

Mixing Presbyopia-Correcting IOLs

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J. Trevor Woodhams, MD
(Atlanta, USA)



FINANCIAL DISCLOSURE

I have been granted stock options in Eyeonics, Inc. and am reimbursed for travel expenses on an occasional speaking basis.

PRESBYOPIC LENS EXCHANGE OPTIONS

- Bilateral monofocal lens w/MV (Monovision)
- Bilateral Crystalens IOLs (Distance set)
- Bilateral Crystalens IOLs (w/modified MV)
- Combination Crystalens & multifocal
 - Crystalens/Restor
 - Crystalens/ReZoom
- Bilateral matched multifocal implants
- Bilateral mixed multifocal implants
 - Restor/ReZoom

VISUAL OUTCOMES WITH MATCHED ACCOMMODATIVE & MULTIFOCAL IOLS

	UCDVA (>20/40)	UCNVA (J3)	Spectacle* Independence	Significant NVS
Monofocal IOL (Lindstrom)	99%	37%	11%	3%
Array** (Bucci, Fine, Javitt, Steinert)	97%	91%	76%	10%
ReStor (Kohnen)	99%	98%	74%	10%
Crystalens (Fine, Lindstrom, Vigo)	100%	98%	74%	5%

*Never or almost never

**No longer commercially available

THE PREMIUM IOL OPTICS

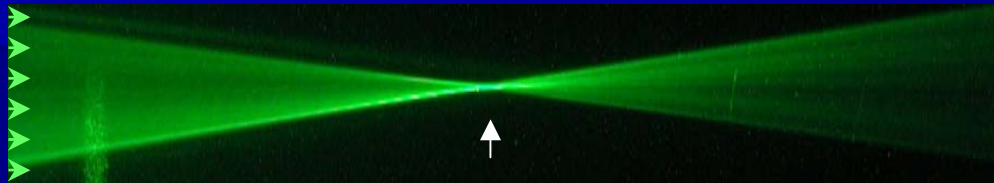
■ Accommodative Lens

- Monofocal – All available light focused to a single point
- Full Range of Vision – Lens responds to the natural accommodative response
- Accommodative arching – occurs in both the natural lens and the Crystallens

■ Multi-focus Lenses

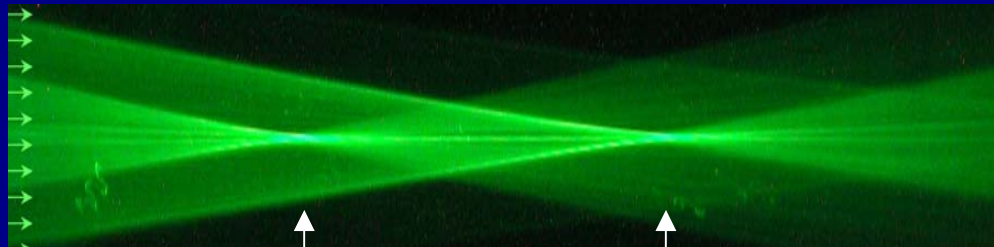
- Multiple focal points in the eye with distortion &/or loss of available light
- Engineered, fixed focal points
 - Near dominant - ReSTOR™
 - Distance dominant - ReZoom™

LIGHT RAYS THROUGH PREMIUM IOLS



focus

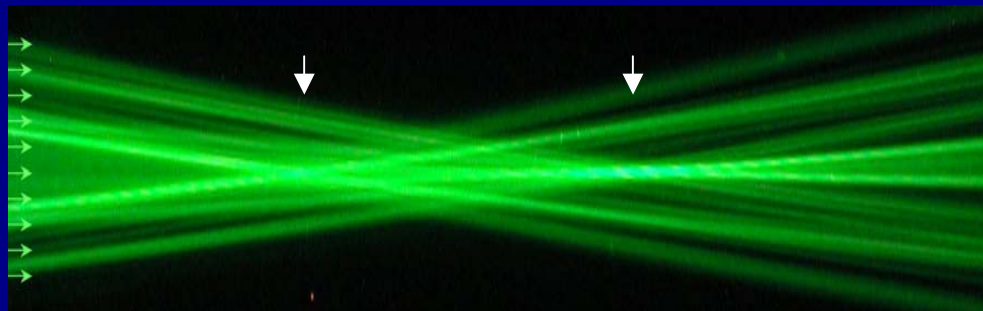
Monofocal
(Accommodative)



