Outcome of Implantable Collamer Lens (ICL) Implantation in Patients with High Myopia in Iraq

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Abstract

Aim: To study the visual outcome and the possible complications following implantable collamer lenses implantation (ICL) in patients with high myopia.
Methods: Thirty eyes of 15 patients(8 males and 7 females) with myopia ranging from -9 to -19 Diopters underwent the procedure of implantable collamer lens implantation between February 2010 and July 2010 in Ramadi city, Iraq . The mean age was 26.7 ± 5.58 years. Detailed ophthalmological examination was carried out for all patients including preoperative visual acuity (uncorrected and the best spectacle corrected visual acuity), slitlamp examination, fundus examination, intraocular pressure measurement, corneal topography, anterior chamber depth, Pachymetry and horizontal corneal diameter (white to white distance).
Results: The uncorrected visual acuity of 6/18 or better was achieved in 90% (27 eyes) after six months from the ICL implantation. This study showed that the preoperative best spectacle corrected visual acuity (BSCVA) was 6/6 in 40% (12 eyes), 6/9 in 33% (10 eyes), 6/12 in 10% (3 eyes), 6/18 in 10% (3 eyes) and 6/24 in 6.6% (2 eyes). Postoperatively, we found that the uncorrected visual acuity (UCVA) was 6/6 in 36% (11 eyes), 6/9 in 36% (11 eyes), 6/12 in 10% (3 eyes), 6/18 in 10% (3 eyes), and 6/24 in 6.6% (2 eyes). Intraocular pressure was measured at each postoperative visit i.e. the first postoperative day, the third postoperative day, the seventh postoperative day, after one month, after two months, after three months and after six months. The mean intraocular pressure was 19.93 ±4.83 mmHg, 15.50 ±1.85 mmHg, 15.07 ±1.51 mmHg, 14.63 ±1.73 mmHg, 14.57 ±1.77 mmHg, 14.23 ±1.74 mmHg, 14.13 ±1.55 mm Hg, respectively.
Conclusion: Implantable collamer lenses implantation is a reliable solution for patients with high myopia . The procedure showed predictable results and it is safe with no serious complications. However, longer period of follow up is needed.
Key words: collamer lenses, high myopia, intraocular pressure.

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Introduction:

The Implantable Collamer Lens, or Visian ICL, is one of the posterior chamber phakic intraocular lenses (PCPIOLs) and is made of a hydrophilic material known as collamer, which is a collagen copolymer. The optic of the PCPIOLs is vaulted both to avoid contact with the crystalline lens and to allow aqueous to flow over the crystalline lens.[1]

Implantation of phakic intraocular lenses (IOLs) like ICL has many advantages over keratorefractive procedures such as laser-assisted in situ keratomileusis (LASIK). In the treatment of high-degree myopia by LASIK, relatively large amounts of cornea must be ablated, small effective optical zones are created and the predictability and stability of the procedure begin to diminish.[2,3]

It is first approved by the US Food and Drug Administration (FDA) in 2005 for the correction of myopia between -3.00 diopter (D) and < -15.00 D and for the reduction of myopia between -15.00 D and -20.00 D. With few complications reported in the 3-year follow up multicenter study, the short-term safety and efficacy of the ICL lens is well established ,[4] long-term stability of these lenses is still being evaluated. This surgical procedure is largely reversible and the lens is exchangeable, unlike LASIK, even when unexpected refractive changes occur after surgery. However, complications of ICL implantation such as cataract formation, endothelial cell loss, pigmentary glaucoma, and pupillary block have been reported, and these complications are expected to increase with time.[5-10] The aim of this study was to investigate the clinical outcomes of ICL implantation for the correction of high myopia.

