Intraocular Lenses for Presbyopia

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Defining Presbyopia

Options:

• near visual loss (Moshirfar et al., 2017; Zeri et al., 2018)
• age-related progressive decline in the crystalline lens’ ability to accommodate, resulting in the inability to focus on near objects (Abdelkader, 2015; Arines et al., 2017; Benozzi et al., 2012; Fedtke et al., 2017; Moarefi et al., 2017).
• “A refractive condition in which the accommodative ability of the eye is insufficient for near vision work, due to ageing” (Millodot, 2007).
• “Presbyopia is a condition of age rather than ageing and as such is devolved from the lamentable situation where the normal age-related reduction in amplitude of accommodation reaches a point when the clarity of vision at near cannot be sustained for long enough to satisfy an individual’s requirements” (Gilmartin, 1995)
• presbyopia causes the loss of accommodation (Sha et al., 2016)
Defining Presbyopia

Epidemiological (Holden et al., 2008)
Functional - needing a significant optical correction added to the presenting distance refractive correction to achieve a near visual acuity absolute (such as N8 or J1) or relative (such as 1 line of acuity improvement) criteria
Objective - where the significant optical correction is defined (such as ≥1.00 D) and added to the best optical distance correction to achieve a defined near visual acuity.
• typically defined as a person aged greater or equal to 35 years who is unable to read binocularly N8 (or 6/12) at 40 cm or their habitual working distance, and additionally in some studies limited to those whose near vision improves with additional lenses (Cheng et al., 2016; Girum et al., 2017; Kaphle et al., 2016; Muhit et al., 2018; Nsubuga et al., 2016).
Defining Presbyopia

derived from (Gualdi et al., 2017):

- Ancient Greek πρέσβυς translated into Latin (présbus, “old man”) and
- ὀψ (óps, “eye” or to “see like”)

“presbyopia occurs when the physiologically normal age-related reduction in the eyes focusing range reaches a point, when optimally corrected for distance vision, that the clarity of vision at near is insufficient to satisfy an individual’s requirements.”
1. Visual quality assessment after presbyopic laser in-situ keratomileusis
   By: Lim, Dong Hui; Chung, Eui-Sang; Kim, Myoung Joon; et al.
   INTERNATIONAL JOURNAL OF OPHTHALMOLOGY Volume: 11 Issue: 3 Pages: 462-469 Published: MAR 18 2018
   Find it @ Aston Free Full Text from Publisher View Abstract

2. Assessment of a novel pinhole supplementary implant for sulcus fixation in pseudophakic cadaver eyes
   By: Tsoulos, K. T.; Werner, L.; Trindade, C. L. C.; et al.
   EYE Volume: 32 Issue: 3 Pages: 637-645 Published: MAR 2018
   Find it @ Aston Full Text from Publisher View Abstract

3. Individual neural transfer function affects the prediction of subjective depth of focus
   By: Leube, Alexander; Schilling, Tim; Ohlendorf, Arne; et al.
   SCIENTIFIC REPORTS Volume: 8 Article Number: 1919 Published: JAN 30 2018
   Find it @ Aston Free Full Text from Publisher View Abstract

4. Patient-Perceived and Laboratory-Measured Halos Associated with Diffractive Bifocal and Trifocal Intraocular Lenses
IOL Monovision

- systematic review and meta-analysis RCT monovision vs multifocal IOLs (9 suitable trials) (Kelava et al., 2017)
  - monovision with IOLs was inferior in visual outcome to MIOLs
  - laser induced monovision tended towards equivalence, but the data was limited and largely inconclusive
- review of wider range of pseudophakic monovision for presbyopia correction - high rate spectacles independence with minimal dysphotopsia side effects (Labiris et al., 2017)
- poor intermediate vision (Greenstein and Pineda, 2017)
- some neural activity reduced while other areas compensate with monovision, hence fluid brain adaptation in visual and non-visual areas (Zeri et al., 2018)
MIOLs

- available from the late 1980s (Hansen et al., 1990; Keates et al., 1987)
  - concentric refractive
  - aspheric
  - diffractive optics (largely pupil independent)
  - asymmetric refractive segments – generally less dysphotopsia & good CS (Moore et al., 2017; Venter et al., 2014).

