Quality of Life in High Myopia

Implantable Collamer Lens Implantation versus Contact Lens Wear

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Purpose: To compare vision-related quality of life in implantable Collamer lens (ICL) recipients and successful contact lens (CL) wearers not seeking refractive surgery.

Design: A comparative cross-sectional study of consecutive cases.

Participants: Forty-one consecutive cases of bilateral ICL implantation in Moorfields Eye Hospital, London, and a control group of 41 CL wearers with a similar starting level of myopia attending consecutively at 1 of 2 community optometric practices in the London area.

Intervention: Quality of Life Impact of Refractive Correction questionnaire administration in a semistructured interview.

Main Outcome Measure: Quality of Life Impact of Refractive Correction score.

Results: Quality of Life Impact of Refractive Correction scores were significantly higher ($P<0.001$) in ICL recipients (53.67±4.50) than in CL wearers (44.42±5.07). Age (mean±standard deviation [SD], 37.7±7 vs. 37.5±7.3), gender distribution (% female, 90% vs. 74%; $P = 0.295$), and preoperative (ICL recipients) or uncorrected (CL wearers) refractive error (mean refractive spherical equivalent±SD, 11.0±2.7 vs. 11.3±3.5) were similar in ICL recipients and CL wearers, respectively. Postoperative uncorrected visual acuities in ICL recipients (0.04 [20/20]±0.18) and CL-corrected visual acuities in control patients (0.01 [20/20]±0.14) measured in the better eye in each group also were similar ($P = 0.53$).

Conclusions: Implantable Collamer lens implantation may offer significant quality-of-life advantages over CL wear for patients with high myopia.

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Intraocular Collamer Lenses (ICLs; Staar Surgical, Monrovia, CA) are soft, foldable, sulcus-placed posterior chamber phakic intraocular lenses that can be implanted through a small (3.0 mm) self-sealing limbal incision. ICL implantation is technically undemanding, has a good safety profile, and is increasingly popular as an alternative to laser refractive surgery, refractive lens exchange, and other phakic intraocular lenses in the surgical correction of higher levels of myopia.[1–7] In the recent United States Food and Drug Administration trial of toric ICL implantation in the treatment of myopic astigmatism (3–19 diopters [D] preoperative sphere; 1–4 D preoperative cylinder; mean refractive spherical equivalent [MRSE], 9.36±2.66; 210 eyes of 124 patients; 12-month postoperative results), 77% of eyes were within ±0.5 D of the predicted MRSE, 91% had <1 D astigmatism, and 83% had an uncorrected visual acuity of ≥20/20. In 1.6%, ≥2 lines of best-corrected visual acuity were lost, 3 ICLs were removed, and in 1 eye, a clinically significant cataract developed.[3]

Quantification of visual outcomes after ICL implantation largely has been restricted to measures of refraction and visual acuity, with some testing in the contrast domain.[8] These objective measures are useful, but correlation with subjective visual function after surgery may be incomplete[9] and functional problems in specific areas, such as glare or halo symptoms affecting night driving,[10] may not be identified.

Questionnaire instruments recently have been developed to measure vision-related quality of life after refractive surgery. Validated instruments include the Refractive Status and Vision Profile,[11,12] the National Eye Institute Refractive Quality of Life (NEI-RQL),[13–16] and the Canadian Refractive Surgery Research Group instrument.[17,18] These instruments use Likert scoring in which responses to questionnaire items on a 4- or 5-category scale are summated to give the overall score. Each item and each category on the response scale are given equal weight. A more sophisticated approach, Rasch analysis, has been used recently by Pesudovs et al[19,20] and Garamendi et al[21] in the development of their Quality of Life Impact of Refractive Correction (QIRC) questionnaire. In essence, Rasch analysis refines conventional Likert scoring by excluding redundant items and converting categorical data to an appropriately weighted linear scale. This both shortens the questionnaire and enhances discriminatory power in scoring.

