Efficacy, safety and stability of implantable collamer lens 
incorrection of high myopia

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ABSTRACT
PURPOSE: To evaluate efficacy, safety and stability of implantable collamer lens in high myopia.
METHODS: This study was non-randomized comparative prospective consecutive interventional study. It included 34 eyes with high myopia (≥ -6 Ds) attended to the outpatient ophthalmic clinic of Sohag university hospitals from the period from Jan.2016 to Jan.2017.
RESULTS: UCVA preoperative was (1.90±0.29) and UCVA postoperative was (0.27±0.21) with (p-value<0.000*). BCVA preoperative was (0.526±0.272) and that of BCVA postoperative was (0.217±0.128) with (p-value<0.001*). VA values are improved in 100% of cases which can be up to (0.1 logMAR or more) after 6 months follow up (p<0.000*). Spherical equivalent preoperative was (-15.173±4.079) and that of postoperative was (-0.269±0.787) with (p-value<0.000*), which didn’t change of spherical equivalent of manifest refraction ≥ 1.00 D within 6 months follow up period.
CONCLUSIONS: Implantable collamer lenses proved high efficacy, safety and stability for high myopic patients.
Keywords: High myopia, implantable collamer lens, efficacy, safety, stability.

Introduction:
Myopia often known as “being short sighted” causes vision to be blurry in the distance but clearer when looking at things up close. Myopia eye which bends the coming light too much, which means that the light comes to a focus point before it reaches the retina. When moving closer to an object, this changes the focusing of the light and the object is then in focus on the retina and therefore looks clear.
Myopia depends on:
•The length of the eyeball from front to back
•How steep the cornea is
•How powerful the lens is.
Classification of myopia (1):
•Mild myopia includes powers up to -3.00 diopters (D)
•Moderate myopia, values of -3.00 to -6.00D
•High myopia is usually myopia over -6.00D
Phakic intraocular lenses (PIOLs) are generally accepted as an alternative treatment for ametropia correction among various refractive ranges. Fast visual recovery, high efficacy, predictability and stability of visual quality, preservation of accommodation, and reversibility are several advantages that have been attributed to PIOL implantation. (2, 3)
The Visian Implantable Collamer Lens (ICL; STAAR Surgical Co, Monrovia, California) is approved by the United States Food and Drug Administration (FDA) for the treatment of moderate to severe myopia. The lens material, trade-named Collamer, is a hydrophilic collagen-polymer combination with a water content of 34% and a refractive index of 1.45. (2)
ICL implantation can correct myopia (3, 4), hyperopia (5, 6), or astigmatism (7, 8), with clinical and visual results as good as or better than laser procedures (7, 8). Patients who are not suitable candidates for corneal reshaping procedures, and in whom optical correction with spectacles or contact lenses is either challenging or have poor results (9, 10) can benefit from ICL surgery.

Although the ICL offers outstanding advantages, there have been reports in the literature of postoperative complications associated with both high and low degrees of vault of the ICL over the crystalline lens. Low vault may lead to mechanical contact with the crystalline lens or inadequate aqueous circulation, which is responsible for a high incidence of anterior capsular opacification and cataract formation (11, 12). Conversely, excessively high vault causes mechanical contact between the ICL and the iris, resulting in inflammation, high intraocular pressure, angle-closure glaucoma and pigment dispersion syndrome (13).

Recently, a new implantable collamer lens (ICL V4c), with a 360 μm central hole that allows for the natural flow of aqueous humor without the need for a peripheral iridotomy, which may reduce the risk of anterior capsular opacification and cataract formation comparing to the old forms of ICL (14, 15). Previous studies have shown that the pupil constriction in response to light can affect the vault, eventually causing the ICL to move posteriorly towards the crystalline lens, leading to a significant decrease in central vault under photopic conditions (9, 14). Du et al. reported that the distance between the ICL and the crystalline lens reduced as the ICL was moved posteriorly by the iris as a result of pupil constriction during pharmacologic accommodation with topical pilocarpine. Simultaneously, the anterior surface of the crystalline lens became more convex and moved anteriorly, further reducing the central vault of the ICL (15). Furthermore, it has been reported that vault has a tendency to decrease over time, along with physiologic increase of lens thickness with age (3, 13, 16).

**METHODS**

**Subjects**

Twenty individuals (34 eyes) aged 27-35 years who attended to the outpatient ophthalmic clinic of Sohag university hospitals from the period from Jan.2016 to Jan.2017. Spherical refractive errors mean value - 13.576D (±3.945) with astigmatism - 1.134 D (±0.617). The patients had clear intraocular media and no known ocular pathology.

The tenets of the declaration of Helsinki were followed. Informed consent was obtained from each participant after verbal and written explanations of the nature and possible consequences of the study were provided. The study protocol received institutional review board approval.

