# Visual outcomes and patient satisfaction after implantable collamer lens and Toric implantable collamer lens correction for moderate to high myopia and myopic astigmatism

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## ABSTRACT

**الأهداف** : المقارنة بين النتائج البصرية ورضاء المرضى وتقييم الأعراض البصرية قبل وبعد عملية زراعة العدسات لتصحيح النظر.

**الطريقة**: شملت هذه الدراسة على 112 مريض يعانون من قصر النظر بين 2.75 – إلى 19.50– درجة وتم زراعة عدسات لتصحيح النظر. تم زراعة العدسات في مستشفى مغربي للعيون باليمن خلال الفترة من سبتمبر 2007م إلى أكتوبر 2010م. تم فحص جميع المرضى وشمل الفحص على حدة الإبصار بالنظارة وبدون نظارة قبل وبعد العملية ومقاسات النظارة. كما تم إجراء استبيان لمعرفة رضى المرضى والنتائج البصرية بعد زراعة العدسات.

**النتائج**: كان معدل العمر 26.74 ± 5.6 عام. تحسنت معدل قوة الإبصار قبل التصحيح من 0.01 ± 0.04 إلى 0.75 ± 0.22. أما معدل قوة الإبصار بدون نظارة بعد التصحيح ( 0.75 ± 0.23 ) مقارنة بمعدل قوة الإبصار بالنظارة قبل التصحيح ( 0.61 ± 0.23 ) يشير إلى تغير كبير بشكل ثابت مع قيمة ( $p$<0.001 ) وارتباط بيرسون ( r= 0.818 ). تشير قوة الإبصار بالنظارة ما قبل العملية مقارنة مع قوة الإبصار بالنظارة بعد العملية إلى تحسن النظر 5 أسطر في 2.5%، تحسن في 4 أسطر في 4.4%، تحسن 3 أسطر في 14.2%، سطرين في 32.8%، تحسن سطر واحد في24% وتم المحافظة في 20.1% وفقدان سطر أو أكثر في 2%. كان معدل النتيجة في الرضاء العام 2.67 ± 0.45. اشتكى 15.2% من هالات بصرية، 13.4% من رؤية نجوم حول الأضواء و 23.2% من رؤية وهج في الرؤية.

**خاتمة**: أن زراعة العدسات لتصحيح قصر النظر آمنة وفعالة وتوفر نتائج ممكن التنبؤ بها لتصحيح عيوب الإبصار مع رضاء جيد من المرضى في حالات تصحيح النظر لقصر النظر من الدرجة المتوسطة والعالية مما يشير إلى قدرتها للبقاء كأحد حلول تصحيح قصر النظر.

**Objectives:** To compare preoperative and postoperative visual outcomes, determine patient's satisfaction, and evaluate visual symptoms after implantable collamer lens (ICL) implantation.

**Methods:** One hundred and twelve patients with myopia between -2.75 and -19.50 diopter had ICL or Toric ICL (TICL) implantation. The implantations were carried out at the Cornea and Refractive Unit, Magrabi Eye Hospital, Sana'a, Republic of Yemen between September 2007 and October 2010. Preoperative and postoperative uncorrected visual acuity (UCVA), best spectacle corrected visual acuity (BSCVA), and refraction was evaluated. Patient's satisfaction and visual symptoms were evaluated using a questionnaire.

**Results:** The mean age was 26.74 ± 5.6 years. The mean preoperative UCVA improved from 0.01 ± 0.04 to 0.75 ± 0.22. The mean postoperative UCVA (0.75 ± 0.23) versus preoperative BSCVA (0.61 ± 0.23) had a significant statistical change ($p$<0.001), and Pearson correlation of 0.818. Preoperative BSCVA versus postoperative BSCVA gained 5 lines in 2.5%, 4 lines in 4.4%, 3 lines in 14.2%, 2 lines in 32.8%, and one line improvement in 24%, whereas it was maintained in 20.1%, and lost one or more lines in 2%. The mean score for the overall satisfaction was 2.67 ± 0.45. A total of 15.2% reported complaint of halos, 13.4% reported perception of stars around lights, and 23.2% had glare.

**Conclusion:** Implantation of ICL and TICL is safe and effective and provides predictable refractive results with good satisfaction in the treatment of moderate to high myopia, suggesting its viability as a surgical option for the treatment of myopia.

