

Aspheric Apodized Diffractive Multifocal IOL With +2.5 D Add Power: 6-Month Results

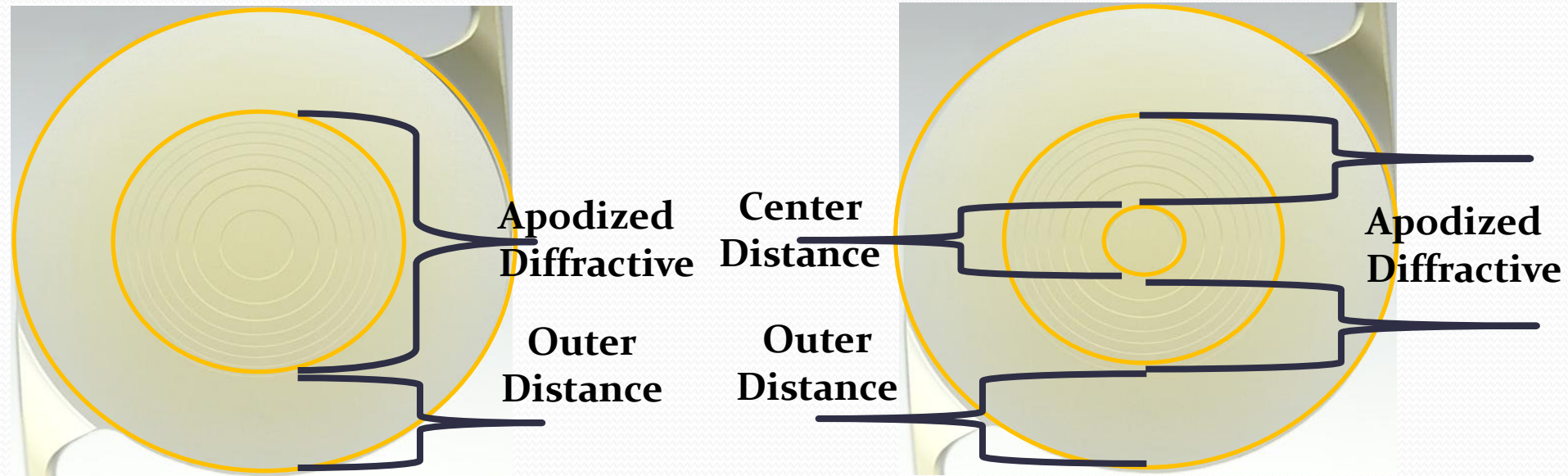
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Francesco Carones, MD is Paid Consultant for Alcon Laboratories, Inc.
This poster reports a medical device whose use in USA is off-label