The authors set out to compare vision-related quality of life in successful contact lens (CL) wearers and ICL recipients with similar starting levels of myopia using the QIRC instrument.

Patients and Methods

The study design, a cross-sectional review comparing QIRC scores in successful CL wearers and ICL recipients with similar starting levels

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of myopia, was approved by the Moorfields Eye Hospital Local Research and Ethical Committee and the City University Research Governance Committee. Patients were recruited using standard informed consent procedures[22] between April and August 2007.

General exclusion criteria included poor comprehension of written or spoken English and vulnerable patient groups.[23] All study participants were 21 years of age or older and in good general health with a corrected visual acuity of at least 20/40 in the better eye and no other ocular pathologic features. Presbyopic patients with a monovision correction who were not spectacle dependent for reading were included in both arms of the study.

Intraocular Collamer lens recipients were consecutive cases of bilateral ICL implantation for high myopia (MRSE, ≥7 D) performed between July 2004 and January 2007 by 2 consultant surgeons at Moorfields Eye Hospital. All patients had undergone surgery at least 3 months before questionnaire administration. The equally sized control group was recruited from consecutive established, successful CL wearers with a similar level of myopia (MRSE, ≥7 D) attending scheduled review appointments at 1 of 2 community optometric clinics, both in the London area. Established, successful CL wearers were defined as patients wearing a CL correction for myopia for at least 3 months with good comfort in daily wear soft or rigid gas permeable CLs and average daily wearing times of 10 hours or more who did not envisage opting for refractive surgery in the near future.

Data collected to examine possible differences between the study groups (Table 1) included basic demographic data (age and gender), preoperative MRSE in ICL recipients, MRSE at the time of the survey in ICL recipients and CL wearers, uncorrected logarithm of the minimum angle of resolution visual acuity at the time of the survey in ICL recipients, and CL-corrected logarithm of the minimum angle of resolution visual acuity at the time of the survey in CL wearers. Monocular data from the better eye was used throughout[24] for comparisons between groups. Similarity of starting levels of myopia was examined by comparing the preoperative MRSE in ICL recipients with the MRSE at the time of the survey in CL wearers. Similarity of visual acuities in the patients' habitual corrections at the time of the survey was examined by comparing postoperative uncorrected visual acuity in ICL recipients with CL corrected visual acuity in CL wearers.

The QIRC questionnaire was administered verbally by one investigator (AI) either by telephone or at a further interview after completion of the informed consent process. Anonymized details of age, gender, preoperative refraction and months since surgery (for ICL recipients), current refraction, and visual acuity were collated for analysis on an Excel (Microsoft Corporation, Seattle, WA) spreadsheet. A free, downloadable Excel spreadsheet available at http://www.pesudovs.com/konrad/questionnaire.html (date accessed, July 2007) that automatically converted original numerical response values into a Rasch-weighted QIRC score was used to collate and analyze QIRC responses. Detailed instructions for QIRC scoring also are available at this site.

Unpaired 2-tailed *t* tests were used for statistical comparison of overall QIRC scores (the main outcome measure) and in an exploratory analysis of scores for individual questionnaire items with *P* values <0.01 classified as statistically significant. A lower *P* value than standard ($P<0.05$) was chosen to denote statistical significance in recognition of the multiple comparisons performed in the exploratory analysis of individual questionnaire item responses.

Patients were invited to make free text comments about issues related to their refractive correction or refractive surgery that are not covered by structured items in appended space at the end of the QIRC questionnaire. Informal review of common themes in these appended free text responses was included in the analysis.

Intraocular Collamer lens recipients also were asked to rate their overall satisfaction with the results of surgery on a 5-category scale (very satisfied, satisfied, neither satisfied nor unsatisfied, dissatisfied, very dissatisfied) and to comment on whether the level of any night vision symptoms (glare, halo, starburst) was the same, more, or less than that before surgery.

