Evaluation of Phakic Posterior Chamber Intraocular Implantable Contact Lens for High Myopia

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Abstract

Purpose: To evaluate efficacy, predictability and safety of the surgical correction of high myopia using the phakic posterior chamber implantable collamer lens.

Design: A prospective, nonrandomized, non-comparative interventional case series.

Participants: Twenty seven eyes of fifteen patients aged from 20 to 46 years having high myopia were included.

Intervention: STAAR modified collamer implantable contact lenses (version 4) were implanted for correction of high myopia.

Main Outcome Measures: Uncorrected visual acuity (UCVA) best-corrected visual acuity (BCVA), intraocular pressure, lens opacity analysis, postoperative inflammation and distance between the ICL and crystalline lens assessed at slit-lamp and other postoperative complications.

Results: The mean postoperative spherical equivalent (SE) was -0.629 ± 0.98 D (range -2.25 to +1.25) for 27 eyes with mean preoperative SE -16.667 ± 3.43 D (range 10-22 D). 74.07% of eyes had SE ± 1.00 D. The mean postoperative UCVA was 0.58±0.22 Snellen decimal visual acuity (from 0.2-1.00 Snellen visual acuity). 25.9% had IOP >21 mmHg at 1 month interval. 11.11 % had lens opacity with 3.7% having significant lens opacity requiring surgery.

Conclusion: The implantation of modified collamer posterior chamber implantable contact lenses for high myopia shows adequate safety, predictability and stability. The main concerns over potential cataract formation and changing anterior segment dimensions still exist and needs long term follow-up.

No financial disclosure of author in STAAR ICL.

Key Words: Phakic lenses – High myopia.

Introduction

REFRACTIVE surgery is characterized by its constant evolution and the development of newer techniques. After many improvements in their design, phakic intraocular lenses (pIOLs) have grown to be the method of choice for the correction of high refractive errors. To this contributes the fact that the use of excimer laser corneal ablation has some limitations concerning the amount of corneal tissue that can be removed [1]. Specifically the predictability and stability of photorefractive techniques decrease with the amount of attempted correction, while corneal ectasia might occur as a result of large ablation depths [2]. Additionally altering the shape of the cornea in high attempted photorefractive corrections may result in poor quality of vision [3].

Clear lens extraction (CLE) has been used with good results in high myopia, but a higher risk of retinal detachment and consequent loss of accommodation must be considered [4,5].

Phakic IOL implantation is less invasive, reversible procedure and preserves accommodation. Anterior chamber lens carries the risk of endothelial cell damage, pupil ovalization, edge dysphotopsias, iris and angle damage [6,7]. The introduction of recent model ICM V4 (FDA approved 2004) for myopic eyes (by STAAR surgical AG, Switzerland) with improved lens design and vaulting to reduce incidence of cataract formation increased its safety.

Patients and Methods

Study design:

A prospective, non-randomized, non-comparative interventional case series was carried from July 2007 to January 2009.

Patient selection:

The study included 27 eyes of 15 patient having myopia between 10 and 22 diopeters, ≤3 D cylinder, ≥20 and ≤45 years of age. Required criteria included
also stable refraction for \( \geq 12 \) months, corneal diameter \( \geq 11 \) mm, anterior chamber depth (ACD) \( \geq 2.8 \) mm, absence of lens opacity, intraocular pressure in the statistically normal range (10-21 mmHg), absence of iris transillumination defects or pigment dispersion and absence of retinal breaks or peripheral degenerations.

Patients were informed of all associated risks and written consent reviewed several days prior to surgery.

**Preoperative assessment:**
Uncorrected visual acuity, manifest refraction, best spectacle corrected visual acuity, routine slitlamp examination, IOP measurement using Goldmann applanation tonometer (Haag-Streit, Switzerland) and fundus examination by indirect ophthalmoscopy and slit lamp 90 D auxiliary volk lens.

Specular microscopy using non-contact specular microscope.

ACD, horizontal white to white diameter and corneal topography were measured using anterior segment scheimflug imaging by pentacam HR (Oculus GmbH, Germany). ICL diameter, power and optic size calculations were performed by STAAR surgical Inc. using a modified vertex formula based on the above diameters with targeted postoperative emmetropia and adequate lens vaulting.

**Surgical technique:**
Bilateral sequential surgery was performed unless patient was anisometrope with planned lasik in the other eye or no refractive surgery was required in the other eye.

In no case preoperative laser iridotomy was performed.

