{C10}

{AMD IOLs}

{11 June, 2017}

{08:00 - 09:30 hrs}

{Von Graefe}

HAND-OUTS
Objective

• The aim of this work is to review the lenses in age-related macular degeneration with the assessment of their advantages and disadvantages.

Introduction

• Age-related macular degeneration (AMD) is one of the most disabling diseases of visual quality.
• 90% of the severe central visual acuity loss associated with AMD.
• Central scotomas appear in the final stage of macular degeneration. It usually does not affect the peripheral vision.[1,3]
• Age-related macular degeneration has been described as the leading cause of legal blindness, affecting 10%-13% of adults over 65 years of age in North America, Europe, Australia and, recently, Asia.[2]

Materials and methods

• We used PubMed web platform to search for implantable devices in various stages of AMD
• We have searched for prospective or retrospective studies and case reports.
• We selected English-language articles.
• We included articles strictly connected with intracocular lenses used in diagnosed AMD.
• Only lenses with peer-reviewed, published clinical outcomes in human patients affected by AMD, were considered for this review.
Results

OPTICAL FUNDAMENTALS OF IOls for AMD

CASSEGRAIN CONFIGURATION

- Used in the LMI.
- Mirrors instead of lenses.
- It can provide high magnification.
- Higher manufacturing costs.
- Additionally, the use of small mirrors might generate the risk of glare effects, due to diffraction and ghost reflections in the elements that should be further investigated in clinical trials. [12,13]

FRESNEL PRISM

- Fresnel Prism Intraocular lens provides no magnification at all.
- It only displaces the retinal image from a potentially damaged central macula to a more peripheral healthier area in the retina.
- The Fresnel approach (the partition of the optical surface in Fresnel zones) is necessary here to provide the required tilt of the image, as the introduction of a direct prism in the whole surface of the lens would not be possible in practice (the lens would be too thick in one of the edges).
- A potential problem of this approach might be diffraction and scattered light by the edges of each Fresnel zone. As shown in the figure 5 there might be some light that is scattered away from the focal point and might be a source for glare. [14]

SCHARIOTH MACULA LENS

- Based on magnification by closer distances. The closer the object to the eye, the higher the magnification is.
- This approach needs to consider that the subject is unable to accommodate and for that reason it incorporates a +10 D central area in the lens.
- Magnification is only achieved when the object is in a range of 10 to 1.5 cm close to the eye.
- It provides no distance vision magnification. [18]

1. INTRAOcular MAGNIFIER TELESCOPE (IMT)

- The "WA" prefix is used in respect to the two product models available offering magnification of Wide Angle 2.2X and Wide Angle 2.7X. The latter one fulfil full field of 60 degrees, second order astigmatism via the same lens for both models.
- The IMT, combined with the optics of the cornea, produces a telephoto effect that images in patients' central visual field with additional degree field of approximately 20 degrees.
- Monocular implantation
- Provides central vision, while the other eye remains "as is" to retain peripheral vision, which is important for maintaining balance and orientation.
- IMT allows patients to use both dynamic and static situations of new environments, and distance vision ranges. [17-19]
- The IMT is a fixed-focus quartz glass lens with wide-angle micro-optics, which is implanted in the capsular bag through a 10-12 mm incision after the natural lens has been removed. (Figure 1) Larger than most implanted devices, the IMT is a keystone long-telescope combination in a single, retaining demonstrator hybrid intraocular diameter of 13.5 mm. Two modified C-loops facilitate in-the-bag fixation. The lens extends through the pupil and remains on average 2.2 mm from the patient’s cornea, preventing Against the endothelium. [5,9,22]
1. **INTRAOCULAR MAGNIFIER TELESCOPE (IMT)**