Results

The age and gender distributions were similar in ICL recipients and CL wearers participating in the study, with a slightly higher ratio of females to males in the ICL group (Table 1). The range and distribution of preoperative and current refractive errors in ICL recipients and CL wearers, respectively, also were similar (Table 1). Most ICL recipients (98%) included in the study were spectacle independent after surgery, but 1 patient wore a reading correction and 1 patient wore a distance correction for night driving. Postoperative uncorrected visual acuity in ICL recipients was similar to corrected acuity in CL wearers at the time of questionnaire administration (Table 1). Both groups had a similar starting level of myopia (Table 1). The median time between second eye surgery in

Table 1. Demographic Characteristics, Refraction, and Visual Acuity in the Intraocular Collamer Lens Recipients and Contact Lens Wearers Studied

	Intraocular Collamer Lens Recipients	Contact Lens Wearers
Female/male (% female)	37/4 (90%)	29/12 (71%)
Age (mean±SD)	37.7±6.5	37.5±7
Preoperative MRSE (mean±SD)	11.0±2.7	N/A (not applicable)
MRSE at survey (mean±SD)	0.13±0.23	11.3±3.5
UCVA at survey (mean±SD)	0.04 (20/20)±0.18	N/A
CLCVA at survey (mean±SD)	N/A	0.01 (20/20)±0.14

CLCVA = contact lens corrected visual acuity; F = female; ICL = intraocular Collamer lens; M = male; MRSE = mean refractive spherical equivalent; N/A = not answered; SD = standard deviation; UCVA = uncorrected visual acuity.

Demographic characteristics (mean±SD) are summarized for each of the study groups above. Age was similar in both arms of the study, as were other relevant comparators. Differences in the gender distribution (F/M) were nonsignificant ($P = 0.295$, Fisher exact test). The preoperative MRSE in ICL recipients was similar to the MRSE in contact lens wearers at the time of the survey ($P = 0.78$, *t* test). The UCVA in ICL recipients and the CLCVA in contact lens wearers also were similar at the time of the survey ($P = 0.53$, *t* test). Mean logarithm of the minimum angle of resolution visual acuities listed above are presented alongside approximate median Snellen acuities for clarity (20/20 in both groups). The table above refers to the better eye throughout for both refraction and acuity figures.[24]

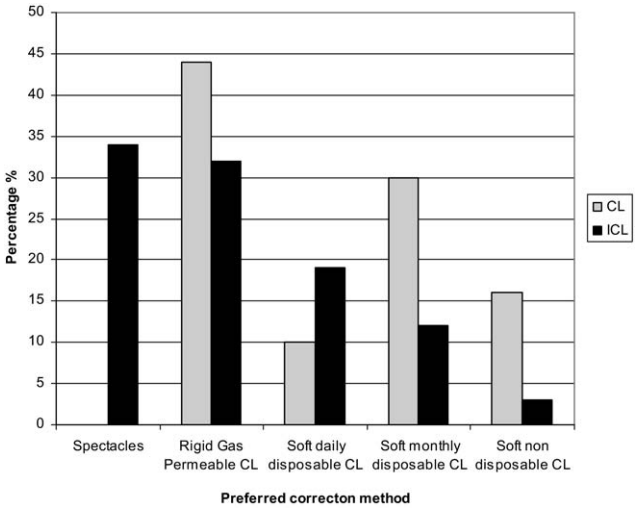

Figure 1. Bar graph showing preferred preoperative method of refractive correction in intraocular Collamer lens (ICL) recipients versus preferences in contact lens (CL) wearers participating in the study. The distribution of preferred preoperative myopic correction methods in ICL recipients is charted above in comparison with the preferred CL type in the control group of successful CL wearers.

ICL recipients and questionnaire administration was 8 months (range, 3–24 months).

The principal methods of refractive correction used in the months before surgery in ICL recipients and preferences in CL wearers at the time of surgery are summarized in Figure 1. Approximately two thirds of ICL recipients wore CLs before surgery.