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In recent years, a number of possible surgical procedures in ophthalmology have been offered to people with myopia as an alternative for the need to wear glasses or contact lenses.[1] Several laser and non-laser refractive surgical procedures have been used to modify the shape of the cornea and correct myopia, hyperopia, astigmatism, and presbyopia. Currently, the 2 most popular procedures for correction of myopia are photorefractive keratectomy (PRK) and laser in situ keratomileusis (LASIK).[1] Laser keratorefractive surgeries, such as PRK and LASIK, have limitations when used for the correction of high refractive errors.[2,3] Studies on PRK have shown it to effectively correct up to -8.00 diopter (D) of myopia, and it is less effective on moderate to high myopia ≥-8.00D. Complications from PRK on eyes with high myopia include loss of best spectacles corrected visual acuity (BSCVA), regression, and haze.[4] LASIK has emerged as the refractive corneal surgical procedure of choice for correction of low myopia between -1.00D and -8.00D. But in moderate to high myopia po pulation (>-6.00D), an insufficiency layer of untouched stromal base tissue can quickly lead to ectasia, which has been reported to significantly increase glare, additional complications include edema, unstable refraction, loss of BSCVA, significant irregular astigmatism, and corneal ectasia.[5] For the above mentioned complications, the concept of implantable collamer lens (ICL) and toric ICL suggests advantages over previous surgical methods to correct moderate to high myopia and myopic astigmatism.[6] Intraocular refractive procedures offer many potential advantages; a broader range of treatable ametropia, faster visual recovery, more stable refraction, and better visual quality.[7] The Surgical Technology And Applied Research (STAAR) ICL is a lens that is implanted in the eye behind the iris and in front of the natural lens. The lens is intended to correct moderate to severe myopia and myopic astigmatism. The lens is made of a proprietary material called Collamer, a high-water-content hydrophilic copolymer of collagen and hydroxy-ethyl methacrylate (HEMA).[8] It also contains a covalently bound ultraviolet (UV) chromophore. Flexible yet resilient, the foldable lens can be inserted through an incision as small as 2.8 mm. Produced in sizes that range from 11-13 mm long, the ICL is vaulted so that as it sits in the ciliary sulcus, the central optic arches over the crystalline lens.[9] Patient satisfaction following phakic ICL is commonly reported as high and studies of the medical outcome of ICL for the treatment of myopia and astigmatism have shown great success.[10] There have been no studies that looked specifically at quality of life, functional outcomes, and patient satisfaction after ICL for correction of myopia and myopic astigmatism. This study aimed to assess subjective patient satisfaction, self-perceived outcomes and subjective visual improvement after ICL surgery for the correction of myopia and myopic astigmatism.

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**Methods.** A hospital-based prospective study was performed to assess the functional outcome and patient satisfaction after phakic ICL implantation for the treatment of myopia and myopic astigmatism. The ICL procedure was performed by 2 experienced ophthalmic surgeons. Treatments were performed in Magrabi Eye Hospital, Sana'a, Yemen. The implantations were carried out between September 2007 and October 2010, and the follow up for the medical outcome and interval for the self-administration of the questionnaire was between September 2009 and January 2011. One hundred and twelve consecutive patients were enrolled (204 eyes) (79 females and 33 males) in this study from September 2007 and October 2010, aged 18-45 years old. Follow-up time was 3-39 months after ICL surgery. The study protocol allowed planned under corrections or overcorrections of ±1.00D. Patients were enrolled with base line refractive errors between -2.25 to -19.50 D of myopia. A maximum of -6.00D of manifest refractive cylinder was allowed. Patients were required to have documented stable refraction of 0.5D for one year prior to implantation. All patients enrolled in the study were above age of 18 years, and there were no restrictions as to gender, or race. Patients with an anterior chamber depth (ACD) of less than 2.8 mm, (measured from the corneal endothelium to the anterior lens capsule) were excluded from the study. Additional exclusion criteria included clinical signs of iritis, uveitis, diabetic retinopathy, cataract, glaucoma, and patients who are pregnant or nursing. An evaluation of corneal curvature and corneal shape were evaluated with a computerized corneal topography (TMS 2, Tomy Co, Japan, and OPD Scan 2, Nidek, Japan) was carried out by 2 trained technicians. Corneal topography was used to detect early or suspicious keratoconus and pellucid marginal degeneration. Any irregular astigmatism was also detected. Corneal thickness was checked using (UP 1000 Ultrasonic Pachymeter, Nidek Co, Japan). Measurement of ACD (from the cornea endothelium

