One-year Results of Health-related and Vision-related Quality of Life After Clear Lens Extraction and Multifocal Intraocular Lens Implantation

ANTTI VILJANEN, KIMMO KOSKELA, HARRI KOSKELA, RAIMO TUUMINEN, AND HANNU UUSITALO

• PURPOSE: **Multifocal intraocular lenses (MIOLs) are effective in treating presbyopia before cataracts develop. This study measured health-related quality of life (HRQoL) and vision-related quality of life (VRQoL) after clear lens extraction (CLE) and MIOL implantation.**
• DESIGN: **Before-and-after study**
• METHODS: **Patients were treated in Medilaser Coronaria, CorGroup, Oulu, Finland. HRQoL was measured by a generic 15-dimension (15D) instrument. VRQoL was measured with Visual Function Index-14 (VF-14) questionnaire.**
• RESULTS: **CLE and MIOL implantation was performed in 137 patients. The patient age was 57 ± 6.2 years (mean ± standard deviation), and 58% were women. The near add was 2.1±0.3 diopters (D). The overall HRQoL 15D score increased from 0.938±0.058 to 0.955±0.057 at 6 months ($P < .0001$ vs baseline) and to 0.948±0.060 at 1 year ($P = .02$ vs baseline). The VRQoL VF14 score increased from 85.32±15.57 to 96.57±5.07 at 6 months ($P < .0001$ vs baseline) and to 96.61±6.48 at 1 year ($P < .0001$ vs baseline). The increase of HRQoL was correlated with the increase of VRQoL ($P < .04$).**
• CONCLUSIONS: **CLE and MIOL implantation improved HRQoL and VRQoL compared to spectacles in this 1-year follow-up study. Improvement of HRQoL was correlated with VRQoL. (Am J Ophthalmol 2021;227: 240–244. © 2021 The Authors. Published by Elsevier Inc. This is an open access article under the CC BY license (http://creativecommons.org/licenses/by/4.0/))**

Presbyopia is an age-related condition where the eye progressively loses the ability to focus on near objects. This loss of accommodation typically affects individuals 45 years of age and older. In 2015, approximately 1.8 billion people worldwide suffered from presbyopia.[1]

Presbyopia decreases the quality of life,[2] and it is commonly and readily treated with spectacles. However, spectacles can limit active lifestyles, such as participation in sports, or they can be unused for other reasons. Modern surgical implantation of multifocal intraocular lenses (MIOLs) is an option for optical correction of presbyopia that is available before cataracts manifest.[3-5] The procedure is referred to as "clear lens extraction" (CLE), and advances in this technology have enabled it to become a popular refractive procedure.[6-10]

MIOLs can induce aberrant light perception disturbances[11]; thus, motivation to achieve spectacle freedom must outweigh the potential adverse effects. Vision-related quality of life (VRQoL) improves with MIOLs,[12-14] but we do not know if overall health-related quality of life (HRQoL) changes after CLE and MIOL implantation. Therefore, this study was initiated to determine if CLE and MIOL implantation improves HRQoL and VRQoL, as assessed by the HRQoL 15D questionnaire and the VRQoL self-assessed Visual Function Index-14 (VF-14) questionnaire respectively.

METHODS

• STUDY DESIGN AND ETHICS: This was a prospective nonrandomized, noncontrolled follow-up study of 137 patients. The ethical board of Tampere University Hospital, Tampere, Finland, approved the protocol (ETL R14087). Prior to providing consent to participate in the study, each patient was informed about the purpose, methods, and possible complications of the study, including the fact that, for some patients, MIOLs are associated with aberrant light perception disturbances. The study was conducted according to Good Clinical Practice, and the study protocol adhered to the tenets of the Declaration of Helsinki.

The primary outcome was measured as the change in response to the generic HRQoL 15D questionnaire after CLE and MIOL implantation and during the 1-year follow-up. Secondary outcomes were measured as changes in response

AJO.com Supplemental Material available at AJO.com.
Accepted for publication March 25, 2021.

From the Medilaser Coronaria, Silmaasema Silmasairaala, CorGroup, Oulu; Helsinki Retina Research Group, University of Helsinki, Helsinki; SILK, Department of Ophthalmology, Tampere University, Tays Eye Center, Tampere, Finland
Inquiries to Antti Viljanen, Silmaasema Silmasairaala, Yliopistonkatu 27, FIN-20100 Turku, Finland; e-mail: antti.viljanen@coronaria.fi

0002-9394/$36.00
https://doi.org/10.1016/j.ajo.2021.03.023

to the VRQoL VF-14 questionnaire and visual acuity. Patients were recruited from the clinics of Medilaser Coronaria (Oulu, Finland) where the surgeries were performed.

