

# Evaluation of Bilateral versus Combination Crystallens, ReZoom and ReSTOR

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The author does not have any financial interests in the  
products presented herein

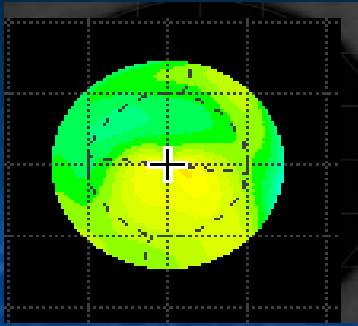
# Presbyopic IOLs

## ■ Accommodative Lenses

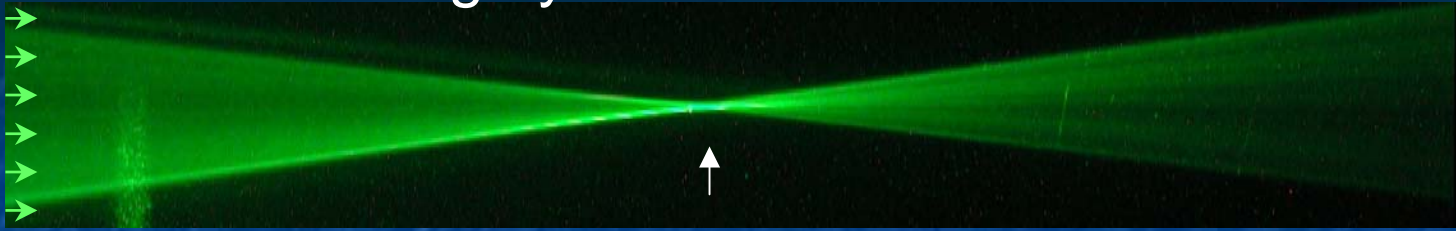
- Monofocal – Available light is focused to a single point
- Lens responds to the natural accommodative response

## ■ Multi-focal Lenses

- Multiple focal points in the eye with the diffraction of available light
  - Near dominant - ReSTOR™
  - Distance dominant - ReZoom™

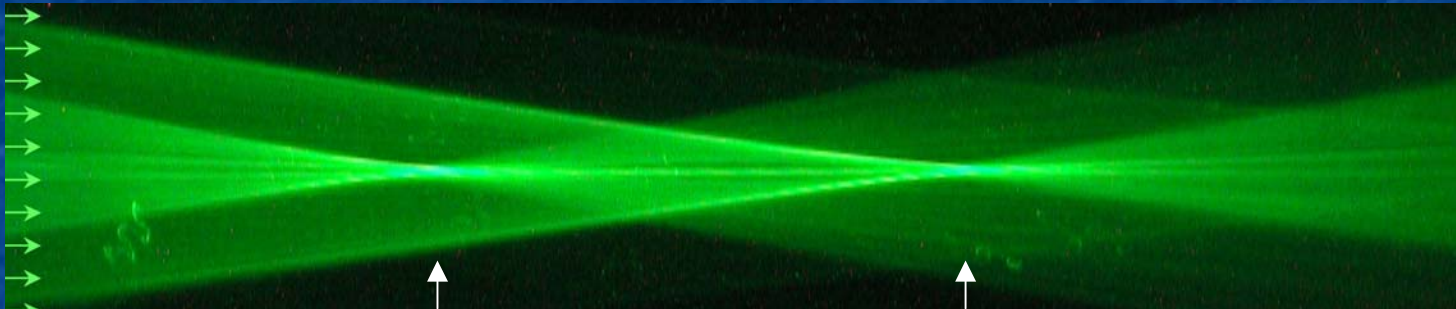
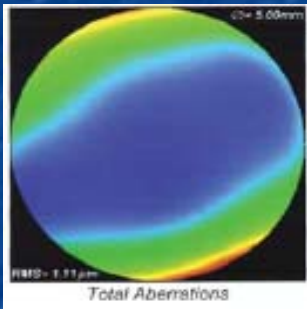