Patients and Methods:

Thirty eyes of 15 patients(8 male and 7 female patients) (figure 1) with mean age 26.7 ± 5.58 years were included in this prospective study. All of them underwent the procedure of implantable collamer lens implantation for the correction of high myopia between February 2010 and July 2010 in Ramadi city, Iraq. The inclusion criteria were the best corrected visual acuity (BCVA) of 6/24 or better, stable refraction and laser corneal surgery contraindication. The exclusion criteria included age below 21 years, anterior chamber depth under 3.0 mm, scotopic pupil diameter over 6.5 mm, cataract, history of glaucoma or retinal detachment, previous corneal or intraocular surgery, macular degeneration or retinopathy, neuro-ophthalmic diseases and history of prior ocular inflammation .

Eyes with keratoconus were excluded from the study by results of a keratoconus screening test using the pentacam (Allegro Oculyzer; Wave light, Germany). Detailed ophthalmological examination was carried out for all patients including preoperative visual acuity (unaided and the best spectacle corrected visual acuity), slitlamp examination, fundus examination through dilated pupil, intraocular pressure measurement using the Goldmann applanation tonometer, corneal topography using the pentacam and Pachymetry using the Tommey pachymeter to measure the corneal thickness. Anterior chamber depth was taken from the pentacam topography maps. White to white distance between 3 and 9 o'clock was measured by the caliper. All surgeries in this study were performed through a 3.2 mm clear corneal tunnel incision in the temporal side of the cornea under topical anaesthesia (proparacaine 0.5%). Thirty minutes before surgery, tropicamide 1% and phenylephrine 10% eye drops were instilled. Five minutes before surgery, povidone- iodine 5% (Betadine®) was instilled. The anterior chamber was filled with methyl cellulose (ROHTO, Japan), which was completely removed at the end of surgery. The ICL was implanted through 3.2 mm clear corneal tunnel incision in the temporal side of the cornea Ciprofluxacine 0.3% and prednisolone 1% eye drops were used 6 times a day for 7 days, and 4 times a day for 3 weeks thereafter. Online calculations were performed using the online calculation and ordering system software from STAAR surgical company. Postoperatively , all patients were examined after one day, three days, seven days, one month, two months, three months and six months. The postoperative examination included the uncorrected visual acuity, the best spectacle corrected

visual acuity, intraocular pressure measurement, and slit lamp examination.

The Patient satisfaction was also reported by asking him/her about his/her satisfaction concerning vision after the ICL implantation.

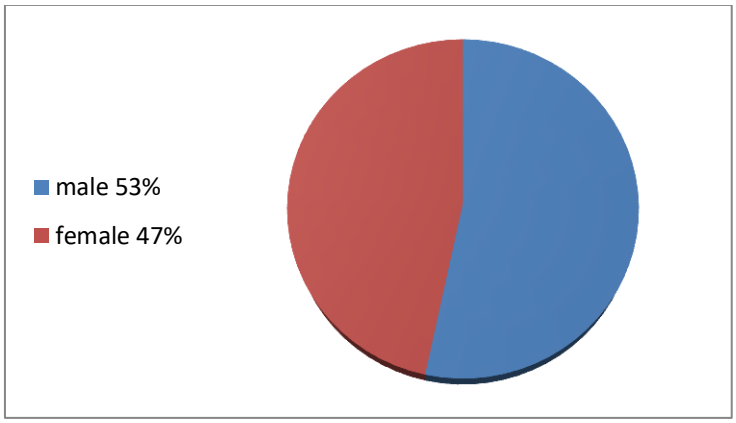

figure 1: shows the gender distribution

Results:

All patients included in this study were satisfied with the result of surgery. No complications occurred during surgery. No eye needed removal or repositioning of the ICL.

Decentering of the ICL lens was not observed and one patient reported halos and glare under daylight conditions but he described that he is satisfied with his vision without glasses. In the postoperative period no case of pupillary obstruction and anterior subcapsular opacities was detected.

One patient needed Nd:YAG laser peripheral iridotomy due to non-patent surgical iridotomy which was done during surgery.

`The age range was 21-38 years, with a mean age of 26.7 ± 5.58 years. 53% (8 patients) of the patients are located in the age group 20-25 years, 20% (3 patients) in both, age groups 26-30 years and 31-35 years and 6.6% (1 patient) in the age group 36-40years (Figure 2).

