Refractive Surgery options for High Myopia

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Social stigma of thick glasses
- Poindexter from “Revenge of the Nerds”
- Appearance of facial distortion through high power plus or minus lenses
- Bookish, clumsy, socially inept

Visual distortions in high spectacle prescriptions
- Pincushion distortion in high myopia
- Image size minification, decreased resolving power
- Sports performance decline

Contact lens option
- Thicker lenses for higher prescriptions
- Daily hassle of cleaning and disinfection
- Cost of contact lenses, exams and solutions
- Daily and Extended contact lens wear risks for infection
- Variable comfort (patients with dry eyes or contact solution sensitivity)

Contact lens independence
- Colorado Lifestyle…
- Hunting, camping, fishing, kayaking etc.
Presentation outline

- LASIK / PRK limitations
- Refractive lens exchange (RLE)
  - Indications and pre-op considerations
  - Post-op concerns
- Phakic IOL - Visian ICL implantation
  - Indications and pre-op considerations
  - Post-op concerns

Why not LASIK / PRK for everyone?

**LASIK Safety**
- Residual bed thickness requirement has been raised to 300 instead of 250 – 270 to avoid post-LASIK ectasia
- Example: myope -9 diopters
  - 300 bed thickness
  - 126 (14 microns/diopter x 9 diopters)
  - 110 micron flap thickness (Intralase flap)
  - = 536 microns of corneal thickness required

**Ectasia case**
- 61 yo state trooper evaluated 2 weeks ago
- Had bilateral LASIK in Canada in 2000
- Spectacle independent x 5 years
- Progressive increase in astigmatism after that
  - -5.25 – 0.50 x 58 OD
  - -4.50 – 0.50 x 68 OS
- Don’t have preop K’s, maps, or K thickness

**PRK Safety**
- Increased risk for corneal haze with high corrections
- Mitomycin C utilized to reduce risk of haze formation.

**Why not LASIK / PRK for everyone?**
Visual quality of LASIK / PRK in absence of ectasia

- Spherical aberration may increase with myopic LASIK / PRK in direct proportion to degree of myopic treatment
- Many surgeons use <35-36 as a cutoff for calculated estimated post procedure flatness and > 47-48 for post surgical values for steepness.

34 yo OD with CV PRK
- Surgery with LS 6/2012
- Pre-op K’s about 42.8
- Pre-op pachs 611
- 8.50 + 0.75 x 82
- SEQ -8.1
- Calculated post-op K’s 34.7 diopters

34 yo ophthalmic technician had traditional LASIK
- Performed with GP in 1997
- Pre-op Ks were 46.37/47.87 @ 84
- -14.75 -1.25 x 159 pre-op manifest OS
- Anticipated post-surgical K’s of 31.8 D
Comparison axial vs tangential maps

Limitations of LASIK and PRK
- Typically from about +4 to -9 or -10
- Corneal thickness limitations
- Lowered optical quality for high corrections
- Induced Dry Eye Syndrome (LINK)
- IOL power calculation inaccuracy for future cataract surgery

Alternatives to LASIK / PRK
- Refractive lens extraction (RLE) and Phakic IOL's (Visian, Verisyse) complement but do not replace corneal refractive surgery (LASIK & PRK)
- Still encourage LASIK or PRK for those who qualify (extraocular vs. intraocular procedure).

Refractive Lens Exchange (RLE) and Implantable Collamer Lens (ICL)
- Surgical parameters / guidelines at Spivack Vision Center
  - >9 to 20 diopters of myopia
  - 5 to 9 diopters if inadequate corneal tissue thickness or other contraindications to LASIK / PRK
  - Low to Mid-40s or younger → ICL
  - Late 40s or older → RLE
  - RLE for high hyperopia >3.5 - 4 diopters

Refractive Lens Exchange
- A.K.A. Clear Lensectomy
- Performed for high hyperopia or high myopia
- Refractive procedure for those "out of range" for LASIK or PRK
- Intraocular procedure similar to cataract surgery
- Preference for those in late 40s and older vs. phakic IOLs for younger patients