- First approved in June 2010 (US FDA), since 2014 is restricting implantation to patients older than age 65.
- Alió et al. (first systematic clinical report) performed a multicenter study: IMT was implanted in 40 eyes of 40 patients with dry-type AMD (12 months):
  - IMT played an important role in improving near and far visual acuity in patients with stable dry-type AMD. However, they stressed the problem of severe visual field restriction and the cumbersome postoperative visual rehabilitation.
- Disadvantage of IMT implantation is a confined central visual field to 20-degree angle: binocularity is lost with this procedure.
- The IMT is well documented in the literature. Two multi-year clinical studies have been conducted to evaluate the safety and efficacy of the telescope implant: the IMT-002 pivotal safety and efficacy study and the IMT-002-LTM long-term monitoring safety study.
- At the 12-month mark, an assessment using the National Eye Institute Visual Functioning Questionnaire-25 (VFQ-25) demonstrated that the telescope implant significantly improved quality of life in study population.
- Ocular complications included endothelial cell loss, inflammatory/pigment deposits, transient cornea edema and IOP elevation.
- 3 eyes was necessary the explantation of the lens because of patient dissatisfaction and was implanted a conventional posterior chamber IOL.
- Low vision specialists are an integral part of the procedural team because they teach patients exercises related to static and dynamic movement.

Limitations of the IMT:

- Diagnosis and management of CNV requires an OCT of the macula.
  - The first obstacle is due to the IMT itself: it is difficult to get a clear view of the macula through the IMT. Fundus photography or angiography through the IMT creates a minimized, distorted image.
  - Second limitation is that patients with the IMT may be unable to focus on the fixation target during an OCT session due to the loss of central vision, resulting in constant scanning or moving of the eye. Surface visualization of the surface with artificial tears, best as possible dilation of the pupil, using anatomical landmarks such as the optic nerve to locate the macular region.
- Some modifications in certain features of the OCT machine increase the likelihood of detecting subfoveal eyes with the IMT.

1. **INTRAOCULAR MAGNIFIER TELESCOPE (IMT)**

- Consists of 2 IOLs that reproduce an intraocular Galilean telescope.
  - IOLs are intraocular Galilean telescopes: 2 biconvex or plano-convex lenses, connected by a short cable.
  - Both lenses are made of polymethyl methacrylate, have a 1-piece design, and provide ultraviolet light filtering.
  - The optical of the 2 lenses is 5 mm in diameter, with a maximum axial thickness of 1.5 mm for the AC IOL and peripheral thickness of 1.5 mm for the in-the-bag IOL; their total length is 13 mm. The system provides an estimated magnification for distance of 1.3.
  - Insertion of IOL-VIP System is preceded by a standard phacoemulsification.

2. **IOL-VIP SYSTEM**

- Consists of 2 IOLs that reproduce an intraocular Galilean telescope:
  - A plano-convex Castroviejo IOL and a plano-convex IOL: the 2 lenses are connected by a short cable.
  - Both lenses are made of polymethyl methacrylate, have a 1-piece design, and provide ultraviolet light filtering.
  - The optical of the 2 lenses is 5 mm in diameter, with a maximum axial thickness of 1.5 mm for the AC IOL and peripheral thickness of 1.5 mm for the in-the-bag IOL; their total length is 13 mm. The system provides an estimated magnification for distance of 1.3.
  - Insertion of IOL-VIP System is preceded by a standard phacoemulsification.

2. IOL-VIP SYSTEM

- The candidates are selected using dedicated software that collects their clinical data.
- All patients undergo 2-week preoperative training (4 30-minute training sessions) and a 3-month postoperative rehabilitation program (3 30-minute training sessions per week for 12 weeks) aimed at training and consolidating the preferred retinal locus (PRL).
- One report described the outcomes observed in forty eyes of thirty-five consecutive patients. All patients showed an improvement of visual acuity (VA) due to the surgical and rehabilitative procedure, confirming or exceeding the preoperative expected results.
- The mean postoperative best corrected visual acuity (BCVA) was 0.77, the mean postoperative best reading magnification gain was 6.2, and the mean postoperative reading distance gain was 7.6 cm.

- Well tolerated and did not seem to limit the peripheral vision field or interfere with binocular vision, thus making it suitable for monocular or binocular implantation.
- There were no severe complications intra or postoperatively with the exception of pupillary block. Preoperative iridotomy was performed in all other cases.
- Given the size of the 2 IOLs and their proximity to critical ocular structures such as the corneal endothelium and lens, exceedingly low endothelial cell count, and/or guttata are obvious contraindications.

