

Preliminary Clinical Outcomes of PRECIZON PRESBYOPIC

Prof. Kim & Prof. Jeon

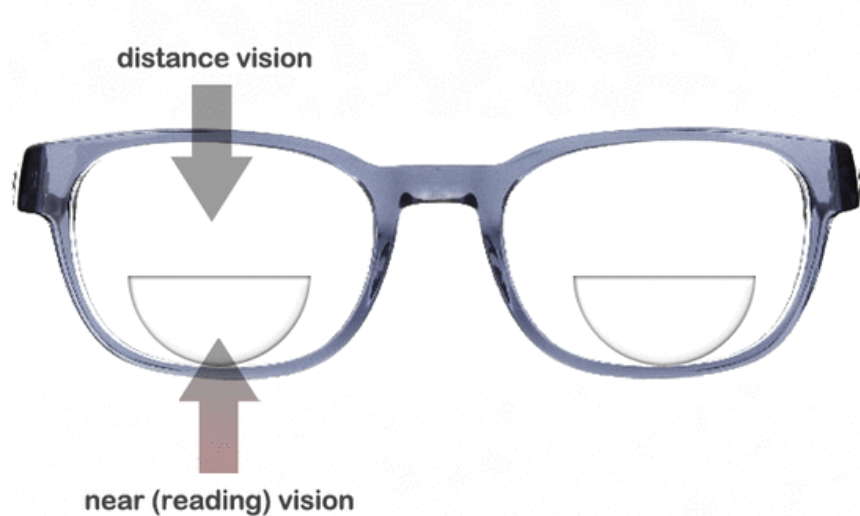
PRECIZON[®] NVA
Aspheric Presbyopic IOL

Presbyopia



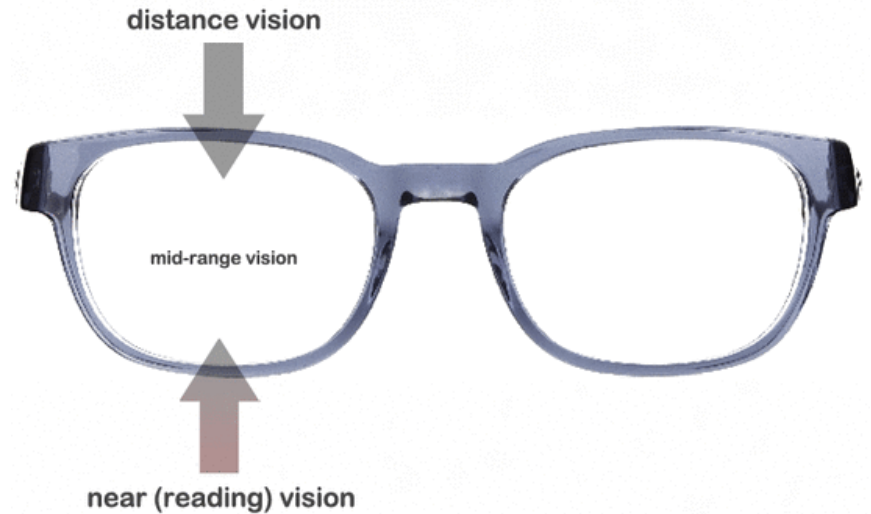
Magnifying glasses

How bifocals work



(c) Dr. M.K. Randhawa Optometric Corporation.

Progressive lenses



(c) Dr. M.K. Randhawa Optometric Corporation.

Uncomfortable glasses



Multifocal Intraocular Lens



Multifocal IOL



Monofocal IOL

Recent trends of Multifocal IOL

2012년 한국백내장굴절수술학회 및 대한안과학회 회원 설문 조사
- 한국에서의 백내장 수술의 최근 경향 -

J Korean Ophthalmol Soc 2015;56(8):1181-1187

Survey by The Korean Society of Cataract and Refractive Surgery and The Korean Ophthalmological Society Members in 2012
-Recent Trends in Cataract Surgery in Korea-

44% of the members performed Multifocal IOL implantation

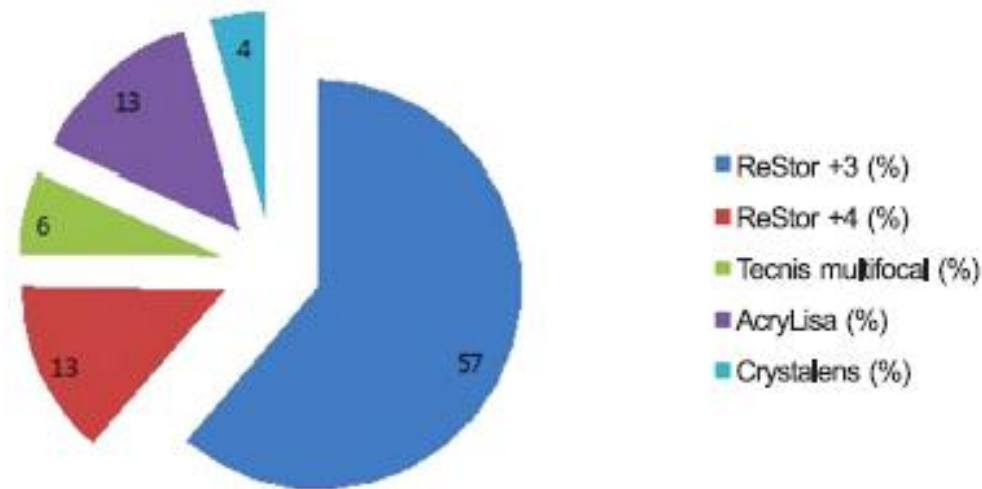


Figure 8. Preferred multifocal intraocular lens.

Recent trends of Multifocal IOL



ESCRS

CLINICAL
TRENDS
SURVEY

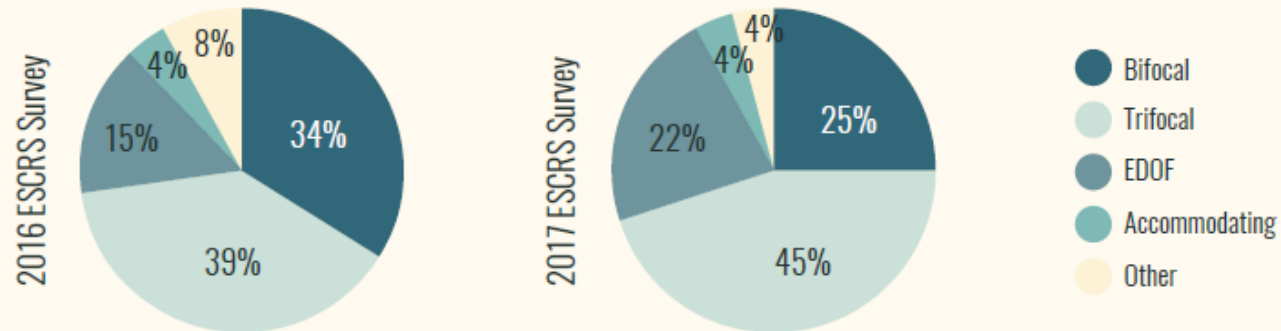
2017
Results

Presbyopia Correction

6% of current cataract procedures involve a presbyopia-correcting IOL

43% of current cataract procedures are targeted for monovision or mini-monovision

What type of presbyopia-correcting IOL technology is used in the majority of your presbyopia-correction patients?



