

Visual Outcomes and Complications of Spherical Intraocular Collamer Lens Implantation (ICL), One Year Follow up.

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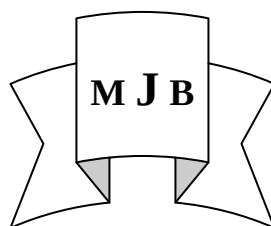
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Abstract

Aim: This is a Prospective nonrandomized clinical study designed to assess the safety and efficacy of the Implantable collamer Lens (ICL) to treat moderate to high myopia.

Material and Methods: It included fifty eyes from 31 patients with between -5.50 and -21.0 diopters (D) of myopia without or with astigmatism up to -2.0 diopters.

The Main Outcome Measures were Uncorrected visual acuity (UCVA), refraction, best spectacle-corrected visual acuity (BCVA), IOP, adverse events, operative and postoperative complications, subjective satisfaction, and symptoms.

Results: Twelve months postoperatively 54.0% of patients had a visual acuity of 6/12 or better, and 84.0 % had an uncorrected visual acuity of 6/18 or better. Patients averaged a 1.31 line improvement in UCVA and 86.0% were within 0.00 to -1.00 D. Only one case (2%) lost more than

2 lines of BCVA. Gains of 2 or more lines of BCVA occurred in 18 cases (36.0%) at 1 year after ICL surgery. Late onset surgically induced anterior subcapsular (AS) opacities were seen in 2 cases (4.0%); and one eye developed traumatic dislocation of ICL at 9 months postoperatively which was repositioned without any visual compromise; iritis developed in one eye (2%) which was first observed at 1 month of the surgery; one of cases had clinically and cosmetically insignificant pupil ovalisation postoperatively. Early postoperative IOP rise (more than 21mmHg) seen only in 3 eyes (6%). Patient satisfaction (very/extremely satisfied) was reported by 96.0% of subjects on the subjective questionnaire.

Conclusions: The results support the safety, efficacy, and predictability of ICL implantation to treat moderate to high myopia.

Key words: Intraocular collamer lens, Spherical, Myopia, Astigmatism.

الابصار والاختلالات الناجمة عن استخدام عدسة كولامر الكروية: متابعة لمدة سنة واحدة

الخلاصة

الهدف: دراسة غير عشوائية استشرافية لتقييم سلامة وفاعلية زرع عدسة كولامر الكروية لعلاج درجات قصر البصر المتوسطه والعاليه.

المواد والطرق: اشتملت الدراسة على ٥٠ عين من ٣١ مريض يعانون من قصر البصر بين -٥.٥ و -٢١.٠ دايوبتر بدون او مع

استجماتزم بما لايزيد على -٢ دايوبتر. تم خلال الدراسة زرع عدسة كولامر الكروية (ICL) داخل العين المشمولة بالدراسة.

النتائج التي تم قياسها اشتملت على حدة البصر ، خطأ الانكسار ، أفضل حدة بصر مصححه ، ضغط العين ، الاختلالات الجراحية، فتحة القرنية، عتامه العدسة العينية، مضاعفات ما بعد الجراحه والقناعه الذاتيه للمريض.

النتائج: بعد مضي اثنا عشر شهرا ، كانت حدة البصر في ٥٤% من العيون المدروسة هي 6/12 او افضل وفي ٨٤% منها كانت حدة البصر ١٨/٦ او افضل. في المعدل كان هناك تحسن في حدة الابصار غير المصحح بحوالي ١,٣١ خط و ٨٦% من العيون كانت الاخطاء الانكساره تقع بين ٠.٠ و ١.٠- درجة بؤريه. فقط عين واحده (٢%) خسرت اكثر من خطين رؤيه .