near

far

Diffractive

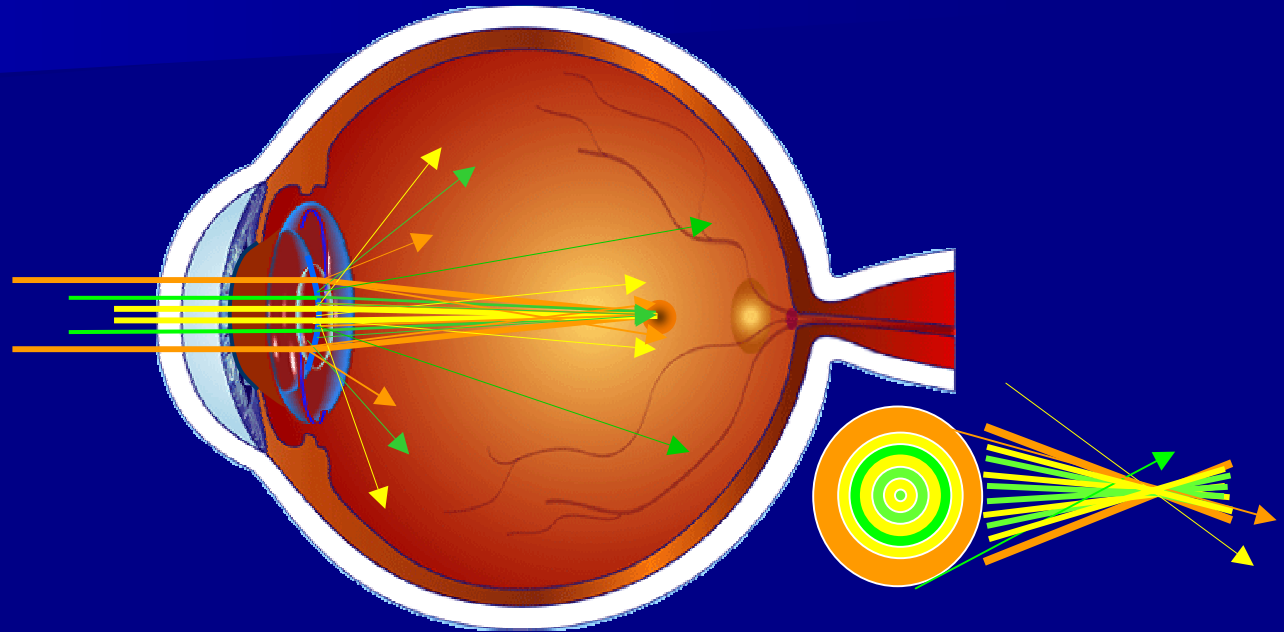


Multifocal

MULTI-FOCUS LENSES



Diffractive



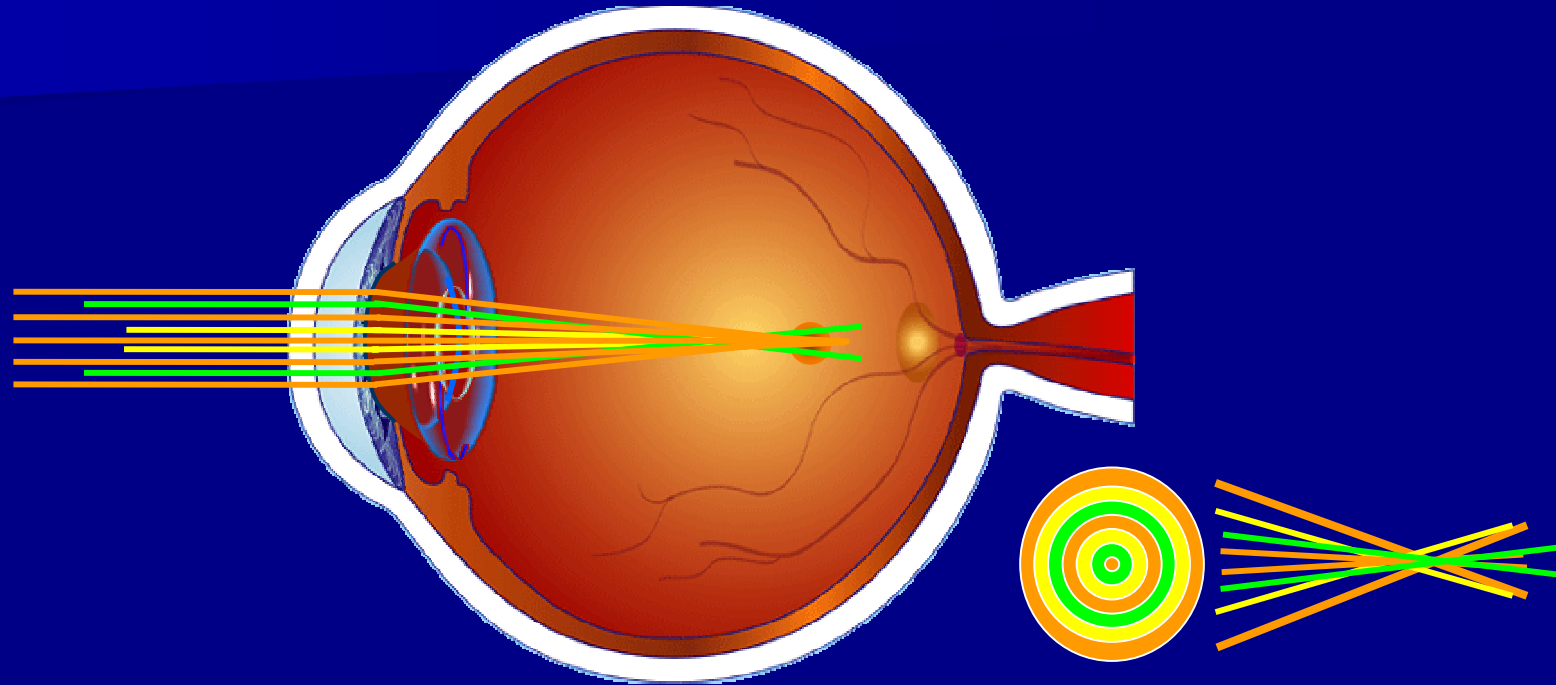
	% Light Distribution*			
	Near	Intermediate	Far	Light Lost
2 mm Pupil	40%	0%	40%	20%
5 mm Pupil	10%	0%	84%	6%

* ReSTOR® Product labeling

Multi-Focus Lenses



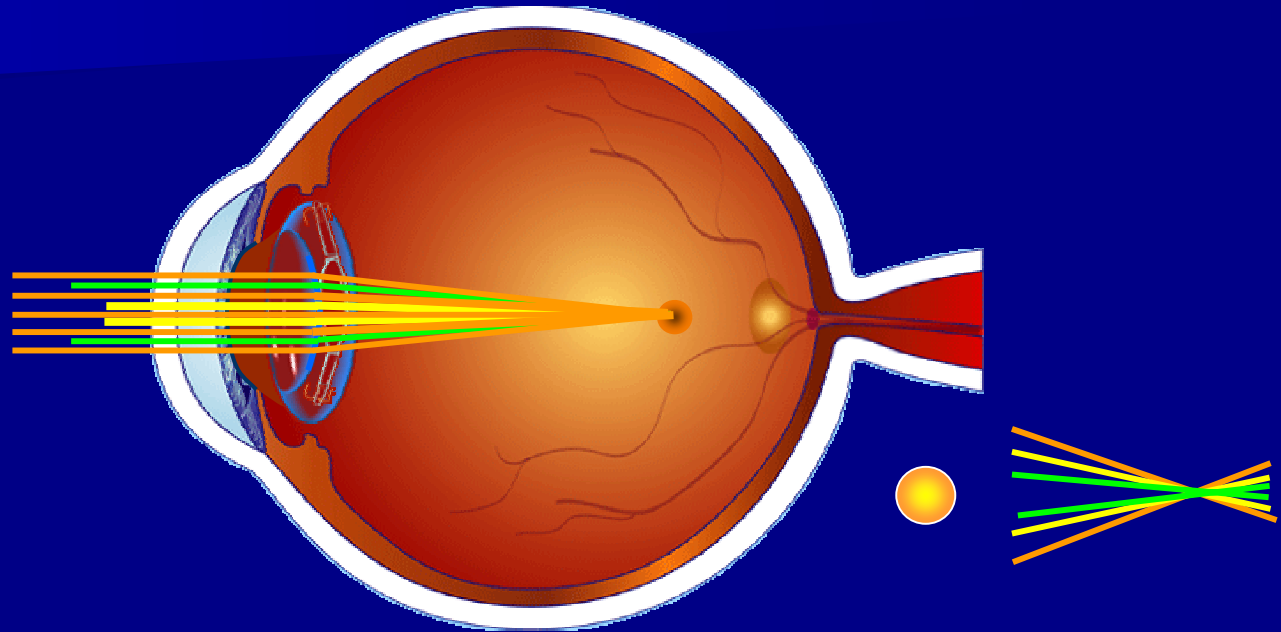
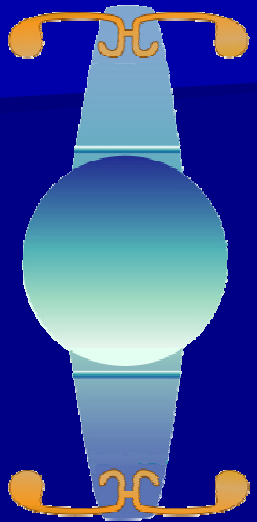
Refractive



	% Light Distribution			
	Near	Intermediate	Far	Light Lost
2 mm Pupil	0%	17%	83%	0%
5 mm Pupil	30%	10%	60%	0%

*ReZoom® Product labeling

ACCOMMODATIVE LENS



	% Light Distribution			
	Near	Intermediate	Far	Light Lost
2 mm Pupil	100%	100%	100%	0%
5 mm Pupil	100%	100%	100%	0%

WHY MIX IOL STYLES AND RISK ANISOMETROPIC PROBLEMS?