• **INCLUSION AND EXCLUSION CRITERIA:** Inclusion criteria were limited to patients with distance-corrected near visual acuity <0.5 Snellen at 40 cm using the standardized 40-cm reading chart, ages 40-75 years, eligible for bilateral surgery, and corrected distance visual acuity ≥0.8 Snellen in both eyes to exclude significant cataract. Exclusion criteria were age <40 or >75 years, unilateral surgery, corrected distance visual acuity <0.8 Snellen in either eye, clinically significant signs of or pre-existing glaucoma, age-related macular degeneration, amblyopia, cornea dystrophy or opacity, phacodonesis, or previous refractive surgery.

• **CLINICAL EVALUATION:** Preoperative examination included refraction, slit lamp evaluation, and funduscopy. The following clinical indexes were evaluated: monocular uncorrected distance visual acuity, binocular uncorrected distance visual acuity, binocular uncorrected near and intermediate visual acuity (UNVA 40 cm, UIVA 63 cm, UIVA 100 cm) using the Early Treatment of Diabetic Retinopathy Study (ETDRS) charts with the 40-cm/63-cm/100-cm ruler string, intraocular pressure (Icare tonometer; Revenio, Vantaa, Finland), and biometry (IolMaster 500; Carl Zeiss, Jena, Germany). Toric lenses were selected when applicable.

• **GENERIC HRQOL:** The generic HRQoL was assessed by the HRQoL 15D questionnaire (www.15d-instrument.net) that evaluates 15 dimensions: mobility, vision, hearing, breathing, sleeping, eating, speech (communication), excretion, usual activities, mental function, discomfort and symptoms, depression, distress, vitality, and sexual activity. For each dimension, the study subject chooses one of the 5 levels that best describe his or her state of health at present time. The valuation system uses multiattribute utility theory, and the dimension levels are calculated from a health state descriptive system by using a population-based preference.[15] The single index score (HRQoL 15D score) varies on a 0-1 scale (1 = full health). The HRQoL 15D scores were obtained prior to CLE and MIOL implantation and at 6 months and 1 year after surgery. A change of 0.015 is considered to be clinically meaningful.[16]

• **VRQOL:** VRQoL was measured with the self-assessed VF-14. VF-14 scores were obtained prior to CLE and MIOL implantation and at 6 months and 1 year after surgery.

• **NEED OF SPECTACLES:** The need for spectacles after surgery was evaluated with our 6-scale Likert-type questions (6 = always, 5 = most of the time, 4 = half of the time, 3 = less than half of the time, 2 = sometimes, 1 = never).

• **INTRAOCULAR LENSES:** Surgeons selected MIOLs that were implanted with their own and their patients' preferences. MIOLs were implanted into the lens bag after phacoemulsification. The MIOLs were Tecnis +3.25 bifocal (Johnson & Johnson, Santa Ana, CA), Tecnis Symfony extended depth of focus IOL (Johnson & Johnson), PanOptix trifocal (Alcon, Fort Worth, TX), FineVision trifocal (PhysIOL, Liège, Belgium), and AT LISA tri trifocal (Carl Zeiss).

• **STATISTICAL ANALYSIS:** Data were calculated as means ± standard deviations. The HRQoL 15D and VF-14 data were analyzed as previously described.[15,17] Repeated measures analysis of variance was used to assess factors affecting HRQoL 15D scores. Associations were tested with Spearman nonparametric correlations. Statistical analysis was done with SPSS for Windows software (version 26.0; IBM Corp, Chicago, IL). *P* values <.05 were considered to be statistically significant.

RESULTS

• **CHARACTERISTICS OF THE STUDY SUBJECTS:** The age of the study population was 57 ± 6 years and 58% were women. All patients completed the 6-month follow-up, and 134 completed the 1-year follow-up. The near add was 2.1 ± 0.3 diopters (D). Visual acuity and refraction changes are presented in Table 1. Nd:YAG laser capsulotomy (LCT) was performed on 5.5% of the eyes, and laser refractive enhancement was performed on 7% during the 1-year follow-up. There were no intraoperative complications, and no lens removals were performed during the follow-up period.

