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Original Research Article

Visual Outcome and Vision Related Quality of Life after Implantable Collamer Lens for Moderate to High Myopia and Myopic Astigmatism

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ABSTRACT

Background: To examine visual outcome and vision related quality of life after Implantable Collamer Lens for Moderate to High Myopia and Myopic Astigmatism.

Material and methods: A hospital-based prospective, interventional, observational study has been carried out to evaluate functional outcomes and patient satisfaction following phakic ICL implantation for the treatment of myopia and myopic astigmatism. In this study, we included 44 eyes of 26 patients, 15 females (58%) and 11 males (42%), mean age 24.56 ± 4.98 years (range: 18-35) with preoperative myopia (mean ± standard deviation [SD] refraction spherical equivalent, -11.485 ± 4.78 D). To investigate the effects of ICL implantation, we had compared between two groups: one group before surgery and another group one month after surgery. Measurements including uncorrected distance visual acuity (UCVA), corrected distance visual acuity (CDVA), spherical equivalent (SE) of manifest refraction, and corneal topography were obtained for all participants. The Quality-of-Life Impact of Refractive Correction (QIRC) questionnaire was administered to compare VRQOL between before and after ICL implantation.

Results: The postoperative mean UCVA demonstrated a significant statistical improvement ($p<0.001$) from pre operative data, increasing from 0.04 ± 0.035 to 0.87 ± 0.23 (decimal acuity). The preoperative BCVA 0.85± 0.23 versus the mean postoperative BCVA 1.0 ± 0.18. The mean ± standard deviation of the preoperative refraction spherical equivalent was -11.485 ± 4.78 D. After surgery, this value decreased to -0.87 ± 0.40 D, demonstrating a statistically significant improvement ($p<0.05$).
After surgical procedures, the QIRC scores were significantly higher (postoperative QIRC score: 53.84±7.14; $P<0.001$) versus preoperative QIRC score [mean ± SD], 43.68±5.69, with significant increases ($P<0.001$) for 14 of the 19 items. After ICL surgery, the group's scores on items concerning convenience, well-being, and health problems were much higher than they were prior to the surgery. Despite the fact that nine patients (34%) encountered more concerns of night vision after surgery (mostly nonspecific glare and halo or arc effects), overall patient satisfaction was excellent, with 88% reporting that they were either satisfied or very satisfied with the surgical outcomes. Overall, none of the patients reported dissatisfaction.

Conclusion: Implantation of an ICL for moderate to high myopia and myopic astigmatism resulted in both significant improvements in visual acuity and a substantial enhancement in vision-related quality of life (VRQOL) for the subjects. This suggests that ICL implantation can be a successful treatment option for these patients, leading to improved vision and a greater enjoyment of daily activities.

Keywords: Implantable Collamer Lenses, QIRC questionnaire, Quality of Life, Visual Outcomes

INTRODUCTION

The study highlights the alarmingly high prevalence of myopia worldwide, particularly among adolescents (70-81%) and young adults (up to 22.9%).[1,2,3] This increasing tendency poses a significant public health concern. The study stresses the association between high myopia (>-6.00D) and vision-threatening eye diseases due to retinal stretching and elongated optic axis. High myopia is identified as a major contributor to blindness.[4,5] Traditional approaches like glasses, contact lenses, and various surgical interventions are stated. The growing demand for spectacle independence has driven the development of alternative surgical options for correcting vision in myopic individuals.[6,7] Laser procedures like photorefractive keratectomy (PRK) and laser in situ keratomileusis (LASIK) have gained popularity for correcting mild-to-moderate myopia. However, their efficacy diminishes with high myopia (>-8.00 diopters). Studies suggest that PRK struggles to effectively correct myopia beyond -8.00D, leading to complications like regression, haze, and loss of best-spectacle corrected visual acuity (BSCVA).[8] While LASIK performs well for low myopia (-1.00D to -8.00D), it encounters limitations in moderate-to-high myopia. The insufficient stromal base tissue remaining after LASIK in high myopia can lead to ectasia, causing glare and further complications like edema, unstable refraction, and significant visual issues. Given the limitations of laser procedures in high myopia, implantable collamer lenses (ICLs) emerge as a promising alternative.[9]