- Poor intermediate distance performance of Restor IOL
- Reading distance of bilateral Restor too close for many people accustomed to presbyopia-induced distance
- Compromise of optical performance inherent in diffractive IOL design
- Low amplitude of accommodation (as yet)

STUDY GOALS

- To Evaluate & Compare Binocular Visual Function of Mixing:
 - Crystalens-Restor IOLs in Presbyopic Lens Exchange

At:

Using:

1) Distance

A) Single eye (Dominant)

2) Intermediate

B) Single eye (Non-Dominant)

3) Near

C) With Binocular Viewing

INVESTIGATION DESIGN

(1)

- 50 consecutive patients with planned LEXiS-P (Presbyopic Lens Exchange Surgery)

INVESTIGATION DESIGN

(2)

- Dominant Eye: Crystalens
- Non-Dom: Restor
- 2-6 weeks apart
- Goal: +0.25 D. OU

DEMOGRAPHICS

- #M:#F :: 23:27
- Age Range (50-74)
- Ocular Dominance in OD in 30 of 50 patients
- BSCVA \geq 20/20 (all eyes)

SECONDARY PROCEDURES

Crystalens

- 10 YAG
- 1 LASIK

Time to YAG: >3
months

Restor

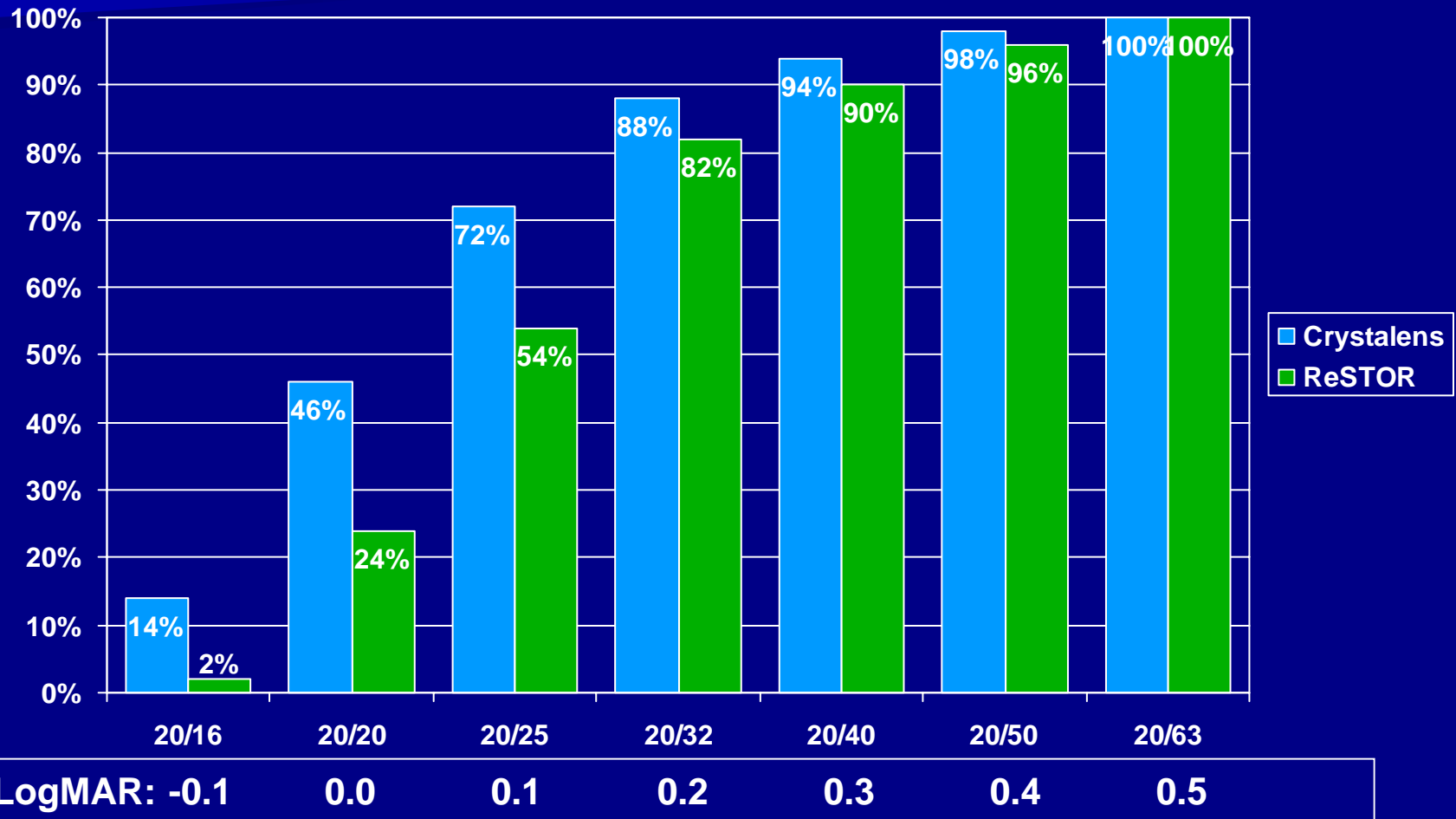
- 5 YAG
- 1 LASIK

Time to LASIK: >3
months

ACCOUNTABILITY

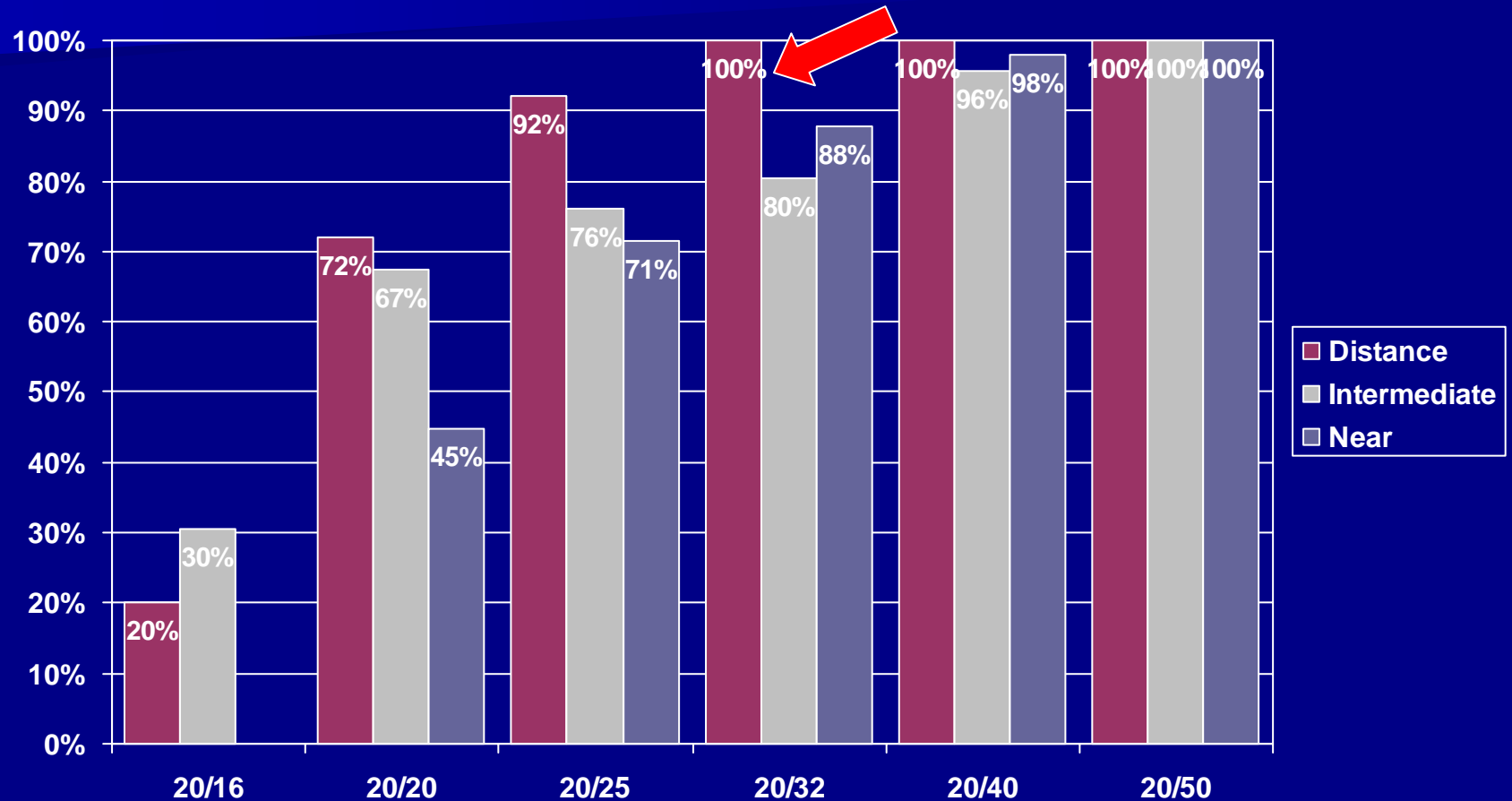
- 50 (100%) available at 3+ months post IOL surgery
- Exams >3 months post LASIK (in both cases)

UNCORRECTED DISTANCE ACUITY (monocular)



UNCORRECTED VISUAL ACUITY

Binocular



LogMAR:	-0.1	0.0	0.1	0.2	0.3	0.4
Jaeger (Int):	J2	J3	J5	J6	J8	J10
Jaeger (Near):	---	J1+	J1	J2	J3	J5

HOW WAS "NEAR" VISION MEASURED?

- Patient self-selected "sweet" spot, distance then recorded*

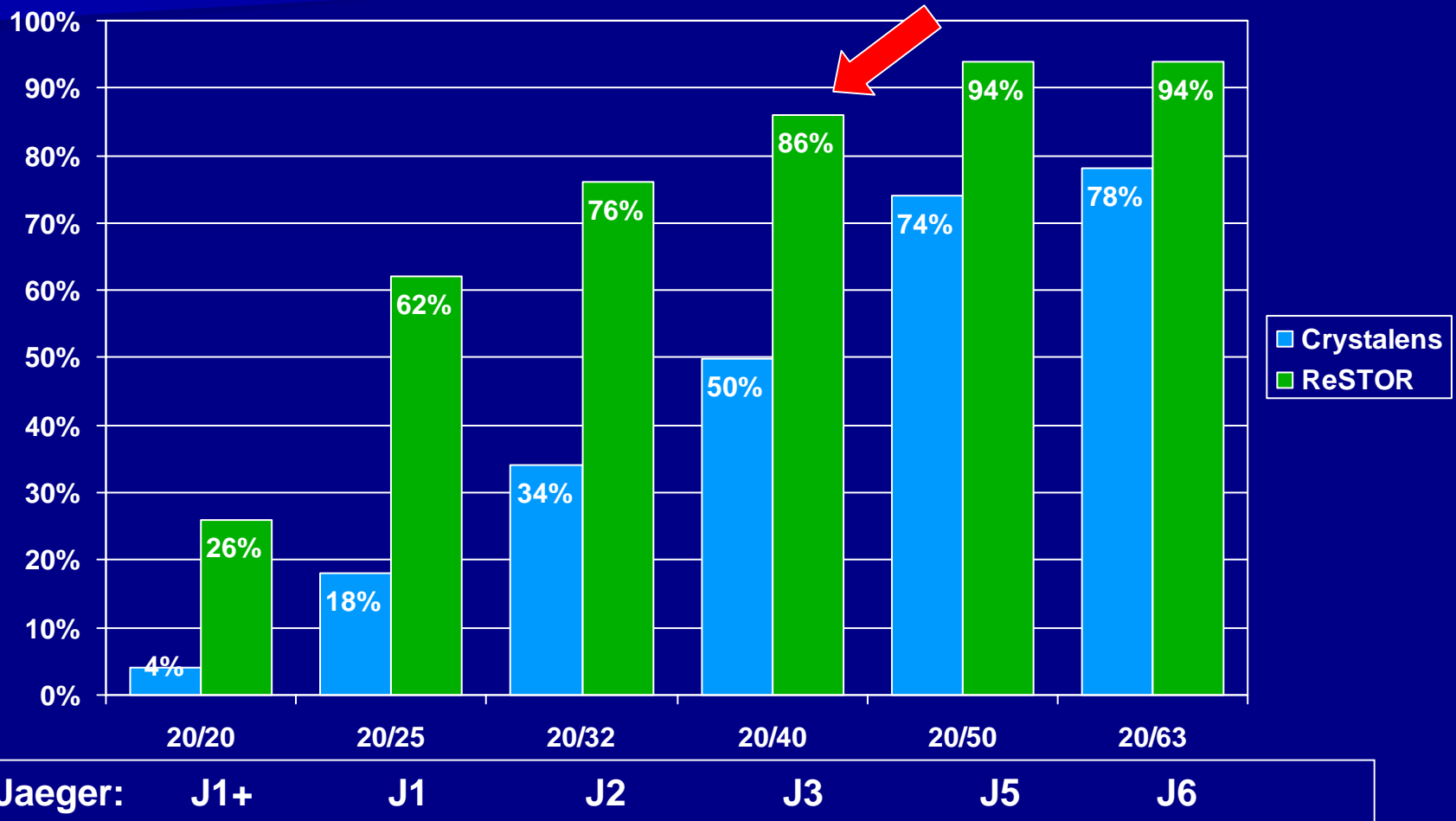
Crystalens	
Mean	15"
Range	9 - 19
SD	6.0

Binocular	
Mean	14"
Range	9-19
SD	5.5

Restor	
Mean	12"
Range	7-16
SD	2.5

*inches

UNCORRECTED NEAR VISUAL ACUITY (monocular)



Note: Near card was held at an average distance of 14 inches and ranged between 9 and 19 inches.

