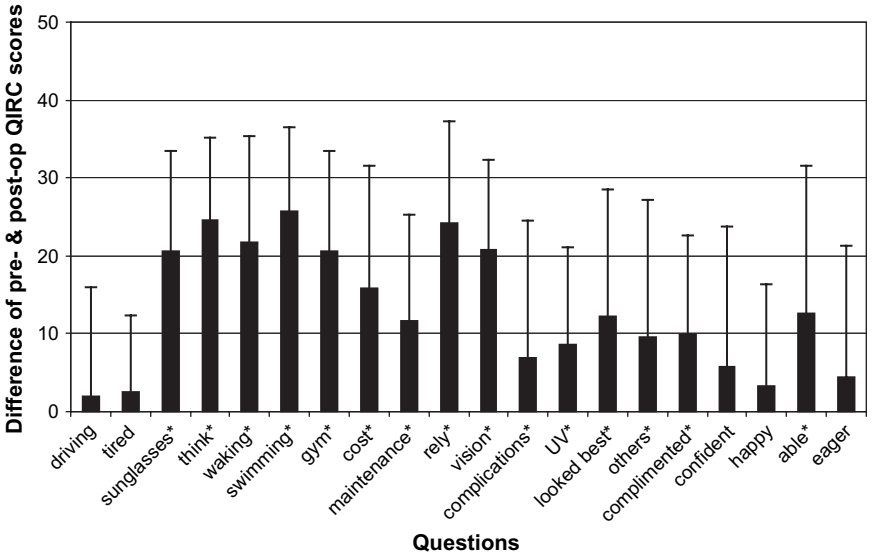

Figure 1. Columns showing mean difference (error bars ± 1 SD) of preoperative and postoperative responses on each QIRC question (*significant difference by 1-way analysis of variance).

Three patients (4.5%) had a lower QIRC score postoperatively (preoperative mean 43.32 ± 2.35; postoperative mean 41.95 ± 2.47).

Table 3 shows a comparison of preoperative QIRC scores with data from a sample of spectacle and contact lens wearers from optometric practice (N = 173). These data were from the validation study adjusted to have matching proportions of spectacles (60%) and contact lens wearers (40%).[22] The refractive surgery group (40.07 ± 4.30) had significantly lower overall QIRC scores preoperatively than the spectacle and contact lens group (42.41 ± 3.89; $F_{1,237} = 46.064$, $P<.001$). Thirteen of the 20 items showed statistically significant differences in QIRC scores between the samples. Preoperative patients reported worse QoL on items associated with all 5 convenience issues ($P<.05$), all 4 health concern issues ($P<.05$), and 4 of 7 issues on the well-being domain ($P<.05$). There were no differences between responses regarding visual function, symptoms, economic concerns, and 3 of the well-being items.

DISCUSSION

This study showed a large improvement in QoL in the majority of prepresbyopic patients after LASIK refractive surgery. These large improvements in QoL are consistent with results in conventionally validated previous reports of refractive-error-related QoL as a result of surgery.[7,8] McDonnell et al.[8] assessed refractive-error-related QoL in patients following refractive surgery with the NEI-RQL; a 42-item questionnaire that included subscales related to clarity of vision, expectations, near vision, far vision, diurnal fluctuations, activity limitations, glare scale, symptoms, dependence on correction, worry, suboptimal correction, appearance, and satisfaction with correction. Improved QoL was mostly correlated with expectations, near and far vision, diurnal fluctuations, activity limitations, symptoms, dependence on correction, worry, perceptions about having suboptimal correction, appearance, and satisfaction with correction. However, symptoms of glare were significantly worse after refractive surgery and clarity of vision showed no significant change. Schein and coauthors[7] used the RSVP, a 42-item questionnaire to measure vision-related health status in patients with refractive error including domains such as concern, driving, expectations, physical and social functioning, symptoms, optical problems, glare, and problems with corrective lenses. Patients reported significantly improved QoL after refractive surgery in subscales related to expectations, physical and social functioning, and problems with corrective lenses. However, driving, symptoms, optical problems, and glare showed significantly worse scores after surgery. McGhee et al.,[5] Khan-Lim and coauthors,[24] and

Table 3. Comparison of mean ± SD QIRC scores from preoperative LASIK patients (N = 66) and an optometric sample of spectacle wearers and contact lens wearers (N = 173).