Implantable Collamer Lenses (ICLs) provide several potential benefits over conventional surgical techniques such as LASIK.[10] These advantages include ICLs, which may lessen problems and preserve the normal biomechanics of the eye by preventing corneal reshaping. Comparing ICLs to some laser solutions, a wider range of myopia can be corrected.[11] Following ICL implantation, visual recovery might happen more quickly than following laser surgery. Long-term refractive results from ICLs may be more stable. According to studies, ICLs may offer superior overall visual quality than specific laser treatments. In contrast to some operations, ICLs purport to maintain the eye's inherent capacity to focus, which may have further advantages.[12] ICLs are becoming more and more popular as a myopia treatment option since clinical data demonstrates their efficacy and safety. Studies also show significant improvements in patient's quality of life after ICL implantation, especially compared to LASIK in the long term. Research also determines that patients' quality of life significantly improves with ICL implantation, predominantly when compared to LASIK over an extended period.[13]

This research aims to investigate the visual outcomes and patient satisfaction following ICL correction for moderate-to-high myopia. By comparing ICL results with existing laser procedures in this specific population, we can assess the potential benefits and limitations of ICLs and contribute to informed decision-making for patients and surgeons.

MATERIAL AND METHODS

A hospital-based prospective, interventional, observational study was conducted to evaluate functional outcomes and patient satisfaction following phakic ICL implantation for the treatment of myopia and myopic astigmatism. The ICL operation was carried out by competent ophthalmic surgeons. Treatments were performed at Shree K.P. Sanghvi Eye Hospital in Surat, Gujarat. The implantations took place between August 2022 and May 2023, with a follow-up period for the visual outcome and a self-administered questionnaire between September 2022 and June 2023.

During this period, twenty-six consecutive patients (44 eyes) (15 females and 11 males) aged 18-35 years old participated in this study. The follow-up period was one month following ICL surgery. The study procedure allows for under or overcorrections of ±0.5. D. Patients were included with baseline refractive errors ranging from -2.00 to -20.00 D of myopia. A maximum of -6.00D manifest refractive cylinder was allowed. Prior to implantation, patients had to have a confirmed stable refraction of±0.5D for at least one year. The research study included all patients over the age of 18, with no constraints on gender or race.

The study excluded patients having an anterior chamber depth (ACD) of less than 3.0 mm, as

measured from the corneal endothelium to the anterior lens capsule. Additional exclusion criteria were clinical symptoms of iritis, uveitis, diabetic retinopathy, cataract, glaucoma, and pregnancy or nursing history.

Trained optometrists performed an examination of corneal curvature and shape using computerized corneal topography (Sirius). Corneal topography was utilized to identify early or suspect keratoconus and pellucid marginal degeneration. Any irregular astigmatism was also identified. Corneal thickness was measured using an Ultrasonic Pachymeter (Nidek). ACD (from the cornea endothelium to the anterior capsule), white-to-white (WTW), and axial length were measured using (Lenstar).

Preoperative and postoperative parameters: Preoperative and 1-month postoperative routine exams included measurements of uncorrected visual acuity (UCVA), best corrected visual acuity (BCVA) in decimal, manifest refraction, intraocular pressure (IOP), and corneal topography. The IOP was measured using a noncontact tonometer (NCT, Topcon Computerized Tonometer). Subjective patient satisfaction was measured using a QIRC questionnaire [A free, downloadable Excel spreadsheet available athttp://www.pesudovs.com/konrad/questionnaire.html(date accessed, July 2007), which automatically converted original numerical response values into a Rasch-weighted QIRC score was used to collect and analyse QIRC responses. This website also provides detailed instructions for QIRC scoring. Patients completed a survey form at their last visit to assess the visual outcome of the treatment.

Surgical techniques: The operation was carried out in full accordance with standard operating protocols (ICL implantation surgery). Composition Tropicamide drops were used for mydriasis 30 minutes before surgery. Following topical anesthetic, ICL was placed into a specialized push device under a microscope (Carl Zeiss, Germany). 3.0 mm clear corneal symmetrical assisted incisions were created on the right and left sides, each about 0.4 mm broad, with the ACM put in the left incision. Following the injection of sodium hyaluronate into the anterior chamber, ICL was gently moved into the iris plane and subsequently to the middle of the posterior ciliary sulcus using hooks. Viscoelastic intraocular material was squeezed out following surgery, and the corneal incision was sealed with water. There were no noticeable difficulties during or after surgery. The fourth-generation posterior chamber intraocular lenses (ICL V4) have been purchased from STAAR. Emmetropia was the desired outcome in all of the eyes investigated. After the procedure, steroids and antibiotics were given four times a day for 30 days, and lubricating eye drops were taken for one month.