ReSTOR 3.0

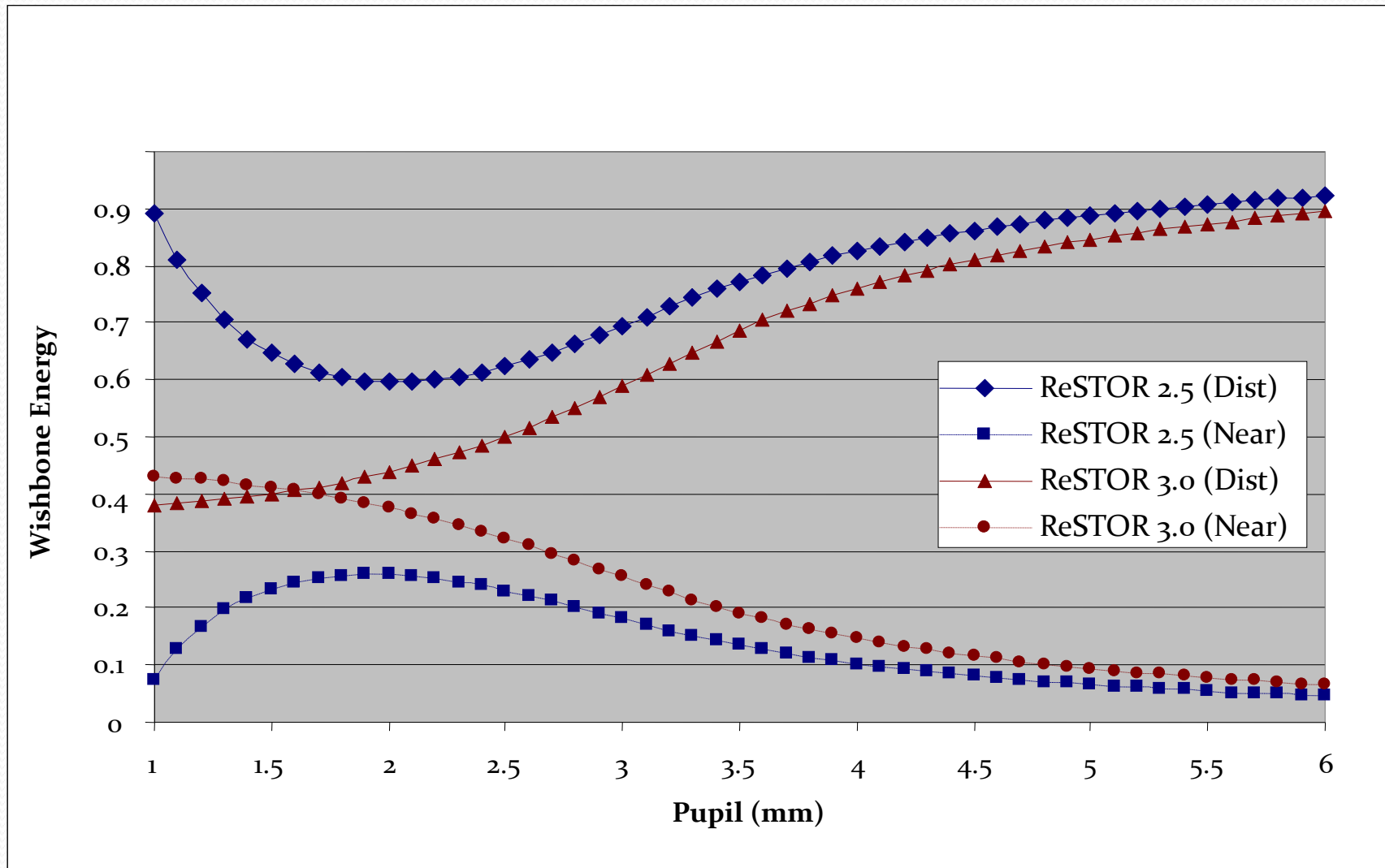
ReSTOR 2.5



- Reduced the add power from 3.0 D to 2.5 D by:
 - Reducing diffractive steps from 9 to 7 and increasing spacing
- Altered the light distribution by:
 - Increasing the distance function of the center zone from 41% to 100%
 - Reducing apodized diffractive area by 18% (from 10.2mm² to 8.4mm²)
 - Increasing the outer distance area by 6% (from 1.2mm to 1.3mm)

	ReSTOR +3.0 D	ReSTOR +2.5 D
Energy @ 3mm at IOL Plane (Starting Phase) Central Zone	Distance: 59.0% Near: 25.5% (0.521 waves) Diffractive	Distance: 69.4% Near: 18.0% (0.503 waves) Refractive
Add Power (Number of Zones) Apodized diffractive zone	+3.0 diopters (9 rings) 3.6 mm (diam.)	+2.5 diopters (7 rings) 3.4 mm (diam.)
Asphericity	-0.1 micron (center diffractive)	-0.2 micron (center refractive)

Energy Comparison of +2.5 D vs +3.0 D



Study Setup

80 ReSTOR 2.5 implanted

- 20 bilateral implants
- 40 monolateral implants (in the dominant eye, ReSTOR 3.0 in the non-dominant)
- Eyes with estimated postoperative astigmatism greater than 0.50 D were implanted with a toric IOL (39)
- Results at the last follow-up available (6 months)

Criteria for Implant

Bilateral ReSTOR 2.5

- Patients more concerned about quality of vision but still seeking for some spectacle independence
 - Reading glasses not a problem
- Patients with significant activities at intermediate, younger and taller

Blending ReSTOR 2.5 and 3.0

- Patients more interested in a full-range of unaided vision and not too much concerned about quality of vision
 - Eye dominance assessment possible and reliable
 - 2.5 in the dominant eye
 - 3.0 in the non-dominant eye

Outcomes Assessment

- Refraction
- Best distance-corrected visual acuity
- Uncorrected visual acuity
 - 4 meters for distance
 - 60 cm for intermediate
 - 40 cm for near
- Subjective evaluation questionnaire, scale 0-5
 - Spectacle dependence
 - Light dependence for reading
 - Patient satisfaction

Results – Refraction

ReSTOR 2.5

- 72/80 eyes (90%) were within ± 0.50 D of intended MRSE (range +0.75 to -0.75 D)
- 73/80 eyes (91.2%) had 0.50 D or less residual refractive astigmatism (range 0 to 1.00 D)