to anterior capsule) and white-to-white measurement (WTW) and axial length by A-scan ultra-sonography (Echo Scan US-3300 Nidek Co, Japan and IOL Master, Zeiss, Germany). Subjective patient satisfaction and visual outcome evaluation of the treatment was assessed by patients completing a survey questionnaire at the last visit.[11] Sizing of myopic lenses (11.5-13.0 mm) was determined by the horizontal WTW measurements (measured by Nidek (ARK-700), Japan); Auto refracto keratometer or IOL master, Zeiss, Germany) and the ACD measurement (measured by Echo Scan US-3300 Nidek Co, Japan or IOL master Zeiss, Germany). For eyes with ACD measurements of 2.8-3.5 mm, the lens size calculated by adding 0.5 mm to the horizontal WTW measurement. When the ACD is more than 3.5 mm, an addition of 1.0 mm is added to the WTW. Maximum length available is 13.0 mm and patients with <2.8 mm are excluded from the surgery and the study. Lens sizes are available in 0.5 mm steps, and ACD is rounded to 3.5 mm accordingly. The ICL power was selected based on subjective refraction, keratometry (ARK-700); Autorefractokeratometer), pachymetry (UP 1000 Ultrasonic Pachymeter, Nidek Co, Japan), and ACD (Echo Scan US-3300 Nidek Co, Japan or IOL master Zeiss, Germany). The questionnaire that was used in our study was developed and validated by 2 ophthalmologists and 2 optometrists in Yemen Magrabi Eye Hospital. It has been used for the evaluation of patient satisfaction after LASIK to assess postoperative visual symptoms.[11] The questionnaire was written in English language and translated to Arabic language without changes to the contents and construction of the original questionnaire. The procedure proved to be reliable by a high level of internal consistency with Cronbach's alpha coefficients of ≥0.75. In the questionnaire, 25 items were self-administrated by the patients, 12 months or more after the ICL implantation procedure. Scale scores increased with satisfaction, ranging from 1 (dissatisfied) to 3 (very satisfied). Each of the 7 scales covered a specific aspect of quality of vision that included global satisfaction, quality of uncorrected and corrected vision, quality of night vision, glare, daytime driving, and night driving. Patients were informed regarding the study procedure and provided verbal informed consent.

Statistical analyses were performed using the Statistical Package for Social Sciences version 18.0 (SPSS Inc, Chicago, IL, USA). Percentages, means and standard deviations were used for data analysis and statistical applications. For statistical purposes, uncorrected (UCVA) and best-corrected (BCVA) visual acuity in decimal and foot system were used for calculation. Correlation between the scale scores and clinical parameters were assessed with Pearson r coefficient of correlation, the strength between 2 variables is defined as strong (r>0.60), moderate (0.30<r>0.60), or weak (0.10<r>0/30). For analysis purposes, items of the questionnaire were grouped into 7 distinct scales, and each of these scales will represent a concept. Scales increase with satisfaction ranging from 1 to 3 (that was coded in SPSS program as: 1 - very dissatisfied; 1 to 1.65 - dissatisfied; 1.66 to 2.33 - satisfied; and 2.33 to 3 - very satisfied). The study was approved by the Research and Ethics committee of Yemen Magrabi Eye Hospital, and the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional or regional), and with the Helsinki Declaration of 1975, as revised in 2000. The risk of the surgery was fully explained to the patients in accordance with the Helsinki Declaration, and verbal informed consent was obtained.