١٨ عين (٣٦%) كسبت خطين او اكثر كافضل حدة بصر مصححه بعد مرور سنه واحده من اجراء العمليه الجراحيه.عتمه المحفظه الاماميه للعدسه (anterior subcapsular cataract) الناجحه من الجراحه حصلت في حالتين (٤%).خلع عدسه (ICL) حصل في حاله واحده نتيجه اصابه مباشره للعين بعد مرور تسعة اشهر من الجراحه وتم اعادتها الى وضعها جراحيا بدون عواقب سلبيه على البصر.التهاب القزحيه حصلت في حاله واحده فقط (٢%) من الحالات المدروسة بعد مرور شهر واحد من زرع.تشوه شكل البؤي (pupil (ovalisation حصل في حاله واحده (٢%) من العيون المدروسة ولم يكن له اي تأثير سلبى على البصر او شكل العين.ارتفاع ضغط العين (اكثر من ٢١ ملم زئبق) حصل في ثلاث حالات (٦%) خلال الاسبوع الاول من العمليه.

٩٦% من المرضى كانوا مقتنعين جدا من النتائج من سؤلهم مباشرة عن ذلك.

الاستنتاج: النتائج تؤكد السهوله والفعاليه والقدرة على التنبؤ بالنتائج من زرع عدسة CL في حالات قصر البصر المتوسط والعاليضمن المدى المشمول بالدراسة.

الكلمات المفتاحية: عدسة كولامر، كروية، قصر البصر، اللابؤرية.

Introduction

Initial studies on phakic intraocular lenses (IOLs) have proven them to have good predictability with a low incidence of complications.[1-2] An initial report from the first phase of the U.S. Implantable Contact Lens (ICL) for Myopia Study in combination with international series, has found a high level of best-corrected vision preservation or improvement, minimal intraoperative/postoperative complications, a reduction in subjective patient symptoms, an early and stable improvement in vision, and a high degree of predictability in this refractive treatment for moderate to high myopia.[3-4].

Because the former Implantable contact Lens is made of a material referred to as Collamer, proprietary hydrophilic porcine collagen (0.1%)/hydroxyethylcopolymer containing an ultraviolet chromophore, STAAR Surgical has changed the name to Implantable Collamer Lens (ICL) to retain the ICL acronym, which is well recognized [5]. Common observations with the Myopic ICL include a high level of best-corrected vision preservation and even improvement relative to preoperative values, a reduction in patient symptoms in

combination with a high patient satisfaction rating, and minimal operative and postoperative complications, with a rapid improvement in uncorrected acuity and refraction that is stable over time. [6]

In Iraq the ICL implantation procedure started around the January 2010, since then the idea of following these patients up to assess the outcomes emerged. However since there is a toric and spherical models of this lens, the idea was to enroll the patients in tow different series. One to include those to whom spherical ICL implanted and those with toric ICL implantation.

ICL (Myopic, Hyperopic and toric versions) indicated for patient with refractive errors within the range from -1 to -23 Diopters with or without Astigmatism of -1 to -6 Diopters, as a primary treatment or for patients who are not fit for photorefractive procedure .ICL which is intended for placement in the posterior chamber needs a minimum Anterior chamber depth (ACD) of 2.8 mm and a stable refraction within 0.5 Diopters for 1 year prior to implantation.[19]

Contraindications included in addition to a minimum ACD of 2.8mm,included history and/or clinical signs of

iritis/uveitis, diabetic retinopathy, glaucoma, previous ocular surgery, and ocular hypertension, progressive sight-threatening disease other than myopia, monocular vision, pseudoexfoliation, diabetes ,pregnant and nursing woman where ICL is contraindicated.[10-19].

ICL for Myopia

ICL Device. The subject of this study is a posterior chamber phakic IOL termed by its manufacturer the Implantable Contact Lens (STAAR Surgical Co., Monrovia, CA). The ICL is designed to vault anteriorly to the crystalline lens and is intended to have minimal contact with the natural lens [4].

The lens is made from a new generation of biocompatible IOL materials termed Collamer. Collameris composed of a proprietary, hydrophilic porcine collagen (0.1%)/hydroxyethyl methacrylate copolymer into which an ultraviolet-absorbing chromophore has been incorporated into the polymer chains [2].