RLE Benefits
- Reduces dependence on glasses and contact lenses for high hyperopia or myopia
- Obviates need for cataract surgery down the road
- Stable refractive error after surgery (no significant regression after healing period)
- High quality of vision (preserves natural shape of cornea).
- Common surgical procedure familiar to cataract surgeons.
RLE Drawbacks
- Loss of accommodation
  - Ideal candidate late 40s or older
- Multifocal IOL associated glare / halo

Risks
- Induced PVD / Retinal detachment
- Endophthalmitis
- Retrobulbar hemorrhage
- Retinal Vascular occlusion
- Edge Dysphotopsia

RLE Risks
- Intraocular procedure
  - Endophthalmitis (1 in 1000)
  - Retinal tears/detachment (1 in 200)
  - Suprachoroidal / retrobulbar hemorrhage (1 in 1000)
- Visual distortion
  - Loss of accommodation
  - Visual aberration with multifocals
  - Edge dysphotopsia with all IOLs

Range of Refractive Lens Exchange
- -10 to +40 for standard monofocal IOL
- +6 to +34 for ReSTOR
- +10 to +33 for Crystalens AO
- +5 to +34 for Tecnis Multifocal

Very high myopia -10 or more, may not have option of premium IOL or may need to combine premium IOL + further LASIK

Not FDA approved procedure
- No FDA approval for IOLs to be used in clear lensectomy.
- Labeling of IOLs for implantation after cataract surgery

RLE Risks
- RLE is performed as any other cataract procedure
- Decreased use or absence of phacoemulsification energy.
- Improvements in the fluidics of the instrumentation enhance safety

Retinal detachment risk
- Incidence (per year) of retinal detachment is 1 in 20,000 in the general population.
- Incidence (per year) in patients over 50 is 1 in 5000.
- Normal lifetime risk is 1 in 300
- Patients with high myopia (>6 diopters) have a 1 in 20 lifetime risk
- High hyperopia not associated with retinal increased retinal detachment
Cataract surgery/ RLE induces retinal detachment?

- Estimated 4 fold relative increased risk of RD after CE/IOL
- Bjerrum et al., *Ophthalmology* 12/2013

4 fold risk of RD by CE/IOL
Bjerrum et al., *Ophthalmology* 12/2013

- Danish national patient registry data analyzed: 202,226 patients who had CE/IOL from 2000 through 2010 in only one eye
- 575 developed RD: 465 in operated eye (0.2%) vs 110 (0.05%) in non-operated eye
- Highest risk in 1st 6 mos, but still elevated at 10 years with hazard ratio of 3
- Excluded trauma, prior vitreoretinal surgery or complex cataract surgery cases

Malpractice Insurance Coverage

- OMIC
  - Has covered RLE since 1999
  - For patients >-10 diopters or between +3 and +15
- COPIC
  - has always covered without restrictions
  - reserves the right to change coverage
  - continual monitoring

Vitreous Synchysis and syneresis

- Synchysis
  - Hyalonic acid dissociation from collagen fibers leads to vitreous liquefaction
- Syneresis
  - Collagen fiber aggregation / clumping and collapse of gelatinous vitreous

Published incidences of retinal detachment following clear lens extraction

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Prevalence age related:
- Unusual before age 45
- 6% between 46 and 65
- 66% between 66 and 86

Syneresis occurs earlier and more extensively in myopic eyes and after cataract surgery
Syneresis precedes PVD

Syneresis occurs earlier and more extensively in myopic eyes and after cataract surgery

Mirshahi et al., JCRS (09’35(6)987-991)
- 186 patients prospective study (German hospital)
- Small-incision phaco, capsular bag, average age 77
- Preop 69% had PVD, 31% without
  - 1 week post op: 21% had developed PVD
  - 1 month post op: 52% had developed PVD
  - 1 year post op: 59% had a PVD, partial or complete.