**Results.** A total of 112 patients were included in the study. The patient's characteristics are listed in **Table 1**. The mean patient age was 26.74 ± 5.61 (range: 18-45). Only 8 patients (7.1%) were less than 20 years of age and one patient (0.9%) was more than 40 years. Preoperatively, the mean UCVA decimal Snellen's of all eyes was 0.014 ± 0.035. The mean preoperative BSCVA was 0.61 ± 0.23 (range; 0.05-1.00) with Snellen's chart (decimal), mean postoperative UCVA was 0.75 ± 0.23 (range: 0.1-1.00), and mean postoperative was BSCVA 0.78 ± 0.18 (range: 0.3-1.00) (**Table 2**). Over time, BSCVA in the study cohort improved after ICL and TICL implantation relative to preoperative levels. **Table 3** illustrates the change in preoperative BSCVA lines versus postoperative UCVA and postoperative BSCVA. Preoperatively, no eyes had myopic refractive spherical equivalent (MRSE) ≤-2.50D (range: -2.75 to -19.50D). Thirty-nine eyes (19.1%) had myopia of ≤-6.00, 83 eyes (40.7%) had myopia of -6.25 to -10.00, and 82 eyes (40.2%) had myopia of -10.25 to -19.50. Fifty-eight eyes (28.4%) had 0.25 to 1.00 cylinder, 58 eyes (28.4%) had 1.25 to 2.00 cylinder, 56 eyes (27.5%) had 2.25 to 4.00 cylinder, and 13 eyes (6.4%) had 4.25 to 6.00 cylinder. Postoperatively, the mean spherical refraction was -0.16 ± 0.48 (range +0.25 to -3.50), the mean cylinder was 0.32 ±0.53 (range: 0.50-2.75) and the mean spherical equivalent improved from 9.66 ± 3.96 to 0.31 ± 0.56 (range: -0.25 to -4.00). Postoperatively, 117 eyes (57.4%) were emmetropic, and only 5 eyes (2.4%) had MRSE of -2.25 to -4.00D. Postoperative manifest cylinder: 135 eyes (66.2%) had no astigmatism; and only 3 eyes (1.5%) had -2.25, -2.50, and -2.75D of astigmatism. Preoperative intraocular pressure (IOP)

**Table 1 -** Characteristics of patients included in an implantable collamer lens study conducted at Magrabi Eye Hospital, Sana'a, Yemen (N=112).

| Variables | n (%) | Range |
|---|---|---|
| ***Gender*** | | |
| Male | 33 (29.5) | |
| Female | 79 (70.5) | |
| ***Mean age (years)**** | 26.74 ± 5.61 | |
| Age range (years) | 18-45 | |
| ***Number of eyes (N=204)*** | | |
| Right eye | 103 (50.5) | |
| Left eye | 101 (49.5) | |
| ***Follow up time (months)*** | 3-39 | |
| Range (months) | 7.84 ± 7.39 | |
| ***Refraction (diopter)**** | | |
| Sphere | -8.74 ± 3.96 | -2.25 to -19.00 |
| Cylinder | 1.85 ± 1.33 | 0.25 to 6.00 |
| Spherical equivalent | -3.8 ± 1.62 | -2.75 to -19.50 |

*mean ± standard deviation

**Table 2 -** Preoperative BSCVA versus postoperative UCVA and BSCVA of patients included in a study conducted at Magrabi Eye Hospital, Sana'a, Yemen (N=112).

| Visual acuity | Pre-op BSCVA | Post-op UCVA | Post-op BSCVA |
|---|---|---|---|
| | | n (%) | |
| 20/20 | 21 (10.3) | 50 (24.5) | 64 (31.4) |
| 20/22 | 19 (9.3) | 11 (5.4) | 15 (7.4) |
| 20/25 | 21 (10.3) | 38 (18.6) | 42 (20.6) |
| 20/30 | 30 (14.7) | 33 (16.2) | 33 (16.2) |
| 20/35 | 29 (14.2) | 22 (10.8) | 15 (7.4) |
| 20/40 | 33 (16.2) | 22 (10.8) | 20 (9.8) |
| 20/50 | 19 (9.3) | 12 (5.9) | 7 (3.4) |
| 20/70 | 22 (10.8) | 11 (5.4) | 6 (2.9) |
| 20/100 | 6 (2.9) | 4 (1.9) | 2 (0.9) |
| 20/200 | 2 (1.0) | 1 (0.5) | 0 (0.0) |
| 20/400 | 2 (1.0) | 0 (0.0) | 0 (0.0) |

BSCVA - best spectacle corrected visual acuity, UCVA - uncorrected visual acuity

**Table 3 -** Change in preoperative BSCVA lines versus postoperative UCVA and postoperative BSCVA in patients included in a study conducted at Magrabi Eye Hospital, Sana'a, Yemen.

