Corneal Based Solutions For Presbyopia

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Disclosures

- None
Presbyopia

- Greek origin, “presbyteros” meaning elder
- Loss of ability to accommodate and focus at near
- Most common refractive disorder in people over 40 years
- Multiple theories
  - decreasing capsule elasticity and increasing stiffness/sclerosis of lens
  - decrease in ciliary body contractility
  - decrease in the distance between the equatorial edge of the lens and the ciliary body, which decreases zonular tension
- Proliferation of smart phones increases the importance of near vision
Dysfunctional Lens Syndrome (DLS)

- 3 stages
- Patients must understand that presbyopia is a lens problem and they must know which stage they are in
- Helps to clarify that LASIK does not wear off
- Optical scatter index provides an objective measurement of lens dysfunction
Stages of Dysfunctional Lens Syndrome (DLS)

- **Stage 1**
  - 43 y/o
  - Lens remains clear
  - Onset of presbyopia
  - LASIK/PRK Monovision
  - Corneal Inlays
  - > +3.00 hyperopia – consider refractive lens exchange
Stages of Dysfunctional Lens Syndrome (DLS)

- **Stage 2**
  - 50-60 y/o
  - Lens turns yellow
  - Worsening night vision
  - More light needed to read
  - Refractive Lens Exchange
  - LASIK/PRK Monovision
  - Optical quality not sufficient for inlays
Stages of Dysfunctional Lens Syndrome (DLS)

- **Stage 3**
  - 70+ y/o
  - Visually significant cataract
  - Cataract Extraction with IOL
What do you think will be your primary surgical presbyopia correction solution(s) in the next 3 years?
LASIK

- Laser-assisted in situ keratomileusis
- First performed in 1990 by Pallikaris
- Femtosecond laser creates a corneal flap
- Microkeratome can be used if corneal scars are present
- Excimer laser reshapes the cornea under the flap
- Flap is replaced
- Faster healing than PRK, less discomfort, allows the patient to return to work the next day
LASIK

- Approved for -14D to +6D with up to 6D of astigmatism
- Common range treated: -12D to +3D
- At least 250 microns of residual stromal bed, but most surgeons leave at least 300
- Higher risk of corneal ectasia than PRK
- Risk of epithelial ingrowth
LASIK Procedure

**Step 1:** Creating the Flap

**Step 2:** Reshaping the Cornea
LASIK Procedure

Flap is reflected

Laser treatment

Original curvature
New curvature

Courtesy of: Basic and Clinical Science Course, AAO 2011
Contraindications to LASIK

- Forme fruste keratoconus
- Steep keratometry
- Thin corneal pachymetry
- Dry eye
- Anterior Basement Membrane Dystrophy
- Unstable refractions
- Collagen vascular diseases (RA, Sjögren’s)
- Eyelid abnormalities
- Previous HSV, HZV infection
- Medications: isotretinoin, amiodarone
- Uncontrolled DM
- DM retinopathy
- Patients who are pregnant or nursing
- Patients with unreasonable expectations
• First performed by McDonald and colleagues in 1988
• Epithelium is removed mechanically
• Flap is not created
• Laser reshapes the cornea, large epithelial defect remains
• Patient wears a bandage contact lens for about 1 week
• Slower healing
• More discomfort during healing
• Higher risk of infection until epithelium fully regenerated
• Same residual bed thickness of 250-300 microns, but without the need for a flap
• Thinner corneas can be treated since no flap is created
PRK

- No risk of epithelial ingrowth
- Higher risk or stromal haze than LASIK, but this risk decreases with the use of Mitomycin C
- Lower risk of corneal ectasia especially in patients with thinner corneas or abnormal topography
- Enhancements are more commonly performed with PRK
  - Lifting the flap after a long period of time may be difficult
  - Lifting the flap can result in epithelial ingrowth
PRK Procedure
LASIK for Presbyopia

- About 14% of laser refractive procedures involve a monovision approach
- Monovision option
  - Dominant Eye: Plano, emmetropia is essential
  - Non-dominant Eye:
    - -0.75D to -1.50D for ages 40 to 50 years
    - Up to -2.50D for ages 50 to 60 years
- Enhancement can reverse the monovision for patients who cannot tolerate:
  - Loss of stereopsis
  - Loss of contrast sensitivity
  - Unable to suppress intraocular blur
  - Complain of poor binocular visual acuity
- Hyperopes require a greater laser correction in the non-dominant eye to induce myopia
LASIK for Presbyopia