ReSTOR 3.0

- 37/40 eyes (92.5%) were within ± 0.50 D of intended MRSE (range +0.25 to -0.75 D)
- 37/40 eyes (92.5%) had 0.50 D or less residual refractive astigmatism (range 0 to 1.00 D)

Results – Visual Acuity

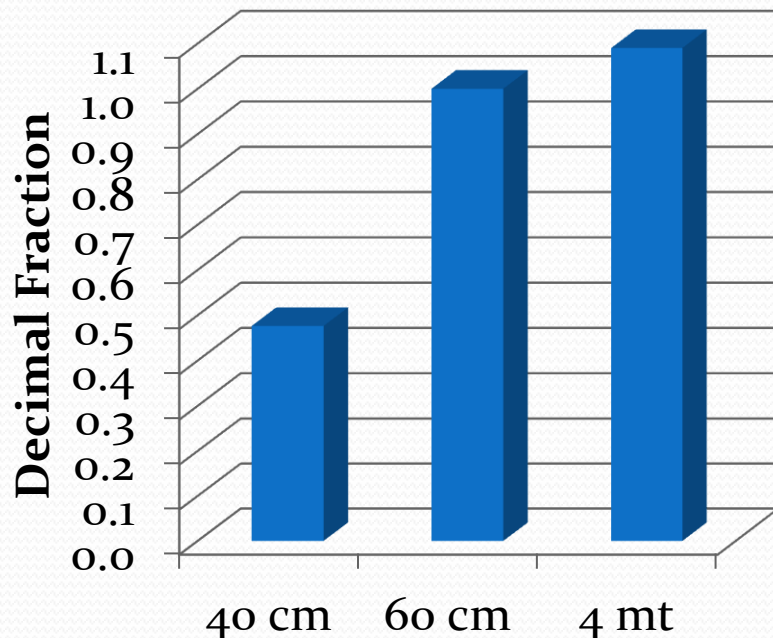
- All 80 eyes with ReSTOR 2.5 had 20/20 or better BSCVA
- All 40 eyes with ReSTOR 3.0 had 20/20 or better BSCVA
- For 20 patients implanted bilaterally with ReSTOR 2.5 when assessed binocularly:
 - All patients had 20/20 or better UCVA at 4 meters
 - All patients had 20/20 or better UCVA at 60 cm
 - 6 patients (30%) had 20/20 and all had 20/50 at 40 cm
- For 40 patients who received ReSTOR 2.5 in the dominant eye and 3.0 in the non-dominant eye, when assessed binocularly:
 - All patients had 20/20 or better UCVA at 4 meters
 - 37 patients (92.5%) had 20/20 or better UCVA at 60 cm
 - 30 patients (70%) had 20/20 and all had 20/32 at 40 cm