Accommodating eye focused at distance



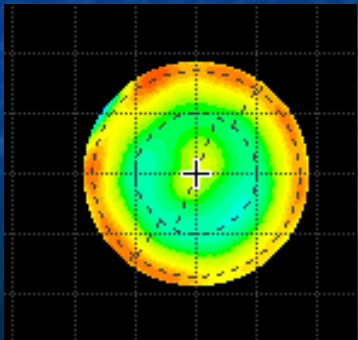
far focus

Diffractive lens focused at distance

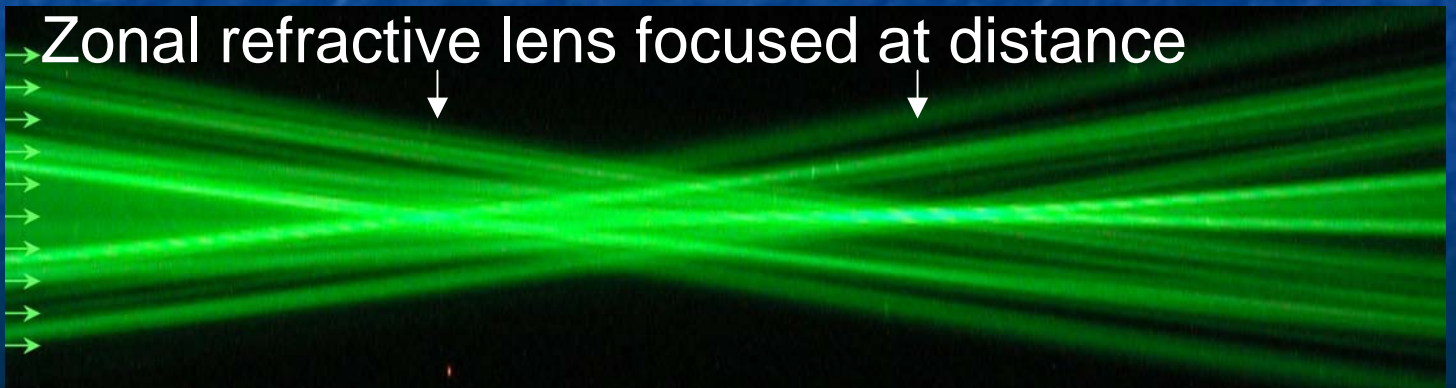


near focus

far focus



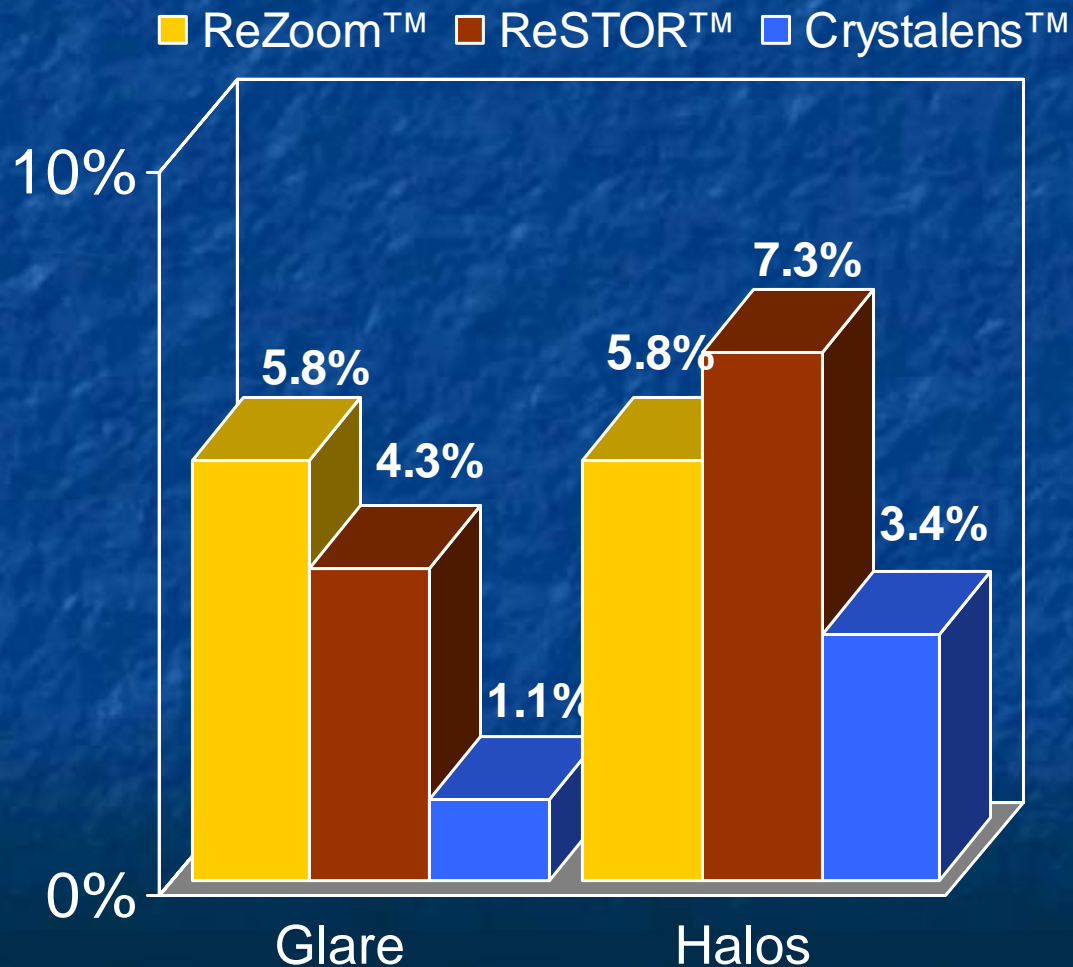
Zonal refractive lens focused at distance



# Distribution of Light Rays

	<b>Pupil</b>	<b>ReZoom</b>	<b>ReStor</b>	<b>crystalens</b>
Near	2 mm	0%	40%	<b>100%</b>
	5 mm	32%	84%	<b>100%</b>
Distance	2 mm	83%	40%	<b>100%</b>
	5 mm	58%	10%	<b>100%</b>
Intermediate	2 mm	17%	0%	<b>100%</b>
	5 mm	10%	0%	<b>100%</b>
Lost	2 mm	0%	20%	<b>0%</b>
	5 mm	0%	6%	<b>0%</b>

- Multifocal IOLs are associated with more halos and glare





# Multicenter Clinical Trial

- 6 clinical sites
- Five Arms
  - Bilat. Crystalens (n=14)
  - Bilat. ReSTOR (n=12)
  - Bilat. ReZoom (n=14)
  - Crystalens-ReSTOR (n=6)
  - Crystalens-ReZoom (n=3)

# Multicenter Clinical Trial

- Study Design
  - Prospective
  - Bilateral implantation
  - Small incision phacoemulsification
  - Inclusion: Best Distance Corrected VA 20/40 or better
  - Exclusion:
    - Corneal astigmatism  $> 1.5$  D
    - Anterior segment, retinal pathology
    - Glaucoma
    - Congenital cataracts
    - Intraoperative complication
    - Mesopic pupil  $> 6$  mm

# Diagnostic Testing: Postop 4-6 m

- UCVA at Distance (UCD with ETDRS chart)
- UCVA at Intermediate (UCI at 32")
- UCVA at Near (UCN at 16")
- Manifest refraction
- Distance-corrected VA at Intermediate (no Add; DCI at 32")
- Distance-corrected VA at Near (no Add; DCN at 16")
- Best corrected Near VA (BCN with manifest and add at 16")
- Optec Contrast Sensitivity Function
  - With best distance correction: Mesopic, with & without glare
  - 1.5, 3, 6, 12, 18 cpd
- Questionnaires
  - SVQ (Frankel et al. J Refract Surg 2004;20:10-19)
  - NEI RQL (McDonnell et al. Ophthalmology 2003;110:2302-2309)