Topical 0.4% Benoxinate HCL was applied for anesthesia. Marking of Steepest meridian was done using Mednez marker positioned on slit lamp marks of 3, 6 and 9 o’clock meridia. A 3.2 mm clear corneal incision was performed at steepest corneal meridian for cases with cylinder \( \leq 1.5 \) D using metal keratome. For cases with astigmatism \( >1.5 \) D, a double clear corneal incisions were performed at steepest meridian. Paracentesis was performed 90º and aqueous humour was replaced by hydroxypropyl methylcellulose. Careful loading of ICL into cartridge using special microforceps and with partial lubrication by mixture of saline and viscoelastic, to eliminate electrostatic forces. The lens was then slowly injected into anterior chamber using Staar micro STAAR injector (STAAR surgical. Monrovia, CA) anterior to iris plane and allowed to unfold. The positioning holes on the distal and proximal footplates of the lens were checked to ensure proper orientation. The lens was rotated to be in horizontal AC position. Each corner of the Footplate was tucked beneath the iris carefully with a modified lens spatula. Care should be taken not to touch central optic or crystalline lens. Once the lens was well positioned, the viscoelastic material was irrigated and aspirated out of the eye with balanced salt solution. Correct centration of ICL at pupil was ensured. Miotic (miochol) was injected into the anterior chamber to constrict the pupil. Peripheral iridotomy was performed at 12 o’clock using vitrectomy probe to prevent papillary block. Stromal hydration of corneal incision was then performed.

**Postoperative management:**
Oral acetazolamide 250 mg twice was given in the first 24 hours. Topical antibiotic (gatifloxacin 0.3%) and prednisolone acetate (1%) 4 times daily were gradually tapered over 4 weeks postoperative.

**Outcome parameters:**
Outcome parameters were assessed for a period pf 6 months to 14 months with a mean follow-up duration of 9.6 months. The following parameters were recorded:

- Last visit uncorrected visual acuity (UCVA), refraction and best spectacle corrected visual acuity (BCVA).
- Slit-lamp examination of lens opacity and distance between ICL and crystalline lens at 1, 3, 6 months.
- IOP at 1, 3, 6 months.
- Postoperative inflammation at 1 week, 2 weeks and 1, 3, 6 months.
- Pentacam evaluation of ACD and non-contact specular microscopy after 6 months.
- Other postoperative complications.
- Secondary procedure requirement.

**Results**

**Patient population:**
Of 27 eyes of 15 patients, 9 patients were females (60 %), mean age at time of implantation of 31.13±7.84 years (range from 20-46 years). Only 3 patients had unilateral ICL implantation (20%).
Visual acuity:

All eyes had counting fingers or worse UCVA preoperatively. The mean postoperative UCVA was 0.58±0.22 Snellen decimal visual acuity (from 0.2-1.00 Snellen visual acuity). At last visit, UCVA of these 27 eyes was better than preoperative BCVA in 10 eyes (37%) and the same as preoperative BCVA in 8 eyes (29.63%). Therefore 66.63% of eyes had postoperative UCVA better than or equal to preoperative BCVA. Postoperatively, 23 eyes (85.18%) achieved UCVA ≥ 0.5. Also 18 eyes (66.67%) of the 27 eyes gained ≥ 1 lines of BCVA, 8 (0.29%) eyes remained the same and only one eye lost one line of BCVA.

Refractive outcome:

The mean preoperative manifest spherical equivalent – 16.667 ± 3.43 D (range 10-22 D). Emmetropia was targeted for inserted ICL with reduction of preoperative astigmatism by incision along steepest meridian whether single or double according to degree of astigmatism.

The mean postoperative spherical equivalent was – 0.629 ± 0.98 D (range -2.25 to + 1.25 ). The spherical equivalent was within ± 1.00 in 20 eyes (74.07%) and within ± 1.25 in 23 eyes (85.18%). The refraction remained stable with statistically insignificant change (p>0.5) at each interval during follow-up. 11 (91.6%) out of the 12 patients who received bilateral ICL remained spectacle independent for most of their daily activity.

Intraocular pressure:

The mean preoperative IOP was 16.32 mmHg (range 12-21 mmHg). The mean postoperative IOP at follow-up intervals (Table 2).
Thus no significant postoperative inflammation was noted beyond 3 months follow-up.

### Lens opacity:

Three forms of lens opacity were evaluated postoperatively in this case series, anterior subcapsular opacity, nuclear opacity and posterior subcapsular opacity. Evaluation was done at slit-lamp after pupil dilation with tropicamide 0.5% (mydriacyl) and phenylephrine 2.5%, considering incidence of any of these types and significance. Lens opacity was considered significant if patient loses related ≥2 lines of his best spectacle corrected visual acuity. Lens opacity was also analysed regarding age, sex, degree of myopia and adequate lens vaulting with adequate ICL-crystalline lens space at slit-lamp.

