IOL Review and FLACS Update

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Disclosures

- All material and information for this course was developed independently
- No financial disclosures
- Years ago, I was diagnosed with frostbite from eating ice cream with my bare hands

IOL Basics

- The first intra-ocular lens was implanted by Sir Harold Ridley in 1949. Prior to that, after cataract removal patients would be prescribed aphakic (massive) glasses
- Pilots in World War II sometimes got pieces of the plane canopy blown into their eyes. Ridley had noted the material seemed inert in the eye, which led to using Polymethylmethacrylate (PMMA) to make IOLs

IOL Material - PMMA

- PMMA remained the primary IOL material for several decades (IOL implantation was not really widely done until the 1970s).
- PMMA is a rigid material that will not fold. It also produces (even compared to newer material) relatively minimal inflammatory reaction, and because of these two properties is still used in the U.S. to make anterior chamber IOLs and is sometimes used for sulcus or iris-fixated IOLs. It is still broadly used in the developing world

IOL Material – Silicone

- In an effort to make incision sizes smaller, there was a push to develop a foldable IOL. In 1978, the first silicone IOL was implanted. Silicone was foldable and found to have good biocompatibility and PCO resistance
- Silicone lenses early on had some propensity to develop opacifications, and with the advent of silicone oil use for retinal detachment repair, were found to adhere irreversibly to injected silicone oil. Additionally, the material did not lend itself to the one-piece open loop style that had come into favor.

IOL Material – Hydrophilic Acrylic

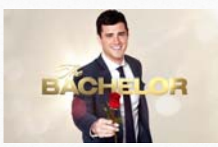
- The design for hydrophilic acrylic IOLs was actually done in the 1950s although they were not used until later on. These are very flexible, have good uveal bio-compatibility, and have a low index of refraction (may decrease dysphotopsias)
- However, the capsule biocompatibility is poor, leading to more opacification issues. More importantly, a few different models developed calcifications severe enough to require lens explantation. These have generally fallen out of favor in the U.S.

IOL Material – Hydrophobic Acrylic

- This the dominant material used in the U.S. today. A little less flexible than the hydrophilic and a little less uveal biocompatibility, but not enough to cause issues. They have excellent capsular biocompatibility, and are easily folded at room temperature with the one-piece open loop design.
- Higher index of refraction leads to more dysphotopsia – which has improved with progression of IOL design, but still an issue to consider

Why do we care?

- I don't know, why do people care about:



The Unhappy 20/20 Post-Op

- This is why we care. There's a lot more to vision than Snellen acuity, it's just that the other components are much more difficult to measure. Lens material/size/shape can affect these, as of course can patient expectations

So, back to IOL Design

- IOLs may have “sharp” or “rounded” edges.
  - A sharp or square edge helps prevent lens epithelial cell migration, decreasing PCO rates
  - A round edge, while more prone to PCO, is less likely to induce dysphotopsias

Optic size

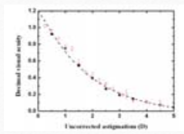
- Optic sizes for the most commonly used lenses range from 5.5-6.5mm
- Optics smaller than 6mm have been shown to have higher rates of dysphotopsias
- There also seems to be an inverse correlation between optic size and PCO rates at 1 year post-op

How about blue light filtering?

- Blue light filters were initially added to IOLs to help prevent photo-toxicity to the macula which could accelerate macular degeneration. However, later studies have fairly conclusively disproved the benefit of a blue filter with regards to macular degeneration progression
  - However, studies have shown that blue filtered IOLs improve glare disability and driving performance in the setting of glare
- Several laboratory studies have shown that blue filtered IOLs reduce incoming light particularly in scotopic conditions, may decrease contrast sensitivity based on the wavelengths blocked, and could cause physiologic changes (including insomnia) due to the loss of the signal these wavelengths provide.
  - However, clinical studies have failed to show any loss of contrast sensitivity or sleep changes with blue filtered IOLs

How about astigmatic correction?