Its plate-haptic design resembles lenses already in use with cataract surgery; however, it incorporates distinct footplates and an anterior vault designed to minimize contact with the crystalline lens. This report addresses the current V4 ICL design. Just few months ago, staar surgical introduced a new model called V4b which is longer for a given white to white measurement. [2]

ICL had been designed to correct myopia (ICM), MyopicAstigmatism (TICM) and Hyperopia (ICH). [8-9]

Patients and Methods

Study Design

This clinical study was designed as a prospective, 1-year, nonrandomized clinical study intended to evaluate the safety and efficacy of the ICL to treat moderate to high myopia. Assessment of ICL outcomes was based on a comparison of preoperative and

postoperative values in conjunction with analysis of adverse events and complications.

Study Outcomes/Patient Follow-up

Patients were examined at 1 day, 1 week, 1 month, 3 months, 6Months and 12 months after ICL implantation.

The main outcome measures were uncorrected visual acuity (UCVA), refraction, BCVA, adverse events, operative and postoperative complications, lens opacity, peripheraliridotomy and subjective satisfaction and symptoms.

Patient Enrollment Criteria

Patients were enrolled with baseline refractive errors between -5.50 to -21.00 D of myopia (manifest refraction spherical equivalent [MRSE]). Although some of these refractive errors come in the range of photorefractive procedures however ICL recommended for them because they have a thin cornea which make them critical cases for LASIK/PRK.

A maximum of -2.00 D of manifest refractive cylinder was allowed. Patients were required to have documented stable refraction for 12 months before study enrollment with a BCVA of at least (6/60) in the study eye. All patients enrolled in the study were between 19 and 41 years old, 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) either by Gallile Double ScheimflugCamera, OculusPentacam excluded from the study based on the recommendation of the manufacturer since in such an eye vaulting of the ICL might turns the anterior chamber excessively shallow[9] .

Additional exclusion criteria included history and/or clinical signs of iritis/uveitis, diabetic retinopathy, glaucoma, previous ocular surgery, and ocular hypertension, progressive sight-

threatening disease other than myopia, monocular vision, pseudoexfoliation, diabetes ,pregnant and nursing woman where ICL is contraindicated.[10]

The FDA approved the ICL as a primary procedure for myopia ranging from -3 to -20 [18].

In this study, a minimum of -5.5 D is included because the availability alternative procedures like LASIK and PRK (with or without Mitomycin 0.02%) which have proven safety profile and cost effectiveness.

All patients enrolled in the study had a thorough discussion about the procedures available and a detailed explanation about the ICL. Every patient had agreed the procedure, received a photocopy of his ophthalmology case sheet (or made ready to him on request) and signed consent.

Lens Sizing and Power Calculation.

Sizing of myopic lenses (11.5–13.0 mm) was determined by the horizontal white-to-white measurement using a calibrated caliber and the ACD measurement. For eyes with ACD measurements of 2.8 mm to 3.5 mm, the lens size was calculated by adding 0.5 mm to the horizontal white-to-white measurement. Eyes exhibiting an ACD greater than 3.5 mm required the addition of up to 1.0 mm to the white-to-white measurement, up to maximum length of 13.0 mm. Patients with an ACD less than 2.8mm were excluded from the study since this depth is out of the approved ranges by the manufacture and the ICL expected to excessively shallows the anterior chamber in such patients and is a contraindication for ICL implantation.

Calculated lens sizes between the available lens diameters (in 0.5-mm steps) were generally rounded down if the ACD was 3.5 and rounded up if the ACD was 3.5 mm. White-to-white measurements were obtained using calipers at a slit lamp. All lens power

calculations were performed by STAAR Surgical Co using amodified vertex formula available as online calculation and ordering webpage (<http://staarag.ch/awweboc/rdefault.as>)

Surgical Procedure.

Complete examination of anterior and posterior segments of the eye done preoperatively with white to white measurements under the slit lamp. The UCVA, BSCVA, refraction and corneal topography and ACD all assessed as part of preoperative clinical judgment.