The degree of myopia ranges from -9 to -19 Diopters, with a mean of -12.53 ± 2.77 Diopters. 30% (9 eyes) of the eyes in the range between -5 and -10 Diopters. 53% (16 eyes)of the eyes have myopia in the range between -11 and -15 Diopters. and 17% (5 eyes) in the range between -16 and -20 Diopters (figure 3)

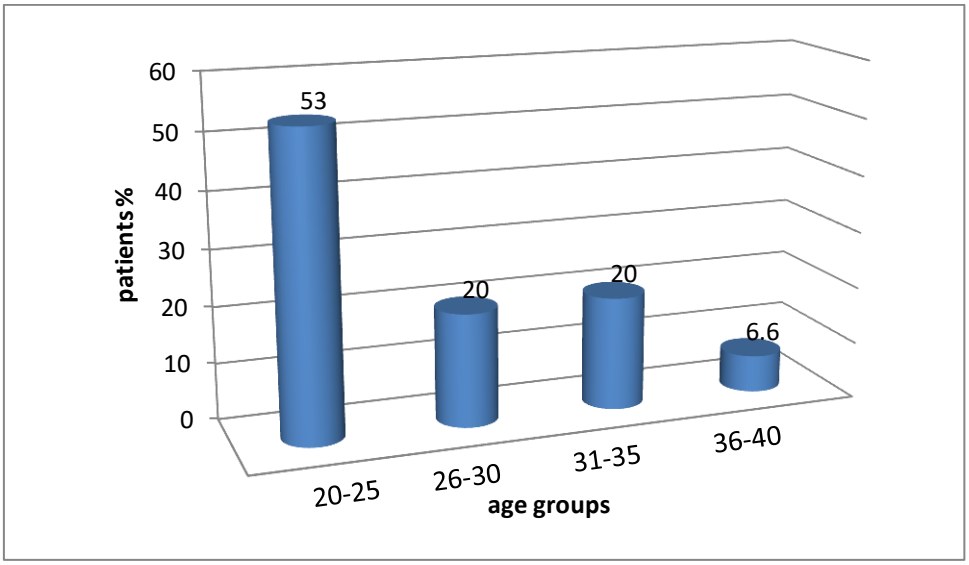

Figure 2: percentage of patients within each age group

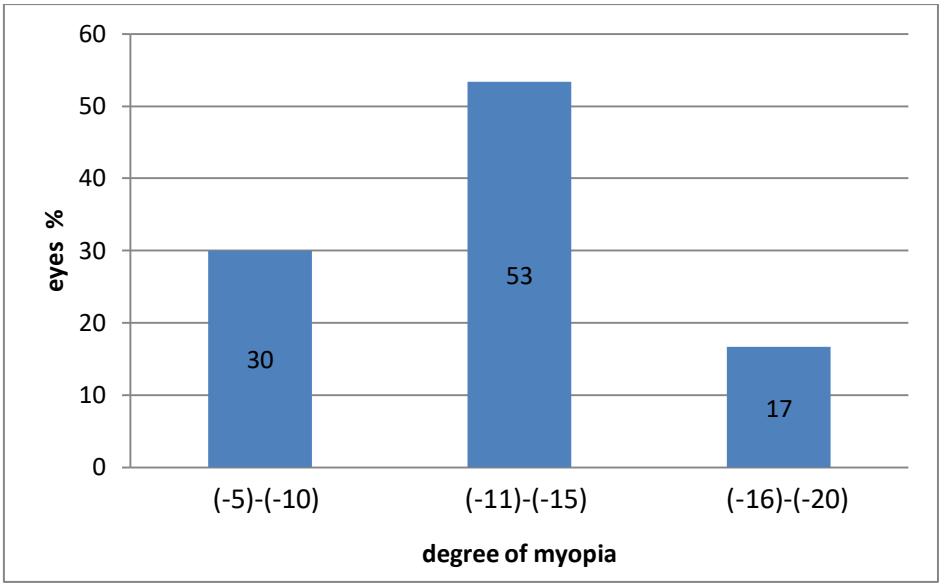

Figure 3: percentage of eyes within each myopic range.