• Nighttime vision may be an problem since non-dominant eye is still myopic
• >90% patient satisfaction reported
• Up to 30% retreatment rate
  – Improve distance in dominant eye
  – Reverse monovision
• Appropriate patient selection is key
  – Strategy to reduce – NOT eliminate visual aids
  – Readers still needed for extended near work
  – Distance spectacles for driving etc.
• Careful evaluation of highly demanding patients, especially those in professions that demand excellent vision for distance or near
LASIK for Presbyopia

- Successful monovision contact lens trial is important
- Patients must ensure they are able to read with monovision
- Myopes
  - Less limitations
  - Retreatment or elimination or monovision relatively easy
- Hyperopes
  - Approved for +6.00 D, most surgeons only treat +3.00 to 4.00 D
  - Treatment needed may exceed the limit
  - Hyperopic ablations are more sensitive to centration
  - Regress more commonly than myopic ablations
- Plano Presbyopes
  - Also require hyperopic ablation but lesser magnitude
  - Difficulty adopting to monovision given excellent pre-op binocular UDVA
  - Extended contact lens trial recommended
LASIK for Presbyopia

• Limitations
  – Reduced stereoacuity
  – Reduced contrast sensitivity

• When to avoid
  – Moderate amblyopia (20/30 or worse)
  – History of strabismus surgery
  – Phorias which can cause loss of fusion and binocular diplopia

• Monovision reversal
  – Wait 6-12 weeks before considering reversal in patients who cannot tolerate it
  – LASIK retreatment carries the risk of epithelial ingrowth
  – Potential for irregular astigmatism in emmetropic or hyperopic reversal
Monovision

- 284 patients 45 years or older
- 188 (67%) chose Monovision
- 85% chose their dominant eye to be corrected for distance
- Patients who selected their dominant eye for near vision correction had similar acceptance and refractive success rates
- Hyperopic patients achieved results comparable to those of myopic patients
- 7% enhanced the near eye to distance
- 27.9% enhancement of their distance vision eye

Monovision in LASIK

Erick H. F. Braun, MD,1 Jane Lee, MD,2 Roger F. Steinemann, MD1

Purpose: To evaluate the preoperative characteristics and postoperative outcomes of pseudomyopic and pseudohyperopic patients selecting monovision correction by LASIK.

Design: Retrospective observational case series.

Participants: One hundred seventy-two sequentially treated myopic and hyperopic patients, 45 years or older, who opted for LASIK vision correction with the goal of monovision.

Methods: Patients treated with monovision correction by LASIK were measured and categorized. All treatments were conducted using conventional microkeratome technology.

Main Outcome Measures: Acuity, refractive and functional success of monovision correction based on postoperative manifest refraction relative to target correction, and patient enhancement rate.

Results: Of 172 cases, 94 (55%) were corrected for monovision and 78 (45%) chose bilateral distance correction. Of the patients seeking target vision correction, women (66%) outnumbered men (69%), and women selected monovision slightly more often than men (59.9% vs. 53.5%; P = 0.14). A majority of patients (60%) chose their dominant eye to be corrected for distance vision, yet 39% of patients treated with monovision correction, only 7% chose to forego monovision and subsequently enhance the near eye to distance vision. However, 87.8% of monovision patients underwent subsequent enhancement of their distance vision eyes.

Conclusions: LASIK monovision correction represents a viable and increasingly popular method of correcting pseudomyopic and pseudohyperopic patients considering refractive surgery. Crosslinked monovision may be applied successfully to appropriately chosen patients. The distance vision eye in the monovision patient may have a lower tolerance for residual recentering error and requires a higher rate of enhancements than a standard LASIK vision correction patient. Ophthalmology. 2008;115:1196–1202 © 2008 by the American Academy of Ophthalmology.

The strategy of monovision correction for pseudomyopia allows a patient to have one eye corrected for near vision and the other eye corrected for distance vision, eliminating or markedly reducing dependency on spectacles and contact lenses for most activities. Monovision has been used successfully for years by contact lens wearers and more recently adopted as an option for refractive surgery candidates. Although contact lens monovision has the advantage of less lens intolerance than spectacle monovision, monovision correction to distance and residual astigmatism still limit its functionality. Contact lens monovision has a reported success rate of 30% to 60%, with increasing success rates when failures due to contact lens intolerance were excluded. By applying a refractive surgery approach to monovision, the problems of contact lens intolerance are avoided and an effective optical solution to monovision is achieved.