# Monocular Refractive Results at Postoperative 4 m – 6 m (mean values)

Lens	n	UCD (20/)	BCD (20/)	Sphere (D)	CYL (D)	Add (D)
<b>Crystalens</b>	37	25.45	16.59	-0.37	-0.41	1.51
<b>ReSTOR</b>	31	28.38	21.90	+0.23	-0.30	0.98
<b>ReZoom</b>	32	23.69	19.66	+0.30	-0.43	1.13

- No statistical difference in Mean UCdVa b/w 3 groups
- BCDVa better in Crystalens ( $p < 0.05$ )
- Crystalens with myopic Sphere relative to other 2 groups ( $p < 0.05$ )
- Crystalens required a higher Add at 16" than ReSTOR or ReZoom ( $p < 0.05$ )
- No statistical difference in Reading Add for ReSTOR & ReZoom ( $p = 0.39$ )

# Monocular Refractive Results at Postoperative 4 m – 6 m (mean values)

Lens	n	UCI (20/)	DCI (20/)	UCN (20/)	DCN (20/)	BCN (20/)
<b>Crystalens</b>	37	17.84	20.84	31.76	41.00	19.78
<b>ReSTOR</b>	31	38.94	35.85	27.77	32.61	22.84
<b>ReZoom</b>	32	28.03	28.03	35.56	37.09	23.06

- UCI & DCI: Crystalens statistically better than both ReSTOR & ReZoom ( $p < 0.05$ ). UCI/DCI better for ReZoom than ReSTOR.
- UCN: ReSTOR better than ReZoom ( $p < 0.05$ ), but not different from Crystalens ( $p = 0.15$ )
- DCN: With manifest refraction (but no Add), ReSTOR mean near acuity statistically better than Crystalens ( $p < 0.05$ )
- BCN: Crystalens better than both ReSTOR & ReZoom ( $p < 0.05$ ); no statistical difference b/w ReSTOR & ReZoom ( $p = 0.88$ ).

# Binocular Refractive Results at Postoperative 4 m – 6 m (mean values)

	n	UCD (20/)	BCD (20/)
Crystalens OU	14	18.82	15.43
ReSTOR OU	12	22.75	<b>19.46</b>
ReZoom OU	14	17.86	17.14
CCL – RS	6	17.00	14.92
CL – RZ	3	18.67	19.17