| BSCVA Lines | Pre-op BSCVA versus post-op UCVA | Pre-op BSCVA versus post-op BSCVA |
|---|---|---|
| | n (%) | |
| Gain 5 lines | 4 (2.0) | 5 (2.5) |
| Gain 4 lines | 2 (1.0) | 9 (4.4) |
| Gain 3 lines | 21 (10.3) | 29 (14.2) |
| Gain 2 lines | 52 (25.5) | 67 (32.8) |
| Gain 1 line | 55 (27.0) | 49 (24.0) |
| Maintain | 49 (24.0) | 41 (20.1) |
| Lost 1 line | 10 (5.0) | 3 (1.2) |
| Lost 2 lines | 9 (4.4) | 1 (0.5) |
| Lost 3 lines | 1 (0.5) | 0 (0.0) |
| Lost 4 lines | 1 (0.5) | 0 (0.0) |

BSCVA - best spectacle corrected visual acuity, UCVA - uncorrected visual acuity

**Table 4 -** Global satisfaction scale score of patients included in a study conducted at Magrabi Eye Hospital, Sana'a, Yemen (N=112).

| Global satisfaction | Mean ± SD | Satisfied and very satisfied | Not satisfied |
|---|---|---|---|
| | | n (%) | |
| Expected quality of vision achieved | 2.22 ± 0.68 | 96 (85.7) | 16 (14.3) |
| Surgery was important choice | 2.88 ± 0.32 | 112 (100) | |
| Quickness of vision improvement | 2.75 ± 0.42 | 112 (100) | |
| Main goals achieved from operation | 2.55 ± 0.50 | 111 (99.9) | 1 (0.9) |
| Improved quality of life | 2.91 ± 0.30 | 111 (99.9) | 1 (0.9) |
| Level of happiness in general post-op | 2.73 ± 0.48 | 110 (98.2) | 2 (1.8) |
| Advise operation to friends | 2.62 ± 0.48 | 112 (100) | |

**Table 5 -** Quality of night vision scale score, glare score, and uncorrected vision scale score of patients included in a study conducted at Magrabi Eye Hospital, Sana'a, Yemen (N=112).

| Mean score | Mean ± SD | n (%) |
|---|---|---|
| ***Night vision in comparison before surgery*** | 2.86 ± 0.39 | |
| Better | | 97 (86.2) |
| Same | | 11 (9.8) |
| Worse | | 2 (1.8) |
| Not reported | | 2 (1.8) |
| ***Complaining of halos*** | 1.75 ± 0.7 | - |
| No complaint | | 44 (39.3) |
| Mild complaint | | 46 (41.1) |
| Severe complaint | | 17 (15.2) |
| Not reported | | 5 (4.5) |
| ***Perception of stars around lights*** | 1.70 ± 0. 69 | - |
| No complaint | | 48 (42.9) |
| Mild complaint | | 47 (42.0) |
| Severe complaint | | 15 (13.4) |
| Not reported | | 2 (1.8) |
| ***Glare from oncoming headlights at night*** | 1.78 ± 0.73 | - |
| No complaint | | 42 (37.5) |
| Mild complaint | | 44 (39.3) |
| Severe complaint | | 26 (23.2) |
| ***Uncorrected distance vision (watching TV)*** | 2.53 ± 0.56 | - |
| Much better than preoperative corrected vision | | 63 (56.8) |
| Same preoperative corrected vision | | 44 (39.6) |
| Worse than preoperative corrected vision | | 4 (3.6) |

was 13.6 ± 2.39 (range: 10-19) mm Hg. Postoperative IOP was 15.00 ± 2.52 (range: 10-21) mm Hg. The most frequent reported motivations for desiring correction by ICL and TICL implantation were general dislike of handling glasses (66%), to be less dependent on glasses (17%), and for professional and career