HOW WAS "INTERMEDIATE" VISION MEASURED?

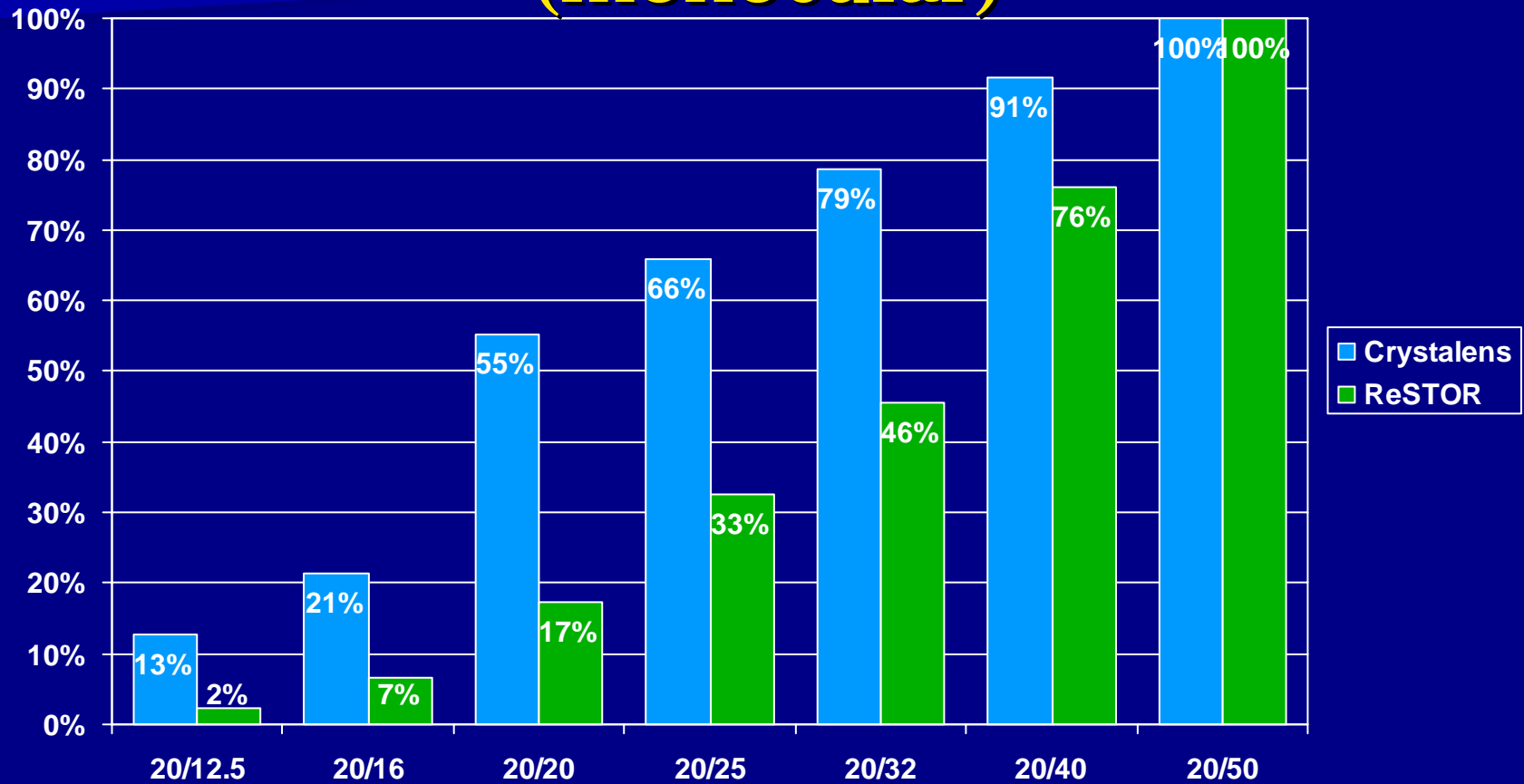
- Self-selected near distance "sweet spot" distance was doubled

Crystalens	
Mean	29
Range	18-36
SD	12.0

Binocular	
Mean	29
Range	18-40
SD	12.0

Restor	
Mean	28
Range	18-36
SD	12.0

UNCORRECTED INTERMEDIATE VISUAL ACUITY (monocular)