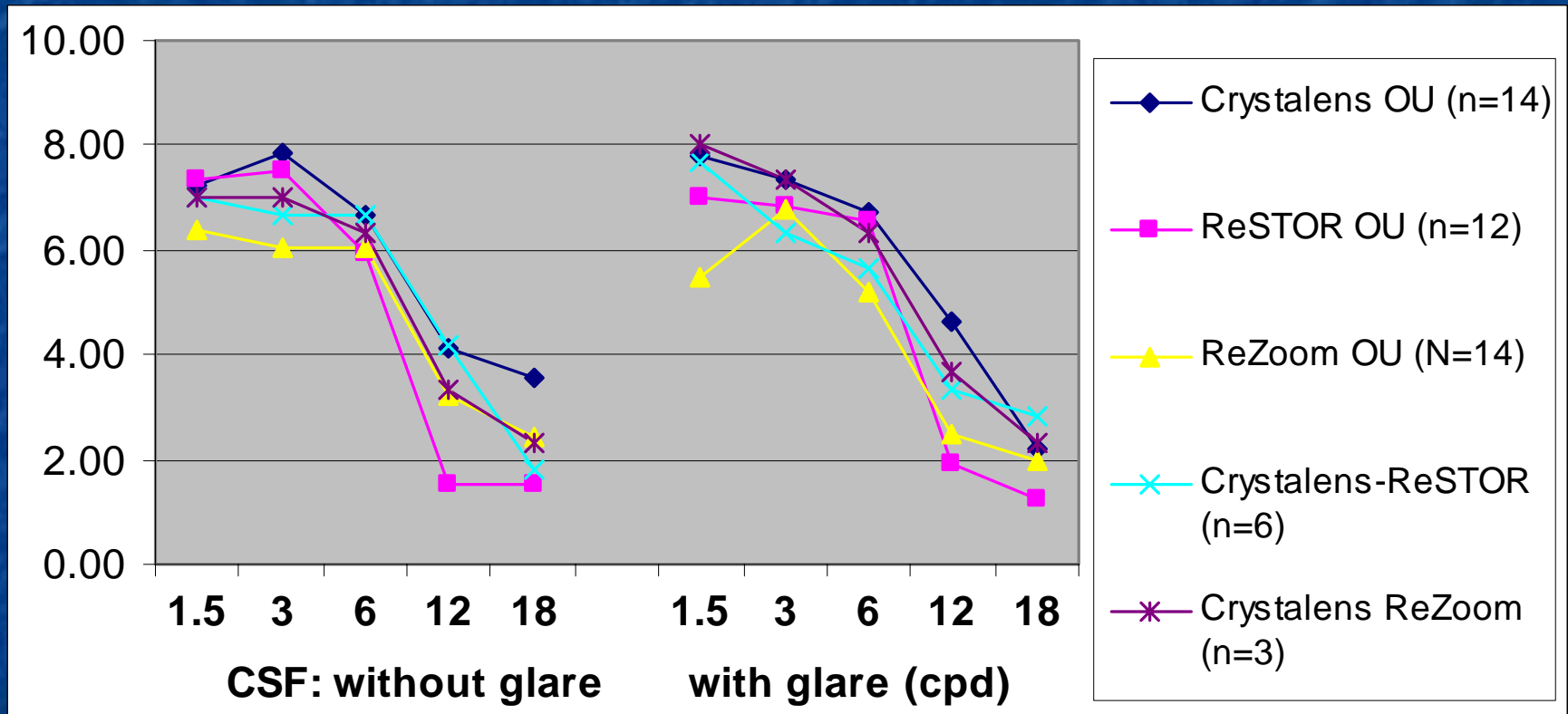
- No statistical difference in Mean UCDA b/w 5 groups
- Lowest mean Best Distance corrected acuity was with bilateral ReSTOR (p=0.027 compared to Crystalens OU)

# Binocular Refractive Results at Postoperative 4 m – 6 m (mean values)

	n	UCI (20/)	DCI (20/)	UCN (20/)	DCN (20/)	BCN (20/)
Crystalens OU	14	14.57	16.96	24.93	31.50	17.43
ReSTOR OU	12	34.21	36.08	21.58	25.59	19.25
ReZoom OU	14	23.79	23.71	30.64	28.36	21.14
CL - RS	6	16.00	14.75	19.50	24.83	15.00
CL – RZ	3	19.00	22.67	32.33	30.67	20.33

- UCI & DCI: Crystalens OU statistically better than both ReSTOR OU & ReZoom OU ( $p < 0.05$ ), but statistically similar to CL-RS ( $p > 0.4$ ) & CL-RZ ( $p > 0.1$ ).
- Near Vision: ReSTOR in one or both eyes provided better near vision (but lowest mean intermediate vision measurements when inserted bilaterally)

