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# Current Safety Events with Premium IOLs

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# Categories

- Toric
- Multifocal
- Accommodating
- Phakic

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# Toric IOLs: Accuracy

- Miscalculation
  - Role of posterior corneal astigmatism
- Misalignment (eg, inaccurate marking)
- Postoperative rotation

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# ANSI standard for rotational stability (ANSI Z80.30, Toric Intraocular Lenses)

- In 90% of the treated eyes, the IOL rotates less than or equal to five degrees between two consecutive visits at least 3 months apart
- Report % of treated eyes with higher amounts of rotation

# Toric IOLs: Rotation (% of eyes)

Rotation	Staar <sup>1</sup>	AMO <sup>2</sup>	B&L <sup>3</sup>	Alcon <sup>3</sup>
$\leq 5^\circ$	62-75%	94%	80-91%	75-92%
$\leq 10^\circ$	90%	100%	98-100%	94-100%
$\leq 15^\circ$	98%	-	100%	100%
$\leq 20^\circ$	98%	-	-	-

1- Chang DF. J Cataract Refract Surg. 2003;29:935-40

2- Ferreira TB and Almeida A. J Refract Surg. 2012;28:551-5.

3- Kwartz J and Edwards K. Br J Ophthalmol. 2010;94:1003-6.

# Toric IOLs: Accuracy

- Safety issue:
  - Increased postoperative astigmatism
    - ◆ At a new meridian oblique to preop meridian
  - Patient difficulty with new spectacles
  - Need for surgical reintervention
    - ◆ Relaxing incisions, corneal ablation
    - ◆ IOL reposition or exchange

# Toric IOLs: Visual distortion

- Patient discomfort with:
  - Astigmatic correction
  - Induced cylinder
  - Induced HOAs
- Incidence: not reported
  - Personally have never seen it after first 2-3 weeks (in 2 patients)

# Multifocal IOLs: Quality of vision

- Loss of contrast sensitivity
  - Small and variable
- Glare (moderate: 21% - 36%<sup>1,2</sup>), halos (moderate: 16.3% - 22%<sup>1,3</sup>)
  - But high patient satisfaction overall
- Sensitivity to ametropia & astigmatism
  - Ideally  $\leq 0.5$  D for both



# Multifocal IOLs: Exchange rate

- Multifocal IOLs exchange rate:<sup>1</sup>
  - 7% in dissatisfied patients
- Randomized trial of multifocal IOLs vs. monovision with monofocal IOLs<sup>2</sup>
  - IOL exchange rate within 1 year:
    - ◆ Multifocal arm (Tecnis ZM900): 5.7%
    - ◆ Monovision arm (Akreos AO): 0%

1- Woodward MA, Randleman JB, Stulting RD. J Cataract Refract Surg. 2009;35:992-7  
2- Wilkins et al. Ophthalmology. 2013 Sep 23, doi: 10.1016/j.ophtha.2013.07.048. [Epub ahead of print]

# Multifocal IOLs: Exchange

- Multifocal IOLs exchange (n=30 eyes)<sup>1</sup>
  - IOL type:
    - ◆ Diffractive - 25 eyes (83%)
    - ◆ Refractive - 4 eyes (13%)
    - ◆ Progressive - 1 eyes (4%)
  - Common visual complaints:
    - ◆ Blurred vision - 11 eyes (36%)
    - ◆ Halos – 8 eyes (27%)

1- Tassignon et al. Acta Ophthalmol. 2013 May 7. doi: 10.1111/aos.12093. [Epub ahead of print]

# Accommodating IOLs: Mechanical

## ■ Subluxation

- Z syndrome with Crystalens<sup>1,2</sup>
  - ◆ Sporadic reports
  - ◆ Nd:YAG, reposition, exchange
- Anterior dislocation
- Posterior dislocation into vitreous

1-Yuen et al. J Cataract Refract Surg. 2008;34:1986-9

2- Jardim et al. J Cataract Refract Surg. 2006;32:347-50

# Accommodating IOLs: Other?

- Optical
  - Smaller optical zone
  - Induction of irregular astigmatism due to optic flexure if too flexible

# IOL exchange safety issues

- Overall excellent safety profile
  - No reported LOV in multifocal IOL exchange studies
- Two most common scenarios, assuming capsular fixation of IOLs
  1. Capsule intact, zonules intact
  2. Capsule open, zonules intact
  3. (Zonular support inadequate)

# Capsule and zonules intact

- High % of cases:
  - Reopen capsule
  - Lens exchange with new IOL in capsule

# Capsule open, zonules intact

- Anterior vitrectomy usually required
- Capsular fixation of new IOL rarely possible
  - Optic capture often possible

# Our series of MF IOL exchange: 45 eyes

- Anterior vitrectomy: 8 eyes (17.8%)
- Pars plana vitrectomy: 3 eyes (6.7%)
- Complications: 0%
- Loss of  $\geq 2$  lines: 0%



# Phakic IOLs<sup>1</sup>

- Cataract formation
  - In most studies, below 5% for clinically significant opacities but some are higher
- Endothelial cell loss
  - Verisyse: 4.8% in 3 years<sup>2</sup>
  - Cachet: 3.3% - 15.3% up to 3 years<sup>3,4</sup>
- Uveitis, glaucoma, synechiae
- Pupil ovalization

1-Kohnen T et al. *J Cataract Refract Surg* 2010; 36:2168-94

2- Stulting RD et al. *Ophthalmology*.2009;115:464-472

3- Silva RA, et al. *Arch Ophthalmol*. 2008;126:775–81.

4- Javaloy J, et al. *J Refract Surg*. 2007;23:147–58

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# Thank you for your attention