The study was approved by the Institutional Ethics Committee of Shree Bharatimaiya College of Optometry & Physiotherapy in Surat, and the procedures used were by the ethical standards of the responsible committee on human experimentation (institutional or regional), as well as the Helsinki Declaration of 1975, as revised in 2000. The risks associated with the procedure were discussed to the patients in line with the Helsinki Declaration, and verbal informed consent was obtained.

Analysis: All data were analyzed with IBM SPSS software VERSION 25. The quantitative data were recorded as mean ± SD. All data were analyzed by ANOVA followed by paired 2-tailed t-tests to compare pre-and post-operative data, as well as total QIRC scores (the major outcome measure). We also conducted an analytical study of scores for specific questionnaire questions, with P values <0.01 indicating statistical significance. To account for multiple comparisons in the exploratory analysis of individual questionnaire item responses, a P-value < 0.05 was used to indicate statistical significance.

RESULTS

Baseline parameters

A total of 44 eyes of 26 patients,15 females (58%) and 11 males (42%), mean age 24.56 ± 4.98 years (range: 18-35), were included in the study. The patient's characteristics are listed in Table 1.

The average spherical equivalent before and after ICL operation: The average spherical equivalent in all eyes

(n = 44) was -11.485 ± 4.78 D before ICL operation; however, it significantly decreased to -0.87 ± 0.40 D following 1 month after the operation, respectively (P<0.05 against pre-operation).

Changes of visual acuity and QIRC in myopia patients after the ICL implantation: Two parameters in visual acuity including UDVA (uncorrected distant visual acuity) and CDVA (corrected distant visual acuity) were measured. Preoperatively, the mean UCVA decimal Snellen's of all eyes was 0.04 ± 0.035. The mean preoperative BCVA was 0.85± 0.23 with Snellen's chart (decimal), mean postoperative UCVA was 0.87 ± 0.23, and mean postoperative BCVA was 1.0 ± 0.18.

These data indicated that UDVA and CDVA in high myopia patients were significantly improved by ICL implantation 1 month later. (Table 2).

Table 3 shows the overall QIRC score for the two groups. Between groups, there was a statistically significant difference in the overall QIRC scores (P <0.001). Following ICL implantation, the group's overall QIRC scores were higher than those obtained before to ICL implantation.

When individual scores from the groups were compared, the convenience, well-being, and health concern showed significantly greater scores in the group that had the ICL implantation, than those before surgery.

Even though nine patients (34%) encountered more concerns of night vision after surgery (mostly nonspecific glare and halo or arc effects), overall patient satisfaction was excellent, with 88% reporting that they were either satisfied or very satisfied with the surgical outcomes. Overall, none of the patients reported dissatisfaction.

The primary motivations given for desiring ICL and TICL implantation correction were a general dislike of handling glasses, the need to be less dependent on glasses, and career and professional reasons.

Table-1: Demographic Characteristics in implanted Collamer lenses (ICLs) recipients

Demographic Characteristics	**ICL Recipients**
Female/Male (% female)	15/11 (58%)
Age (mean ± SD)	24.56 ± 4.98
Spherical ICL/ Toric ICL	20/24

Table-2: Visual functions and mean total score of QIRC for ICLs recipients

	Before Implantable Collamer Lens	**After Implantable Collamer Lens**
SE (mean ± SD)	-11.485 ± 4.78	-0.87 ± 0.40 D
UCVA	0.04 ± 0.035	0.87 ± 0.23
BCVA	0.85± 0.23	1.0 ± 0.18
Mean total score of QIRC	43.68±5.69	53.84±7.14

SE: Spherical equivalent, UCVA: Uncorrected visual acuity (decimal), BCVA: Best corrected visual acuity (decimal).