reasons (17%). **Table 4** shows global satisfaction scale score. The mean score for the overall satisfaction was 2.67 ± 0.45 (3 meaning totally satisfied). The majority of patients (99.9%) reported that their main goal had been achieved, in 99.9% the surgery improved their quality of life, and 100% will advise friends to have the operation. One hundred percent had quick recovery of vision improvement, and 98.2% were happy in general, postoperatively. The mean score for all patients was 2.56 ± 0.59. **Table 5** shows the uncorrected vision scale. The mean score for night vision was 2.31 ± 0.55. Night vision was considered same or better than before surgery by 86.2% patients, and was considered worse than before surgery by 1.8% patients (**Table 5**). The mean glare score was 1.74 ± 0.71. After surgery, glare from oncoming headlights was considered not bothersome by 42.9% of patients, and considered more bothersome by 13.4% of patients (**Table 5**). The mean score for daytime driving was 2.81 ± 0.45, and nighttime driving was 2.57±0.65. Correlation between the clinical parameter and satisfaction scales are shown in **Table 6**. There was no correlation between age and satisfaction scales. There was a correlation between UCVA postoperatively and global satisfaction, uncorrected vision, night vision, and glare. The mean spherical equivalent postoperatively has a correlation with global satisfaction, while there was no correlation between satisfaction scales and mean astigmatism postoperative (**Table 6**).

**Discussion.** Patients' satisfaction is regarded as a measure of the quality of treatment provided, and a proven relationship exists between patient satisfaction and utilization of medical service. They present objective clinical results and provide little to no subjective detail regarding aspects such as patients' perspectives, as to whether the procedure had achieved their goals and expectations, issues such as visual ability in everyday situations, whether patients were experiencing symptoms, and where they were having the most difficulties.[11] Therefore, satisfaction studies can provide important feedback regarding the quality of care and outcome, which in turn allows the medical provider to improve the services offered. Hence, there has been much interest in trying to quantify and qualify various aspects of patient satisfaction after refractive surgery.[11]

As refractive surgeons, we generally assumed that patient satisfaction following refractive surgery with LASIK, PRK, and ICL was high. However, anecdotal impressions are often flawed. Many refractive surgery patients are excessively enthusiastic of their treatment; this leads ophthalmic personnel to equal enthusiasms. Conversely, a small number of unhappy patients can create a disproportionally negative attitude, both to the ophthalmic personnel and to other patients. To maintain a balanced impression, it is important to review visual outcomes and patient satisfaction.[12] As yet, no previous studies of visual outcomes and patients satisfaction after ICL for correction of myopia and myopic astigmatism have been published. We report here on Visian ICL phakic intraocular lens (PIOLs) implanted in Yemeni eyes.

The study cohort consists of 204 eyes of 112 study subjects. This number of subjects is considered good when compared with other studies.[6,7,10] Gender

**Table 6 -** Correlation coefficients between clinical parameters and satisfaction scales of patients included in a study conducted at Magrabi Eye Hospital, Sana'a, Yemen (N=112).

| Parameters | Global satisfaction | Uncorrected vision | Corrected vision | Glare | Night vision | Day driving | Night Driving |
|---|---|---|---|---|---|---|---|
| *Age of patient* | | | | | | | |
| Pearson correlation | -0.019 | 0.203 | 0.186 | 0.169 | 0.182 | 0.258 | -0.042 |
| *P*-value | 0.841 | 0.062 | 0.050 | 0.078 | 0.062 | 0.094 | 0.784 |
| *Mean post-op UCVA* | | | | | | | |
| Pearson correlation | 0.228* | 0.344† | 0.100 | 0.334† | 0.326† | 0.195 | 0.257 |
| *P*-value | 0.029 | 0.003 | 0.343 | 0.001 | 0.002 | 0.255 | 0.125 |
| *Mean post-op BSCVA* | | | | | | | |
| Pearson correlation | 0.152 | 0.190 | 0.121 | 0.273† | 0.306** | 0.209 | 0.198 |
| *P*-value | 0.148 | 0.116 | 0.252 | 0.009 | 0.004 | 0.221 | 0.239 |
| *Mean post-op SE* | | | | | | | |
| Pearson correlation | -0.261* | -0.198 | -0.021 | -0.178 | -0.166 | 0.039 | -0.226 |
| *P*-value | 0.012 | 0.101 | 0.846 | 0.093 | 0.120 | 0.819 | 0.178 |
| *Mean post-op astigmatism* | | | | | | | |
| Pearson correlation | -0.188 | -0.116 | -0.031 | -0.178 | -0.073 | -0.116 | -0.189 |
| *P*-value | 0.072 | 0.337 | 0.773 | 0.093 | 0.495 | 0.501 | 0.264 |