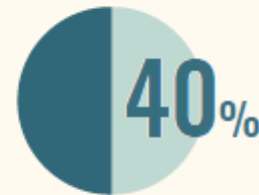
Top 3 concerns about performing more presbyopia-correcting IOL procedures



Cost to patient



Concern over night-time visual quality



Concern over loss of contrast visual acuity

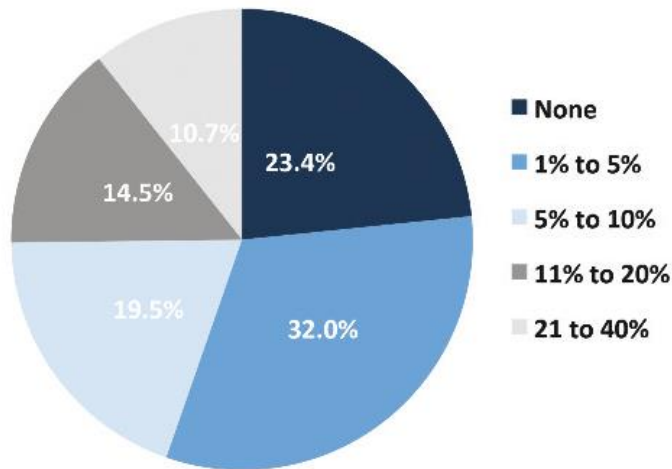
Recent trends of Multifocal IOL

ASCRS Clinical Survey
2018

ASCRS Clinical Survey 2013: NT cataract procedures involve

Presbyopia Correcting IOL

Percent of current cataract procedures that involve presbyopia-correcting IOLs



- Average % of cataract procedures is presby-correcting IOLs is 7.9%
- Average % targeted for monovision
 - Overall 18.9%

nt cataract procedures

ths



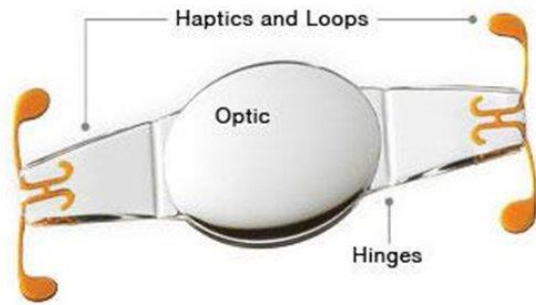
Average Pct	
All	9%
US	9%
NonUS	11%

Type of Multifocal IOL

- **Accommodative IOL**
- **Multifocal IOL**
 - **Refractive**
 - **Diffraction**

