2014 Monterey Symposium
Surgical Options for Presbyopes:
Corneal Based and Lens Based

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National Statistics - Trends

Market Scope
Monthly Newsletter

ASCRS/ISRS/AAO Surveys
R.J. Duffey, MD
1997-2013

The Baby Boomer Generation
Born between 1946 - 1964
- Large, rapidly growing demographic
- Educated, financially secure
- Increased life expectancy
- Longer working careers
- Demand high quality vision
- New requirement for near vision (computers)
- Unwilling to compromise active lifestyle
- Higher BMC quotient?

U.S. Statistics…..
Or things that make you go hmmm

80 million baby boomers began turning 60 in 2006
* Ostrich egg going through a python
In 2012 estimate 43 million > age of 65
By 2020 will increase to 55 million > 65
By 2025 ~ 60% of US population ≥ 55
Over 50% > age 65 have visually significant cataracts
Currently estimated that cataracts affect > 22 million in US
Currently 3 million+ cataract surgeries per year in US
That number is expected to increase to > 30 million by 2020

Hmmmmm…..
Part deux

Incidence of cataract surgery dramatically increasing
- Improved access to surgery
- More surgeons
- Adoption of widening indications for surgery
Between 1998–2004 28% of patients had 2nd eye sx by 90 d
Between 2005-2011 increased to 60%
Surgical Presbyopia Options

Monovision
- LASIK and PRK
- OK (Conductive Keratoplasty)
- Has FDA approval
- Monofocal ICLs
- Monofocal IOLs

Multifocal Implants (PC-IOLs)

On the horizon
- Multiple new designs of PC-IOLs
- Multifocal excimer ablations – presbyLASIK
- Pinhole corneal inlays (Kamra by AcuFocus)
- Received FDA panel recommendation in June
- Create corneal flap or pocket with femtosecond laser
- Other corneal inlays
- Raindrop (Revision Optics)

Monovision….mini-monovision

2nd most popular treatment for presbyopia
- Glasses is number 1
- Works with CLs, Lasik, PRK, ICLs, Cataract Sx, Inlays
- Most people treat non-dominant eye for near
- Not a universal rule
- Never try surgically without confirming
  - Loose lens trial
  - CL trial – perhaps just 1 day
- ‘How do you primarily want to function?’
- How to deal with extremes

Mini-monovision
- Intermediate rather than near eye
- Very popular with PC-IOLs

Preferred Surgery for Presbyopia

ISRS/AAO 2014 Survey - Duffey

Monovision + mini-monovision is 61%

ASCRS 2013 Survey - Duffey

Monovision + mini-monovision is 70%

Corneal Options

Excimer Laser
- Lasik - monovision
- PRK – monovision
- Multifocal ablations
- Not FDA approved and not really close

Conductive Keratoplasty

Corneal Inlays
- Kamra
- Raindrop

General Guidelines

LASIK:
- All flaps should be femtosecond
  - Standard femto flap is 100-120 microns
- Minimum tissue left in bed 250-300 microns
- Expect remove up to 16 microns/diopter @ 6.5 OZ
- Don’t flatten below K’s of 36-37 in myopes
- Don’t steepen above K’s of 49-50 in hyperopes
- Depending upon laser approval up to:
  - -12.00 – consider ICLs above 6ish
  - +6.00 – consider CLX above 3ish
  - 6 D of cylinder
General Guidelines

PRK:
Whenever LASIK is contraindicated or patient requests
Outcomes are identical to LASIK
Previous corneal surgery or ‘significant’ scars +/-
All s/p RK patients
Many LASIK enhancements now with PRK
In our hands - If we did not perform the original surgery
If virgin cornea less than 480ish microns
Pentacam that make us ‘a little nervous’
EBMD and some other corneal dystrophies
NOT REQUIRING PRK
Dry eye & scleral buckle

Technology Does Makes a Difference

• Sophisticated Corneal Analysis
  - Pentacam is the ‘Gold Standard’
  - More thorough Screening
• Femtosecond Laser for flap making
  - Safer procedure versus microkeratomies
  - “Uh, you had me at blade versus no blade”
• Modern Excimer lasers
  - Small spot scanning lasers
  - Custom
  - Eye tracking

Some facts to digest

• VisX is most commonly used Excimer in US
• Alcon Allegretto is currently best selling Excimer
• Nidek and B & L and Zeiss are minor players
• Over 80% of US cases are ‘Custom’
  - Treating HOAs or WFO/WFG
• Over 65% with femtosecond laser
• About 15% is PRK