- Bifocal – poor intermediate vision (Hutz et al., 2008)
- Trifocal – less diffractive light lost (~16% vs 18%) and better intermediate (Sheppard et al., 2013; de Medeiros et al., 2017; Vilar et al., 2017)
- Quadrifocal optic [pan-focal] (diffractive step heights giving focal planes at 40 cm, 60 cm, and 120 cm) – acts as trifocal (Kohnen, 2015; Kohnen et al., 2017)
Extended Depth of Focus’ (EDOF)

- General reduction in add power (Rojas and Yeu, 2016)
- Low near addition diffractive (+1.75 D) (Gatinel and Loicq, 2016; Millan and Vega, 2017; Weeber et al., 2015)
  - Visual benefits across all distances - minimal dysphotopsia – high satisfaction (Cochener and Concerto Study, 2016; Kaymak et al., 2016)
  - Vs diffractive trifocal IOLs equivalent or slightly better DVA, but reduced NVA, equivalent SA and (low) levels of dysphotopsia (de Medeiros et al., 2017; Monaco et al., 2017; Pedrotti et al., 2016; Ruiz-Mesa et al., 2017a; Ruiz-Mesa et al., 2017b).
- Aspheric IOL with +SA central 2 mm zone, -SA pericentral 1mm annulus (Bellucci and Curatolo, 2017; Dominguez-Vicent et al., 2016) – no data
- Light adjustable IOL – EDOF effect (Villegas et al., 2014)
- Pinhole aspheric iris-fixated IOL specifically designed to reduce dysphotopsia and photophobia (Munoz et al., 2015)
- Cubic phase masks - optical transfer function virtually insensitive to defocus suggested (Arines et al., 2017; Mira-Agudelo et al., 2016).
A monococular defocus curve should be obtained by using the best-corrected distance refraction and measuring the visual acuity between +1.50 D and −2.50 D in 0.5-D defocus steps, except in the region from +0.50 D through −0.50 D, which should be done in 0.25-D steps. Letters should be randomly presented to avoid

The EDF IOL needs to have at least 50% of eyes achieving monocular DCIVA of better than or equal to logMAR 0.2 (20/32) at 66 cm. A logMAR visual acuity chart in 0.1 log unit steps should
How to select?

- based on clinical intuition - more evidence to support appropriate management of complications (Alio et al., 2017)
- dissatisfaction after largely multifocal and some pseudo AIOL implantation (n=49), identified residual refractive error and dry eye as principal factors (Gibbons et al., 2016).
- adaptive optics potential (Akondi et al., 2017; Dorronsoro et al., 2016; Papadatou et al., 2016; Vinas et al., 2017)
Accommodating IOLs

1CU - HumanOptics

Kellen TetraFlex
KH-3500 - Lenstec

Crystalens - B&L

Synchrony - AMO

Aston University
Birmingham
Dual Optic
AIOLs

- Publications decreased
- Few studies, measure accommodation
- Early designs - small amount of (?) ciliary muscle driven ‘accommodation’ (Leng et al., 2017), but only for a short period before it is presumed lens fibrosis and capsular shrinkage reduced the lens flexibility (Wolffsohn et al., 2006a; Wolffsohn et al., 2006b).
- Increased level of spectacle independence, but principally from pseudoaccommodative mechanisms (Pepose et al., 2017a)
- Newer designs (few clinically tested) include dual optics, shape changing optics and refractive index changing optics (Ben-Nun and Alio, 2005; DeBoer et al., 2016; McCafferty and Schwiegerling, 2015; Tomas-Juan and Murueta-Goyena Larranaga, 2015).
- In conjunction prevention &/or treatment of capsular contraction to prevent mechanisms inhibition explored (Pepose et al., 2017b).
Analysis of Accommodative Performance of a New Accommodative Intraocular Lens

Jorge L. Alió, MD, PhD, FEBophth; Aleksey N. Simonov, PhD; Daniel Roncero, BSc; Alexander Angelov, MD; Yavor Angelov, MSc; Willem van Lawick, MD; Michael C. Rombach, PhD

ABSTRACT

Satisfactory vision for both reading and far distances in presbyopic or pseudophakic eyes implanted with intramuscular lenses (IOls) can be achieved by extending