Type of Multifocal IOL

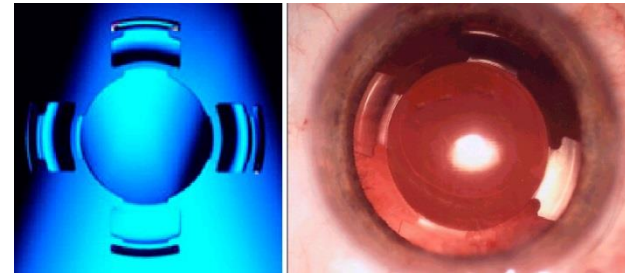
- **Accommodative IOL**



Crystalens



Tetraflex



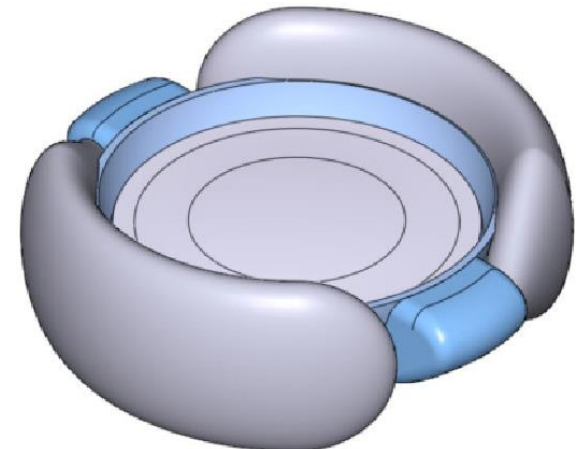
1CU



Synchrony Dual optic IOL



NuLens



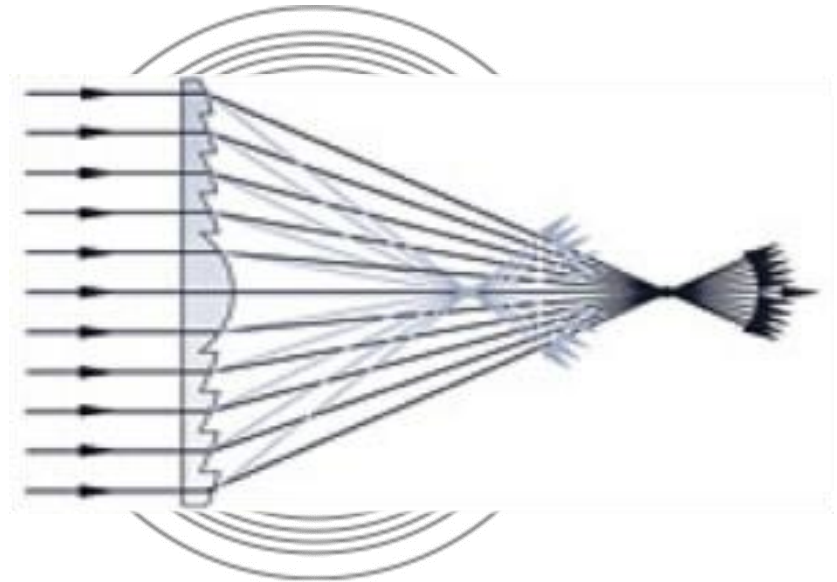
FluidVision

Type of Multifocal IOL

- **Multifocal IOL**
 - Refractive
 - Diffractive



Refractive type

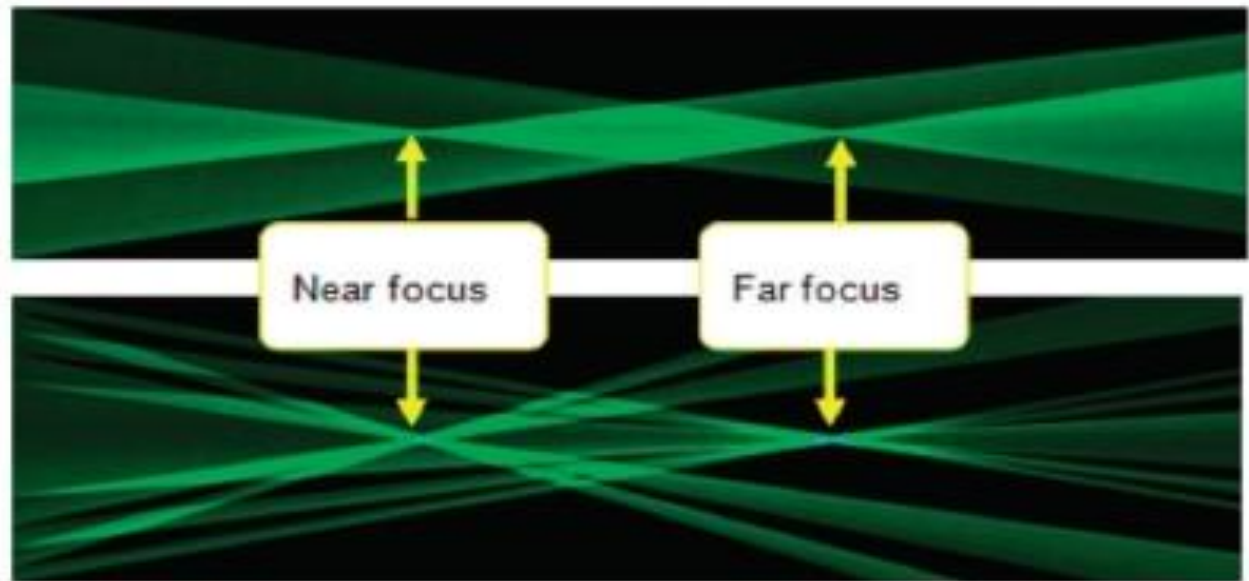


Diffractive type

Type of Multifocal IOL

- Light distribution

Diffractive type

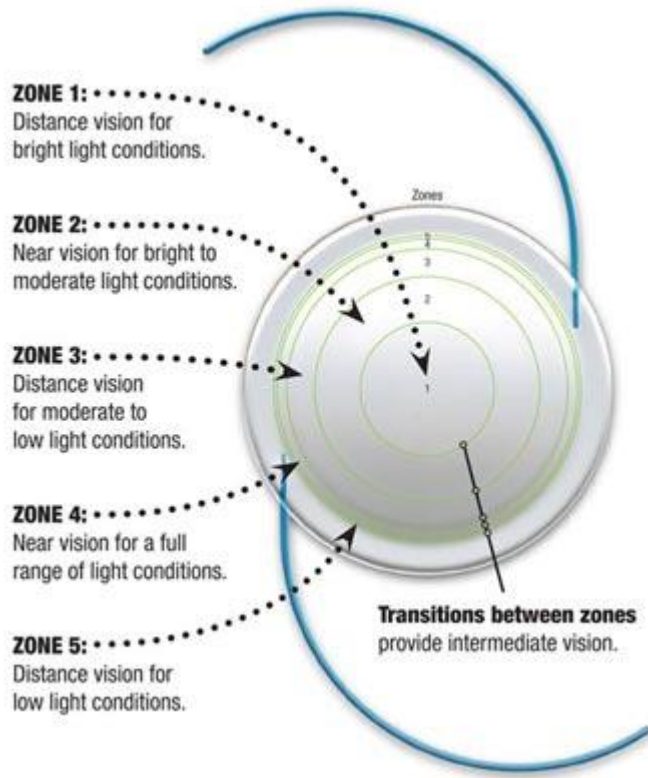


Refractive type

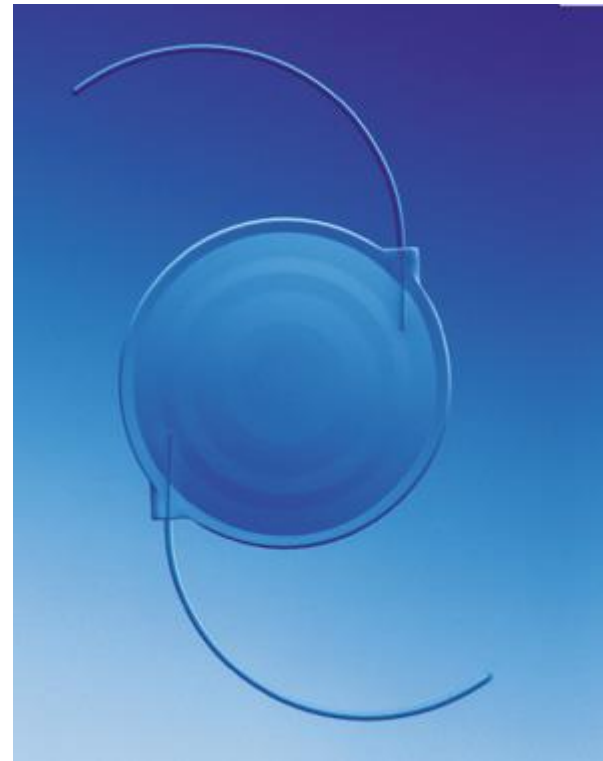
** Simulated images generated using a custom paraxial beam tracing program.
Image simulations by Edwin J. Saver, PhD, Saver and Associates, Inc., Carbondale,
Illinois.

Type of Multifocal IOL

- **Refractive Multifocal IOLs**



ReZoom

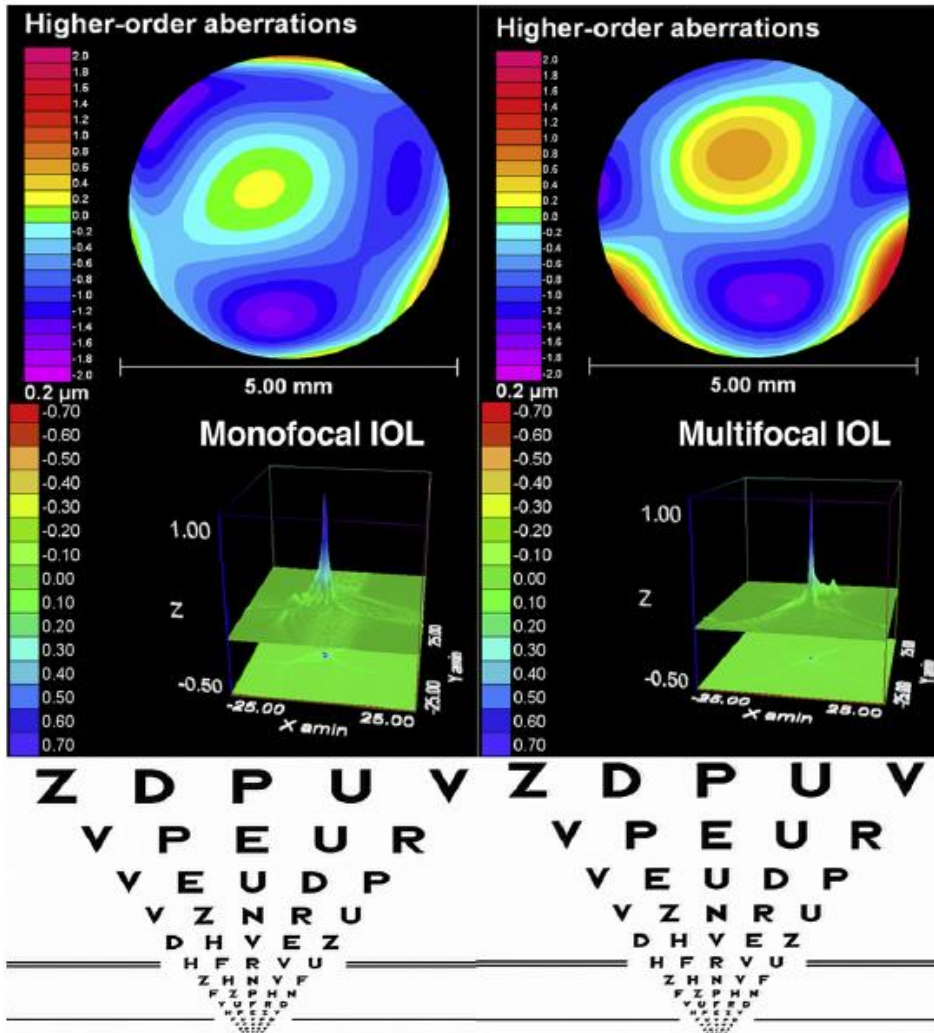


Array

Type of Multifocal IOL

Refractive Multifocal IOLs	Diffractive multifocal IOLs
Excellent intermediate and distance vision	Excellent reading vision and very good distance vision
Near vision fair but may not be sufficient to see very small print	The intermediate vision is acceptable but not as good as the far and near vision.
Pupil dependent, variable depending of the design	Less dependent on pupil
High sensitivity for lens centration	More tolerant to the kappa angle and decentration
Potential for halos and glare due to rough areas between the zones	Energy lost caused by light scattering at the diffractive surfaces
Intolerance to kappa angle which varies from patient to patient	High potential of producing halos and glare due to more nontransition areas.