• **GENERIC HRQOL CHANGES DURING FOLLOW-UPS:** The generic HRQoL 15D score increased from 0.938 ± 0.058 to 0.955 ± 0.057 at 6 months ($P < .0001$ vs baseline) and to 0.948 ± 0.060 at 12 months ($P = .02$ vs baseline). The HRQoL 15D scores for vision, discomfort and symptoms, distress, and vitality improved over the baseline values (Figure 1, $P < .05$ for each). At the 12-month follow-up, only the vision dimension was improved ($P < .0001$). In repeated measures analysis of variance, age, gender, need of spectacles, refractive sphere, refractive cylinder, surgery location, surgeon, lens manufacturer, IOL focality, and baseline HRQoL 15D score were not associated with HRQoL improvement. Also, at the end of the follow-up, UNVA, UIVA, UDVA, need of spectacles, refractive sphere, refractive cylinder, and LCT or laser refractive enhancement were not associated with HRQoL improvement.

• **USE OF SPECTACLES AND CHANGES IN VF-14 AFTER CLE AND MIOL IMPLANTATION:** The use of spectacles, rated from 1 (never) to 6 (always), was reduced from 5.1 before CLE and MIOL implantation to 1.1 at both 6 and 12

TABLE 1. Health-Related and Vision-Related Quality of Life After Clear Lens Extraction and Multifocal IOL Implantation

Parameter	Preop. (n = 137)	Postop. 6 mo (n = 137)	Postop. 12 mo (n = 134)
UDVA (logMAR)			
Right eye	0.57±0.52	0.04±0.10*	0.03±0.09*
Left eye	0.55±0.51	0.04±0.11*	0.04±0.10*
Binocular UNVA (40-cm) (logMAR)	0.59±0.15	0.07±0.09*	0.08±0.09*
Binocular UIVA (63-cm) (logMAR)		0.06±0.11	0.05±0.10
Binocular UIVA (100-cm) (logMAR)		0.09±0.13	0.07±0.12
Refraction sphere (D)			
Right eye	0.79±2.46	0.18±0.39*	0.19±0.38*
Left eye	0.72±2.65	0.23±0.37*	0.23±0.33*
Refraction cylinder (D)			
Right eye	–0.66±0.47	–0.49±0.31*	–0.49±0.28*
Left eye	–0.62±0.42	–0.50±0.28*	–0.50±0.27*

D = diopter, logMAR = log(minimum angle of resolution), Postop. = postoperative, Preop. = preoperative, UDVA = uncorrected distance visual acuity; UIVA = uncorrected intermediate visual acuity, UNVA = uncorrected near visual acuity.

Data show preoperative and postoperative 6-month and 12-month results of visual acuity and refraction.

*$P < .05$ compared to preoperative values.

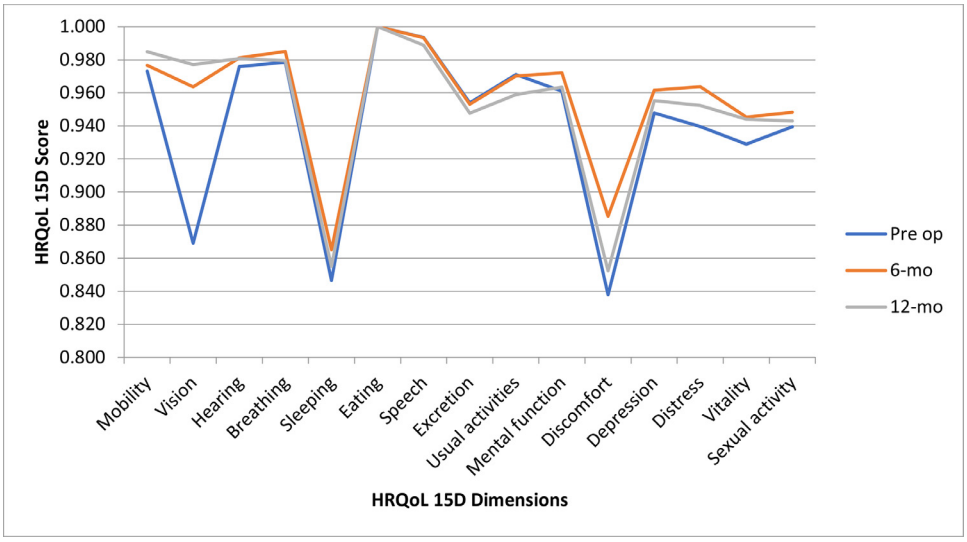

FIGURE 1. Health-related quality of life (HRQoL) after clear lens extraction and multifocal IOL implantation. 6-month and 12-month results of HRQoL 15D dimensions.

months after CLE and MIOL implantation ($P < .0001$ for both). The VF14 score improved from 85.32 ± 16.57 at baseline to 96.57 ± 5.07 at 6 months ($P < .0001$) and to 96.61 ± 6.48 at 12 months ($P < .0001$). The increase of VRQoL VF14 score correlated positively with the increase of HRQoL 15D score ($P < .04$).