3. LIPSHITZ MACULAR IMPLANT (LMI)

- Created by Dr. Lipshitz in two versions:
  - 1-The Lipshitz macular implant (LMI) conventional IOL that incorporates 2 miniature mirrors in the Cassegrain telescopic configuration, magnifying the retinal image on the retina 2.5 times. The patient thus sees a magnified central image through the mirror telescope and a normal non magnified image through the peripheral IOL (Figure 3).
  - Overall diameter of the IOL is 13.0 mm and the optic is 6.5 mm. The anterior central mirror is 1.4 mm. The posterior mirror, which is doughnut shaped and 2.8 mm in diameter, has a central clear area of 1.4 mm in diameter. The peripheral zone of the optic is similar to that of a normal IOL to provide undisturbed peripheral vision. The reflecting surfaces of the LMI are coated with multiple layers of titanium oxide (dielectric coatings) which creates a mirror effect. The mirrors are 1 to 2 mm thick. The entire IOL is placed through a 6.5-mm corneal tunnel in the capsular bag.

- Implanted in six worse-seeing eyes of 6 patients. However only four of operated eyes had AMD. Two were with other macular pathology. Preoperatively, visual acuity was worse than 20/200 and improved with a 2.5 magnifying external telescope preoperatively.
- There were no intraoperative complications.
- The mean gain in distance acuity was 3.66 lines ± 1.88 (SD), and the mean increase in the Early Treatment Diabetic Retinopathy Study (ETDRS) score for near acuity was 50.83 ± 9.15 logMAR. The best corrected distance acuity and near acuity improved significantly (both P<0.01).

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3. LIPSHITZ MACULAR IMPLANT (LMI)

- The younger and improved brother of LMI has the same function - to magnify the central image while the peripheral field remains normal.
- The main difference between the two lenses is that the newer LMI-SI is the equivalent of two IOLs and is well supported by placement within the capsular bag alone. LMI-SI is a non-foldable one-piece IOL, positioned in the sulcus over a regular bag-implanted IOL.
- It is 5 mm or 6 mm in diameter, and it contains loops that have a similar configuration as a regular IOL loop diameter of 13.5 mm. However, the LMI-SI is thicker, with a central thickness of 1.25 mm. After standard phacoemulsification the incision is then enlarged to 5 mm to 5.5 mm. After implantation a peripheral iridectomy is then done surgically.[13]

3. LIPSHITZ MACULAR IMPLANT (LMI)™

- According to a publication three patients were operated using LMI-SI. The inclusion criteria for a pilot trial included patients with bilateral AMD (dry type, wet type or scar stage) of similar macular lesions in which visual acuity ranged between 20/80 and 20/800 in each eye and improved for distance and/or near when tested with 2.5 magnification using an external telescope. Postoperative visual acuity of these patients is not given in the publication.[13]
- The LMI and LMI-SI provide magnified central images up to 2.5 times while maintaining the normal peripheral vision through the peripheral portion of the lens. Because of this, both of them can be implanted in both eyes of a patient.[12,13] (figure 3)

4. FRESNEL PRISM INTRAOCULAR LENS

- Non-foldable implant made of PMMA. (figure 4)
- Created for optical displacement of the central scotoma caused by AMD, instead of moving the retina with all the risks involved in macular translocation surgery.[14]
- For implantation there is a standard phacoemulsification performed and after a scleral tunnel incision is made for insertion.
- The prototypes of the device have a single optical power (+20.0 diopter) for aphakic correction, with a Fresnel Prism IOL fashioned on the posterior surface of the optic producing a fixed 6-degree deviation, which gives retinal image displacement of 1.8 mm (thus describing a circular area of 3.6 mm diameter) for a 23.1 mm average eye.[14]

4. FRESNEL PRISM INTRAOCULAR LENS

- The only one publication we found about Fresnel Intraocular Lenses was that the implant was fixed unilaterally in a phakic patient with bilateral advanced nonexudative AMD.
- The patient described diplopia. One patient reported that the preferred unoperated eye to the operated was the aphakic eye; the second patient had no change in visual acuity in the operated or unoperated eye. The reduction of diplopia was 50%.[14] (figure 4)
**5. IolAMD**

- IolAMD is the newest type of hydrophobic acrylic device to improve vision to people suffering from AMD.