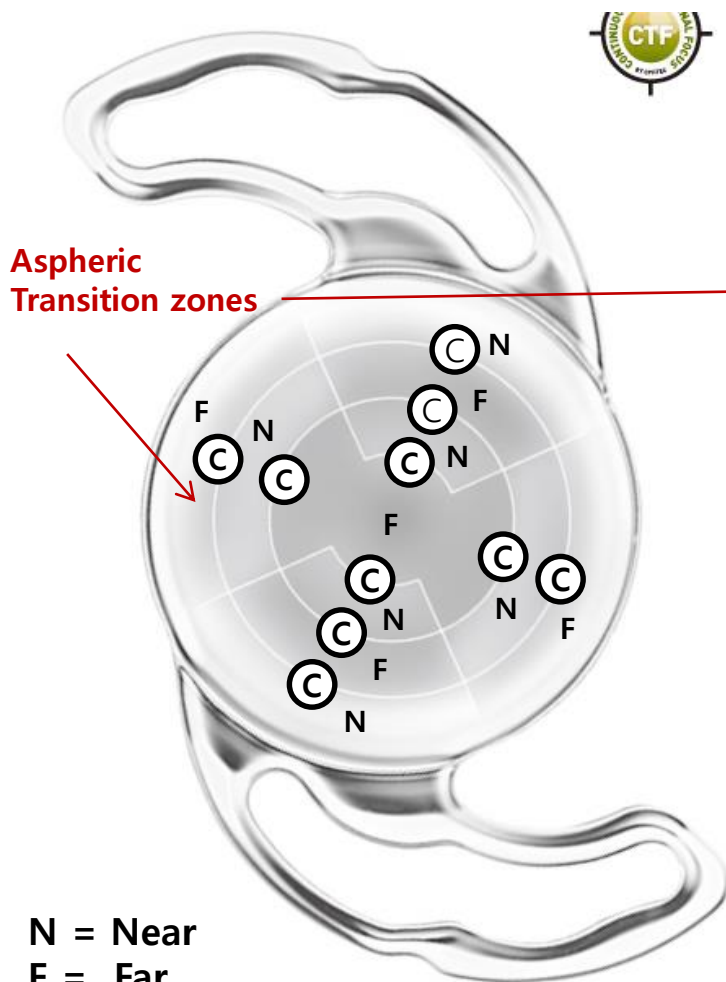
Type of Multifocal IOL



c refractive type

- No optic ring
 - Avoid light scatter
 - Less halo and glare
- Various Add power (+1.50D, +2.0D, +3.0D)
- May provide good near vision.
- Increasing energy to the near vision when the pupil enlarged
- Increase coma aberration

PRECIZON PRESBYOPIC

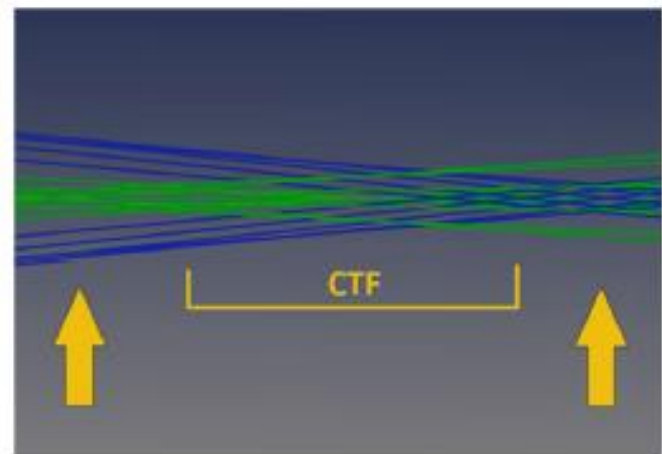
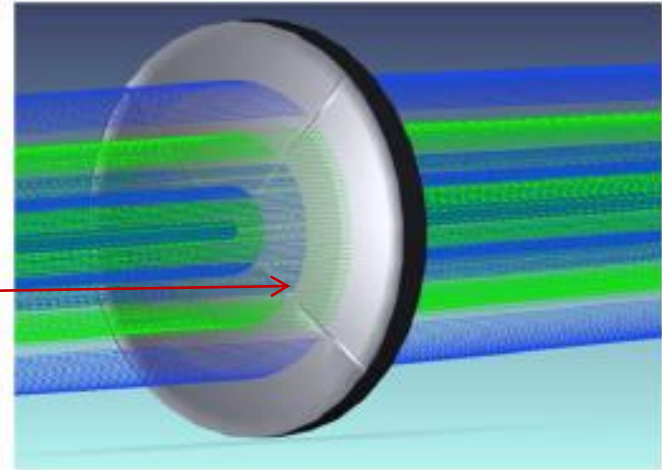


N = Near

F = Far

C = Continuous Transitional Zone

Add power +2.75 D



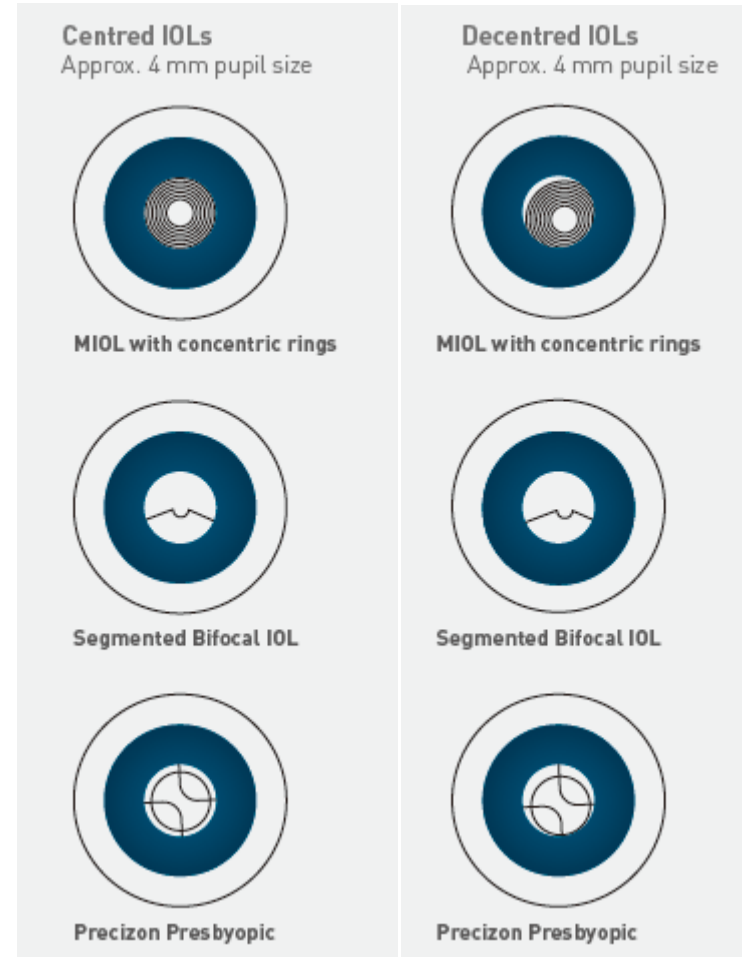
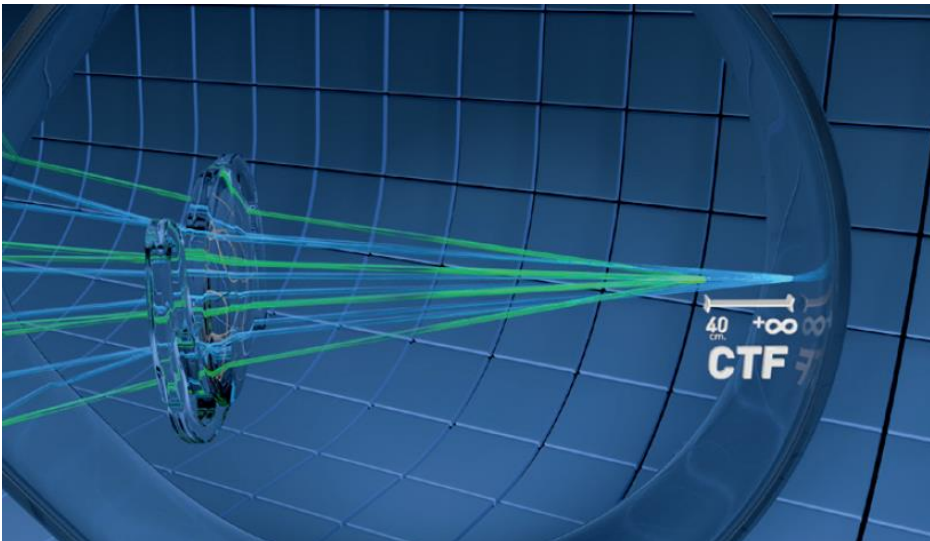
Continuous Transitional Focus (CTF)