The visual outcome, which is the main target for this procedure, was assessed by Snellen visual acuity chart.

This assessment showed that uncorrected visual acuity of 6/18 or better was found in 67% (20 eyes) in the first postoperative day, 80% (24 eyes) in the third postoperative day, 83% (25 eyes) in the seventh postoperative day and 90% (27 eyes) after one month, two months, three months and six months postoperatively (figure 4)

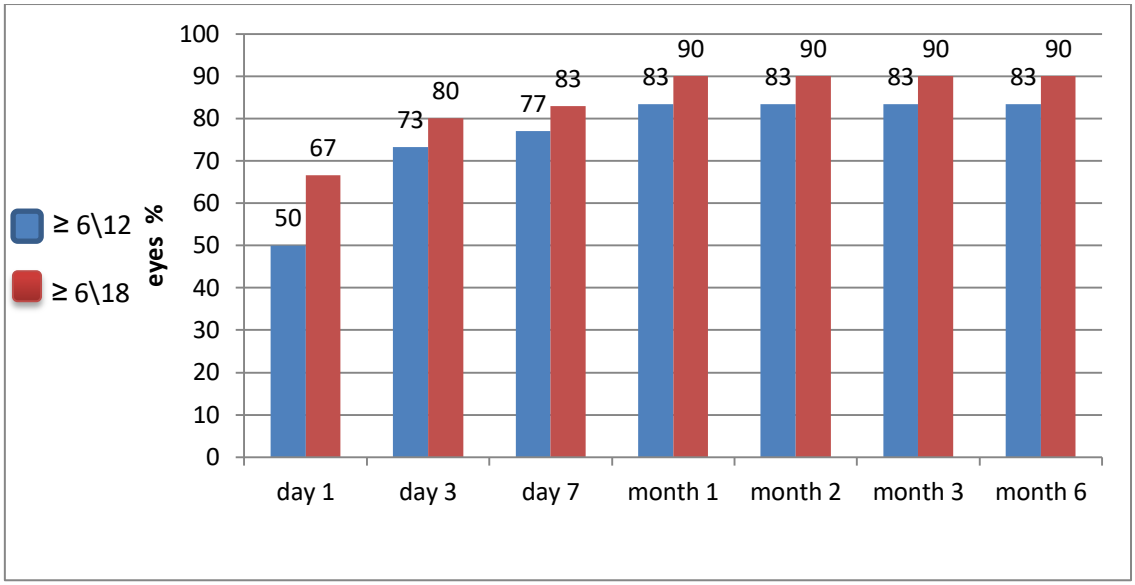

Figure 4: the uncorrected visual acuity after implantation of ICL.

When the preoperative BSCVA compared with the postoperative UCVA, this study showed that the preoperative BSCVA was 6/6 in 40% (12 eyes), 6/9 in 33% (10 eyes), 6/12 in 10% (3 eyes), 6/18 in 10% (3 eyes) and 6/24 in 6.6% (2 eyes). Postoperatively we found that the UCVA was 6/6 in 36% (11 eyes), 6/9 in 36% (11 eyes), 6/12 in 10% (3 eyes), 6/18 in 10% (3 eyes), and 6/24 in 6.6% (2 eyes).

