2014 Monterey Symposium

Surgical Options for Presbyopes:
Corneal Based and Lens Based

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National Statistics - Trends

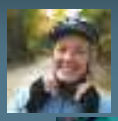
Market Scope
Monthly Newsletter

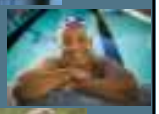
ASCRS/ISRS/AAO Surveys
R.J. Duffey, MD
1997-2013

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

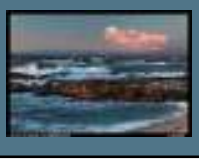
80 million baby boomers began turning 60 in 2006
Ostrich egg going through a python
In 2012 estimate 43 million > age of 65
By 2020 will increase to 55 million > 65
By 2025 ~ 60% of US population ≥ 55
Over 50% > age 65 have visually significant cataracts

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%



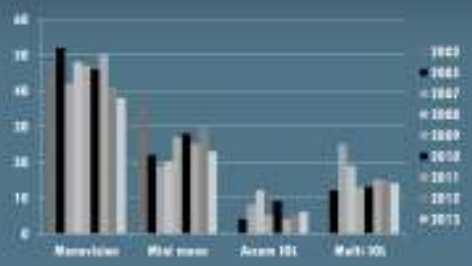
Surgical Presbyopia Options

- **Monovision**
  - LASIK and PRK
  - CK (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

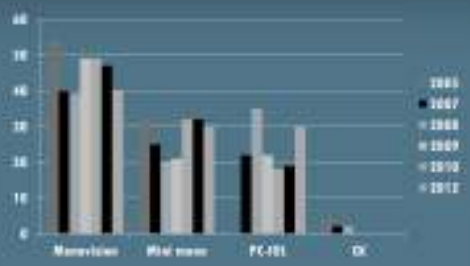
- **2nd most popular treatment for presbyopia**
  - Glasses is number 1
- **Works with CLs, Lasik, PRK, ICLs, Cataract Sx, Inlays**
- **Most people treat non-dominant eye for near**
  - Not a universal rule
- **Never try surgically without confirming**
  - Loose lens trial
  - CL trial – perhaps just 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-mono is 61%

Preferred Surgery for Presbyopia
ASCRS 2013 Survey - Duffey



Monovision + mini-mono 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

Pentacams 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 microkeratomes
  - "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 monovison/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

Kamra Corneal Inlay

diagrams from freevision.com

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

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

Phakic Intraocular Lenses

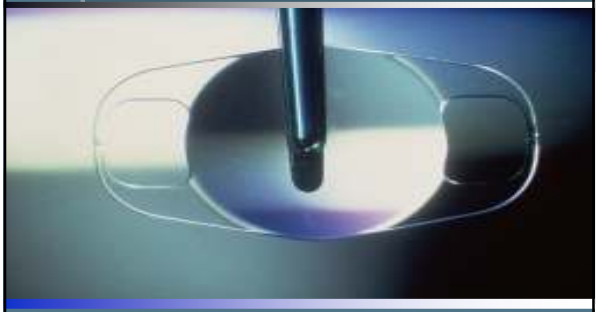
Phakic IOL's - Inserting an IOL in front of natural lens to correct refractive error. AKA Implantable Contact Lens (ICL) or CL Implant (CLI).