**Based on a Galilean telescope using two lenses manufactured so that they can be injected with a standard 3.0-mm incision size (Figure 5).**

After implantation, both implants allow a magnification of the image and distribution of the retinal picture 3° apart from the fovea due to the slight intended decentration of the sulcus implanted IOL (0.85 mm).

The capsular bag positioned IOL (IOL1) is a high-minus-power lens (-49 diopters [D]) with a 4.0-mm optic and an overall length of 11.0 mm. The plate haptic is symmetrical and vaulted posteriorly approximately 15°. The sulcus-positioned IOL (IOL 1) is a high-plus-power lens (+63 D) and the 5.0-mm hyper-aspheric optic is slightly decentered on the plate haptic. The overall diameter is 11.75 to 12.0 mm and the haptic is bent anteriorly to enhance the recommended distance between the optics of 2 mm after implantation.

**5. iolAMD**

- 3 eyes of two patients with visually significant cataract and dry macular degeneration.

- Preoperative corrected distance visual acuity ranged from 0.03 to 0.16 and corrected near visual acuity was 0.03 or less.

- Postoperative corrected distance and near visual acuity increased to levels between 0.5 and 0.8 uncorrected distance and 0.5 to 0.8 uncorrected near visual acuity was 0.1 to 0.8.

- All surgeries went without complications. No intraocular pressure or iris-related problems.

- The patient with bilateral implantation perceived no double vision because the decentration axis in both eyes was vertical. The other patient with singular implantation recognized an increase in visual acuity but complained about diplopia in a vertical direction. This could be solved by prismatic spectacle correction. All lenses had been placed in a vertical axis, and the IOL implantations could be obtained safely and were stable during the 3-month follow-up. No postoperative rotation was necessary.

Another study 18 eyes of 12 patients had IolAMD implanted.

- All surgeries were uneventful except in 1 eye in which the high-plus IOL was vaulting anteriorly, causing a reduction in the quality of vision. The high-plus IOL was replaced with a standard-size IOL, after which there were no short-term sequelae. A precautionary intraoperative peripheral iridectomy was performed in 9 eyes (including the eye of patient 11 in which the highplus IOL was replaced). In 8 eyes, a single 10-0 nylon suture was used to secure the wound, and there was no difference between the mean preoperative and postoperative intraocular pressure. The mean endothelial cell density was reduced by 18%. The mean decimal CDVA improved from 0.12 preoperatively to 0.20 at 4 months, a 67% gain.

- One patient recognized diplopia, but this was averted by inserting the IOL with a single 10-0 nylon suture used to secure the wound. No complications were noted.

- Disadvantage: no power ranges available, limiting the technology to eyes with an axial length of 21 to 23 mm with a resulting power of 21 D. The IOL power cannot be adapted perfectly to patient anatomy right now.
6. SCHARIOOTH MACULA LENS

- Schiatoth macula lens is a one-piece foldable intraocular lens, which is implanted into the ciliary sulcus.
- The optimal IMT placement is farthest from the optical center of the capsular bag, which is above the optical center of the capsular bag.
- The optimal IMT placement for pseudophakic eyes with an oblique axis is above the optical center of the capsular bag.
- The overall diameter of the lens is 13.0 mm with symmetric haptics. It has a central portion of 1.5 mm diameter, which remains free of optical damage.
- Scharioth Macula Lens and LMI-SI, the macular add-ons to standard IOL, have the advantage that they can be easily implanted in the ciliary sulcus years after cataract surgery without the need to remove a clouded lens. Another exceptional feature of this device is the smallest incision required for implantation - 2.2 mm.
- The macular add-on IOL can be easily implanted in the ciliary sulcus of pseudophakic eyes, which improves central binocularity at normal reading distance. Binocularity is reduced only at a reading distance of 3 m. At this distance, the range of the other eye is the only factor for reading disability.