DISCUSSION

In this prospective follow-up study, we found improvement of HRQoL after CLE and MIOL implantation. This improvement was related to enhanced VRQoL, and there were no specific anatomic or MIOL-related factors that predicted these results. Therefore, we conclude that patients with presbyopia have a greater need for vision correction than spectacles alone can provide.

Porela-Tiihonen and associates reported that standard cataract surgery increases the HRQoL in the first eye operation, but not after an operation on the fellow eye.[18] In another study, HRQoL improved only after bilateral cataract surgery.[19] In these studies, the patients were older and their postoperative HRQoL was lower than an age-matched control population.[18,19] The HRQoL 15D instrument measures 15 dimensions, of which only 1 is about

vision. We found positive changes also in other dimensions at 6 months, including discomfort and symptoms, distress, and vitality. This is consistent with cataract studies in which improvement in dimensions other than vision were measured.[18,19] These findings suggest that vision deficiency caused by either presbyopia or cataract broadly affect patient well-being, and further, that ocular intervention has a wide impact on the quality of life beyond vision.

VRQoL measurements assessed with the VF-14 questionnaire improved after CLE and MIOL implantation. Preoperative evaluation included the need for spectacles. Preoperatively lower VF-14 values among patients with spectacle dependence indicates dissatisfaction with multifocal spectacles or the use of reading glasses. These concerns may motivate patients to seek CLE and MIOL implantation in an effort to gain spectacle independence. VF-14 improvement after MIOLs has been previously reported.[12,20] In our current study, we measured near and intermediate visual acuities at 40 cm, 63 cm, and 100 cm with properly scaled ETDRS-type charts with rulers. These distances are representative of modern vision needs, for example, use of smart phone, computers, and automobile dashboards. MIOLs provide excellent vision at these distances.

There was no major adverse event during any of the surgeries. LCTs and refractive enhancements were performed on a small portion of subjects. The retreatment rate was lower than reported in a previously published retrospective study.[21] Analysis of our data showed that these operations did not influence HRQoL improvement.

There are 3 limitations of this study. One is that subjects taking self-assessed questionnaires have a bias to please the study investigators.[22,23] Patients also want to convince themselves that CLE and MIOL implantation helped to resolve their needs. A second limitation is that the study included different lens types, that is, bifocal, extended depth of focus, and trifocal MIOLs. They all have lens-specific, optimal focal areas at intermediate and near distances, or both. In the comparison of bifocal and trifocal lenses, there were no differences in HRQoL or VRQoL, which may be related to the small sample size. The third limitation is that MIOLs can cause light perception disturbances, such as halos around bright lights and glare.[11] We did not measure halos or glare because standardized tools to measure these phenomena are not available.[22]

In summary, we showed that CLE and MIOL implantation for presbyopia improves HRQoL and VRQoL. These improvements were independent of preoperative anatomy, MIOL type, and postoperative outcomes.

Funding/Support: This study was funded by Business Finland, Helsinki, Finland, and Medilaser Coronaria, Cor Group, Oulu, Finland. Financial Disclosures: The authors indicate no financial support or conflicts of interest. All authors attest that they meet the current ICMJE criteria for authorship.