Uncorrected Visual Acuity

Bilateral ReSTOR 2.5

Blending ReSTOR 2.5 and 3.0

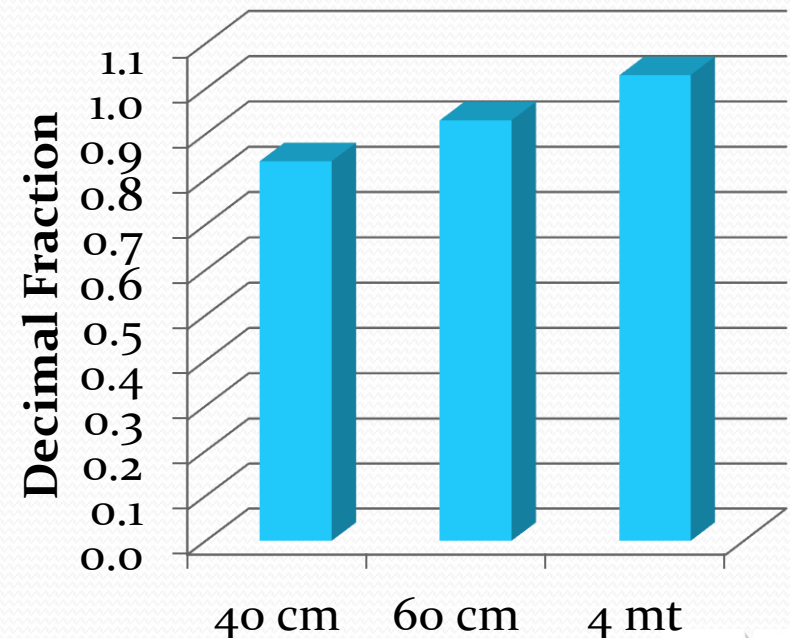
Mean UCVA



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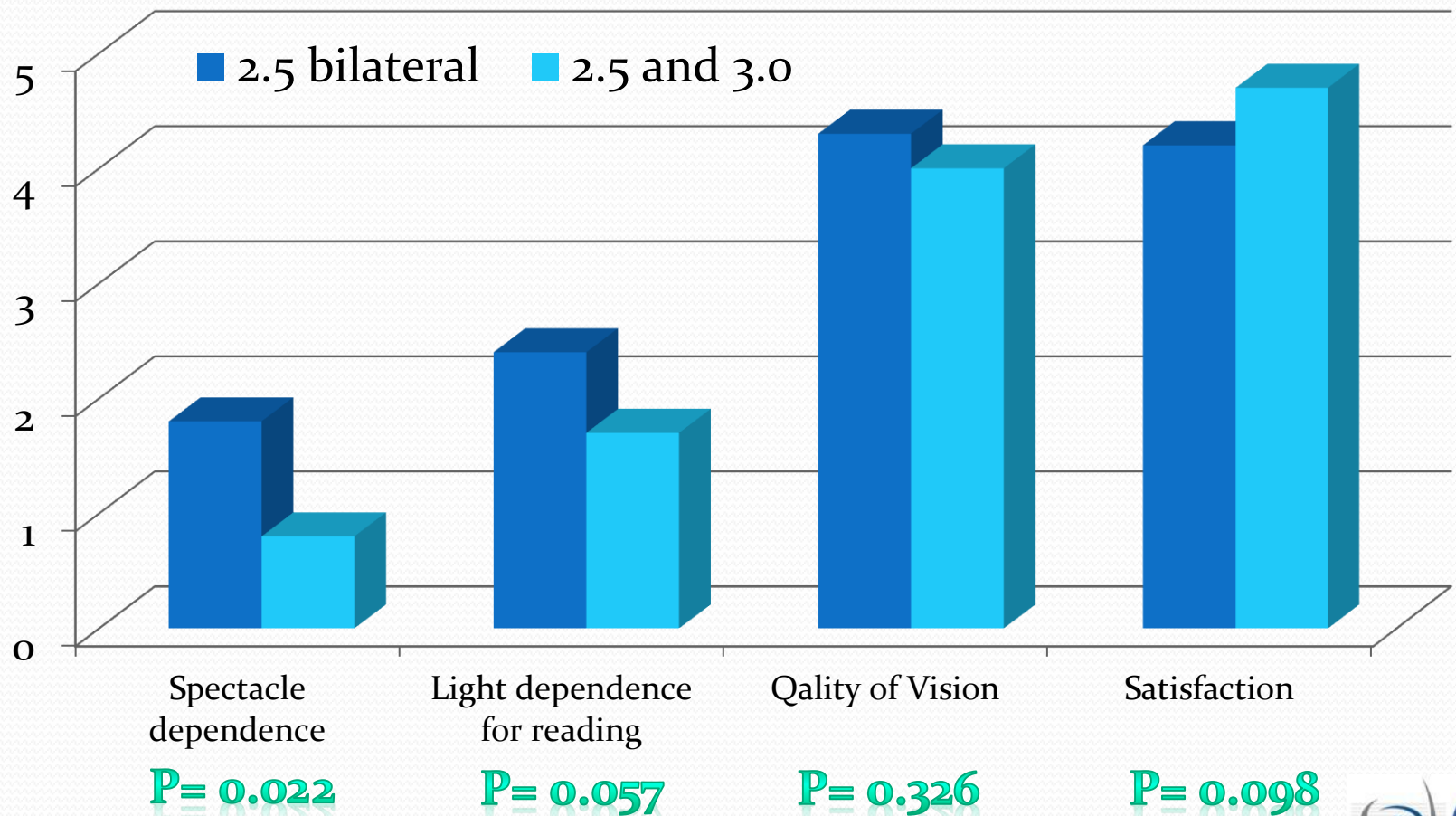
*P= 0.0012

Mean UCVA



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Subjective Questionnaires



Conclusions

- According to the subjective patient assessment, the ReSTOR 2.5 provides very good results in terms of vision sharpness and absence of meaningful night-vision problems.
- When implanted bilaterally, the ReSTOR 2.5 meets the expectations of those patients concerned about quality of vision but willing to gain some spectacle independence (particularly for intermediate tasks like computer and monitor use), who do not care occasionally using reading glasses for their activities at near.
- The blended approach (ReSTOR 2.5 implanted in the dominant eye and ReSTOR 3.0 implanted in the non-dominant eye) seems to improve overall spectacle independence and therefore patient satisfaction, without significantly affecting quality of vision and night-time disturbances.