The QIRC questionnaire results were completed by 41 ICL recipients and 41 CL wearers (Table 2). Overall QIRC scores were significantly higher for ICL recipients than for CL wearers ($P<0.001$), indicating that ICL recipients enjoy a better quality of life. The mean±standard deviation QIRC score for ICL recipients was 53.67±4.50 versus 44.42±5.07 in CL wearers.

Higher overall QIRC scores in ICL patients were driven by significantly higher scores for individual items relating to the subjective value of relative freedom from reliance on refractive correction on waking, during travel, and for sport—especially water sports (Table 2; items 4–7). Intraocular Collamer lens recipients also had significantly less concern over limitations in their vision and the possibility of medical problems resulting from their choice of refractive correction (Table 2; items 11–12). Contact lens wearers scored higher than ICL recipients only for 1 item, difficulty driving in glare conditions (Table 2; item 1), but the differences here were not significant ($P = 0.77$).

Overall levels of satisfaction with ICL surgery were very high (Fig 2). Any dissatisfaction largely related to a perceived increase in night vision symptoms (glare, halo, or starburst) in some patients. Fourteen patients (34%) reported that night vision symptoms were increased compared with those before surgery, 22 (54%) described no change, and 3 (7%) patients described a decrease (2 patients could not answer).

In free text responses appended to the questionnaires, 14 (17%) of 82 patients described difficulties in giving precise answers to questionnaire items addressing well-being (items 14–20). Several patients reported that they believed that responses in this section

Table 2. Quality of Life Impact of Refractive Correction Questionnaire Responses in Intraocular Collamer Lens Recipients versus Contact Lens Wearers

Quality of Life Impact of Refractive Correction Questionnaire Item	% n/a	Intraocular Collamer Lens Recipients	Contact Lens Wearers	*P* Value (*t* Test)
1. Difficulty driving in glare conditions	11	44.22±12.59	45.06±11.68	0.77
2. Eyes feeling tired or strained	0	52.67±9.28	46.27±9.47	0.03
3. Trouble using off-the-shelf sunglasses	5	55.17±5.85	52.64±9.96	0.174
4. Trouble thinking about correction before traveling, sport, swimming	1.1	59.05±7.46	41.78±12.47	<0.001
5. Trouble not seeing on waking	1.1	59.32±0	35.96±9.85	<0.001
6. Trouble not seeing on beach, in pool	1.1	63.17±3.37	34.58±4.69	<0.001
7. Trouble with spectacles or contact lenses when at the gym or keeping fit	35	55.17±0	48.83±11.05	0.01
8. Concern about initial cost of contact lenses or refractive surgery	0	52.55±12.7	47.28±12.55	0.62
9. Concern about ongoing cost	0	49.32±10.93	42.82±12.72	0.17
10. Concern about increasing reliance on spectacles or contact lenses	1.1	56.35±12.13	47.75±13.13	0.03
11. Concern about vision not being as good as it could be	0	53.08±12.22	40.27±10.29	<0.001
12. Concern over medical complications from refractive surgery or contact lens wear	0	48.56±11.06	36.88±10.42	<0.001
13. Concern about eye protection from ultraviolet radiation	1.1	54.94±12.35	49.98±13.9	0.95
14. How much time you looked your best	0	52.46±15.86	45.09±16.30	0.04
15. How much time you projected a positive image to others	3.4	57.43±15.61	49.85±17.35	0.044
16. How much time you have felt complimented	1.1	52.43±16.79	48.14±13.84	0.22
17. How much time you felt confident	0	55.52±13.03	47.85±16.94	0.024
18. How much time you felt happy	0	55.42±13.30	46.23±15.26	0.05
19. How much time you felt able to do the things you want	0	49.01±14.41	42.03±16.13	0.042
20. How much time you felt eager to try new things	0	47.44±16.73	38.95±16.03	0.021
Total QIRC scores		53.67±4.5	44.42±5.07	<0.001

CL = contact lens; D = diopter; ICL = intraocular collamer lens; N/A = not answered; QIRC = Quality of Life Impact of Refractive Correction; SD = standard deviation.