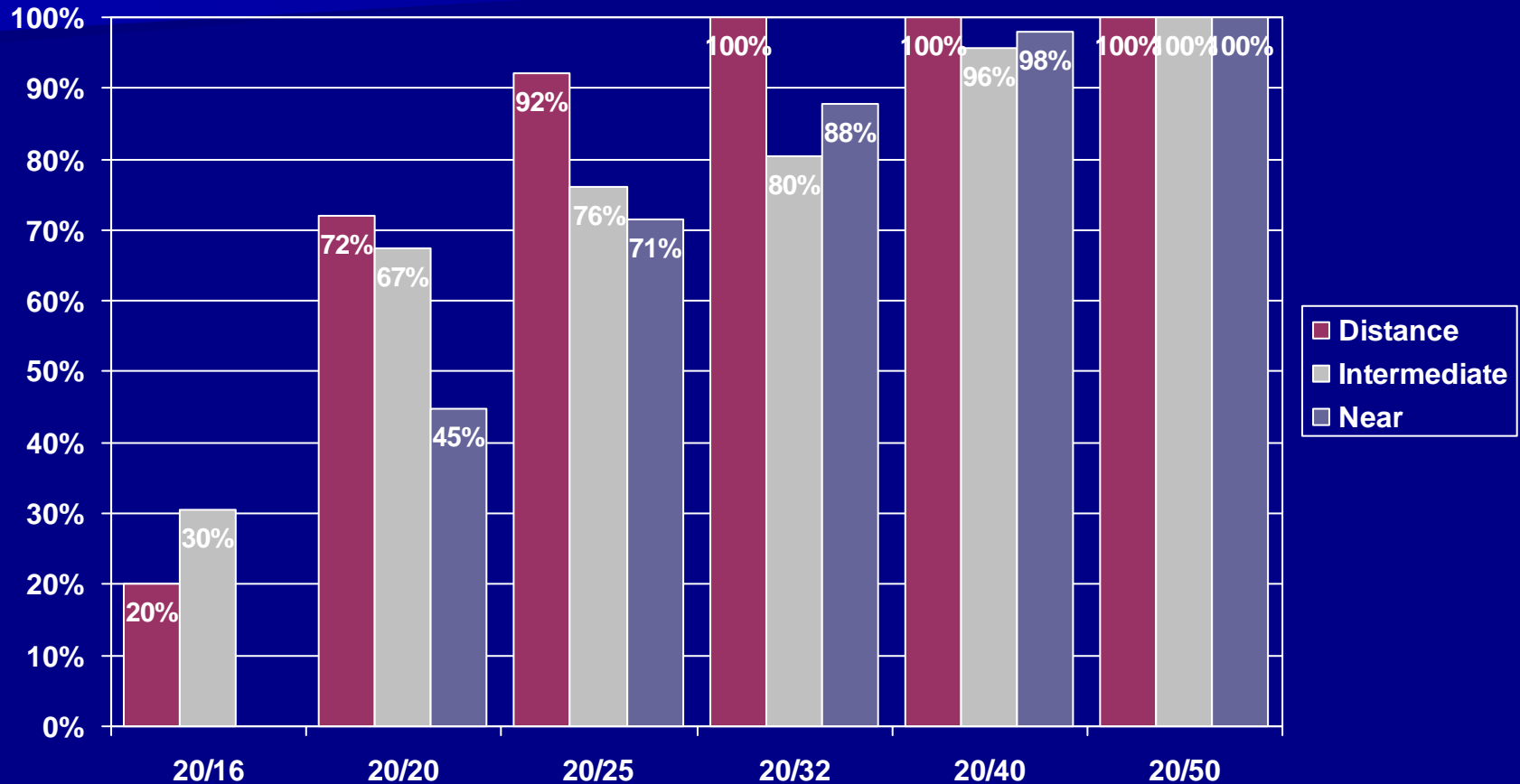


Jaeger: J1 J2 J3 J5 J6 J8 J10

Note: Intermediate card was held at an average distance of 29 inches and ranged between 18 and 40 inches

UNCORRECTED VISUAL ACUITY

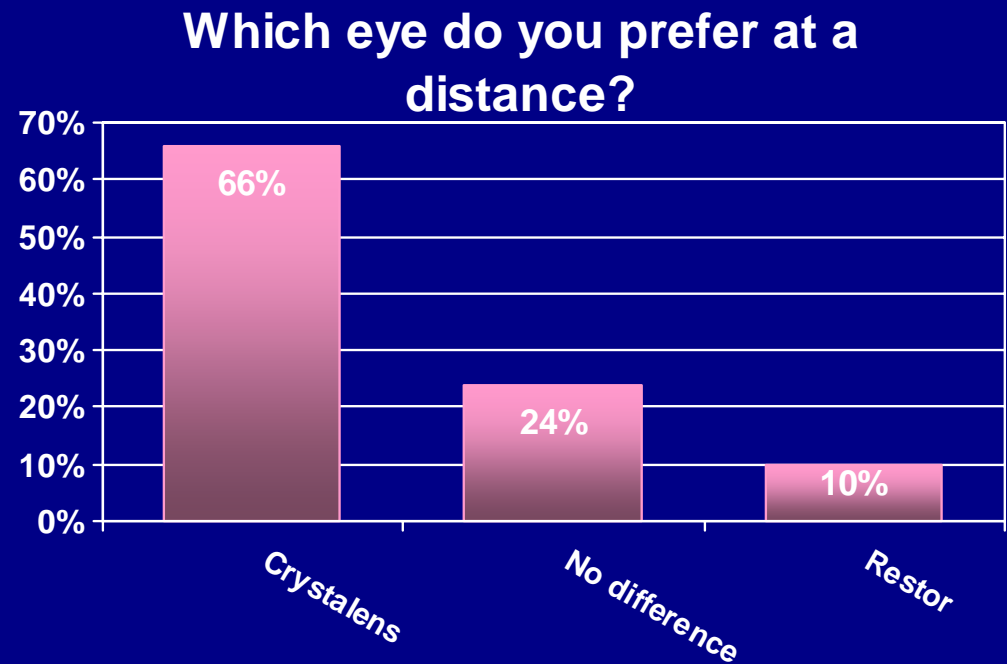
Binocular



LogMAR:	-0.1	0.0	0.1	0.2	0.3	0.4
Jaeger (Int):	J2	J3	J5	J6	J8	J10
Jaeger (Near):	---	J1+	J1	J2	J3	J5

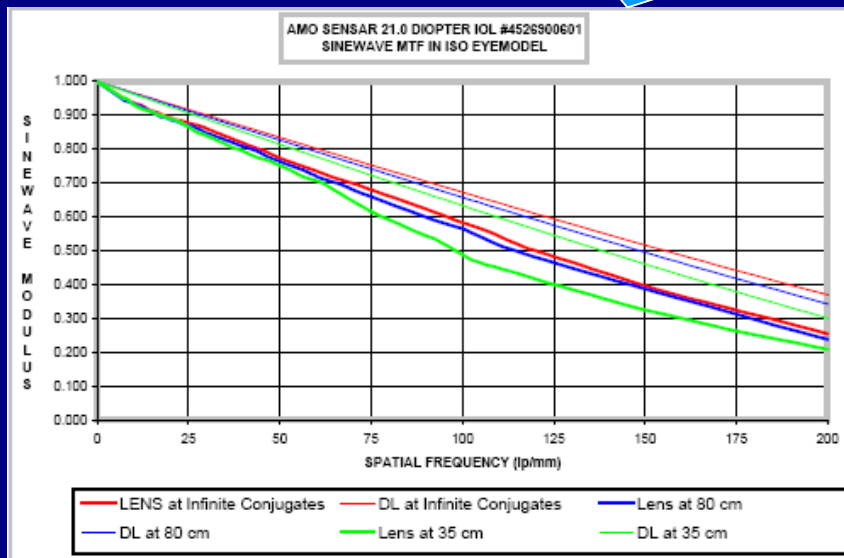
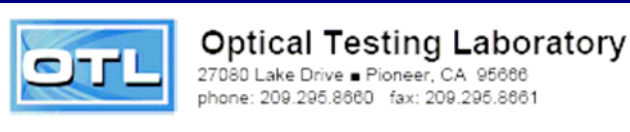
WHICH EYE DO YOU PREFER?

- The Crystalens was judged to be "better" for distance by a 2:1 ratio.