Table-3: Vision-related Quality of Life Impact of Refractive Correction Questionnaire Responses after recipients of implanted Collamer lenses (ICLs) for myopia correction

S. No.	**Quality of Life Impact of Refractive Correction Questionnaire Item**	**Before Implantable Collamer Lens**	**After Implantable Collamer Lens**	**P Value (t Test)**
1	Difficulty driving in glare conditions	38.69±11.00	45.06±6.90	0.256
2	Eyes feeling tired or strained	45.25±11.80	49.30±8.59	0.054

3	Trouble using off-the-shelf sunglasses	43.84±14.84	52.56±9.79	0.002
4	Trouble thinking about correction before traveling, sport, swimming	38.04±11.85	52.43±12.25	<0.001
5	Trouble not seeing on waking	41.98±13.24	50.44±11 54	0.002
6	Trouble not seeing on beach, in pool	41.08±11.62	56.19±10.92	<0.001
7	Trouble with spectacles or contact lenses when at the gym or keeping fit	34.71±13.16	49.61±9.85	<0.001
8	Concern about initial cost of contact lenses or refractive surgery	49.16±12.49	55.94±10.39	0.034
9	Concern about ongoing cost	41.16±12.79	50.21±11.54	0.004
10	Concern about increasing reliance on spectacles or contact lenses	38.97±8.92	55.80±12.87	<0.001
11	Concern about vision not being as good as it could be	37.02±6.76	47.93±11.65	<0.001
12	Concern over medical complications from refractive surgery or contact lens wear	36.32±11.04	46.85±11.19	<0.001
13	Concern about eye protection from ultraviolet radiation	47.74±12.28	45.52±11.33	0.722
14	How much time you looked your best	41.30±13.88	59.97±18.52	<0.001
15	How much time you projected a positive image to others	52.18±16.90	56.91±14.68	0.013
16	How much time you have felt complimented	52.70±16.39	64.64±14.54	<0.001
17	How much time you felt confident	54.34±16.52	62.88±15.52	0.002
18	How much time you felt happy	47.77±16.41	59.62±15.73	<0.0001
19	How much time you felt able to do the things you want	39.15±16.42	52.08±15.16	<0.001
20	How much time you felt eager to try new things	48.31±15.98	56.21±15.93	0.07
	Total QIRC scores	43.68±5.69	53.84±7.14	<0.001

QIRC = Quality of Life Impact of Refractive Correction; SD = Standard deviation.

Abbreviated QIRC questionnaire items and Rasch weighted response scores (mean ± SD) for ICL recipients 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.

DISCUSSION

Refractive errors can be effectively treated with refractive surgery, which reduces the need for optical correction. It offers patients comfort as well as improved visual acuity with a low risk of side effects.[14] ICL surgery was performed on patients with myopic refractive error who were older than eighteen, stable refractive error, no ocular pathology, history of previous ocular surgery, ocular infection or inflammation in the previous few months, significant systemic disorders, pregnancy, or lactation. This study was a hospital-based prospective, interventional, observational study that was carried out to evaluate functional outcomes and patient satisfaction following phakic ICL implantation for the treatment of myopia and myopic astigmatism. The implantations occurred between August 2022 and May 2023, with a follow-up period for visual outcomes and a self-administered questionnaire for vision-related quality of life between September 2022 and June 2023.

Out of 26 patients, 18 underwent ICL in both eyes, whereas 8 required ICL in one eye and LASER refractive surgery in the other. All 18 patients had their second eyes operated on within 7 days of their first operation. In 2018, Zhipeng Yan et al 15 conducted a study on “Two-year outcomes of Visian Implantable Collamer Lens with a central hole for correcting high myopia” in 61 eyes of 32 patients.

Our study found a 42% male and 58% female distribution, indicating that women are more prone to seek surgery. This might be due to social reasons or a desire for a more attractive appearance. In 2022 Mark Packer 16 conducted a study on “Evaluation of the EVO/EVO+ sphere and toric Visian ICL: 6-month results from FDA clinical trial”. They found out that females account for 65% (213) out of 327 subjects. Similarly, Luis Fernandez-Vega-Cueto et al 17 in their study “Implantable Collamer Lens with central hole: a 3-year follow-up” found female dominancy, 62 females out of a total of 92 patients.

The mean age of the patients undergoing ICL in our research was 24.46 ± 4.98 years. This age takes into consideration things like independence from spectacles and contact lenses, stability of refraction, and a more attractive appearance at a marriageable age. This may also be the case because younger patients—particularly those pursuing careers in sports, the military, or the navy—do not want spectacle getting in the way of their professional goals. Similarly, Zhipeng Yan et al 15 conducted a study that had patients with a mean age of 30.87 ± 8.03 years.