Continuous Transitional Focus (CTF)

- A CTF optic is an optic with an **anterior surface with zones at 2,3 and 5 mm ; every zone has multiple segments for far and near.**
- An aspheric **smooth transition zone from far to near** is achieved between the segments with the patented Transitional Conic Technology (TCT).
- Regular Multifocal IOLs will cause positive dysphotopsia, due to light scattering of the concentric rings
- CTF aspheric smooth transition zones minimize transmissions light loss to reduce the problem of halos and glare and more **tolerant to lens decentration**

PRECIZON PRESBYOPIC Benefit

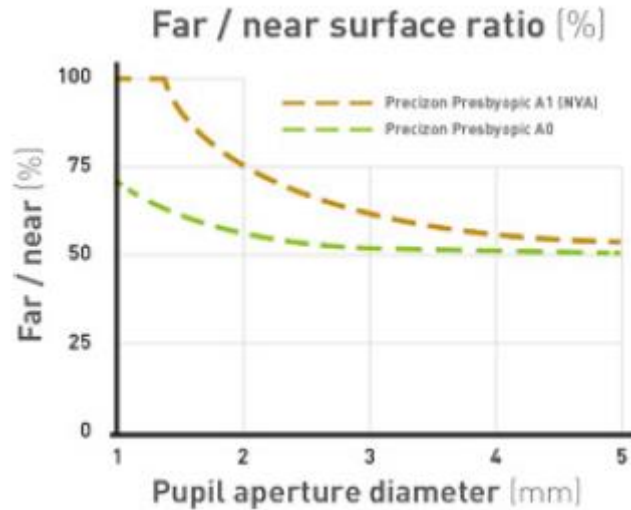
- **Natural vision at all distances**
- **Reducing glare and halos**
- **Pupil independence**
- **Decentration tolerance.**



PRECIZON PRESBYOPIC



PRECIZON PRESBYOPIC A0
Central far zone size 0.5 / 2.0 mm
Aberration Neutral



PRECIZON PRESBYOPIC A1 (NVA)
Central far zone size 1.4 / 2.6 mm
Aberration negative (-0.11 μm)

Clinical Outcomes from Company

- **Visual Acuity**

Table 1: Near Visual Acuity at 3 months

Near Visual Acuity	Monocular N=122			Binocular N=61		
	Mean LogMAR	≤0.3 LogMAR	≤0.0 LogMAR	Mean LogMAR	≤0.3 LogMAR	≤0.0 LogMAR
Uncorrected	0.20	83.6%	11.5%	0.14	93.4%	18.0%
Corrected	0.11	95.9%	16.4%	0.06	98.4%	32.8%
Distance Corrected	0.19	87.7%	5.7%	0.14	95.0%	11.7%

Table 2: Distance Visual Acuity at 3 months

Distance Visual Acuity	Monocular N=122			Binocular N=61		
	Mean LogMAR	≤0.3 LogMAR	≤0.0 LogMAR	Mean LogMAR	≤0.3 LogMAR	≤0.0 LogMAR
Uncorrected	0.10	93.4%	23.0%	0.03	98.4%	45.9%
Corrected	0.04	99.2%	41.8%	-0.02	100.0%	60.7%

Table 3: Intermediate Visual Acuity at 3 months

Intermediate Visual Acuity	Monocular N=122			Binocular N=61		
	Mean LogMAR	≤0.3 LogMAR	≤0.0 LogMAR	Mean LogMAR	≤0.3 LogMAR	≤0.0 LogMAR
Uncorrected	0.15	89.3%	12.3%	0.06	96.7%	39.3%
Distance Corrected	0.16	86.1%	15.6%	0.08	93.4%	27.9%