**INTRAOCULAR LENS**

The Visian ICL is a plate-haptic single-piece intraocular lens, which is a flexible. It can be folded and implanted in the posterior chamber via a 2.8–3.2 mm corneal incision. It has a high degree of biocompatibility, good permeability of gases and metabolites, and good absorption of ultraviolet radiation. The ICL design has been modified many times in the past. In this study, the phakic IOL patients were ICL V4c lens designs. The ICL V4c is a 6.00 mm wide lens and comes in four sizes (12.1, 12.6, 13.2 and 13.7 mm in length). Its optic zone diameter is 4.9–5.8 mm, with a spherical power range of -0.50 to -18.00 DS and a cylindrical power range of +0.50 to +6.00 DC. ICL power calculations were performed by the manufacturer.
(STAAR Surgical) using a modified vertex formula. The variables in the formula included preoperative manifest spherical and cycloplegic refractions, keratometric power, central corneal thickness and central ACD (ACD, Pentacam, measured from the corneal endothelium to the anterior lens). The size (length) of the implanted ICL was determined based on the patient’s WTW and ACD. For the ICL V4c, the sizes (lengths) of 12.1, 12.6, 13.2 and 13.7 mm were equal to the ICL V4 sizes (lengths) of 11.5, 12.0, 12.5 and 13.0 mm, respectively. (17)

**Efficacy:** Percentage of eyes with uncorrected visual acuity (UCVA) of 20/20 and 20/40 (2) Efficacy index, which is the ratio of the mean postoperative UCVA to the mean preoperative BCVA (i.e. mean postop. UCVA / mean preop. BCVA). (This is most easily calculated by converting the values of geometric mean acuities to decimal values)This measure is particularly useful in describing outcomes of high myopia when the preoperative BCVA is worse than 20/20.(18)

**Safety:** Number and percentage of eyes losing two or more lines of best spectacle corrected visual acuity BCVA. (2) Safety index, which is the ratio of mean BCVA over mean preop. BCVA (i.e. Mean postop.BCVA / mean preop. BCVA) this is most easily calculated by converting the values of geometric mean acuities to decimal values.(18)

**Stability:** The number and percentage of eyes with a change of spherical equivalent of manifest refraction ≥ 1.00 D within a specified interval , the recommended minimal interval is 6 months(18).

**DATA ANALYSIS**

Statistical analysis was performed using SPSS version 16(IBM, USA). An independent samples t-test was used to compare mean values of measured parameters. Pearson's correlation coefficient was used to evaluate the correlation between quantitative variables.

**RESULTS**

UCVA preoperative was (1.90±0.29) and UCVA postoperative was (0.27±0.21) with (p-value<0.000*). BCVA preoperative was (0.526±0.272) and that of BCVA postoperative was (0.217±0.128) with (p-value<0.001*), which means that BCVA postoperative was better than what was expected from the BCVA preoperative.

Spherical error decreased from (-13.576±3.945) preoperative to (-0.0385±0.821) postoperative with (p-value<0.000*).Cylindrical error preoperative was (-1.134±0.617) and postoperative was (-0.352±0.250) with (p-value<0.000*).Spherical equivalent preoperative was (-15.173±4.079) and that of postoperative was (-0.269±0.787) with (p-value<0.000*).

**DISCUSSION**

pressure. Therefore ,asessing visual and outcomes of PIOL is helpful when selecting the more appropriate , safe ,stable and effective procedure to correct high myopia ,especially when the patients have an overlapping range of both procedures(21).

Our study showed excellent refractive and visual outcomes for ICL implantation. The aim of this study was to evaluate the visual outcomes of implantable collamer lenses for correction of high myopia regarding visual acuity, efficacy, safety and stability. It is proved that Phakic IOL implantation has predictability in correction of high myopia (19, 20).Implantation of PIOL can induce complications such as cataract, lens dislocation and elevation of intraocular
the correction of high myopia with and without astigmatism, whose study involved 95 eyes and followed up for one year (25).

- One eye developed postoperative iritis which can be attributed to the manipulations made to remove and reinsert the lens intraoperatively.

- Three eyes were steroid responders and IOP improved by cessation of steroids. This complication is encountered by Sirish Senthil, et al. who studied etiology and management of raised intraocular pressure following posterior chamber phakic intraocular lens implantation in myopic eyes. They studied 638 eyes between 2009 and 2015 (26).

In summary, Implantable collamer lens implantation for high myopia proved high efficacy, safety, and stability.

References:

The study showed that with a pupillary diameter 3-mm, VA values are improved in 100% of cases which can be up to (0.1 logMAR or more) after 6 months follow up (p<0.000*). There is agreement between our results and results of Paul and Taylor who studied refractive outcomes and safety of the implantable collamer lens in young low to moderate myopes. Their study was retrospective study performed by chart review of (104 eyes) with 50 months follow up period (22).

The study showed high efficacy, safety and stability of ICL during the follow up period. These finding were consistent with that of Xun Chen et, al. who studied contralateral eye comparison of the long-term visual quality and stability between implantable collamer lens and laser refractive surgery for myopia. Their study conducted on 52 eyes of 26 high-myopia anisometropia patients who were suitable for surgical treatment. In each patient, the higher-myopia eye was implanted with ICL and the lower-myopia eye was treated with LRS. The patients were followed for 3 years (23).

As regards complications in this study:
Complications can be divided into intraoperative and postoperative complications.

1) **Intraoperative complications:**
- One eye ICL implanted upside down with partially torn haptic during manipulations for removal and reinsertion. It is a rare complication of ICL implantation which is mentioned by Amar Agarwal and Kumar, who studied Visco-cannula assists in reinversion of phakic lens (24).

2) **Postoperative complications:**
- One eye developed cataract. This complications is also mentioned by Seyed Javad Hashemian, MD, et al. who studied the outcomes and complications of ICL and toric ICL for...