### Other complications and second procedures:

Significant pigment dispersion occurred in 1 eye (3.7%) with rise of IOP (21 mmHg). UBM examination revealed ICL iris contact at superior-temporal quadrant, requiring a second procedure in the form of lens rotation to exact horizontal meridian which showed marked improvement.

1 eye (3.7%) had macular dot hemorrhage with drop of BCVA >2 lines with no Fluorescein angiography evidence of choroidal neovascular membrane with spontaneous clearance and improvement of visual acuity to 1 line less than preoperative BCVA.

1 eye developed papillary block glaucoma in the early postoperative interval with evident pigment blocking iridotomy, required glaucoma surgery with rapidly progressing cataract that eventually required cataract extraction with placement
of low power monofocal aspheric PCIOl with final UCVA better than preoperative BCVA for distance work.

No case had retinal detachment, endophthalmitis, dysphotopsia or persistent inflammation during whole follow-up interval.

No case had significant corneal haze or edema.

No case showed refractive overcorrection beyond 1.25 D.

No case of iris chafing or transillumination defects, pupil irregularity or posterior synechiae noted postoperatively.

Anterior chamber depth and endothelial cell count:
ACD and endothelial cell density (ECD) were evaluated after 6 months of ICL implantation testing significant variation. The mean preoperative ACD $3.18 \pm 0.14$ mm (range from $2.99 \text{ mm}$ - $3.42 \text{ mm}$) was significantly reduced to $2.99 \pm 0.17$ mm (range from $2.75-3.3 \text{ mm}$) postoperatively ($p<0.001$). The mean preoperative endothelial cell density was $2477 \pm 240 \text{ cell/mm}^3$ (range from $2014-2997 \text{ cell/mm}^3$) was insignificantly reduced after 6 months ($2353 \pm 321 \text{ cell/mm}^3$).

Discussion

In this series of Visian posterior chamber phakic IOL implantation attempts were made to assess predictability, stability and safety of this refractive surgical procedure to correct high myopia (-10.00 - 22.00 D).

This case series showed comparable predictability with 74.07% of eyes within $\pm 1.00$ D spherical equivalent (SE). This comparable to the results of different studies including ICL for treatment of myopia study group 2003 showing 88.2% of eyes having spherical equivalent $\pm 1.00$ D [8]. Pineda-Fernandez and associates showing 61.1% of eyes having SE $\pm 1.00$ D [9]. Uusitalo and associates showing 81.6% of eyes having SE $\pm 1.00$ D [10].

The most recent ICL model V4 has higher inherent vaulting and is designed to provide larger distance to the crystalline lens thus decreasing incidence of cataract formation. In this case series, overall incidence of lens opacity was 11.11%, with only 3.7% having significant visually compromising cataract. This is comparable to results of Sanders 2008 showing 7% incidence and 1-2% progressing to significant cataract over 7 year follow-up duration [11]. Lackner and associates showed 14.5% incidence and opacification to be related to surgical trauma and age >50 years [12]. In this series degree of myopia was the most significant risk factor. Vukich 2003 showed incidence of anterior subcapsular cataract to be 6.7% at 2 years [13].

Proper sizing and power calculation are the most important factors increasing safety and predictability of ICL implantation results. This could be ensured by proper measurements with pentacam, ultrasound biomicroscopy and anterior segment optical coherence tomography. In this series we relied on pentacam imaging which effectively lowered incidence of complication.

Also proper surgical technique with careful ICL horizontal positioning, proper viscoelastic wash and avoiding ICL optic touch aided in lowering incidence of postoperative complications.

Significant IOP rise in early postoperative course in this case series have been shown reaching 25.9% in 1st month. However this was a transient phenomena that could be controlled medically. This is comparable to results shown by Zaldivar 1998 showing IOP rise of 11.3% and Chang JS 2006 showing 26.2% rise of IOP during first 2 months postoperatively [14,15].

This series showed good visual acuity results and stability can be achieved with the Visian ICL with 86.18% having UCVA $\geq 0.5$, 91.6% spectacle independent and 66.67% gaining $\geq 1$ line better BCVA.

This experience suggests treatment with ICL for severe myopia with favorable predictable results. However there is still certain risk of requiring subsequent cataract surgery. Despite short term follow-up and lower number of cases. The results are comparable to many higher number studies done.

References

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