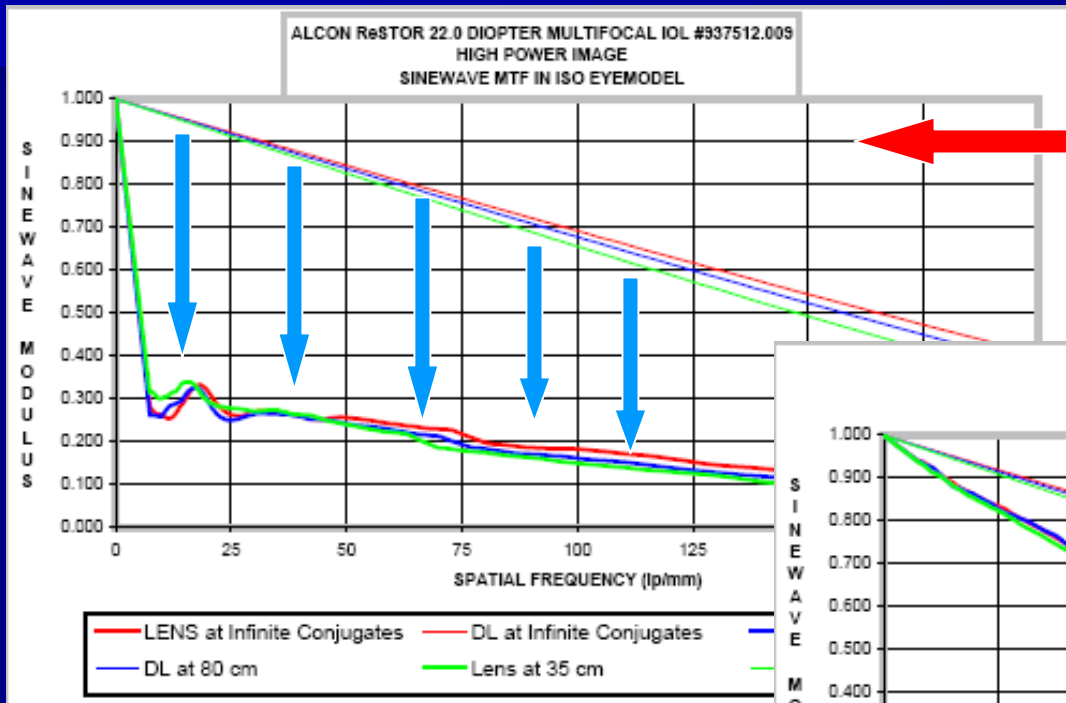
MTF MEASURES QUALITY OF VISION

Modulation Transfer Function = reduction in Contrast Sensitivity by an objective (lens) across a range of frequency (sine wave gratings)

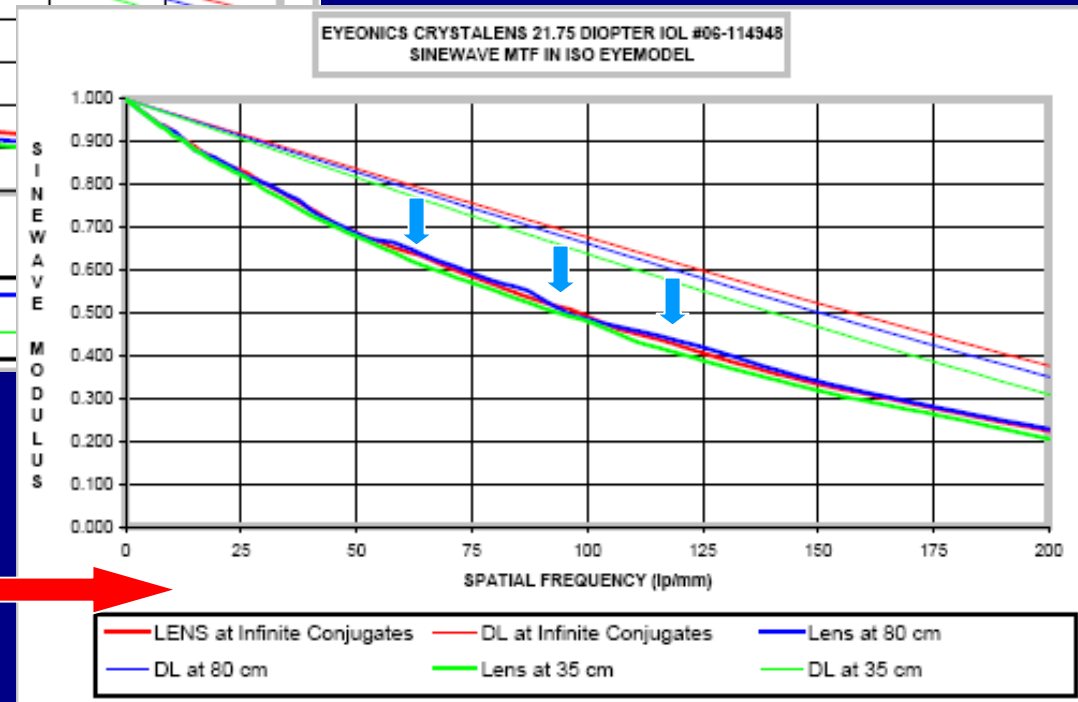


Example of high-quality IOL with excellent MTF curve

MTF MEASURES QUALITY OF VISION



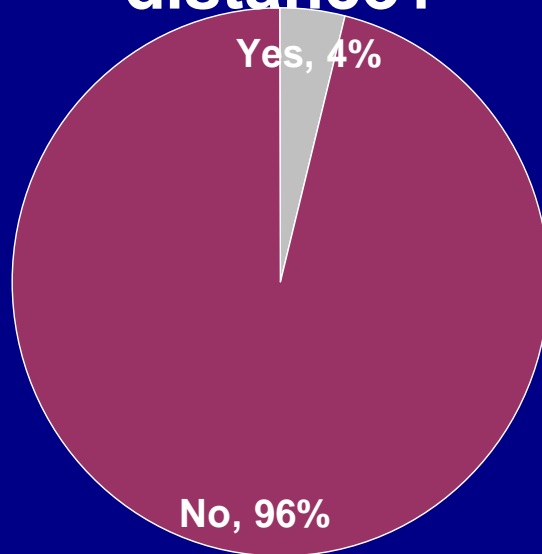
Diffraction IOL



Accommodative
IOL

SPECTACLE INDEPENDENT (1)?

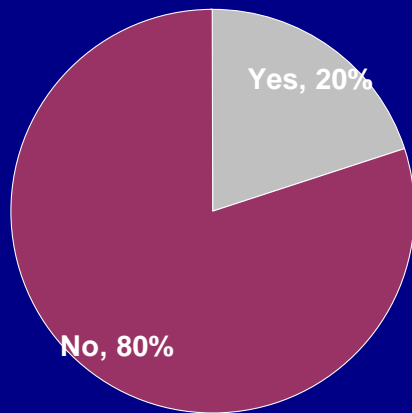
Do you use glasses for distance?



- Of the 2 patients that wear glasses for distance, neither do so except occasionally (e.g. at night)

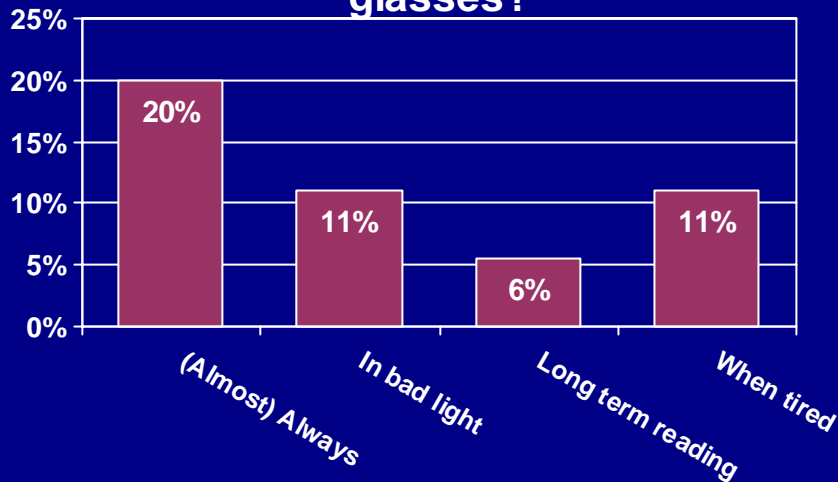
SPECTACLE INDEPENDENT (2)?