Iris Supported
AMO/Ophtec Verisyse

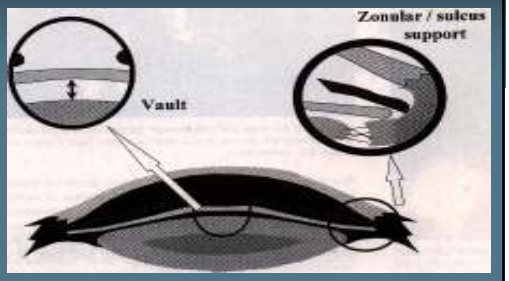
Posterior Chamber
Staar Vision

Anterior Segment
Alcon lens in clinical trials

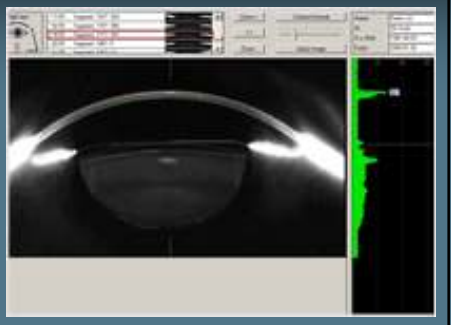
Verisyse Iris Claw IOL



Staar Visian ICL



ICL placement and vault



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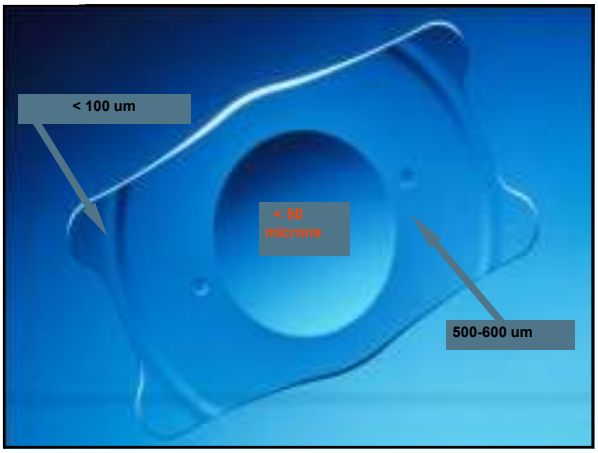
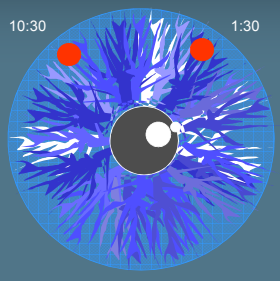


Place two 0.5 mm PI's



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 CrystalLens

Many, many more in development

Clear Lens Extraction 'Issues'

Loss of accommodation
- Unless multifocal IOL

Intraocular surgery risks
- RD
- CME
- Endophthalmitis

$$$$$$$

Cataracts patients only??

Terminology

- **Premium IOLs**
  - Includes toric and PC-IOLs
- **Presbyopia Correcting IOLs (PC-IOLs)**
  - Includes multifocals and accommodating
- **Multifocal IOLs**
  - ReSTOR, Tecnis
- **Accommodating IOLs**
  - Crystalens

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.

Benefits of Premium IOLs

Less dependence on glasses

Exceeding patient expectations

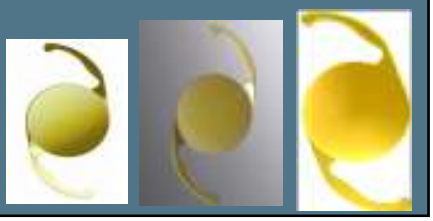
Better quality of life

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**



Multifocal

ReSTOR, Technis MF

Accommodative

Crystalens

Presbyopia Correcting IOLs: In Development

Multifocal Toric - Alcon

Synchrony – Visiogen/AMO

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

Trifocal IOL designs

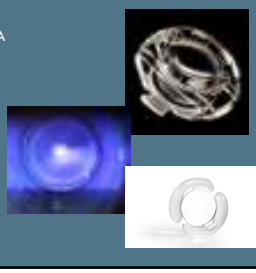
- Carl Zeiss Meditec - AT LISA
- PhysIOL - FineVision

Bifocal IOL designs

- Oculentis – Mplus
- Lenstec – SB3

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

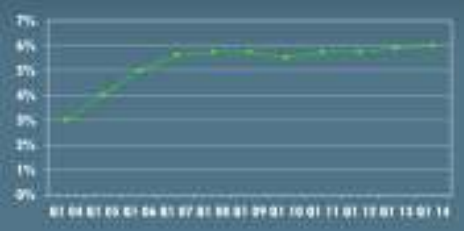
Surgeons

- 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 lens involve compromise**

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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
PITAs

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 <u>will result</u> 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
  - Capsulorrhexis 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