- The first toric IOL was produced in 1992, though not FDA approved until 1998. The original designs often rotated postoperatively, but the rate of significant rotation has fallen to <10%. With the modern design, it has proved itself to be a more reliable means of astigmatism correction than LRI (or anything except excimer laser)
- The graph here demonstrates what visual acuity is achieved if a person achieves a post op spherical equivalent of plano, but has uncorrected astigmatism (+0.75 -1.50)
- This allows us to predict glasses dependence. While a patient with 1D of astigmatism post-op can routinely achieve 20/25 vision uncorrected (with the right SE), with 1.5D of cyl the typical uncorrected vision falls to around 20/40



Astigmatic Correction, cont'd

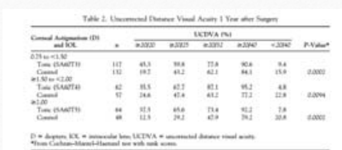


Table 2. Uncorrected Distance Visual Acuity 1 Year after Surgery

Corneal Astigmatism (D) and IOL	n	UCDVA (%) ≥20/20	≥20/25	≥20/32	≥20/40	<20/40	P-Value*
0.75 to <1.50							
Toric (SA60T3)	117	45.3	59.8	77.8	90.6	9.4	
Control	132	19.7	43.2	62.1	84.1	15.9	0.0001
≥1.50 to <2.00							
Toric (SA60T4)	62	35.5	62.7	87.1	95.2	4.8	
Control	57	24.6	47.4	63.2	77.2	22.8	0.0094
≥2.00							
Toric (SA60T5)	64	37.5	65.6	73.4	92.2	7.8	
Control	48	12.5	29.2	47.9	79.2	20.8	0.0001

D = diopters; IOL = intraocular lens; UCDVA = uncorrected distance visual acuity
*From Cochran-Mantel-Haenszel test with rank scores

Astigmatic Correction, cont'd

- So who should we discuss a toric lens with?
  - In patients with high visual needs or wants (police, pilot), it is reasonable to discuss a toric lens when corneal cyl is 0.75D or more.
    - This should come with the caveat that at this level of cylinder, an excimer laser is more precise than a toric. If they are willing to go through a second procedure, LASIK/PRK following cataract surgery would be the most reliable option
  - In my personal opinion, a toric should routinely be offered if corneal cyl >1.25 D. This of course assumes an otherwise healthy eye.

A Bad Joke

- How many optometrists does it take to screw in a lightbublb?
  - Not sure…maybe 1 or 2?

Presbyopia correcting IOLs

- The desire for glasses independence has driven the creation of bifocal IOLs, trifocal IOLs, accommodating IOLs, extended depth of focus IOLs, and more. Each platform has proved to provide superior near and/or intermediate Snellen acuity compared to a monofocal lens.
- However, these lenses have distinct drawbacks (and additional cost) which is why only a small minority of patients receive them

Multifocal IOLs

- Concentric rings on the IOL with diffractive/refractive elements (depending on which brand of IOL) allow for multiple points of focus, and consistently produce good Snellen acuity (20/25 or better) at both distance and near. Intermediate vision traditionally was poor, which has prompted the development of the "trifocal" IOL (still in approval process in U.S.)
- However, by virtue of creating good acuity at specified distances, only a portion of light can be focused at each distance, and light not at those particular distances is out of focus. This leads to poor contrast sensitivity which can create what patients describe as a "waxy" or "washed-out" appearance to their vision
- This design also creates halos and glare, the rates of which are much higher (compared to monofocal lenses) across all multifocal platforms.

Contrast Sensitivity

Multifocal IOLs, cont'd

- Multifocal lenses do not work well when implanted in one eye only, and therefore should only be done in someone who needs bilateral surgery
- The lenses must be perfectly centered with a clear capsule to work well, therefore it is not recommended in someone who has a large angle kappa, and early YAG is needed.
- There is a period after implantation where neuroadaptation occurs (seen on functional MRI) where the brain adapts to using the multifocal properties, and to the dysphotopsias. This process can routinely take 6 months, during which patients may be frustrated with their vision.

Multifocal IOLs, cont'd

- These lenses are not recommended in patients who have type A personalities, have high visual needs/demands, do night driving, or do a lot of intermediate work
- Despite the drawbacks, most patients are happy with multifocal lenses – studies typically find 90-95% of patients would pick the same lens if they had it do over again, and are "highly satisfied" with their outcome. However, for those who are unhappy, often the only treatment is lens explantation.
- In summary, multifocal lenses in the U.S. provide good Snellen acuity at distance and near, but with dysphotopsias, a neuro-adaptation time, and loss of contrast sensitivity

Accommodating IOLs

- The primary accommodating lens used in the U.S. is the CrystaLens, a silicone IOL which is marketed as being able to change shape/lens position with attempted accommodation to allow intermediate vision
- However, objective measurements have never been able to find more than a 0.4D change in the total dioptric power of the eye with accommodation, and some studies have found no change at all. Patients do consistently have improved intermediate vision compared to monofocal lenses, though few achieve good near vision. It is thought that the lens design may have an element of multifocality or local lens distortion centrally with attempted accommodation which allows for the improved intermediate vision
- These lenses do have near identical distance vision compared to monofocal lenses, with near equal contrast sensitivity (better than multifocal).
- In summary, these lenses provide good acuity at distance and intermediate, with minimal additional dysphotopsias or a reduction in contrast sensitivity. The "accommodating effect" is variable, however, and near vision typically remains poor