# Binocular Best Spectacle Corrected Contrast Sensitivity: without and with glare

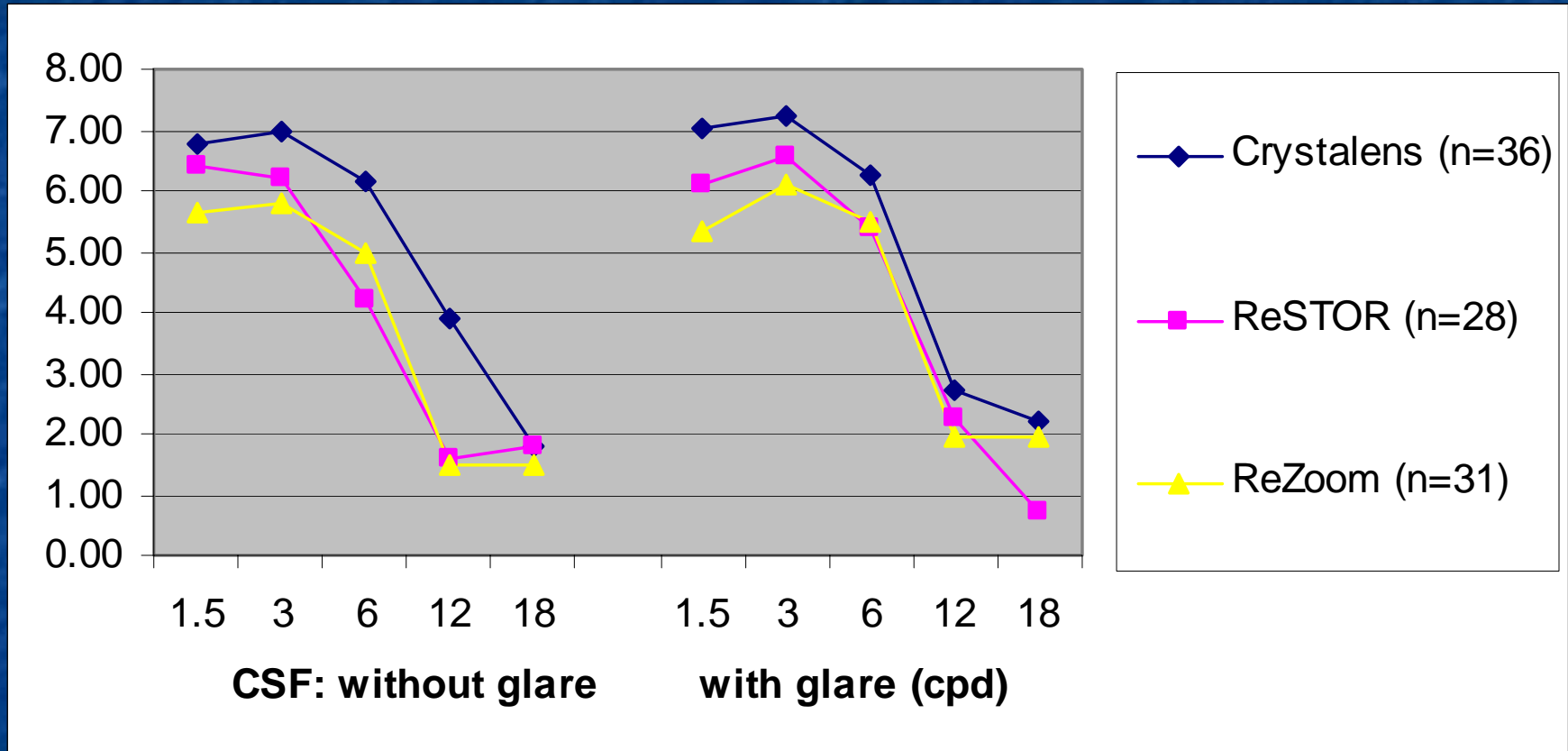


Crystalens OU statistically higher CSF scores than:

ReSTOR OU at 12 cpd, 18 cpd without glare & 12 cpd with glare

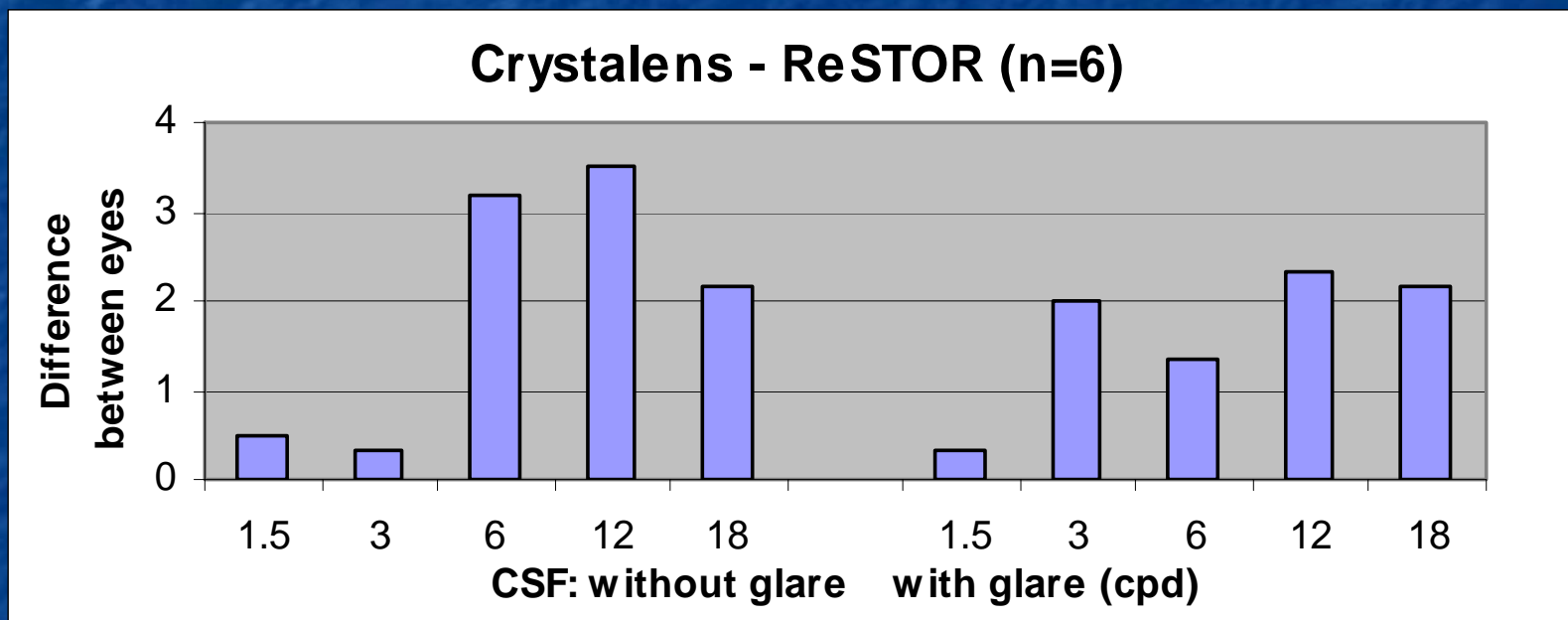
ReZoom OU at 3 cpd without glare & 1.5 cpd with glare