The day of surgery, patients were administered dilating and cycloplegic agents tropicamide 0.5% plus phenylephrine 2.5%, on 3 successive occasions at 10 minutes intervals, this will provide an effective dilation of at least 8mm suitable for the implantation of the ICL and at the same time short acting mydriasis that can be easily reversed after putting the ICL behind the iris using intracameral Carbachol.

After that a Fascial block was applied to the operative side and topical anesthetic drops to the eye. A Model V4 ICL which should be already loaded and prepared in the theater was inserted through a small, 3.2 mm, clear corneal, temporal incision. The lens was then injected through the incision into the anterior chamber (StaarMicroSTAARinjector, STAAR Surgical Co., Monrovia, CA) and allowed to slowly unfold in the anterior chamber which should be partially filled with methylcellulose.

Distal and then proximal footplates were tucked under the iris with a modified intraocular spatula. Correct positioning of the ICL in the center of the pupillary zone was verified before the viscoelastic is removed by passive washout and intraocular miotic (carbacol) was used to decrease pupil size.

Peripheral surgical iridotomy is done using anterior vitrectomy cutter. Any

remaining viscoelastic was scrupulously irrigated out of the anterior chamber with balanced salt solution and finally the wound hydrated to seal.

2-6 hours postoperatively, the eyes examined to ensure the patency of the Peripheral iridotomy, ICL vaulting and buff tonometry is done to assess the IOP.

Postoperative Management:

On the day of surgery, oral antibiotics (ciprofloxacin 500mg b.d) and oral Dorzolamide 200mg b.d were given.

On day 1 postoperatively, TobraDex (tobramycin and dexamethasone Suspension; Alcon Laboratories, Ft. Worth, TX) 5 times daily for a total of 20 days, beginning with 1 drop five times daily for the first 4 postoperative days and steadily reducing the dosage by 1 drop every 4 days thereafter.

Results

Patient Population

The Myopia ICL clinical study included 50 eyes from 31 subjects. This study population represents patients implanted with the current ICL design version called V4, between November 2009 and July 2011, who fulfilled the enrollment criteria. Twenty-one of the 31 subjects treated were female (70%). The mean age at the time of the implantation of the STAAR Myopia ICL (primary eye surgery in bilateral subjects) was 27.5 years, with a range of 19 to 41 years.

UCVA (Uncorrected Visual Acuity)

The preoperative UCVA in all cases were worse than 6/60. At 1 week post operation, the UCVA were 6/24 or better in all cases, 6/18 in 88% of eyes, 6/12 in 48% of eyes and 6/9 in 26% of eyes. At 6 months post operation, the VA were 6/24 or better in all cases, 6/18 in 84% of eyes, 6/12 in 54% of eyes and 6/9 in 24% of eyes. All outcome measurements at 12 months were similar to those results at 6 months.

Table 1 Uncorrected Visual Acuity over Time in Patients with Preoperative Best Corrected Visual acuity of 6/60 or worse.

UCVA	preoperative	1 Week	1 Month	6 Month / 1year
6/6 or better	0/50 (0.0%)	0/50 (0.0%)	0/50 (0.0%)	0/50 (0.0%)
6/9 or better	0/50 (0.0%)	13/50 (26%)	12/50 (24%)	13/50 (26%)
6/12 or better	0/50 (0.0%)	24/50 (48%)	27/50 (54%)	27/50 (54%)
6/18 or better	0/50 (0.0%)	44/50 (88%)	42/50 (84%)	42/50 (84%)
6/24 or better	0/50 (0.0%)	50/50 (100%)	50/50 (100%)	50/50 (100%)
6/36 or better	0/50 (0.0%)	50/50 (100%)	50/50 (100%)	50/50 (100%)
6/60 or better	0/50 (0.0%)	50/50 (100%)	50/50 (100%)	50/50 (100%)
Worse than 6/60	50/50 (100 %)	0/50 (0.0%)	0/50 (0.0%)	0/50 (0.0%)

Pre-operative BCVA versus 12 month UCVA**Table 2** Pre-operative BCVA versus 12 month UCVA