DISCUSSION

LIMITATIONS AND COMPLICATIONS OF IOLs FOR AMD

Incision
- The incision sizes are the same as that used for a capsulotomy or a capsular bag implantation.

Freudophobics / Eye
- Schiatoth macula lens is a one-piece foldable intraocular lens, which is implanted into the ciliary sulcus, with an incision size of 2.2 mm.
- The overall diameter of the lens is 13.0 mm with symmetric haptics. It has a central portion of 1.5 mm diameter, which remains free of optical damage.
- Scharioth Macula Lens and LMI-SI, the macular add-ons to standard IOL, have the advantage that they can be easily implanted in the ciliary sulcus years after cataract surgery without the need to remove a clouded lens. Another exceptional feature of this device is the smallest incision required for implantation - 2.2 mm.
- The macular add-on IOL can be easily implanted in the ciliary sulcus of pseudophakic eyes, which improves central binocularity at normal reading distance. Binocularity is reduced only at a reading distance of 3 m. At this distance, the range of the other eye is the only factor for reading disability.

- A minimum CDVA of 0.3 is recommended to achieve sufficient results. PCIOP, especially at 15 cm, the patient is motivated, might be a good candidate for Scharioth Macula lens implantation.

- Possible contraindications to implantation of the macular add-on IOL intravitreal or intracocular surgery, severe double vision, exudative diabetic retinopathy, severe posterior cataract, severe active uveitis, macular edema, retinal detachment, or any other cause of reduced vision.
- The macular add-on IOL was implanted in the better seeing eye in eight patients. The improvement in CDVA at 15 cm versus with +2.5 D correction at 40 cm: it improved by 2.4 lines with the macular add-on IOL at 15 cm versus with +2.5 D correction at 15 cm. No patient showed postoperative visual axis (UNVA) improvement.

- The macular add-on IOL shows no improvement in the better seeing eye. A good central fundus view is possible, but the macular add-on IOL at 15 cm versus with +2.5 D correction at 15 cm: it improved by 2.4 lines with the macular add-on IOL at 15 cm versus with +2.5 D correction at 15 cm. No patient showed postoperative visual axis (UNVA) improvement.
DISCUSSION
LIMITATIONS AND COMPLICATIONS OF IOLS FOR AMD

Rehabilitation
- Some such as ILIOLs, require complicated visual rehabilitation. There is a special software designed to do this, the IOL-Vip System, which designs the rehabilitation strategies based on preoperative and postoperative training. There was a special training program which included at least 30 training sessions per week for 12 weeks. All patients underwent training for at least 12 weeks. Vision field testing was performed weekly. Postoperatively, patients were trained for at least 12 weeks. There were cases of unstable and peripheral preferred retinal loci with large search movements that did not charge with the rehabilitation training.
- Some authors have noted that patients postoperatively require intensive training and may need to undergo training for up to 3 months. It should be performed by trained low-vision specialists.

Vision field
- What makes the serious drawback with some of these lenses is that magnification at both near and far distances is achieved at the cost of a reduction in the visual field and depth of focus. Thus, bilateral implantation is not possible. The lens is implanted in one eye only, leaving the fellow eye to compensate for peripheral vision.
- On the opposite side are macular decompensation lenses which do not affect the peripheral vision and do not require any extra training or extra reading distance correction.

Conclusions
- There is no one ideal lens for use in treating AMD. Some have drawbacks.
- The outcomes reported so far are variable and most probably are only being focused on short-term outcomes.
- The main problems found in the use of this technology are the high patient selection criteria required to avoid quick evaluative forms of AMD and the need to choose eyes with a potential for visual rehabilitation.
- Patients need visual rehabilitation programs and that much of the success will depend on it.
- An important commercial bias may be present, however, in the reports of some of the IOL AMD models due to possible conflict of interest because of financial relations with the companies producing these lenses or are the owners of patent rights.
- Independent clinical studies with longer follow-up data are necessary prior to the general use of these optical devices.
Disclosure

My Disclosure:

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VisionCare Inc.
M: + 972-52-2426400  mail: eli@visioncareinc.net
Regulatory status and world approvals

The IMT (by Dr. Lipshitz) approved for use in:

USA, by FDA (PMA with full CMS reimbursement),
European countries (CE Marked),
Canada - Health Canada Licence
South Korea and Australia - In final process.