Success rates for monovision refractive laser correction range from 72% to 97.6%. Generally, 35- to 55-year-old patients who successfully adapt to monovision have good 20/20 vision (typically found in patients without strong lighting preferences), posture, and accommodation (< 2.50 diopters). Successful distance correction of the dominant eye, relative preservation of stereopsis, lack of esotropia, and good stereoacuity (1500) are also important features.

Possible reasons for higher monovision intolerance with refractive surgery are: 1) improved binocular adaptation with constant optical correction, 2) less astigmatism than with spectacles, and 3) elimination of contact lens discomfort and complications. One study examined distance binocular vision, near acuity, contrast sensitivity, and vergence fusion amplitudes in phakic refractive laser-induced monovision. No statistical difference was found between the monovision and control groups, except that the monovision group had better near vision.

Typically, a refractive surgery approach for conventional monovision takes the dominant eye to correct for near vision and the non-dominant eye to correct for distance vision. However, patient preference or unanticipated refractive surgical outcome may result in crossed monovision, in which the dominant eye is corrected for near vision.

In this study, we investigated the preoperative characteristics of pseudomyopic patients undergoing LASIK who elected monovision for near vision correction. Patient selection, patient enhancement for distance vision, and patient enhancement for near vision were evaluated to determine the success rate and the factors influencing the success of monovision correction.

Multifocal Ablation
Presby-LASIK

- Not yet FDA approved, clinical trials underway
- Various ablation patterns
  - Central presby-LASIK - Steeper corneal center focuses near, surrounded by a flatter periphery focuses distance
  - Peripheral presby-LASIK - Flattened corneal center focuses distance, steeper periphery focuses near
- Bilateral treatment – no loss of stereopsis
- Patients with prior monofocal IOLs are candidates
  - Presbyopia
  - Spherical refractive error and astigmatism
- Complex corneal shapes present challenge for future surgical procedures
  - Difficult IOL power calculations for future cataract extraction
  - Difficult to reverse should the patient be unhappy
Corneal Inlays

- 2 inlays currently FDA approved in the US
- Phakic presbyopes
- Minimal pre-operative spherical refractive error
- Patients must not require glasses for distance vision
- Reduced contrast sensitivity
- Decrease in distance acuity
- Provide near vision in 1 eye only – patients must tolerate near vision
- Inlay combined with LASIK or prior refractive surgery is considered off-label
- Rare removal for cosmesis or immunologic response
- Compared to monovision LASIK
  - Less blur at distance
  - Less impact on stereoacuity
KAMRA

Made from Polyvinylidene Fluoride (PVDF)

Courtesy of: Eyeworld 2012
KAMRA

- KAMRA inlay (Acufocus)
- FDA approved in 2015
- 45-60 y/o phakic presbyope
- +0.5 D to -0.75 D, ≤0.75 D of cyl
- Best results in low myopes
- Patients must not require glasses for distance vision
- Must require near correction of +1.00 to +2.50 D of reading add
KAMRA

- Implanted in non-dominant eye in a femtosecond pocket 200 to 250 µm deep
- Acts like a pinhole
- Restricts the rays to a tight bundle
- Central opening allows only focused light into the eye
- Works on the same principle as a camera aperture by increasing the depth of focus
- Provides near, intermediate and distance vision
- Cataract surgery can be performed with inlay in place
KAMRA

Source: Eyeworld March 2017
KAMRA

Vision with presbyopia

- Lens cannot focus
- Before KAMRA

Vision with the KAMRA inlay

- Using a pinhole effect, the center of the inlayfocuses light.
- After KAMRA

Source: www.kamra.com
• 83.5% of 478 patients UCNVA of 20/40 or better at 1 year
• 87.1% of 417 patients UCNVA of 20/40 or better at 3 years
• Mean endothelial cell loss was 5%
• Dry eye was the most common patient-reported symptom
• 2-3 weeks to achieve UCNVA but may take up to 3 months

• 32 patients
• At 60 months
• 74.2% UNVA 20/32 or better
• 87.1% UIVA 20/32 or better
• 93.5% UDVA 20/20 or better
• One inlay was removed after 36 months because of patient dissatisfaction with vision after a hyperopic shift
• No loss of CDVA or CNVA 2 years after removal.
KAMRA