VA	Pre-op BCVA	12 month UCVA
6/6 or better	0/50 (0.0%)	0/50 (0.0%)
6/9 or better	11/50 (22.0%)	13/50 (26%)
6/12 or better	22/50 (44.0%)	27/50 (54.0%)
6/18 or better	36/50 (72.0%)	39/50 (78.0%)
6/24 or better	41/50 (82.0%)	50/50 (100.0%)
6/36 or better	47/50 (94.0%)	50/50 (100.0%)
6/60 or better	50/50 (100.0%)	50/50 (100.0%)

By comparing the pre-operative BCVA with 12 month pos-op UCVA, we found nobody had VA of 6/6 pre-operatively and thus postoperatively. 22.0% of eyes achieved BCVA of 6/9 or better pre-operatively, while 26% of eyes achieved UCVA with that level at 12 month post-operatively. 44% of eyes had 6/12 or better pre-op, and 54% got this level post-op. Despite that preoperatively 82% of eyes had BCVA of 6/24 or better and 100% of eyes had BCVA of 6/36 or better and all eyes had BCVA of 6/60 or better. At 12th month post-operation, all eyes could get at least 6/24 of UCVA.

BCVA line changes:**Change in Best Corrected Visual Acuity.**

Best corrected visual acuity was well preserved after ICL implantation, with only 2 eyes (4%) of same patient with a loss of 2 lines of BCVA at 12 months postoperatively. The right eye of this patient had preoperative BCVA

of 6/18 partial and at 12 months postoperatively had BCVA of 6/24 due to anterior subcapsular cataract. In the left eye, preoperative BCVA was 6/18, and at all reported visits except the 12-month visit, BCVA was 6/18 yet, at 12 months, BCVA was recorded as 6/60 due to anterior subcapsular and nuclear cataract that mandates removal of ICL and phacoemulsification with IOL implantation.

At the 12-month follow-up, 13 eyes (26%) achieved their preoperative BCVA. Improvement of BCVA by 1 line in 13 eyes (26%) at 12 months postoperatively; a 2-line improvement was observed in 11 eyes (22%). And more than 2 lines improvement seen in 7 eyes (14%). This means that 88% of the investigated eyes achieved their BCVA or better in contrast to only 4 eyes (8%) with a 1-line loss and on other 2 eyes (4%) which lost more than 1 line of their BCVA. Fig.1.

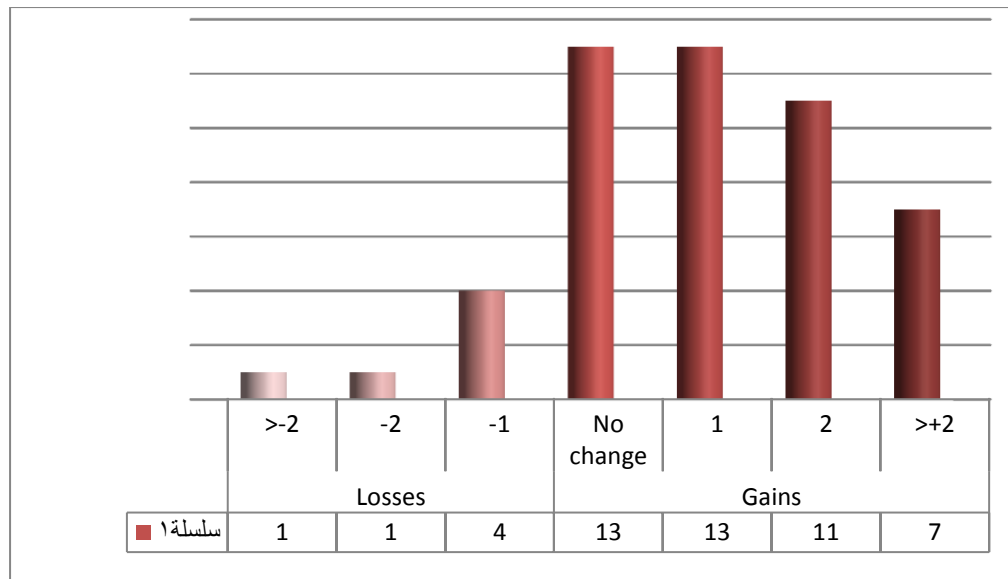


Figure 1 Changes in Best spectacle corrected visual acuity.