REFERENCES

1. Holden BA, Fricke TR, Ho SM, et al. Global vision impairment due to uncorrected presbyopia. *Arch Ophthalmol*. 2008;126(12):1731–1739.
2. McDonnell PJ, Lee P, Spritzer K, Lindblad AS, Hays RD. Associations of presbyopia with vision-targeted health-related quality of life. *Arch Ophthalmol*. 2003;121(11):1577–1581.
3. Wang SY, Stem MS, Oren G, Shtein R, Lichter PR. Patient-centered and visual quality outcomes of premium cataract surgery: A systematic review. *Eur J Ophthalmol*. 2017;27(4):387–401.
4. Hu JQ, Sarkar R, Sella R, Murphy JD, Afshari NA. Cost-effectiveness analysis of multifocal intraocular lenses compared to monofocal intraocular lenses in cataract surgery. *Am J Ophthalmol*. 2019;208:305–312.
5. Grzybowski A, Kanclerz P, Tuuminen R. Multifocal intraocular lenses and retinal diseases. *Graefes Arch Clin Exp Ophthalmol*. 2020;258(4):805–813.
6. Khandelwal SS, Jun JJ, Mak S, Booth MS, Shekelle PG. Effectiveness of multifocal and monofocal intraocular lenses for cataract surgery and lens replacement: A systematic review and meta-analysis. *Graefes Arch Clin Exp Ophthalmol*. 2019;257(5):863–875.
7. Negishi K, Hayashi K, Kamiya K, Sato M, Bissen-Miyajima H. Nationwide prospective cohort study on cataract surgery with multifocal intraocular lens implantation in Japan. *Am J Ophthalmol*. 2019;208:133–144.
8. Zamora-de La Cruz D, Zúñiga-Posselt K, Bartlett J, Gutierrez M, Abariga SA. Trifocal intraocular lenses versus bifocal intraocular lenses after cataract extraction among participants with presbyopia. *Cochrane Database Syst Rev*. 2020;6(6).
9. Schallhorn JM, Schallhorn SC, Teenan D, Hannan SJ, Pelouskova M, Venter JA. Incidence of intraoperative and early postoperative adverse events in a large cohort of consecutive refractive lens exchange procedures. *Am J Ophthalmol*. 2019;208:406–414.
10. Alió JL, Kaymak H, Breyer D, Cochener B, Plaza-Puche AB. Quality of life related variables measured for three multifocal diffractive intraocular lenses: A prospective randomised clinical trial. *Clin Exp Ophthalmol*. 2018;46(4):380–388.
11. de Silva SR, Evans JR, Kirthi V, Ziaei M, Leyland M. Multifocal versus monofocal intraocular lenses after cataract extraction. *Cochrane Database Syst Rev*. 2016;12(12).
12. Akman A, Asena L, Ozturk C, Gür Güngör S. Evaluation of quality of life after implantation of a new trifocal intraocular lens. *J Cataract Refract Surg*. 2019;45(2):130–134.
13. Mojzis P, Majerova K, Plaza-Puche AB, Hrckova L, Alio JL. Visual outcomes of a new toric trifocal diffractive intraocular lens. *J Cataract Refract Surg*. 2015;41(12):2695–2706.

14. Gundersen KG, Potvin R. Clinical outcomes with toric intraocular lenses planned using an optical low coherence reflectometry ocular biometer with a new toric calculator. *Clin Ophthalmol*. 2016;10:2141–2147.
15. Sintonen H. The 15D instrument of health-related quality of life: Properties and applications. *Ann Med*. 2001;33(5):328–336.
16. Alanne S, Roine RP, Räsänen P, Vainiola T, Sintonen H. Estimating the minimum important change in the 15D scores. *Qual Life Res*. 2015;24(3):599–606.
17. Steinberg EP, Tielsch JM, Schein OD, et al. The VF-14. An index of functional impairment in patients with cataract. *Arch Ophthalmol*. 1994;112(5):630–638.
18. Porela-Tiihonen S, Roine RP, Sintonen H, Kaarniranta K, Kokki M, Kokki H. Health-related quality of life after cataract surgery with the phacoemulsification technique and intraocular lens implantation. *Acta Ophthalmol*. 2016;94(1):21–25.
19. Räsänen P, Krootila K, Sintonen H, et al. Cost-utility of routine cataract surgery. *Health Qual Life Outcomes*. 2006;4:74.
20. Labiris G, Giarmoukakis A, Patsiamanidi M, Papadopoulos Z, Kozobolis VP. Mini-monovision versus multifocal intraocular lens implantation. *J Cataract Refract Surg*. 2015;41(1):53–57.
21. Gundersen KG, Makari S, Ostenstad S, Potvin R. Retreatments after multifocal intraocular lens implantation: An analysis. *Clin Ophthalmol*. 2016;10:365–371.
22. Grzybowski A, Kanclerz P, Muzyka-Woźniak M. Methods for evaluating quality of life and vision in patients undergoing lens refractive surgery. *Graefes Arch Clin Exp Ophthalmol*. 2019;257(6):1091–1099.
23. Tuuminen R, Kanclerz P, Grzybowski A. Methodological challenges with randomized clinical trials for multifocal intraocular lenses. *Surv Ophthalmol*. 2020;65(3):391–392.