Do you use glasses for reading?



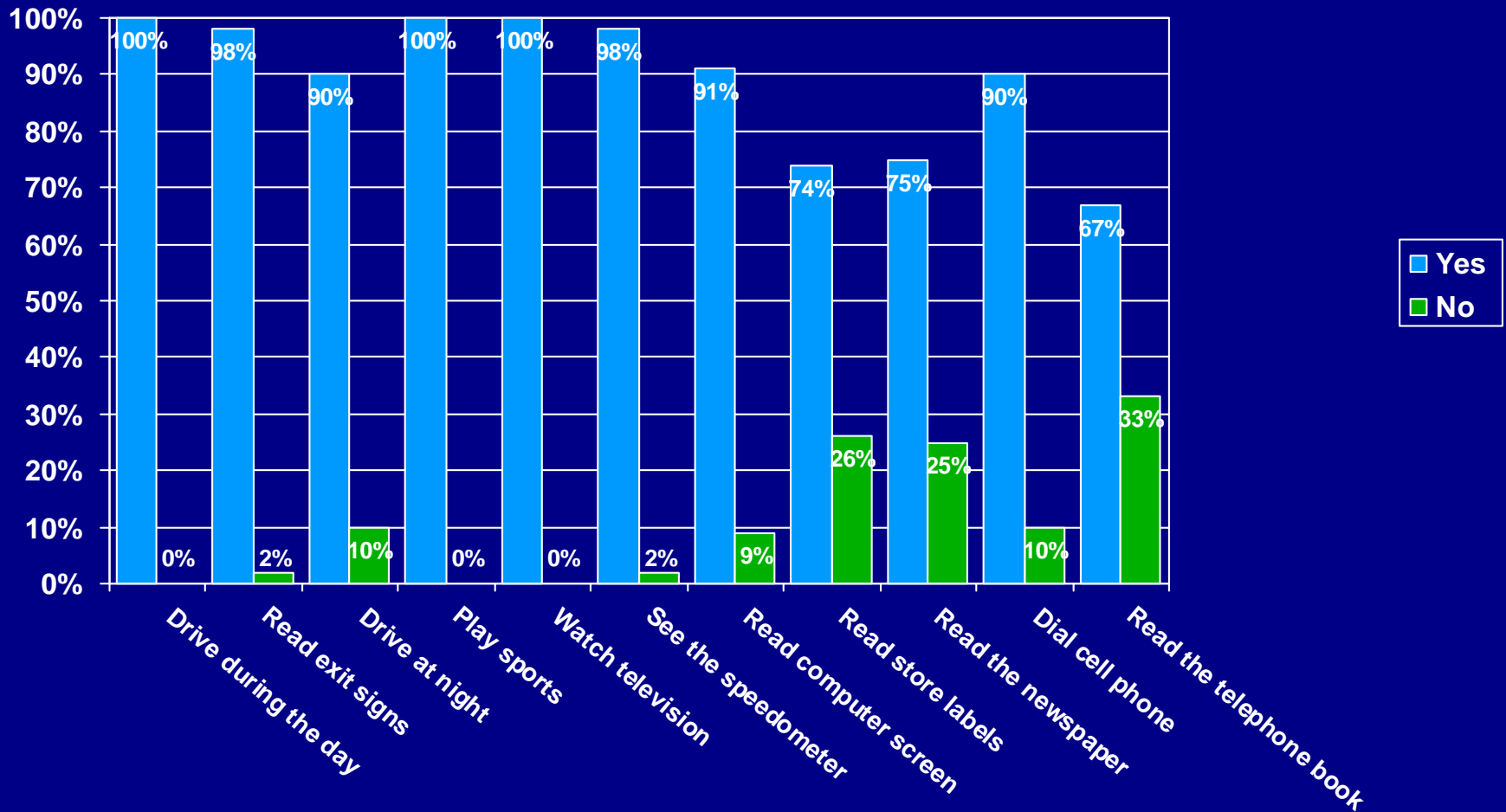
- 80% of the Crystalens/ReSTOR patients never (or almost never) wear glasses for reading.

How often do you use reading glasses?



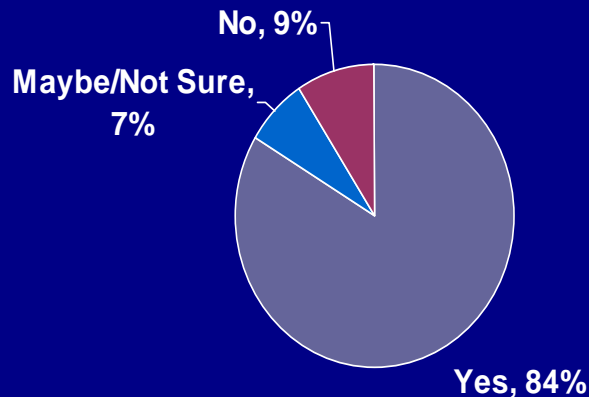
- Of the 20% who do use reading glasses, 50% report they do not wear them routinely.

CAN YOU SEE WELL ENOUGH TO...?

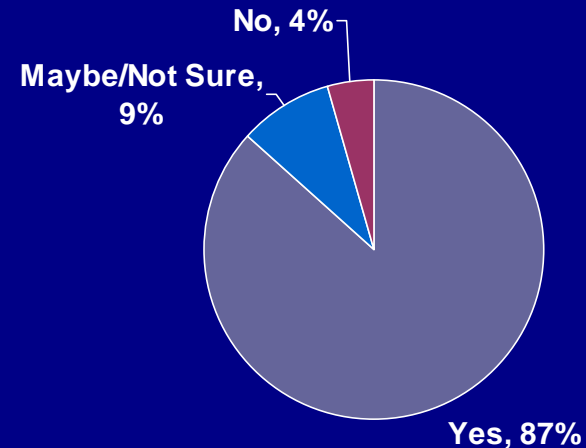


WOULD THE PATIENTS REPEAT / RECOMMEND THE SURGERY?

Would you still have the surgery
knowing what you do now?



Would you recommend this
procedure to a friend?



CONCLUSIONS

- Mixing ReStor & Crystalens in P-Lens Exchange is well tolerated
 1. Intermediate range superior to Restor alone
 2. Near vision is not adversely affected to a significant degree
 3. Distance vision MTF (Quality of Visual Function) in dominant eye is superior (and preferred by most) to Restor distance vision