Refractive Outcomes:

Spherical Equivalent (S E)

Preoperative SE for this study cohort ranged from - 6.5 to -21.50 D of myopia . Only 4% of eyes had a preoperative myopia -7.0 D. At

baseline, no eyes (0%) fell within -1.0 D (SE) compared with 86.00% at 12 months after ICL implantation. And 96% of investigated eyes fall within +1 to -1 Diopters.

Table 3 Spherical Equivalent changes over time

Spherical Equivalent	Preoperative	1 Week	6 Months	12 Months
> +1.01 D	0 (0.0%)	1 (2.0%)	1 (2.0%)	1 (2.0%)
+1.00 to +0.01 D	0 (0.0%)	12 (24.0%)	5 (10.0%)	5 (10.0%)
0.00 to -1.00 D	0 (0.0%)	37 (74.0%)	43 (86.0%)	43 (86.0%)
-1.01 to -2.00 D	0 (0.0%)	0 (0.0%)	1 (2.0%)	1 (2.0%)
-2.01 to -7.00 D	2 (4.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
-7.01 to -10.00 D	7 (14.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
-10.00 to -15.00 D	24 (48.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
-15.01 to -20.00 D	12 (24.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
>-20.00 D	5 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

The distribution of preoperative, 1wk and 6months postoperative SE plotted in Fig. 2 below.

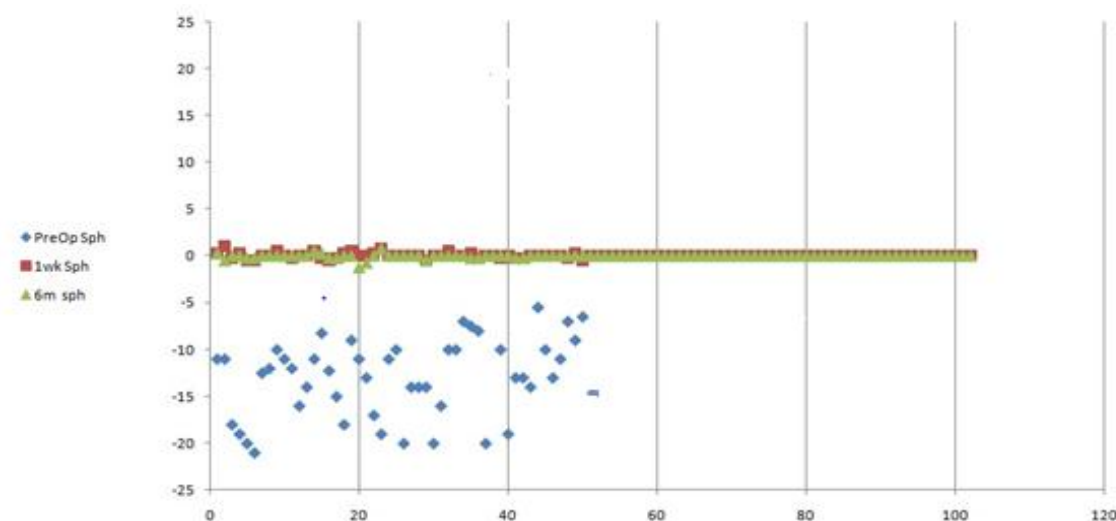


Figure 2 the distribution of preoperative, 1wk and 6 months spherical equivalent.

Complications:

One eye (2%) had pupil ovalisation which was observed on slit lamp examination with no visual impact. Two eyes (4%) developed visually significant cataract after 6 month of surgery. One eye 2(%) developed traumatic dislocation of ICL to the anterior chamber at 9th month of operation which was repositioned without any visual compromise.

Iritis developed in one eye (2%) which is first observed at 1 month of the surgery, it was related to febrile illness however the second eye of the same patient passed uneventfully.

No, Corneal edema at the incision site was observed after the first postoperative week.