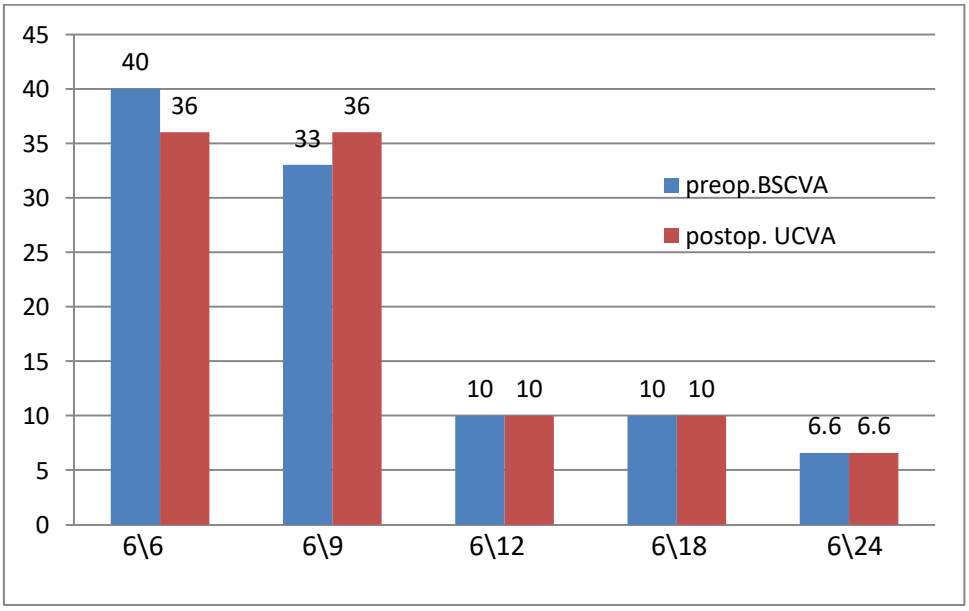

Figure 5: Comparison of Pre-operative Best Spectacle-corrected Visual Acuity with Uncorrected Visual Acuity Six Months After ICL Implantation

The intraocular pressure was measured at each postoperative visit i.e. the first postoperative day, the third postoperative day, the seventh postoperative day, after one month, after two months, after three months and after six months. The mean intraocular pressure was 19.93 ±4.83 mmHg, 15.50 ±1.85 mmHg, 15.07 ±1.51 mmHg, 14.63 ±1.73 mmHg, 14.57 ±1.77 mmHg, 14.23 ±1.74 mmHg, 14.13 ±1.55 mm Hg, respectively (figure 6).

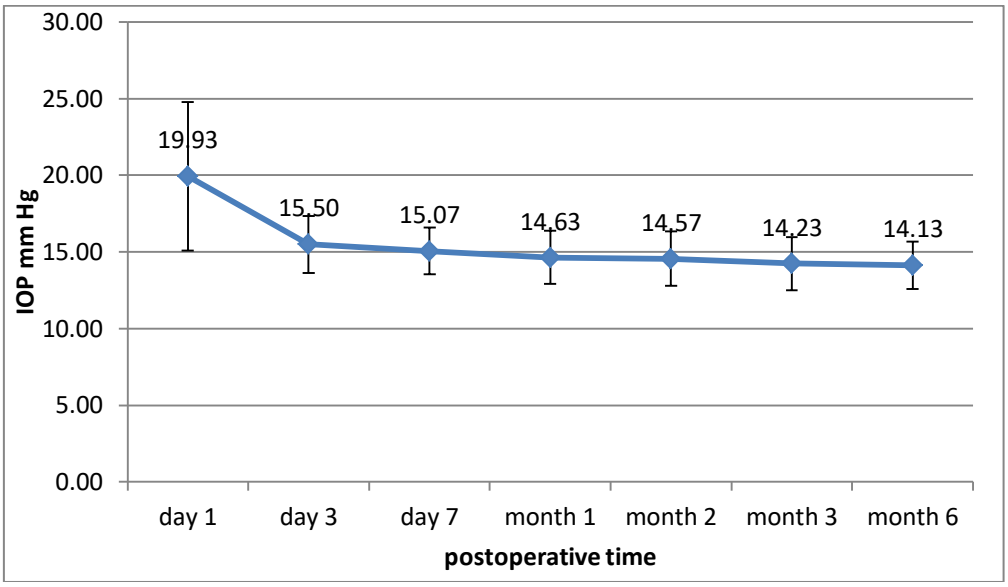

Figure 6: Time course of the mean intraocular pressure after ICL implantation.