Clinical Outcomes from Company

- Refraction

Figure 1: Difference in MRSE between visits

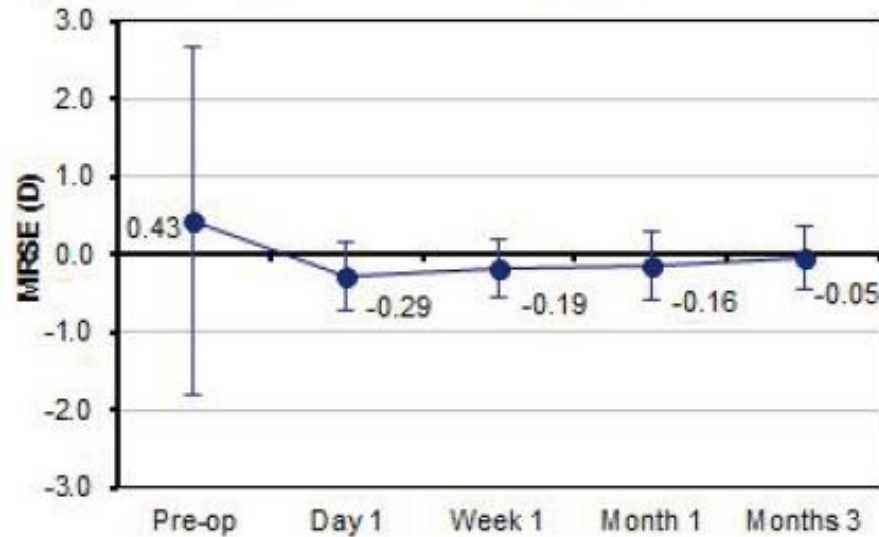


Figure 2: Mean change in MRSE

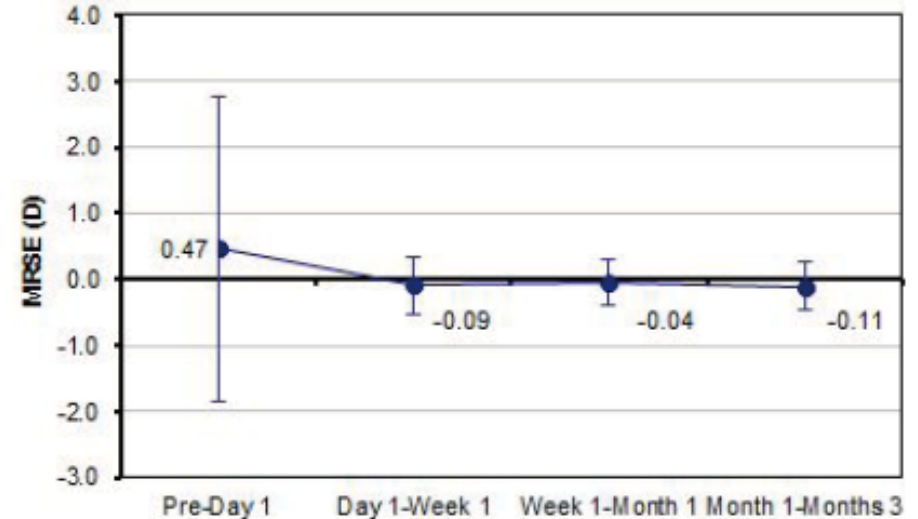


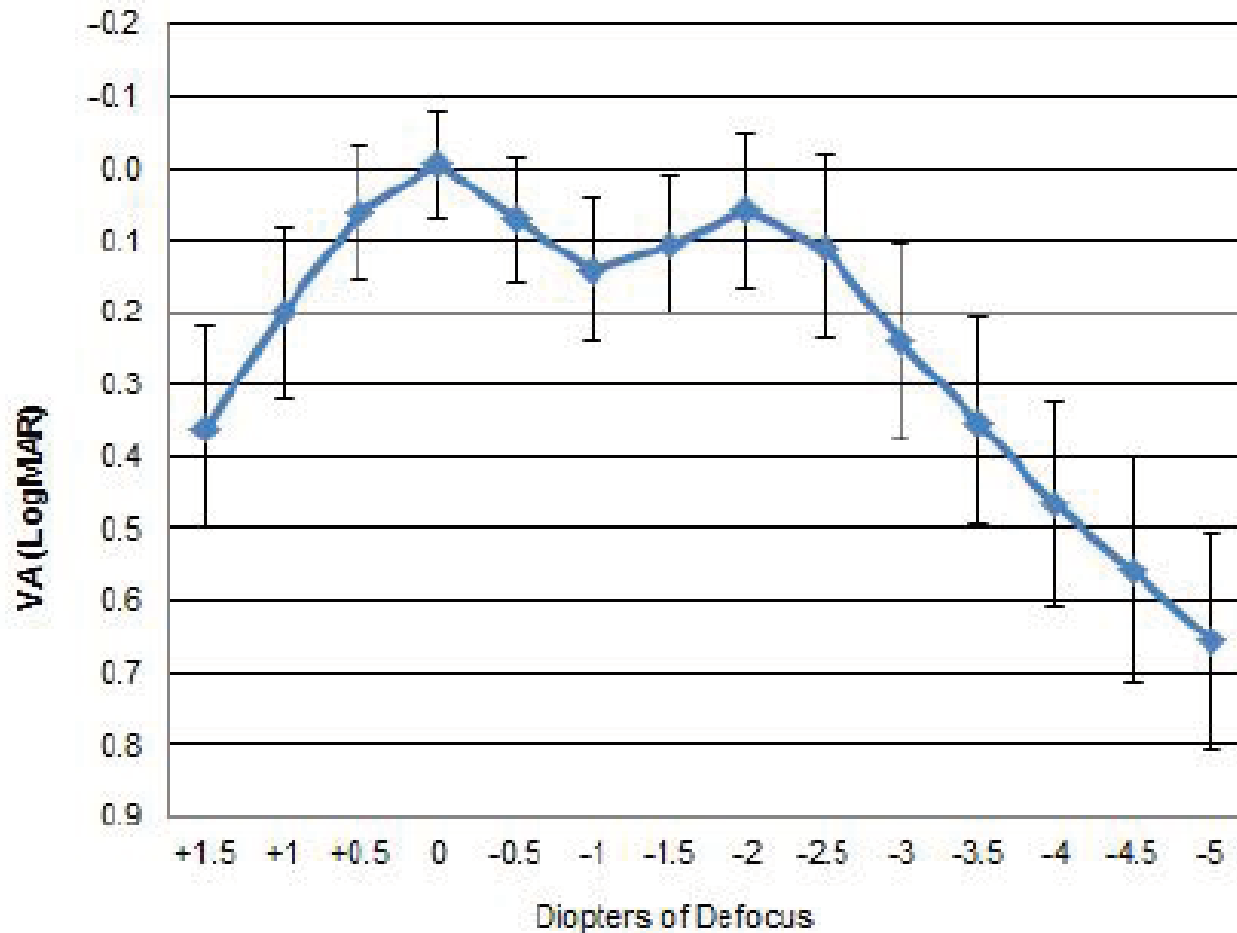
Table 4: Stability of Manifest Refractive Spherical Equivalent

MRSE	N=122
≤ 1.0 of MRSE between Week 1 and Months 3	96.7%
> 1.0 of MRSE between Week 1 and Months 3	3.3%

Clinical Outcomes from Company

- Defocus Curve

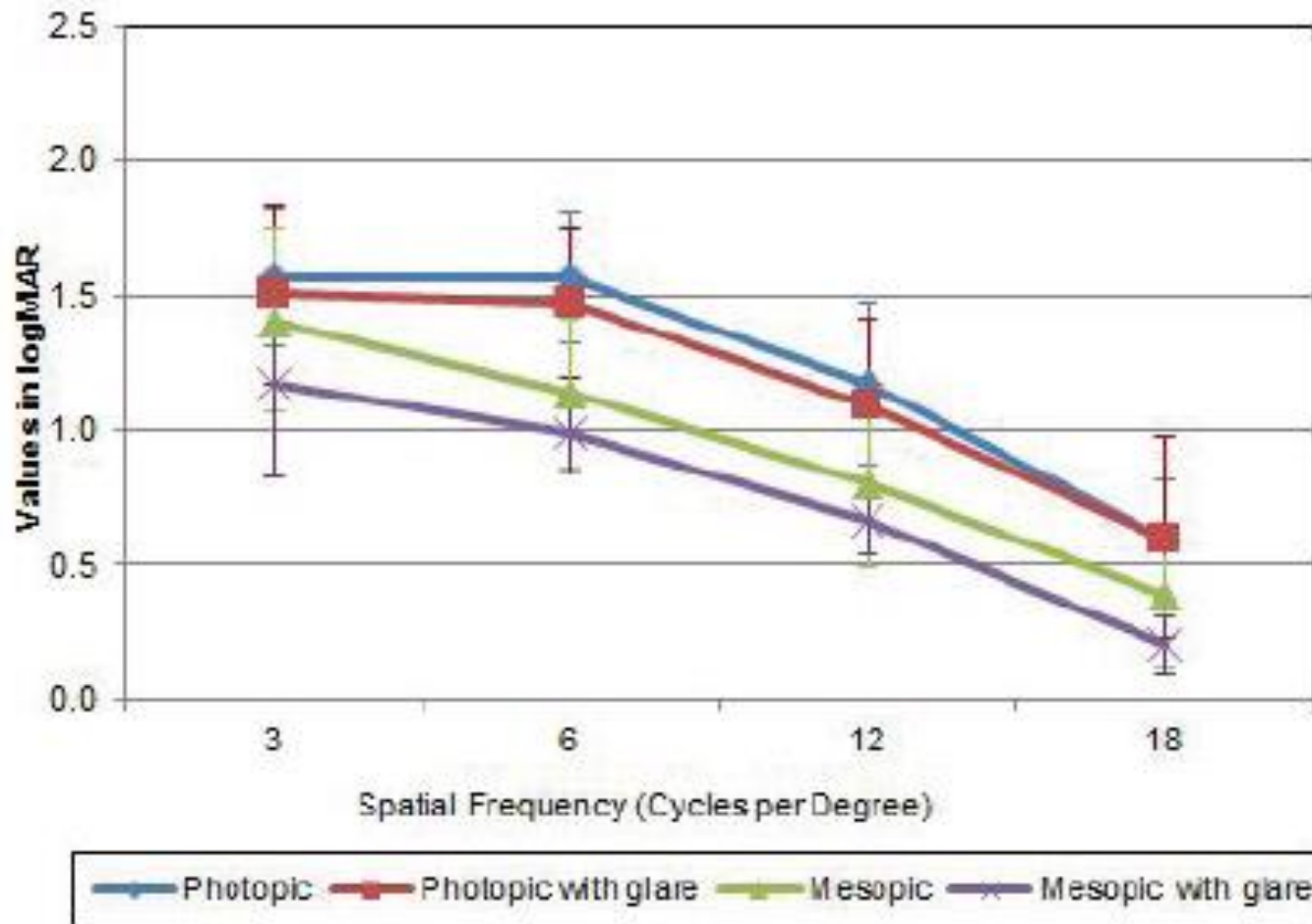
Figure 4: Binocular best corrected defocus curve at 3 months



Clinical Outcomes from Company

- **Contrast Sensitivity**

Figure 3: Post-operative contrast sensitivity scores (logMAR)