Item	Preoperative	Specs and CL	*P* Value*
1. Driving in glare conditions	47.23 ± 12.57	34.02 ± 21.81	.125
2. Eyes feeling tired or strained	47.79 ± 9.96	46.07 ± 10.27	.305
3. Unable to use non-Rx sunglasses	36.11 ± 13.31	35.12 ± 19.93	<.05
4. Having to think about…before doing	34.22 ± 8.60	41.74 ± 15.04	<.001
5. Not being able see on waking	36.63 ± 11.34	41.12 ± 17.17	<.001
6. Unaided vision for swimming	37.37 ± 10.10	38.46 ± 19.13	<.001
7. Trouble with spectacles…for gym…	33.99 ± 12.58	34.95 ± 20.62	<.001
8. The initial and ongoing cost to buy	41.20 ± 10.58	41.76 ± 13.93	.291
9. The cost of unscheduled maintenance	41.37 ± 12.22	43.49 ± 13.22	.146
10. Increasingly reliant upon	36.94 ± 7.34	44.46 ± 14.43	<.001
11. Vision not as being as good as could	35.64 ± 4.48	42.91 ± 13.39	<.001
12. Medical complications from	42.40 ± 13.03	44.16 ± 16.07	<0.05
13. UV protection	41.66 ± 10.11	47.25 ± 13.73	<.001
14. That you have looked your best	39.40 ± 12.75	43.61 ± 17.22	<.05
15. Think others see you the way want	42.53 ± 12.43	42.64 ± 17.86	.111
16. Complimented/flattered	42.54 ± 9.51	45.04 ± 16.64	<.05
17. Confident	44.99 ± 14.58	44.80 ± 15.63	.580
18. Happy	45.67 ± 10.96	45.12 ± 14.73	.900
19. Able to do things you want to	35.23 ± 12.65	45.22 ± 16.23	<.001
20. Eager to try new things	38.40 ± 14.80	46.23 ± 16.88	<.001
Total QIRC score in each group	40.07 ± 4.30	42.41 ± 3.89	<.001

CL = contact lenses; Rx = prescription; Specs = spectacles; UV = ultraviolet
*Analysis of variance

Hill,[10] using nonvalidated satisfaction questionnaires for refractive surgery outcome, reported high levels of patient satisfaction after surgery. These studies suggested that inconvenience issues, freedom from spectacles, and intolerance of contact lenses were the most common reasons for seeking treatment.

In this study, Rasch analysis showed no significant change in QIRC scores after surgery for visual function and symptoms items. From these results, it seems that overall, patients have few symptoms or problems with visual function after surgery that are not corrected and issues such as convenience, cost, health concerns and appearance determine the influence of refractive error correction on QoL (Table 1).

The estimated prevalence figure of 60.6% of women in the study who had refractive surgery is similar to the U.K. population seeking eyecare.[25] To our knowledge, differences in QoL between women and men after refractive surgery have not been reported previously. Overall, women showed significantly higher QIRC QoL after refractive surgery, especially in items related to aspects of well-being. However, women reported significantly lower scores than men preoperatively. This difference suggests that women were more sensitive to the QoL issues assessed by the QIRC and showed a greater improvement in QoL after refractive surgery.

A small number of patients (n = 3; 4.5%) had overall lower QIRC QoL scores after surgery. One former high myope was very disappointed with her quality of vision, and 2 former moderate myopes reported having better vision with their contact lenses prior to surgery than postoperatively. Their QIRC scores showed a worsening in items related to visual function, symptoms, concerns, and well-being. One patient (high myope), who had a significantly lower score postoperatively (preoperative QIRC score 50.57; postoperative QIRC score 42.82), "strongly disagreed" that her QoL improved after refractive surgery. This patient reported some common complications of laser refractive surgery such as having better vision with contact lenses prior to surgery, eyes sensitive to bright light, and misty and unclear vision, especially when driving at night.[8,10,26] None of the patients with improved QIRC scores experienced any complications 3 to 8 months after LASIK.

Comparison of preoperative QIRC scores with previously obtained data from the validation study of spectacle and contact lens wearers not considering refractive surgery[22] showed lower QoL scores in the preoperative population. This indicates that those who seek refractive surgery experience more QoL loss from their refractive correction than those who are content to remain in spectacles or contact lenses. Similar findings have been reported with the NEI-RQL, in which preoperative NEI-RQL scores were substantially lower than scores in a sample of spectacle and contact lens wearers not considering refractive surgery.[8] McDonnell et al.[8] suggest that patients with worse scores on visual functioning and well-being subscales might be more likely to seek refractive surgery correction.

While it is most likely that it is the impact of surgery that causes the improvement in QoL, other factors, such as the Hawthorne effect[27] and cognitive dissonance, should be considered.[28] Participating in a clinical trial or study can make patients report a significant positive effect of the surgery due to the added attention being made toward them (the Hawthorne effect). This should be minimal in this study because patients received standard preoperative and postoperative care with the simple addition of a written questionnaire. Cognitive dissonance states that a change in attitude or belief occurs in an attempt to be consistent with the choice taken. Patients who have chosen to have surgery could justify this choice by indicating that the outcome was successful. Dissonance increases as the degree of change increases. While this probably plays a role, its impact is likely to be greater when asking about satisfaction or overall assessment of outcome because this directly targets justification issues, rather than when using the same questionnaire before and after surgery where the way to distort measurement of outcome may not be as obvious.

In conclusion, the QIRC instrument was used to assess the QoL in 66 patients having refractive surgery. Patients having refractive surgery showed significantly lower QoL scores than spectacle and contact lens wearers from optometric practice not contemplating refractive surgery. There were significant improvements in QoL after LASIK surgery in most (95%) of patients, especially for items related to convenience issues, economic issues, health concerns, and well-being. Women showed greater improvements in QoL than men, with lower QoL before surgery and better QoL after surgery.

The QIRC questionnaire can effectively measure an improvement in the QoL of people having refractive surgery. This quality with the true linear scoring afforded by Rasch analysis makes QIRC an ideal instrument for measuring QoL outcomes of all types of refractive surgery.

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