PVD and cataract surgery

Posterior Vitreous Detachment
- Weiss ring fragment may create perpetual floater or cobweb
- Precedes retinal tears and rhegmatogenous retinal detachments

RD prophylaxis
- All high myopes undergoing RLE at Spivack Vision Center undergo a dilated fundus exam with our retinologists for a discussion of risks and prophylactic laser photoocoagulation depending on presence of pathology
- Lens extraction may proceed two weeks after laser treatment

Endophthalmitis
- <1 in 1000
- Pain, redness, photophobia
- 4+ A/C reaction or hypopyon
- Keratic precipitates
- Fibrin (cottony or stringy whitish material) in A/C
- Vitritis

Edge Dysphotopsia
- Positive dysphotopsia

Figure 1
**Edge Dysphotopsia**
- Negative dysphotopsia
- Dark arc to temporal field of view, worse in bright light
- “horse blinders”
- 10-20% anecdotally

**Edge Dysphotopsia Ray Tracing**
- Internal reflection of 35 degree incident light

**AMO dysphotopsia modification**
- “OptiEdge”
  - Rounded anterior edge
  - Squared off posterior edge
  - Frosted covering to periphery

**Nd:YAG posterior capsulotomy**
- Neodymium-Yttrium-Aluminum-Garnet solid state laser
- Visually significant opacity
- Possible after-YAG refractive shift (especially with Crystalens)

**Multifocal / Accommodating IOLs**

**YAG capsulotomy contact lens**
- Corneal abrasion, more common in EBMD patients
- Goniosol
- Abraham Capsulotomy Lens
  - Focuses laser on posterior capsule
  - Keeps lid from blinking onto laser
YAG capsulotomy

- Should be driven by patient complaints
- Mild to moderate capsule opacity sometimes doesn’t drop Snellen.
- Symptomatic earlier in diffractive multifocals
- Consider before corneal refractive enhancement surgery as can have a refractive shift (especially in Crystalens patients)

YAG capsulotomy sizing

- Crystalens capsulotomy should be smaller than the optic
- 3 mm per manufacturer
- Traditional or multifocal ~5 mm

YAG and RD Risk

- 57,100 medicare beneficiaries 86-87 had CE
- 13,700 underwent YAG capsulotomy through 1988 (24%)
- 337 had RD between 86 and 88 (0.6%)
- 530 had surgery for RD or RT (0.9%)
- 3.9 fold increased rate of RD if the patient had a YAG capsulotomy

Multifocal or Monofocal YAG sizing

- 5 mm or larger posterior capsulotomy for non-Crystalens IOLs.

Implantable Collamer Lens (ICL)

- Phakic IOL technology
- Reduces dependence on glasses and contacts for high myopia (not available in US for high hyperopia)
- Preserves natural accommodative function
- High quality of vision (preserves natural shape of cornea)
- Age 21 to 45

Visian ICL (Implantable Collamer Lens)

- Phakic posterior chamber Lens – sits behind the iris and in front of the natural lens.
Verisyse phakic IOL
- Verisyse lens is in the anterior chamber, "attached" to the front of the iris

Visian ICL vs Verisyse
- Both with good safety and effectiveness
- Visian ICL: invisible to the naked eye
- Visian ICL: smaller wound (3mm) not requiring stitches
- Implantation skills more challenging with the Verisyse (enclavation)
- Verisyse requires enlarging wound (6 mm) at time of future cataract surgery

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Why ICL vs Clear Lens Extraction for young patients
- ICL preserves accommodation
- May allow patients to take advantage of future IOL technologies.
- **Possible** lower risk for retinal detachment vs CLE as crystalline lens remains in place, keeping existing convex posterior outward crystalline lens contour, with possible less disruption to vitreous anatomy

ICL Design
- Posterior Chamber Phakic IOL
- Haptics placed in sulcus
- Optic Vault by design
  - ~500 um over the central crystalline lens
- Orientation marks for proper placement and alignment in injector
- Foldable and injectable through a 3mm incision (self sealing incision)

ICL is Very Thin
- < 100 um
- 500-600 um

ICL diameter
- 4 ICL lengths
  - 12.1, 12.6, 13.2 and 13.7mm
- Choose depending on anticipated sulcus diameter
- White-to-White caliper measurement
- Aim to adequately vault crystalline lens without chronic contact of ICL optic to anterior lens capsule
Indication for Use
STAAR Visian ICL™ is indicated for placement in the posterior chamber of the phakic eye for:

- Correction of myopia -3.0 D to -15.0 D
- Reduction of myopia -15.0 D to -20.0 D
- 21 to 45 years of age
- < 2.5D astigmatism
- ACD 3.0mm or greater
- Stable refractive history with <0.5D change for 12 months

Contraindications

- Progressive refractive error
- Corneal/Endothelial pathology
- History of iritis / synechiae
- Glaucoma
- Narrow angle
- Cataract or capsular opacification
- AC Depth < 3.0mm

Pre- and Post-operative Protocol

- Patient Consultation at Spivack Vision Center
- ICL measurements: IOL master, specular microscopy, retinal evaluation, white to white measurement.
- Peripheral Iridotomies (1-2 weeks before sx)
- Surgical Procedure – ICL implantation, one eye at a time 1 week apart with 4 hour post op check at surgery center
- 1 day – post op
- ~1 week post op before 2nd eye procedure
- ~1 month
- 3 months at OD – consider Laser sx enh, if needed

Peripheral Iridotomies

- PI’s
  - 0.5 mm opening
  - 2 superior placed PIs, ~45-90 degrees apart
  - Prevents Pupillary Block
  - 1-2 weeks before implantation procedure

Post-operative Medications

- Similar to normal cataract postop
  - Antibiotic - Besivance
    - three times per day for one-week
  - Steroid – Durezol
    - three times per day x 2 weeks then bid and qd each for 1 week.

Post-op Day 1, 7 and Beyond

- Visual acuity
- Refraction (Day 7 & beyond)
- Biomicroscopy
  - ICL centration
  - Inflammation
  - Vault-.5x to 1.5x corneal thickness
- IOP
- Evaluation of crystalline lens
**Slitlamp Exam ICL**

1 x Corneal Thickness Vault

**Visian ICL™ Scheimpflug**

1 x Corneal Thickness Vault

**Potential ICL Complications**
- Pupillary Block – IOP spike
- Anterior Subcapsular Cataract
- Retinal Detachment
- Endophthalmitis
- Incorrect IOL width selection

**Pupillary Block**
- Inadequate PI’s
- Insufficient removal of viscoelastic
- Acute Intraocular Pressure Rises
  20/526 (3.8%) in the FDA study
  - 17 eyes – additional YAG iridotomy or enlargement of existing iridotomy
  - 3 eyes – irrigation for removal of retained viscoelastic

**Cataract Inducement**
- 1.4% clinically significant lens opacity rate (NSC and ASC)
- FDA studies, 7 (out of 526) eyes required removal and cataract extraction with IOL

**Endophthalmitis**
- A concern with any intraocular procedure
- No cases in the FDA ICL approval study
- Our rationale for non-simultaneous surgery
- Same rationale for non-simultaneous cataract surgery
- 1/1000 for cataract surgery, should be similar
Pigment on ICL

Retinal Detachment
- US clinical trial included 3 retinal detachments (of 526 eyes) over the three years of the study (0.6%) – Most agree that this was not an unusual finding since the mean myopia in the trial was -10D.
- After any acute PVD symptoms, dilation allowed at any point after ICL surgery, with peripheral retinal exam to look for retinal tears

Excimer Refractive Enhancement
- Intralase *traditional* LASIK after ICL or RLE typically performed
- May be unreliable custom wavefront capture after IOL surgery
  - Diffractive IOL
  - Edge or capsulorrhexis contribution

Summary
- RLE and ICL are refractive surgery options available to your patients at SVC
- Complement but don’t replace LASIK/PRK
- ICL for high myopes that are younger, as it’s main advantage is preservation of natural accommodation
- RLE for high hyperopes and older high myopes
- LASIK / PRK may be needed to fine tune

Timing of Excimer Refractive Enhancement
- Usually 3 months after procedure, with bilateral, simultaneous surgery performed if required for significant residual ametropia.
- LRI’s attempted for pre ICL implantation or pre-RLE for 1.5 diopters or less of cylinder
- Planned LASIK 3 months after ICL for pre-operative corneal cylinder greater that 1.5 to 2 diopters without attempt at LRI’s

Video demonstration of steps

*Video primer*

**ICL implantation: Step by Step**

*Jason Wang, M.D.*

*Spring Symposium March 2008*