Conductive Keratoplasty - CK
Treats hyperopia/presbyopia
Uses high frequency radio waves
  - Produces heat => collagen shrinkage
  - 8-24 spots placed in mid-peripheral ring
  - Creates band(s) of tightening in mid-periphery
  - Causes central steepening

Target Patients for CK
Plano/presbyopes
  - Needs less than 2D of effect
  - Can tolerate monovision/blended vision
  - Who want to, or need to, avoid laser
S/P previous ocular surgery
  - LASIK
  - PRK
  - Cataract surgery
ABSOLUTELY AVOID IN S/P RK PATIENTS!
Very rarely performed now – hyperopic lasik is better!
Kamra Corneal Inlay

- Received FDA panel approval 6/14
- Full FDA approval????
- Approved in 50 countries
- Creates a pinhole effect
- Insert non-dominant eye
- Form of monovision
- Inserted under a ‘Lasik flap’
- Theoretically reversible

Raindrop Corneal Inlay – ReVision Optics

- Hydrogel corneal inlay
- Not even close to FDA approval
- Creates a more prolate cornea
  - Insert non-dominant eye
  - Center area for near – transitions toward periphery
- Yet another form of monovision
- Inserted under a ‘Lasik flap’
- Theoretically reversible

Phakic Intraocular Lenses

- Phakic IOL’s - Inserting an IOL in front of natural lens to correct refractive error. AKA Implantable Contact Lens (ICL) or CL Implant (CLI).
  - Iris Supported
  - AMO/Ophthe Verisyse
  - Posterior Chamber
  - Staar Vision
  - Anterior Segment
  - Alcon lens in clinical trials

Lens Options

- Phakic lenses/ICLs with monovision
- Iris Supported lenses
- Posterior lenses
- Anterior segment lenses
- Cataract surgery/CLX
  - Current/approval IOLs
  - Monofocal IOLs with monovision
  - Multifocal IOLs
  - Accommodating IOLs
  - In the pipeline

Verisyse Iris Claw IOL
Staar Visian ICL

ICL placement and vault

STAAR Visian ICL

Place two small PI’s
Usually LPIs but may be surgical PI
Terminology

• **Premium IOLs**
  - Includes toric and PC-IOLs

• **Presbyopia Correcting IOLs (PC-IOLs)**
  - Includes multifocals and accommodating

• **Multifocal IOLs**
  - ReSTOR, Tecnis

• **Accommodating IOLs**
  - Crystalens

Lens Options For Presbyopia

- **RLE (Refractive Lens Exchange) / CLE (Clear Lens Extraction)**
  - **AKA Walletectomy**

- **Multifocal IOLs**
  - Alcon ReStor 4.0 & 3.0
  - 2.5 approval soon?
  - AMO Tecnis
  - Lower add approval soon?

- **Accommodating IOLs**
  - Eyeonics Crystalens

Many, many more in development

Clear Lens Extraction ‘Issues’

- Losing of accommodation
- Unless PC-IOL
- Intraocular surgery risks
- RD
- CME
- Endophthalmitis

Cataracts patients only??

Benefits of Premium IOLs

- Less dependence on glasses
- Exceeding patient expectations
- Better quality of life
- More referrals
- Increased income for the practice

Lens Options

- **Monofocal** — Corrects one focal length
  - Distance, near, or intermediate in each eye

- **Toric** — Corrects for astigmatism

- **Multifocal** — Corrects multiple distances

Premium IOLs

Requires different mindset/mode of practice

- Medicare model forces physicians to treat for pathology in a high-volume, low cost approach to medicine that emphasizes efficiency.
- Premium IOL model is elective and demands a more patient-oriented business model where the focus is on quality of life rather than quantity of patients.

It’s the refractive surgery model.
Presbyopia Correcting IOLs: In Development

Multifocal Toric - Alcon

Synchrony – Visiogen/AMO

Dual optic aspheric to increase/extend depth of focus (EDOF)

Trifocal IOL designs

Carl Zeiss Meditec - AT LISA

PhysIOL - FineVision

Bifocal IOL designs

Oculentis – Melma

Lenstec – S3

Accommodating IOLs

PowerVision – FluidVision

Medicem – WIOL-CF

Presbyopia Correcting IOLs (PC-IOLs)

Tremendous Early Excitement

Patients

Presbyopia correction is the ‘Holy Grail’

CrystaLens hits the market in 2003

New designs launched by Alcon & AMO in early 2005

Surgeons

Looking to reverse downward trends in reimbursement

Landmark Medicare ruling

Patients allowed to pay a premium for P-IOLs

7000+ of the 11,000 US cataract surgeons trained

IOL Companies

Hoped to invigorate flat U.S. cataract market

PC-IOLs as % of Total IOLs

P-IOL Market Below Expectations

Demand disappointing for all major lenses

Alcon – ReSTOR 3.0

Largely replaced ReSTOR 4.0

ReSTOR 2.5 coming soon

AMO – Tecnis

Similar to ReSTOR 4.0

Lower add power coming soon

Eyeonics – CrystaLens

Best distance vision. Poorest near vision.