Clinical Outcomes from Company

- **Satisfaction and Quality of Vision**

Figure 5: Spectacle usage at 3 months

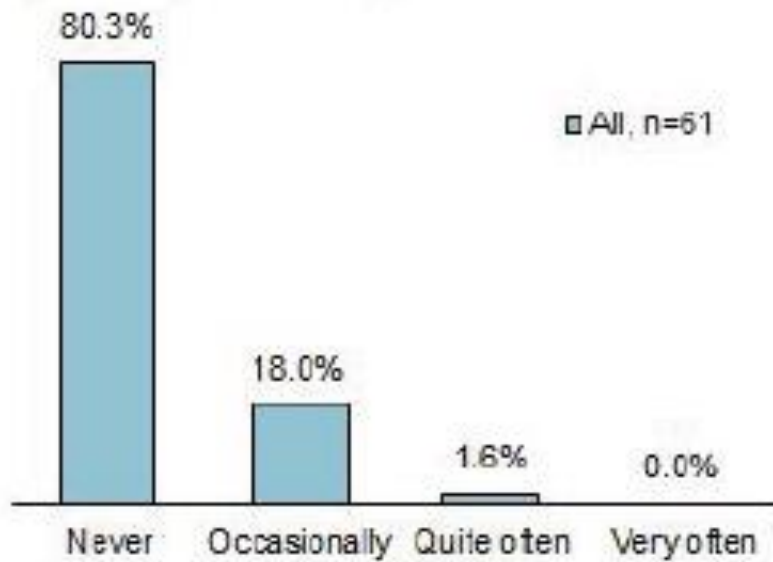
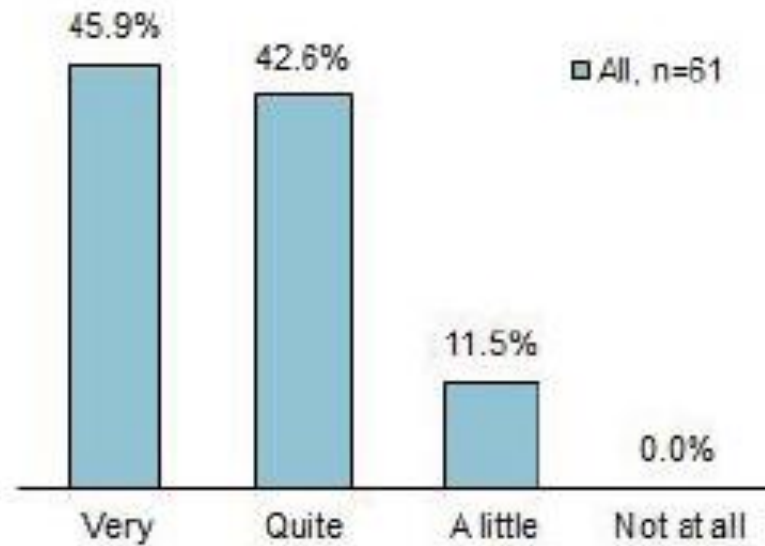


Figure 6: Satisfaction with uncorrected vision at 3 months



Clinical Outcomes from Company

- Satisfaction and Quality of Vision**

Table 6: Satisfaction with near, intermediate and far vision at 3 months

Satisfaction with vision at		N=61	
		n	%
Near	Very	33	54.1%
	Quite	23	37.7%
	A little	4	6.6%
	Not at all	1	1.6%
Intermediate	Very	29	47.5%
	Quite	24	39.3%
	A little	7	11.5%
	Not at all	1	1.6%
Far	Very	27	44.3%
	Quite	23	37.7%
	A little	9	14.8%
	Not at all	2	3.3%

Table 7: Overall satisfaction at 3 months

Satisfied with		N=61	
		n	%
Overall outcome	Very	32	52.5%
	Quite	25	41.0%
	A little	4	6.6%
	Not at all	0	0.0%
Achieved quality of vision	Definitely	29	47.5%
	Quite surely	22	36.1%
	Maybe	6	9.8%
	No	4	6.6%
Choice for this lens	Very	33	54.1%
	Quite	21	34.4%
	A little	6	9.8%
	Not at all	1	1.6%
Elect procedure again	Definitely	38	62.3%
	Quite surely	16	26.2%
	Maybe	4	6.6%
	No	3	4.9%
Recommend this lens to others*	Definitely	37	61.7%
	Quite surely	15	25.0%
	Maybe	6	10.0%
	No	2	3.3%

*One subject did not respond to this question (N=60)

Clinical Outcomes from Company

- Adverse events**

Table 8: Adverse events vs. ISO 19979-7 SPE* rates

Adverse Events		Eyes N=122		ISO SPE* rate %
		n	%	
Cumulative	Cystoid macular edema (CME)	0	0	10
	Hypopyon	0	0	0.2
	Endophthalmitis	0	0	0.2
	Lens dislocation	0	0	1.1
	Pupillary block	0	0	2
	Retinal detachment	0	0	1.2
	Secondary surgical intervention (SSI)	0	0	2.6
Persistent	Corneal stroma edema	0	0	0.5
	Cystoid macular edema	0	0	3.8
	Iritis	0	0	0.9
	Raised IOP requiring treatment	0	0	2.1

* Per ISO 11979-7 (2014) Ophthalmic Implants-Intraocular Lenses (Part 7): The SPE rate is the safety and performance endpoint.

Table 9: complications present at 3 months

Complications	Eyes N=122	
	n	%
PCO	9	7.4
Posterior Capsule Striae	6	4.9

Note: reported with incidence rates of 3% or higher

Clinical Outcomes from Our institution

- **Demographics**

Characteristics	PRECIZON PRESBYOPIC
Number of eyes	14
Sex	M : F = 1 : 6
Age, years old	58.57 ± 7.58 (43 to 69)
Spherical Equivalent (D)	-1.14 ± 2.16 (-5.50 to 1.75)
logMAR CDVA (monocular)	0.13 ± 0.10 (0.00 to 0.30)
logMAR UDVA (monocular)	0.29 ± 0.16 (0.00 to 0.52)
logMAR CDVA (binocular)	0.05 ± 0.05 (0.00 to 0.10)
logMAR UDVA (binocular)	0.15 ± 0.11 (0.00 to 0.44)
Average K (D)	44.78 ± 1.44 (42.83 to 48.13)
Corneal Astigmatism (D)	0.43 ± 0.30 (0.00 to 1.00)
Axial length (mm)	23.74 ± 1.14 (21.21 to 25.21)
Anterior chamber depth (mm)	3.25 ± 0.39 (2.78 to 3.93)
Goal diopter (D)	-0.09 ± 0.13 (-0.36 to 0.14)
Pupil size Photopic (mm)	3.36 ± 1.20 (1.2 to 5.1)
Mesopic (mm)	4.52 ± 0.92 (2.9 to 6.3)

Clinical Outcomes from Our institution

- Visual Acuity**

Near Visual Acuity	Monocular (N=14)			Binocular (N = 7)		
	Mean LogMAR	≤0.3 LogMAR	≤0.0 LogMAR	Mean LogMAR	≤0.3 LogMAR	≤0.0 LogMAR
Uncorrected	0.15	92.9 %	7.1 %	0.07	100 %	14.3 %
Corrected	0.07	100 %	21.4 %	0.05	100 %	28.6 %
Distance Corrected	0.16	85.7 %	7.1 %	0.12	100 %	14.3 %