In our study, the mean spherical equivalent in all eyes (n = 44) was -11.485 ± 4.78 D before ICL surgery, however, it considerably decreased to -0.87 ± 0.40 D 1 month later (P<0.05 compared to pre-operation). Whereas, Zhipeng Yan et al 15 in their study “Two-year outcomes of Visian Implantable Collamer lens with a central hole for correcting high myopia” had a mean spherical power of - 14.62 ± 4.29 Dsph and mean pre-operative cylindrical power of -1.82 ± 1.22 Dcyl.

In our research, two visual acuity parameters were measured: UDVA (uncorrected distant visual acuity) and CDVA. Before surgery, the average UCVA decimal Snellen's for all eyes was 0.04 ± 0.035. The preoperative BCVA was 0.85 ± 0.23 using Snellen's chart (decimal), whereas the postoperative UCVA was 0.87 ± 0.23 and the postoperative BCVA was 1.0 ± 0.18. These findings showed that ICL implantation significantly improved UDVA and CDVA in high myopia patients one month later. Zhipeng Yan et al [15] in their study concluded average post-operative uncorrected visual acuity was 0.84 ± 0.28 decimal.

In this study, we compared the two groups' overall QIRC scores. QIRC scores showed significant differences across groups (P < 0.001). Following ICL implantation, the group's overall QIRC scores were

higher than before the surgical procedure. When individual scores from the groups were compared, the convenience, well-being, and health concerns showed significantly greater scores in the group that had the ICL implantation, than those before surgery. The most common reasons given for seeking ICL and TICL implantation correction were a dislike of maintaining glasses, a desire to be less reliant on glasses, and career and professional concerns.

The study found that patients' VRQoL improved after ICL surgery compared to their pre-operative ratings. Previous research found that laser refractive surgery enhances quality of life. [18]

Although nine patients (34%) encountered more concerns of night vision after surgery (mostly nonspecific glare and halo or arc effects), overall patient satisfaction was excellent, with 88% reporting that they were either satisfied or very satisfied with the surgical outcomes. Overall, none of the patients reported dissatisfaction.

One study found that patients who underwent ICL implantation reported fewer activity limitations, fewer symptoms, and higher satisfaction with correction compared to those who underwent wavefront-guided LASIK. [21]

Another study showed that ICL implantation resulted in better subjective quality of vision, with patients experiencing fewer visual disturbances such as halos and fluctuations of vision compared to those who underwent small incision lenticule extraction (SMILE). [23]

Pesudovs et al.[19] reported that those who had refractive surgery had greater VRQoL scores than those who employed optical correction. Chen et al.[20] found that optical correction for myopia had an adverse effect on various aspects of VRQoL. However, myopes who had refractive surgery had the same VRQoL as emmetropes. Implantable Collamer lens (ICL) implantation has repeatedly been shown in studies to considerably enhance the quality of life in individuals with high myopia (Ieong 2010, 2009).[21] This improvement is most noticeable in terms of activity limits, symptoms, appearance, and satisfaction with the remedy (Kobashi 2014).[22] However, it is crucial to highlight that some patients may develop night vision difficulties after surgery (Ieong 2010).[21] Additional study is required to evaluate the quality-of-life results of ICL implantation to other high myopia correction procedures, such as short incision lenticule extraction (SMILE) (Wei 2020).[23]

These findings suggest that ICL implantation may offer significant QoL advantages over other refractive procedures for high myopia correction.

CONCLUSIONS

Implantation of an ICL for moderate to high myopia and myopic astigmatism resulted in both significant improvements in visual acuity and a substantial enhancement in vision-related quality of life (VRQOL) for the subjects. This suggests that ICL implantation can be a successful treatment option for these patients, leading to improved vision and a greater enjoyment of daily activities.

Limitations of study:

This study has several limitations. First, due to patient inconvenience, we were unable to collect long-term follow-up data at 3 months, 6 months, and 1 year. This limits our understanding of the durability of the ICL's effect on vision and quality of life. Second, we did not assess the post-operative vault of the ICL, which is an important factor for long-term outcomes and potential complications. Additionally, endothelial cell count, a marker of corneal health that can be affected by ICL implantation, was not evaluated. Furthermore, the study excluded patients with hypermetropia and hypermetropic astigmatism, limiting the generalizability of the findings to these populations. Finally, the sample size was not large, which may restrict the statistical power of the study and the applicability of the results to a broader patient population."

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