- 39 patients
- 22 patients at 4 year follow up
- All patients gained 2 lines of UNVA
- Mean UNVA 20/20
- 4 explantations
- No severe corneal complications
Raindrop Inlay

Eyeworld 2015

Eyeworld 2017
Raindrop

- Raindrop Near Vision Inlay (ReVision Optics)
- FDA approved in 2016
- 41-65 y/o phakic presbyope
- +1.0 D to -0.5 D, ≤0.75 D of cyl
- Best results in low hyperopess
- Patients must not require glasses for distance vision
- Must require near correction of +1.50 to +2.50 D of reading add
- Implanted in non-dominant eye under a flap created by a femtosecond laser at 30% thickness
- Reshapes the anterior cornea and gives multifocal function of central cornea
Raindrop

- Provides near and intermediate vision in the nondominant eye
- Clear hydrogel inlay 2 mm in diameter
- 32 µm central thickness
- Dilated pupil allows for unchanged peripheral cornea to provide distance vision
- Less reduction in contrast sensitivity compared to KAMRA
- 92% UCNVA of 20/40 or better at 2 years
- Most common complication - Central corneal haze (16.6%) – Resolved in 89%
Raindrop

- 373 patients at 1-year
- Average 5-line improvement in UNVA
- 2.5-line improvement in UIVA
- 1-line reduction in UDVA
- No loss in binocular distance vision
- Postop glare and halos were minimal
- 93% of subjects achieved UNVA of 20/25 or better in the treated eye
- Mean uncorrected visual acuity for both eyes exceeded 20/20 at all distances with no loss in contrast sensitivity
- 92% rate of satisfaction at 1 year postop

Explanation in 11 of 373 eyes

100% achieved a corrected distance visual acuity of 20/25 or better by 3 months after explant.
Treatment of Presbyopia in Emmetropes Using a Shape-Changing Corneal Inlay

One-Year Clinical Outcomes

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Purpose: To report 1-year safety and efficacy clinical outcomes of a shape-changing corneal inlay for the treatment of presbyopia.

Design: Prospective, nonrandomized, multicenter United States Food and Drug Administration Investigational Device Exemption clinical trial (Identifier: NCT03725848).

Participants: Nondominant eyes (n = 378) of emmetropic presbyopic subjects were implanted at 11 sites with the Raindrop Near Vision Inlay (Prescription Optics, Lake Forest, Calif). CA-340 eyes underwent the 1-year follow-up visit.

Methods: The corneal inlay was implanted under a corneal flap at the center of the light-constricted pupil created with a femtosecond laser.

Main Outcome Measures: For subjects completing the 1-year follow-up, monocular and binocular uncorrected and corrected visual acuity, reflexive stability, contrast sensitivity (C5 photopic and mesopic), symptom and satisfaction questionnaires results, and adverse events.

Results: At 1 year in the treated eye, on average, uncorrected near visual acuity (UNVA) improved by 0.1 line, uncorrected intermediate visual acuity (UIVA) improved by 0.5 line, and uncorrected distance visual acuity (UDVA) decreased by 1.2 lines. From 3 months through 1 year, 90% of subjects achieved UNVA of 20/25 or better, 97% achieved UIVA of 20/25 or better, and 95% achieved UDVA of 20/40 or better. Binocularly, the mean UDVA exceeded 20/20 from months through 1 year. Contrast sensitivity loss occurred only at the highest spatial frequencies, with no loss binocularly. Absent or mild scores were reported in 96% of subjects for visual symptoms, with the majority indicating clear vision, comfort, and comfort, and in 96% for dryness. Adverse events were treatable and resolved. Eighteen Inlays were replaced, usually soon after implantation because of decenteration, but UDVA was little affected in this group thereafter. In the 11 cases requiring Inlay explantations, 100% achieved a corrected distance visual acuity of 20/25 or better by 3 months after explantation.

Conclusions: The Raindrop Near Vision Inlay provides significant improvement in near and intermediate visual performance, with no significant change in binocular distance vision or Cassy. Subject satisfaction is improved significantly with minimal ocular or visual symptoms. Ophthalmology 2016;123:468–475 ©2016 by the American Academy of Ophthalmology.
References

- Basic and Clinical Science Course, AAO 2011
- Whitman et al., Ophthalmology, March 2016
- ASCRS Clinical Survey 2015
- Eyeworld March 2017
- Eyeworld August 2016
Thank you!

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