Discussion and Conclusions:

In this prospective study of 30 eyes, the visual outcome and the possible complications after implantable collamer lenses implantation were evaluated. To our knowledge, this is the first study in Iraq evaluating ICL implantation. We found that ICL implantation in patients with high myopia is effective, predicable and safe. Other previous published studies about ICL implantation showed similar outcomes. Sanders and Vukich compared the results of 1,678 LASIK (Laser-Assisted In situ Keratomeliosis) eyes with 144 ICL eyes for correction of myopia between -4 and -7.88D. Best corrected visual acuity (BCVA) loss of at least two lines was significantly higher in the LASIK eyes in the early post-operative period, whereas a BCVA gain of at least two lines was statistically higher with the ICL at one and six months post-operatively. The proportion of cases seeing 20/15 or better, as well as 20/20 or better, at six months post-operatively was higher in the ICL group. Correction with ICL was statistically more predictable, and stability of refraction was also significantly better in the ICL group.[11] For correction of moderate to high myopia, the same authors compared 559 LASIK eyes with 210 ICL eyes operated on for myopia between -8 and -12D. Again, every index of BCVA, UCVA, predictability and stability of refraction favoured the ICL over LASIK.[12]

In our study, we found that the percentages of eyes seeing 6/12 or better after surgery were 50%, , 73%, 77%, 83%, 83%, 83%, 83% at 1 day, 3 days, 7 days, 1 month, 2 months, 3 months and 6 months,

respectively. We found that the outcome is predictable and this is demonstrated in figure 5, in which the preoperative BSCVA was compared with the postoperative UCVA 6 months after surgery. The percentage of patients with 6/6 BSCVA preoperatively was 40% and the percentage of patients with 6/6 UCVA postoperatively was 36%. For patients with 6/9 BSCVA preoperatively, the percentage was 33% and the percentage of patients with 6/9 UCVA postoperatively was 36%. Regarding patients with 6/12, 6/18 and 6/24 BSCVA preoperatively, the percentages were 10%, 10% and 6.6%, respectively. The patients with 6/12, 6/18 and 6/24 UVA postoperatively, the percentages were 10%, 10% and 6.6%, respectively. These figures indicate that one patient with 6/6 BSCVA had lost one line postoperatively. This finding demonstrates our aim in performing refractive surgery in general and in performing ICL implantation specifically, which is the achievement of postoperative UCVA equal to or near the preoperative BSCVA and this was achieved in our study.

Regarding safety of the procedure, we did not record serious complications during and after surgery, which is consistent with a study published by Jose F. Alfonso *et al*, in which the patients were followed for one year .[13] in our study, one patient only needed Yag laser iridotomy because the surgical iridotomy was found to be non patent postoperatively and the patient did well during the follow up period.

The intraocular pressure (IOP) was measured at each postoperative visit and the mean IOP was found to be near the upper normal value in the first postoperative day (19.93 ±4.83 mmHg) and started to decrease gradually thereafter to become 15.5 ±1.83 mmHg in the third postoperative day, 15.07 ±1.51 mmHg 7 days after surgery, 14.63 ±1.37 mmHg 1 month after surgery, 14.57 ±1.77 mm Hg 2 months after surgery, 14.23 ±1.74 mm Hg 3 months after surgery and 14.13 ±1.55 mm Hg 6 months after surgery. The same figures of mean IOP following ICL implantation was found by a previous study in which the mean IOPs were 14.5 (±3.2), 13.7 (±2.1) and 13.3 (±2.8) mm Hg when measured 1, 3, 6 months after surgery, respectively.[14]

The ICL was found to be stable in the eye and no eye showed decentration or malposition of the ICL although longer period of follow up is needed. The stability of ICL was proved by Mathew B. McCauley *et al*, he reported a case underwent bilateral implantation of ICLs in 2006, 8 months postoperatively, the patient was serving in a combat zone and sustained blunt and fragmentation injuries from a grenade explosion. Despite this injury, his ICLs were well centered and no evidence of lens opacities.[15]

When the patients asked about their satisfaction, they all expressed a high degree of satisfaction and they frequently remarked that the procedure was life changing. This high quality of life after successful refractive surgery was evaluated by many studies.

The emerging message from these studies is that successful refractive surgery offers functional advantages over spectacles or contact lens wear. [16,17,18,19,20]

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