*Correlation is significant at the 0.05 level (*p*-value). †Correlation is significant at the 0.01 level (*p*-value).

distributions showed that females (70.5%) were more than males (29.5%). This finding agrees with other similar studies.[9,13] In Yemen as in other societies in the world, females have high motive to dislike handling glasses for cosmetic reasons more than males. The mean age of patients was 26.74 ± 5.6 (range: 18-45 years), and only 8 patients (7.2%) were less than 20 years of age. This finding agreed with the approval of FDA,[13] that preferred patients should be with age more than 20 years. The mean follow up time was 7.84 ± 7.34 months (range: 3-39 months), and patients with MRSE up to -19.50D and astigmatism up to 5.00D were enrolled in this study. The highest power available from the company is -23.00D that corrects -18.00D of MRSE, and the remaining is corrected with glasses. The UCVA, the primary efficacy variable for the ICL clinical study[9] and most refractive surgeries, showed great improvement over pre-operative values. The mean preoperative UCVA improved from 0.01 ± 0.04 to 0.75 ± 0.23. **Table 2** had shown that the mean preoperative BSCVA was 0.61 ± 0.23 and mean post-op UCVA was 0.75 ± 0.23, this improvement had a highly significant *p*-value (<0.001) and Pearson correlations (0.818). The mean score of uncorrected vision was 2.56 ± 0.59 on a scale of 1 to 3 (3 meaning totally satisfied). Uncorrected vision scale showed positive correlations with postoperative UCVA and had high significant *p*-value (0.003). Only some patients (3.6%) reported that their self-perceived uncorrected vision for distance was worse than the preoperative corrected vision, this result was explained by the fact that those patients had been targeted to be under-corrected. This study reported that after surgery, 97.3% of patients (n=109) did not use glasses or contact lenses, and the regular use of glasses was reported for distance vision (n=2, 1.8%), and near vision (n=1, 0.9% of patients, and this result was considered an optimal result because some patients (17%) aimed to be less dependent on their high-power spectacles instead of being totally spectacle-free. The patient that wears glasses for near vision is 45 years of age, by other means she was a presbyopic patient.

Overall, this study had shown excellent medical outcome in terms of predictability, safety, and efficacy after ICL, consequently this led to high patient's satisfaction rates (the mean score for the overall satisfaction was 2.67 ± 0.45 on a scale of 1 to 3). This score result means that the overall patient satisfaction was excellent and showed better than, or comparable with previous PIOL studies.[13] Most patients (85.7%) experienced a quality of vision as they had expected or more. All patients (100%) reported that the surgery was important or very important choice for them, and 99.9% of patients reported that their main goals of surgery had been achieved. There was a positive relationship between overall satisfaction and mean postoperative UCVA with a significant *p*-value (*p*-=0.029), and negative correlation between overall satisfaction and mean postoperative SE (*p*=0.012), these correlations were expected and similar to a previous PIOL study.[13]

The main limitation of this study was that this study is subjective, and therefore did not attempt to address objective elements, such as contrast sensitivity. The lack of preoperative patient's self-assessment makes the questionnaire postoperative more difficult for a patient to accurately compare his or her preoperative and current quality of vision, and this adds to the limitations of such studies. Also the lack of preoperative and postoperative measurements of some clinical parameters as glare, contrast sensitivity, and optical aberration makes the explanation of these symptoms more difficult to accurately understand the causes of them. The endothelium was not evaluated pre-operatively or postoperatively because of the unavailability of specular microscope.

In conclusion, the mean score for the overall satisfaction was 2.67 ± 0.45 on a scale of 1 to 3 (a score of 3 meaning that the patient was totally satisfied). This study showed significant positive correlations between global satisfaction and mean post-op UCVA, also showed significant negative correlation between global satisfaction and mean post-op SE. It also found significant correlations between mean post-op UCVA with uncorrected vision scale, glare, and night vision scale scores. There was also significant positive correlation between mean post-op BSCVA and glare scale scores and night vision scale scores. Despite these complaints such night vision complaint, glare, halos, and night driving problem overall satisfaction remained high and moderately correlated with clinical parameters. In the future, it is advisable to repeat such self-administration questionnaires, and to include preoperative information, such as complaints regarding day and night driving, glare, and halos to be compared with postoperative complaints.

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