Figure 2. Mean objective accommodation with the accommodative (blue), monofocal (red), and control (green) groups. D = diopters
Inlays

- thin, small diameter, biocompatible materials with high fluid & nutrient permeability (Moarefi et al., 2017)
- femtosecond laser cut flap or pocket (deep) (Moarefi et al., 2017; Moshirfar et al., 2016a) / flocket (Konstantopoulos et al., 2017)
- epithelium remodels within zone ~2x inlay diameter (Lang et al., 2016), with ~19µm thinning regardless Rx (Steinert et al., 2017)
- Pulfrich effect (Plainis et al., 2013b), but no VF effect (Atchison et al., 2016).
- safe (Moshirfar et al., 2017), 2ndry surgical intervention in 12% of thin lens inlays within 3 years (over half explantations)
- meniscus shaped inlays cause only minimal DVA compromise in implanted eye & provide good NVA, stereopsis & CS (Igras et al., 2016a, b; Jalali et al., 2016; Lin et al., 2016; Linn et al., 2017).
- similar outcomes implanted pre/post traditional/femto cataract surgery (Ibarz et al., 2017; Stojanovic et al., 2016) & with simultaneous photorefractive keratectomy (PRK) (Moshirfar et al., 2016b).
- diffractive corneal inlays better performance? (Furlan et al., 2017).
Inlays

- thin ‘lens’ which reshapes anterior corneal surface creating -SA (Whang et al., 2017; Whitman et al., 2016a; Whitman et al., 2016b)
- corneal multifocality (distance vision through a plano central zone surrounded by rings of varying additional power)
- pinhole design to extends depth-of-focus (Dexl et al., 2015)

<table>
<thead>
<tr>
<th>Thickness</th>
<th>Diameter</th>
<th>Implantation Depth</th>
<th>Centration</th>
<th>Material</th>
<th>Mechanism of Action</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Raindrop</strong></td>
<td>32 µm</td>
<td>2 mm</td>
<td>120-200 µm</td>
<td>Central over light constricted pupil</td>
<td>Hydrogel</td>
</tr>
<tr>
<td><strong>Flexivue micro lens</strong></td>
<td>15-20 µm</td>
<td>3 mm</td>
<td>280-300 µm</td>
<td>Over 1st Purkinje image</td>
<td>Hydroxyethyl methacrylate &amp; methyl methacrylate + UV blocker</td>
</tr>
<tr>
<td><strong>KAMRA</strong></td>
<td>5 µm</td>
<td>3.8 mm (1.6mm central aperture)</td>
<td>200-250 µm</td>
<td>Over 1st Purkinje image</td>
<td>Polyvinylidene Fluoride</td>
</tr>
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Optoelectronic adjustable lens technologies

- Birefringent liquid crystals
  - Fresnel lens layers (Srivastava et al., 2015; Wang et al., 2014)
  - Flat gradient index lenses (Naumov et al., 1999; Ye et al., 2004)
  - Diffractive lenses (Li et al., 2006; Valley et al., 2010)
  - Flat lenses using inhomogeneous electric fields (Lin et al., 2005)
    - Demo LC embedded in PMMA contact lens (Milton et al., 2014)
    - Graphene electrodes (high electrical conductivity, transparency, flexibility & elasticity properties (Kaur et al., 2016)
- Electro-wetting lenses - modulate wetting angle of fluid droplet(s) suspended within annular electrode to change power through electric field - size limited by droplet inertial effects
Other

- Alvarez-Lohmann Lenses - complimentary mostly-cubic waveform on two lens elements

- fluid lenses - rigid frame holding elastic membrane filled with a transparent refracting fluid \((\text{Stevens et al.}, 2017)\)
Presbyopia IOLS

- Monovision
- MIOL
- EDOF
- AIOL
- Inlays
- Optoelectronic adjustable lens technologies
- Other
Competitors

- Spectacles
- Contact lenses
  - Monovision
  - Multifocal designs
- Surgical approaches
  - Scleral expansion
  - Laser Refractive
    - Corneal monovision
    - Corneal collagen shrinkage
    - Multifocal corneal laser profile
    - Lenticular ‘softening’
- Pharmaceuticals
- Ciliary muscle electrostimulation
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