Abridged QIRC questionnaire items and Rasch weighted response scores (mean±SD) for ICL recipients and CL wearers with similar starting levels of myopia (mean refractive spherical equivalent, ≥7 D) are summarized above. Higher scores suggest better vision-related quality of life. A 2-tailed Student *t* test was used to derive *P* values in statistical comparisons. Because multiple comparisons were made in this exploratory analysis, the cutoff for statistical significance was lowered to $P<0.01$ (rather than the standard $P<0.05$). Items 14 through 20 addressing well-being all refer to the month preceding questionnaire administration. Percentages of patients unable to answer each item (% N/A) varied between items. A high proportion of ICL recipients believed that item 7 was not applicable because they no longer wore spectacles or CLs for any activity.

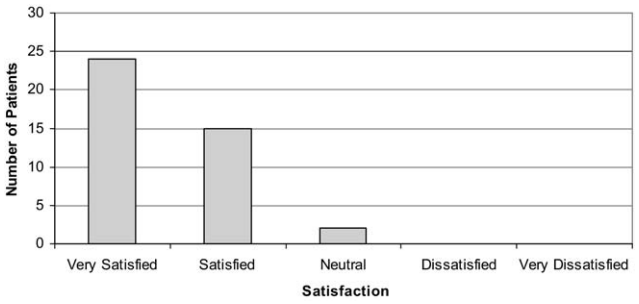

Figure 2. Bar graph showing overall satisfaction after intraocular Collamer lens (ICL) implantation. Intraocular Collamer lens recipients were asked to grade overall satisfaction with the surgery on a 5-point scale. Satisfaction levels generally were very high: 58% of patients were very satisfied with the outcome of surgery and 37% were satisfied. Dissatisfaction related largely to night vision symptoms, with 34% of patients noting an increase in glare and halo symptoms compared with their recollection of vision before surgery. Two patients considered ICL explantation in the early postoperative period because of night vision symptoms, but both concluded that the advantages of ICL implantation outweighed the disadvantages and opted to keep their implants. Night vision symptoms tended to diminish with time after surgery.

were governed, to a large degree, by factors unrelated to their vision or visual correction. Concern over vulnerability without their CLs was cited by 5 of 41 CL wearers. Intraocular Collamer lens recipients outscored CL wearers ($P = 0.021$) in their eagerness to try new things (Table 2, item 20). They frequently remarked that the procedure was life changing and expressed regret at not having opted for surgery sooner (14/41; 34%).

Discussion

The QIRC scores in this study were significantly higher in ICL recipients than in successful CL wearers with similar starting levels of myopia (MRSE, >7 D). Although visual acuities were similar in CL-corrected and ICL-corrected patients, ICL implantation may offer gains in several areas of visual function relevant to quality of life.

There has been no previous comparative evaluation of visual outcomes after phakic intraocular lens implantation using a Rasch-weighted questionnaire instrument designed to quantify vision-related quality of life. High levels of patient satisfaction after surgery have recently been demonstrated in a similar patient group after implantation of the Artisan (iris clip) phakic intraocular lens (AMO, Santa Ana, CA) in a noncomparative study using the Canadian Refractive Surgery Research Group instrument.[25] Previous studies with the Rasch-weighted QIRC instrument comprise a cross-sectional study comparing spectacle wearers, CLs wearers, and LASIK patients[20] and a prospective comparison of preoperative versus 3-month postoperative QIRC scores in LASIK patients.[21] LASIK patients scored higher than CL wearers in both studies, with significant gains versus preoperative scores in the prospective study. Both of these studies address relatively low levels of refractive error (MRSE, <10 D).