Extended Depth of Focus

- The most recently approved lens design, in 2015. This technology does not use the traditional "rings" like the multifocal lens, but instead "echelettes", a different type of diffraction grating to allow a more smooth transition between different distances.
- The advantage to this technology is that the contrast sensitivity is better compared to multifocal lenses, and initial studies reported less glare/halo effects. The intermediate vision is excellent, along with distance vision.
- The disadvantage is that near vision is relatively poor compared to other multi-focal lenses, often requiring reading glasses for smaller print. It still deals with the same glare/halo issues which plague multifocal lenses, with only slightly lower comparative incidence of dysphotopsias. So at this time it seems to have the same profile as an accommodating lens (good distance+intermediate), but still has the disadvantages of the multifocal lenses.

So what to make of all of that?

- Patients with type B personalities who are highly motivated to get out of glasses may prefer what presbyopia correcting lenses have to offer
  - If a patient does a significant amount of near work and little night driving (your reading/knitting crowd), a multifocal lens may be a good choice
  - If a patient does significant intermediate work and is more active, drives at night (the active grandpa golfer): accommodating IOL may be a good choice
  - Extended depth of focus is still looking for its niche…
- Many new lenses are coming down the pipeline and this was by no means an exhaustive list

Enough IOLs…

FLACS (Femtosecond Laser Assisted Cataract Surgery)

- FLACS was introduced in 2009 to much fanfare – automated, consistent wound creation, capsulorrhexis, LRIs, and nuclear fragmentation
- Almost a decade later, studies have yet to prove clear clinical advantages over traditional phaco (while the cost is astronomical). Its role has therefore yet to be established and widespread disagreement remains over its use.

FLACS clinical advantages

- Capsulotomy size and centration are more consistently ideal. As a caveat, this has not been shown to impact refractive outcomes in studies with monofocal lenses. For multifocal lenses where centration is critical, this is probably advantageous.
- Lower variability in surgically induced astigmatism, and on AS-OCT appears to have better endothelial alignment at the wound
- Can quickly make precise LRI – however minimal clinical data published on this yet, nothing to support superiority over traditional LRI
- Lens fragmentation allows for a reduction in effective phaco time, which may responsible for lower AC flare on POD1 (no difference by day 3). Some studies have shown less endothelial cell loss with FLACS, while other studies have not found a difference

FLACS clinical drawbacks

- Surgical time – even for surgeons familiar with FLACS, the time required to have the patient on two beds, the time required for eye "docking", etc. have been consistently shown to lengthen surgery time
- The eye "docking" system elevates IOP greatly and often causes SCH. In those eyes where the corneal curvature creates more unexpected folds when flattened, incomplete capsulotomy and other issues may arise
- The femtosecond capsulotomy will have more tags, rougher edges, and more demarcation lines compared to the manual technique. Re-fixation movements by the eye despite docking allow for stray laser shots which may damage the capsule just adjacent to the capsulotomy. This may explain why some clinical studies have found a higher rate of anterior capsular rents with FLACS compared to manual phaco (this is still up for debate as some studies have found equivocal rates).
- In eyes with poor dilation, can cause iris trauma and is more likely to cause irregular capsulotomy
- Significant increase in prostaglandin (pro-inflammatory) release in the anterior chamber compared to traditional phaco

Cost effectiveness

- This is usually measured for medical interventions with quality adjusted life years (QALYs). A typical well-established surgical intervention in the U.S. will cost between $3,000-$10,00 per one QALY.
- A study was performed assuming a slight improvement in refractive outcomes with FLACS (despite the fact this has not even been established).
  - Still, assuming that the refractive outcome improved by 5% for all FLACS patients, the cost per QALY would be $102,691.
  - In other words, the cost-effectiveness compares very poorly

Where FLACS could be better than manual

- Surgeons who struggle with manual capsulorrhexis creation
- Multifocal lenses
- Eyes with severe zonular weakness (manual capsulorrhexis relies on capsular tension, can reduce stress during nuclear removal)
- Pediatric cataracts (manual capsulorrhexis is more challenging, especially the posterior capsulorrhexis)
- White cataracts (theoretically might prevent Argentinian flag sign)
- ?? In Fuch's, post PKP

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