# Monocular Best Spectacle Corrected Contrast Sensitivity: without and with glare



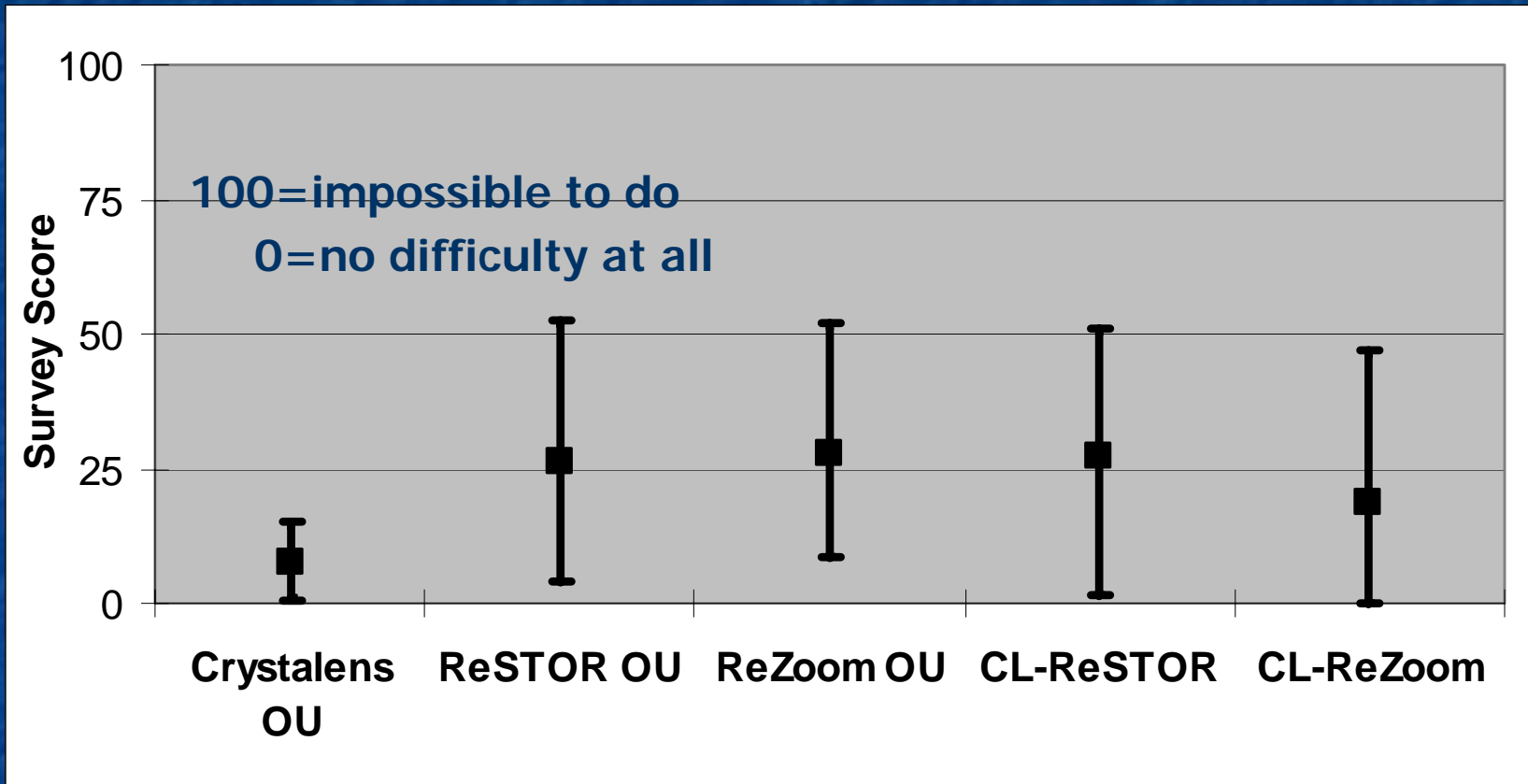
- Mean Crystalens CSF higher at all frequencies tested than both ReSTOR & ReZoom
- Crystalens CSF better than ReSTOR (6,12 cpd; with glare 1.5,18 cpd) ( $p < 0.05$ )
- Crystalens CSF better than ReZoom (1.5,3,6,12 cpd; with glare 1.5, 3 cpd) ( $p < 0.05$ )
- ReZoom CSF not different from ReSTOR (except with glare at 18 cpd,  $p < 0.05$ )

# Difference in Mesopic CSF (without & with glare) in Patients with Crystalens & ReSTOR combination



The difference between mean mesopic CSF was better for Crystalens eyes at all frequencies tested, with and without glare

# Responses to Subjective Vision Questionnaire



The Bilateral Crystalens group had statistically better SVQ scores than the other 4 groups ( $p < 0.016$ )

Fraenkel et al. *J Refract Surg* 2004;20:10-19

# Conclusions

- Monocular testing:
  - Crystalens eyes had statistically better:  
BCD, UCI, DCI, BCN
  - ReSTOR eyes had:  
Statistically better UCN, DCN & required the lowest reading add  
Statistically worse UCI, DCI
- Binocular testing:
  - Any combination of Crystalens in one or both eyes better for Intermediate
  - Any combination of ReSTOR for one or both eyes better for Near
  - Crystalens-ReSTOR combination with better mean Intermediate and Near visual acuities overall
- CSF better with Crystalens when tested monocularly, binocularly and in comparing results in patients enrolled in Crystalens-ReSTOR study arm
- Binocular Subjective Vision Questionnaire was favorable for Bilateral Crystalens group