The emerging message from studies using instruments measuring vision-related quality of life is that successful refractive surgery offers functional advantages over spectacles or CL wear.[15,16,20,21,26] Pesudovs et al[20] noted poor results in a subgroup of LASIK patents with surgical complications, however, and it is important for prospective patients to weigh the risk of surgical complications carefully alongside positive results in uncomplicated cases. ICL surgery is intraocular and therefore is associated with a risk of permanent visual loss.[27] But patients with higher refractive errors have more lifestyle limitations[28] and may accept a low risk of permanent visual loss more readily than patients who are less restricted by their existing visual correction. ICL implantation also, unlike LASIK, is potentially reversible—a factor that narrows the risk of a permanently unsatisfactory visual outcome.

Overall levels of satisfaction with the results of ICL implantation were very high (Fig 2). This was a relatively small series, however, and no significant surgical complications occurred in the 41 consecutive patients (82 eyes implanted) studied. In particular, there were no cases of cataract or pupil block glaucoma. Despite the relatively small sample size, highly significant differences between ICL recipients and CL wearers were identified in overall QIRC scores and for some individual items (Table 2). The finding that CL wearers experience more trouble than ICL recipients with activities such as travel, sport, swimming, and vision on waking (Table 2; items 4–6) is unsurprising. Similarly, greater concern over vision not being as good as it could be among CL wearers (Table 2; item 11) may simply reflect the difficulties CL wearers experience when not using their correction. The finding that ICL recipients have less concern over the potential for medical complications resulting from their choice of correction (Table 2; item 12) is less easy to explain—particularly in the context of the rigorous informed consent that precedes contemporary refractive surgery. In previous QIRC studies, LASIK outperforms CL wear in similar areas, but the trend toward less concern over medical complications is not as strong, although still evident.[20,21]

The study patients and the control groups were well matched for age, gender distribution, the starting level of myopia, and visual acuity (uncorrected in ICL recipients vs. corrected in CL wearers). Neither ethnicity nor social class were studied formally, and it is possible that influential differences between the study arms may have existed. The authors are planning to compliment this cross-sectional study with a similar prospective study comparing QIRC scores within patients before and after surgery to control for these elements. Prospective studies have intrinsic problems of their own, however, because refractive surgery patients tend to be motivated by dissatisfaction with their vision. Previous studies with the QIRC, Refractive Status and Vision Profile, and National Eye Institute Refractive Quality of Life instruments have demonstrated that, before surgery, refractive surgery patients score lower than matched control groups not actively considering refractive surgery.[16,21,29] Both cross-sectional and prospective studies are useful.[20]

The QIRC instrument is designed for self-administration. In pilot work, the authors found administration in a semi-structured interview with explicit rehearsal of the questionnaire instructions to be more successful. In free text re-

sponses, several patients commented on difficulty in seeing the relevance to their vision of some questions, such as, "In the last month, how much of the time have you felt happy/confident," in the well-being domain (items 14 to 20). Similarly, a high proportion of ICL recipients were unable to answer item 7 ("How much trouble are your spectacles CLs when you where them when using a gym/doing keep-fit classes/circuit training, etc.") because they no longer wore any correction and therefore believed that the question was irrelevant. Despite these areas of equivocation, the QIRC instrument was found to be easy and quick to administer during scheduled postoperative review.

Recognized limitations for the QIRC instrument include a relatively limited set of questions and no specific coverage of presbyopia-related items.[19] The questionnaire can be used in postpresbyopic patients, however, and a reduced set of questions developed through Rasch modelling facilitates questionnaire completion. Rasch modelling has recently been applied to reduce the Refractive Status and Vision Profile to 20 items by removal of redundant and misfitting items,[29] and it is unlikely that a longer questionnaire would provide any real benefits. Using the QIRC instrument, this study demonstrated significant quality-of-life gains for ICL recipients in comparison with successful CL wearers with a similar starting level of myopia.

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Footnotes and Financial Disclosures

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