Raised IOP in the early postoperative phase (first 2 to 6 postoperative hours) seen in 3 eyes (6%) of the operated eyes. All these cases treated with oral Acetazolamide and none of them deserved prepping of the wound. None of these patients needed acetazolamide more than 21 days of surgery. No, Raised IOP is seen after the first month of the procedure.

No, decentration of ICL and no, pigment dispersion seen throughout the follow up period.

Complication	rates
pupil ovalisation	2%
visually significant cataract	4%
visually insignificant cataract	0
traumatic dislocation of ICL	2%
iritis	2%
raised IOP	0%
accentuation	0%
pigment dispersion	0%
Second intervention	2%

Subjective Assessments:

At each postoperative visit all patients were asked about their satisfaction after ICL implantation. At 1 year, 96% of cases reported that they were

very/extremely satisfied with the results of their surgery; only 4.0% (2 eyes) reported that they were unsatisfied. Both cases developed cataract.

Discussion

Safety of the STAAR ICL

Preservation of BCVA, which is commonly considered the primary criterion for assessing the safety of a refractive surgical procedure, was reasonably high in the study group presented in this article.

Not only maintenance (26%; 13 eyes) but also an improvement in best-corrected vision was achieved at 6 and 12 months (62%; 31 eyes).

Only one eye (2%) lost more than 2 lines at 12th month postoperative visit, a result of a cataract. Similar result seen by Sanders et al[9] however more recent studies done by El-Danasoury et al did not show any loss by more than one line.[10-12]

Previously published ICL reports have also documented this unique improvement in best-corrected vision after implantation. BCVA was maintained or improved in all eyes in these series (Gonvers et al,[1] Menezo et al,[2]), whereas only one eye with a loss was reported by Assetto et al and Zaldivar et al. In the U.S. ICL study, BCVA improved 2 lines in 22% of eyes and more than 2 lines in an additional 14 % of eyes at 12 months. Only (5 eyes) complications (as a collective of all complications) were reported in the first 12 months after ICL implantation in the 50 study eyes; one eye developed accidental traumatic dislocation of ICL 9 months postoperatively which was repositioned without any visual compromise. This complication has not been reported in any clinical study before.

Ovalisation of the pupil seen in one eye and this was attributed to excessive vaulting which seemed more than 750 micrometers. thought this level of vaulting comes in the upper range of normal vaulting as recommended by the manufacturer, Yet it look high enough to interfere with the normal

movement and contour of the iris. Thus we suggest a target vaulting of 250 to 550 Micrometers, any way it seems not possible to ensure this unless a more precise way is invented for sizing the ICL other than using the Caliber to measure the white to white distance which is the standard method at least till now. Pupil ovalisation seen in one eye in study done by El-Danasoury et al [12]

One case of iritis seen at 1 months postoperatively. This patient developed the iritis after history of febrile illness, referred to ileitis clinic and been investigated, however not clear cut diagnosis where made .the second eye of the same patient which had been operated just one week after the first eye passed normally without any signs of inflammation ever. Iritis in fact is not mentioned as one of the expected complication of ICL lens since the Collier is biologically inert material and in 99.6% to 100% of cases, cellular reaction reported to be absent [13]. This supported the assumption that this iritis case was a coincidence .

Significant Late anterior subcapsular (AS) opacities at 1 year were reported in only two eyes (4.0%), and only one of these was likely due to improper sizing of the ICL and low vaulting. Longer term follow-up may be necessary to fully evaluate the real risk of clinically significant late AS opacities. Cataract surgery done for one of these cases with foldable IOL implantation. Biometry measured with IOL master 500.

Development of cataract had been reported in several other studies [14-7]. Pienda-Fernandez et al [15], investigated the V1, V2, V3 models of ICL and reported a visually significant cataract in 5.6% and a visually non-significant cataract in another 5.6% , however these rates decreased with the introduction of the

V4 model of ICL and reported to be around 2.9% for visually significant and 2.9% for visually non-significant cataract by El-Danasoury et al [12] Mechanical trauma during the implantation of even the best sized ICL may be another important cause for development of cataract. This is more likely to happen during the early phase of the training curve than then after [16]. However, we cannot determine the period after the procedure when development of cataract cannot attribute to trauma any more but there is a general sense that cataract that develops after 6 months of the primary implantation is unlikely to be traumatic. To prove the, a further studies is needed.