The NG, Next Generation device is approved in:

European countries (CE Marked),
Implantable Miniature Telescope
Telescope technology (Galilean concept)

3 Air Spaces
### Device Specifications

#### Telescope

<table>
<thead>
<tr>
<th>Specification</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnification</td>
<td>2.2X / 2.7X</td>
</tr>
<tr>
<td>Optics dia</td>
<td>3.60 mm</td>
</tr>
<tr>
<td>Axial length (height)</td>
<td>4.40 mm</td>
</tr>
<tr>
<td>Weight</td>
<td>120 Mg</td>
</tr>
<tr>
<td></td>
<td>(60Mg in aqueous)</td>
</tr>
<tr>
<td>Overall diameter (haptic loops)</td>
<td>13.5 mm</td>
</tr>
<tr>
<td></td>
<td>(adapted for sulcus fixation)</td>
</tr>
</tbody>
</table>
**CentraSight™ - Patient Process**

**Selection**
- MD (retinal)
- Low Vision

**Treatment**
- Surgical Process

**Rehabilitation**
- Optometric team

[CentraSight™ logo and website]

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Key Criteria
Key Contraindications

- Presence or treatment of active CNV (within last 6 months)
- Hx RD or retinal vascular disease
- Myopia > 6.0 D; Hyperopia > 4.0 D
- Steroid-responsive rise in IOP, uncontrolled glaucoma, IOP >22 mm Hg, or on maximum medication
- Previous intraocular /cornea surgery in the operative eye
Surgical Procedure

Similar to Cataract on a larger scale
Surgical Technique

- 12 mm limbal incision
- Large 7 mm capsulorrhexis
- Multi-viscoelastic technique - Cohesive & Dispersive
Cornea manipulation

Lift cornea 5 to 6 mm

Cohesive OVD

Special device forceps
Wound Closure

- Tight incision by multiple interrupted sutures

- Peripheral iridectomy
Operative Pearls

- Dispersive in AC, Cohesive in bag

- "Dispersive in AC, Cohesive in bag"

- "Dispersive in AC, Cohesive in bag"

- "Dispersive in AC, Cohesive in bag"
Long - Term Visual Acuity - FDA study

217 subjects, 5Y follow up

<table>
<thead>
<tr>
<th>Lines Gained</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>≥ 2 lines</td>
<td>80%</td>
</tr>
<tr>
<td>≥ 3 lines</td>
<td>67%</td>
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<tr>
<td>≥ 4 lines</td>
<td>46%</td>
</tr>
<tr>
<td>≥ 5 lines</td>
<td>27%</td>
</tr>
<tr>
<td>≥ 6 lines</td>
<td>12%</td>
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</table>

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### Visual Acuity – commercial field results

<table>
<thead>
<tr>
<th>Patient</th>
<th>Pre-Op VA</th>
<th>Post-Op VA</th>
<th>Lines Improved</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
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<td></td>
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<td>7</td>
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<td>æ°</td>
<td>Ø</td>
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</tbody>
</table>

**Curtesy of:**

Dr. Aaleya Koreishi, MD, Cornea Consultants of Texas, -  
Fort Worth, Arlington, TX  
www.visioncareinc.net
### Visual Acuity – commercial field results **

<table>
<thead>
<tr>
<th>Pre-op VA</th>
<th>Post-op VA</th>
<th>Lines Improved</th>
</tr>
</thead>
<tbody>
<tr>
<td>CF @ 4ft</td>
<td>20/60</td>
<td>7</td>
</tr>
<tr>
<td>CF @ 3ft</td>
<td>20/100</td>
<td>7</td>
</tr>
<tr>
<td>20/400</td>
<td>20/100</td>
<td>6</td>
</tr>
</tbody>
</table>

** Courtesy of:  

**Dr. Sumit (Sam) Garg M.D., Vice Chair of Clinical Ophthalmology  
Medical Director, Associate Professor  
Gavin Herbert Eye Institute,  
University of California, Irvine**
4-Yr - Endothelial Cell Density Results

Endothelial Cell Density (ECD) Cells/mm²

WA IMT

23%

Annual Chronic Loss 2-3%

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Distribution of BCDVA Change at 2 Years

(186 study subjects)
Success with IMT

Patient selection!