Mini-mono approach often used

Stuff to know

- CrystaLens provides best distance vision
- CrystaLens degrades image quality the least
- CrystaLens has poorest near vision

That’s why it’s NOT the market leader

- Tecnis and ReSTOR 4.0 have closest near points
- ReSTOR 3.0 combines good near with good intermediate
- Most patients want to limit use of readers
- All lenses involve compromise
**Patient lifestyle considerations**

- Patients who want to limit use of readers
- Patients used to reading without glasses
- Patients who work in dim light
- Night drivers and pilots
- Patients who didn’t like bifocals
- Patients who wore CLs
  - Full distance OU
  - Monovision
  - Multifocals

**Other considerations**

- Previous refractive surgery
  - LASIK or PRK
  - RK
- Dry eye
- Astigmatism
- Pathology
- Surgery in one eye only
- Pupil size

**Keys for happy patients**

- Understand the patients’ needs/ranges
  - Distance, intermediate, or near
- Educate the patient before surgery
  - ‘Refractive’ versus a cataract patient
  - Concept of trade-offs
- Hand hold the patient after surgery
  - Timing of 2nd eye
  - Early Nd:YAG
  - Enhance often and early

**PC-IOL: Patient Selection**

**Pre-operative Considerations**

- Patients highly motivated to be glasses-free
- Less than 1D of astigmatism or plan on correcting
- Zero/very low pre-existing ocular pathology
- These lenses decrease quality of vision
- Varied visual demands
- Much like who you would chose for monovision
- Easy going/adaptable personality
- Best to insert bilaterally....and soon.

**Low hanging fruit**

- Good natured mild hyperope who doesn’t wear distance Rx
- With low visual demands
- Who is from out of town
- And has met their deductable

**Additional Patient Considerations**

**Subjective Exclusion Criteria**

- Hypercritical patients
- Patients with unrealistic expectations
- Occupational night drivers
- Individuals with a monofocal lens in one eye +/-
- Large pupils – avoid > 5.5mm mesopic
- PTA’s

**Medical Exclusion Criteria**

- >1.0 D of corneal astigmatism +/-
- Pre-existing ocular pathology
- Previous refractive patients +/-
- Amblyopia

**Additional Counseling Considerations**

- Document precisely what you tell the patient
- Counsel the patient about visual disturbances
- Counsel the patient differently based on lens used
- Tell them it takes time for full adaptation
- Neuroadaptation – hey, it’s the patient’s fault
- Don’t promise “you’ll never wear glasses again”
- Remember, out of pocket expenses will result in higher patient expectations

- These patients take a lot of chair time!
Patient Selection: Intra-operative Events

Exclusion during surgery
- Significant vitreous loss
- Pupil trauma or manipulation to enlarge
- Factors that impact long-term IOL stability
  - Zonular damage
  - Capsulorrhesis tear/rupture
  - Capsular rupture
  - Anterior chamber bleeding
  - Uncontrolled IOP increases

What about those unhappy patients?

Questions to ask –
Residual refractive error? UCVA?
- Astigmatism is #1 reason for complaints so must be managed. Patients typically unhappy w 1D residual and some patients tolerate even less, especially if oblique.
- If monovision distance RE has very little margin of error so be prepared to fix.
  - LRI, LASIK or PRK, IOL exchange.
  - Expect 15% “enhancement” rate

Dry eye?
- Corneal surface is important to provide optimal patient satisfaction. Treat dry eye early and aggressively.
  - Restasis – P plugs – Tears – Omega 3

Unhappy patients part deux

Questions to ask –
Monocular or Binocular?
- Typically patients see a minimum of one line improvement in near and intermediate vision between the first and second eye implant.

Length post-op?
- Patients typically see improvement in their intermediate vision from one week to one month bilaterally.
- Neural adaptation is required. Think monovision.

CME?
- Even sub-clinical CME may compromise a patient’s vision immediately post-op.

Decreasing quality of vision

Patient presents happy at 1 month, but at 3 months complains of diminished near and/or distance vision, and increase of halos or glare.

Questions:
- Occurrence at day or night?
- Change in post-op refraction?
- Is capsular opacification visible?
  - Yag typically beneficial but can cause lens shift! So perform prior to any enhancement

Keys to Success with PC IOLs

Under promise
Over deliver
Be very realistic
Be supportive
Individualize
Enhance early & often

Thank You