Raised IOP in the early postoperative period seen in 3 eyes (6%) and in all cases, this had been related to retained viscoelastic since passive irrigation is unlikely to washout all the methylcellulose used during the procedure. Steroid responsiveness may be also responsible for the raised IOP during the time when steroids are used postoperatively.

Of note, no patients in the study group required long-term anti-glaucoma medication, and there was no, late elevation in IOP after implantation of the ICL for myopia.

Corneal endothelial cell counts was beyond and of the scope of this study and might be a topic for special study, however what can be said here is that in either case no, corneal edema was observed apart of mild edema at the incision site which disappeared in all cases at 1month postoperatively. It is well known now that the rate of corneal endothelial loss is very low over time which enfavours the posterior chamber phakic IOL, The ICL over the anterior chamber phakic IOLs which has much higher rates of endothelial cells loss [17].

Myopic ICL results to date have compared favorably with clinical outcomes with the latest refractive laser surgical treatments. A recent comparative analysis of the safety and effectiveness outcomes from FDA multicenter ICL clinical study with clinical study results using LASIK for -8 to -12 D myopes demonstrated that every index of BCVA, UCVA, predictability of refraction, and stability favored the ICL over the LASIK procedure. [18]

In summary, the outcomes of this study clearly support the overall short-term and intermediate-term safety of ICL surgery. Both intraoperative and postoperative complications were low. The incidence of best corrected vision loss by 2lines is substantially lower than PRK rates and lower than or comparable to approved U.S. LASIK studies, despite the large proportion of high myopes in the ICL clinical study [18].

Preservation and even improvement of best-corrected vision is a key benefit of this technique. A longer follow up period may be essential to make these observation a more sold fact.

Effectiveness of the STAAR Implantable Collamer Lens

Uncorrected visual acuity represents the primary efficacy variable for the ICL clinical study and the majority of refractive laser surgery clinical investigations. The dramatic improvement in UCVA after ICL surgery in the subset of eyes with low myopia exceeded all FDA targets and was better than or comparable to all approved LASIK clinical study results.[18]

Predictability outcomes were excellent during the ICL for Myopia clinical study and, specifically, for the subset of eyes with myopic refractive errors of -7 D and higher errors.

Predictability within 1.0D with the ICL result (96%), exceeding all LASIK

outcomes (80.0%, 84.2%, 86.8%, 87.5%, 89.7%, 90.0%, 94.4%, 94.5%, and 95.7%) [18]. The efficacy of the ICL procedure has been shown to be superior to that of LASIK for myopia between -8 and -12 D.[11]

These data suggest that the ICL should be given serious consideration for use in eyes within the study range of myopia.

Clinical study outcomes presented in this study substantiate the overall safety of the Myopic ICL in this moderate to high myopia patient population. The low incidence of complications or adverse events reported with the Myopic ICL should be taken in the context of the potential alternative refractive surgical procedures available to myopes with between -5.5 and -21.0-D refractive errors.

If the cost effectiveness and the long term experience with photorefractive procedures to correct myopia (with and without astigmatism) in equivalent ranges, it seems wise not to extend the use of ICL to lower refractive ranges though the manufacturer recommend its use to much lower degrees.

Subjective patient satisfaction was high 1 year after ICL surgery, reflecting the positive acceptance of this procedure by the moderate and high myopic patient population, who currently has fewer optimal alternatives for the correction of their high refractive errors. At 1 year, 96.0% reported that they were very/extremely satisfied with the results of their surgery; only 4.0% stated that they were unsatisfied.

In summary, this study leads to the conclusion that the current ICL design offers a reasonably safe, effective, and stable alternative for the correction of moderate to high myopia. These clinical outcomes are better or comparable to existing refractive surgery alternatives.

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