- Motivated patient

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Clinically Effective / Cost Effective

- 10 US peer-reviewed publications
- Top-tier ophthalmic journals
- Conclusions: “clinically meaningful improvements” for unmet need
PCO treatment (Needling)

Rare, 1 case from 250 subjects
Importance of the Peripheral lights restrictor

- **Image contrast and brightness** are critical parameters in dual optical systems.

- Light rays pass through telescope and through the periphery as well creating on retina superposition of two images which have **different magnification and light density**.

- The image brightness formed through the periphery is **higher** than the image formed by the telescope (due to magnification).

- When those two images formed superposed on the retina, the resulted image contrast is dramatically reduced by power periphery lights.

- This is the reason why the periphery light blocked by light restrictor, and assuring best contrast of the telescope image.
NG Device & Preloaded Injector
NG Device - what is it?

- Restore the Center of Your World

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What improved?

Surgery related:

- CentraSight

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What improved? (continued)

Design related:

- [Image of a medical scan with labels PCL, CC, PCR]
- [Image of a medical scan with labels PCL, CC, PCR]
## NG Device risk reduction

<table>
<thead>
<tr>
<th>Parameters</th>
<th>NG device</th>
<th>WA device</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Corneal incision size</strong></td>
<td>7 mm</td>
<td>10-12 mm</td>
</tr>
<tr>
<td><strong>Capsulorrhexis size</strong></td>
<td>5.5 mm</td>
<td>7 mm</td>
</tr>
<tr>
<td><strong>Surgery duration</strong></td>
<td>30 min</td>
<td>60 min</td>
</tr>
<tr>
<td><strong>ECD - density loss</strong></td>
<td>9 – 14 %</td>
<td>23-25%</td>
</tr>
<tr>
<td>(surgery related)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Corneal clearance - ACD (avg)</strong></td>
<td>3.5 mm</td>
<td>2.5 mm</td>
</tr>
<tr>
<td><strong># of stiches</strong></td>
<td>3-4</td>
<td>10-12</td>
</tr>
<tr>
<td>(risk of astigmatism related)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Manipulation</strong></td>
<td>Low</td>
<td>High</td>
</tr>
</tbody>
</table>

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CentraSight

[www.visioncareinc.net](http://www.visioncareinc.net)
NG Device assembling

- Same telescope + black haptic & restrictor
- Sterile Barrier system – manual loading accessories (available)
- Automatic preloaded injector – phase 2
Sophisticated injector

1st.
First loop acts as “Lever of Archimedes”

2nd.
Other two loops slide into the bag

“Lever of Archimedes”
Auto-aligned & stable fixation

Orientation dot aligned to 12 o’clock

CentraSight
Restore the Center of Your World

www.visioncareinc.net
Surgeon’s point of view....

Same Efficacy - Better Safety - Auto Aligned Fixation.

Credited to Dr, David Keegan

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Patients point of view ...

- **Fast rehabilitation on week one PO**
  (vs 5 weeks with WA)

- **Better indication basket**

- **less traumatised eye post op**
Endothelial Cell Loss - comparison

![Graph showing Endothelial Cell Density (ECD) in Cells/mm² over time with comparison between NG IMT and WA IMT, showing a decrease in cell density with time.]
Human Surgery – Dr. Keegan, Dublin

6.5 mm cut
32 min duration
3 stitches
2\textsuperscript{nd} phase (R&D) - preloaded injector

**Objectives (2018):**

- Pre-loaded automatic injection system
- System embedded with Dual Action Tip (DAT)
- DAT used with OVD injector + NG injection
Thank You

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