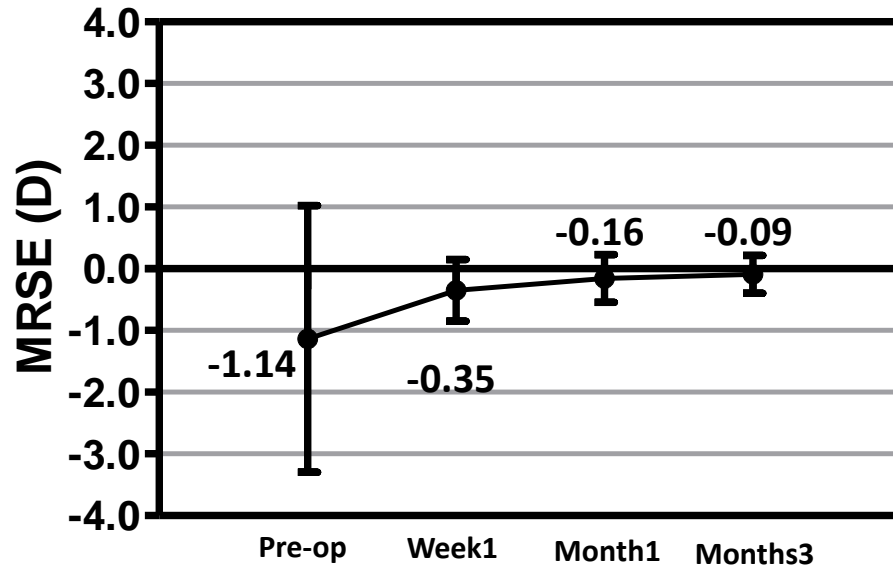
Distance Visual Acuity	Monocular (N=14)			Binocular (N = 7)		
	Mean LogMAR	≤0.3 LogMAR	≤0.0 LogMAR	Mean LogMAR	≤0.3 LogMAR	≤0.0 LogMAR
Uncorrected	-0.01	100 %	64.3 %	-0.08	100 %	85.7 %
Corrected	-0.05	100 %	85.7 %	-0.06	100 %	100 %

Intermediate Visual Acuity	Monocular (N=14)			Binocular (N = 7)		
	Mean LogMAR	≤0.3 LogMAR	≤0.0 LogMAR	Mean LogMAR	≤0.3 LogMAR	≤0.0 LogMAR
Uncorrected	0.17	92.9 %	0.0 %	0.08	100 %	14.3 %

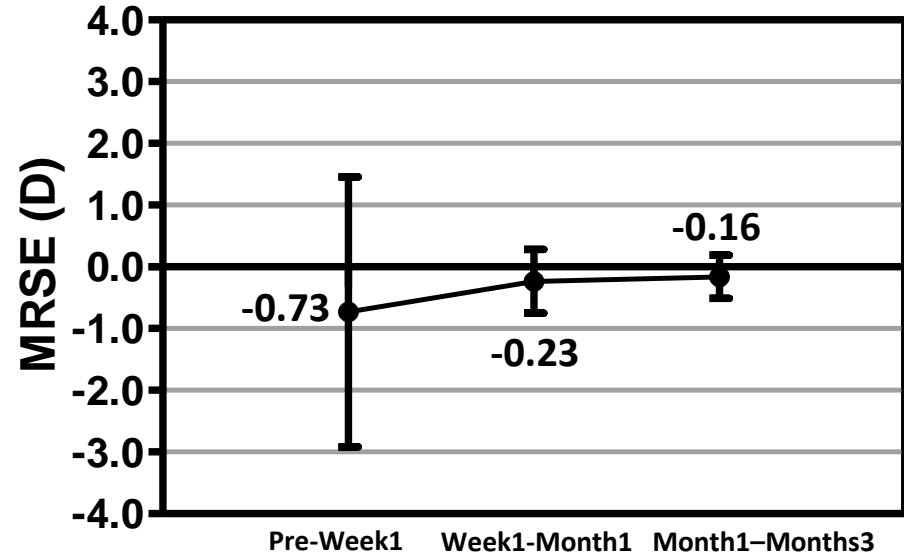
Clinical Outcomes from Our institution

- Refraction

Difference in MRSE between visits



Mean change in MRSE

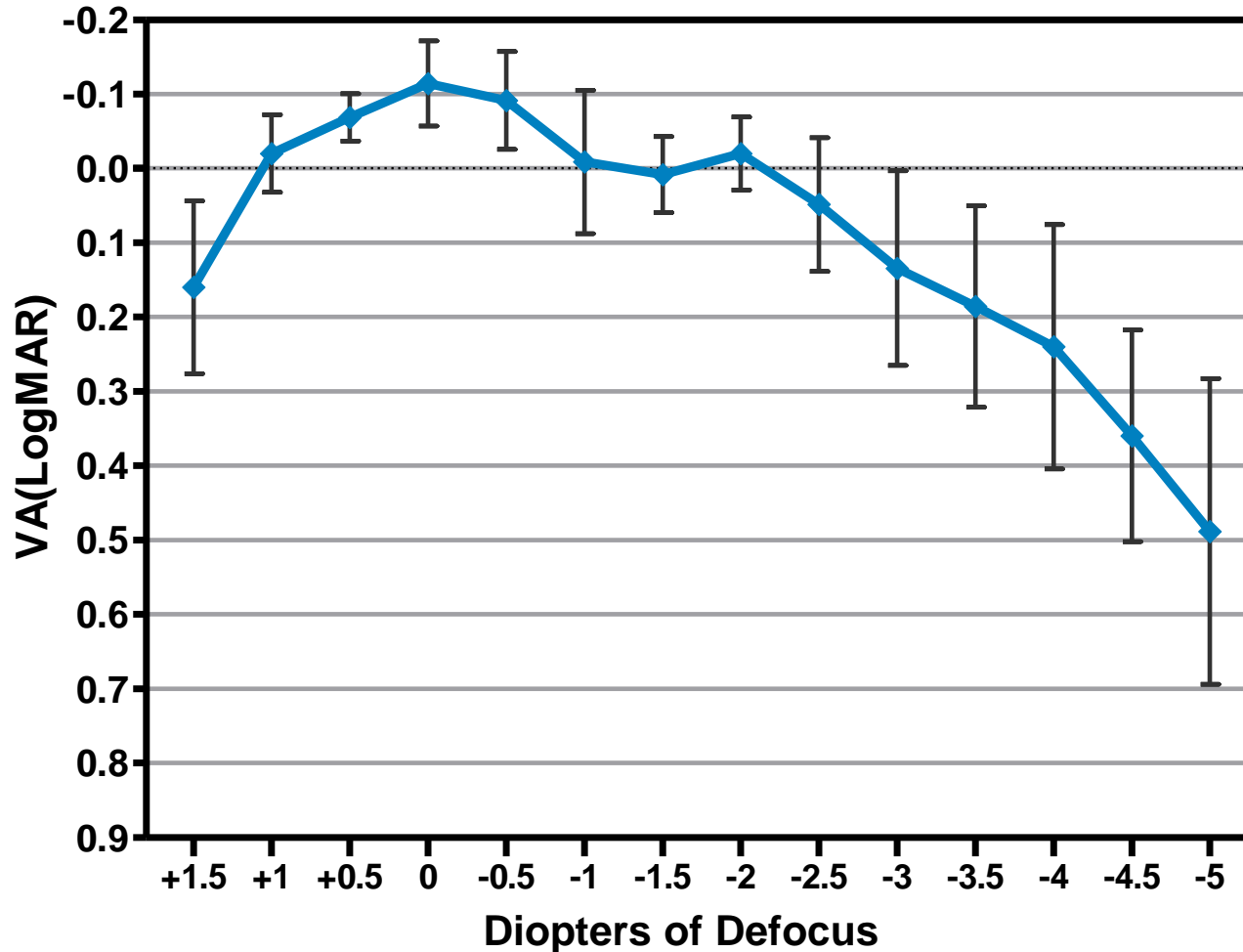


MRSE	N=14
≤ 1.0 of MRSE between Week 1 and Months 3	100 %
> 1.0 of MRSE between Week 1 and Months 3	0 %

Clinical Outcomes from Our institution

- Defocus Curve

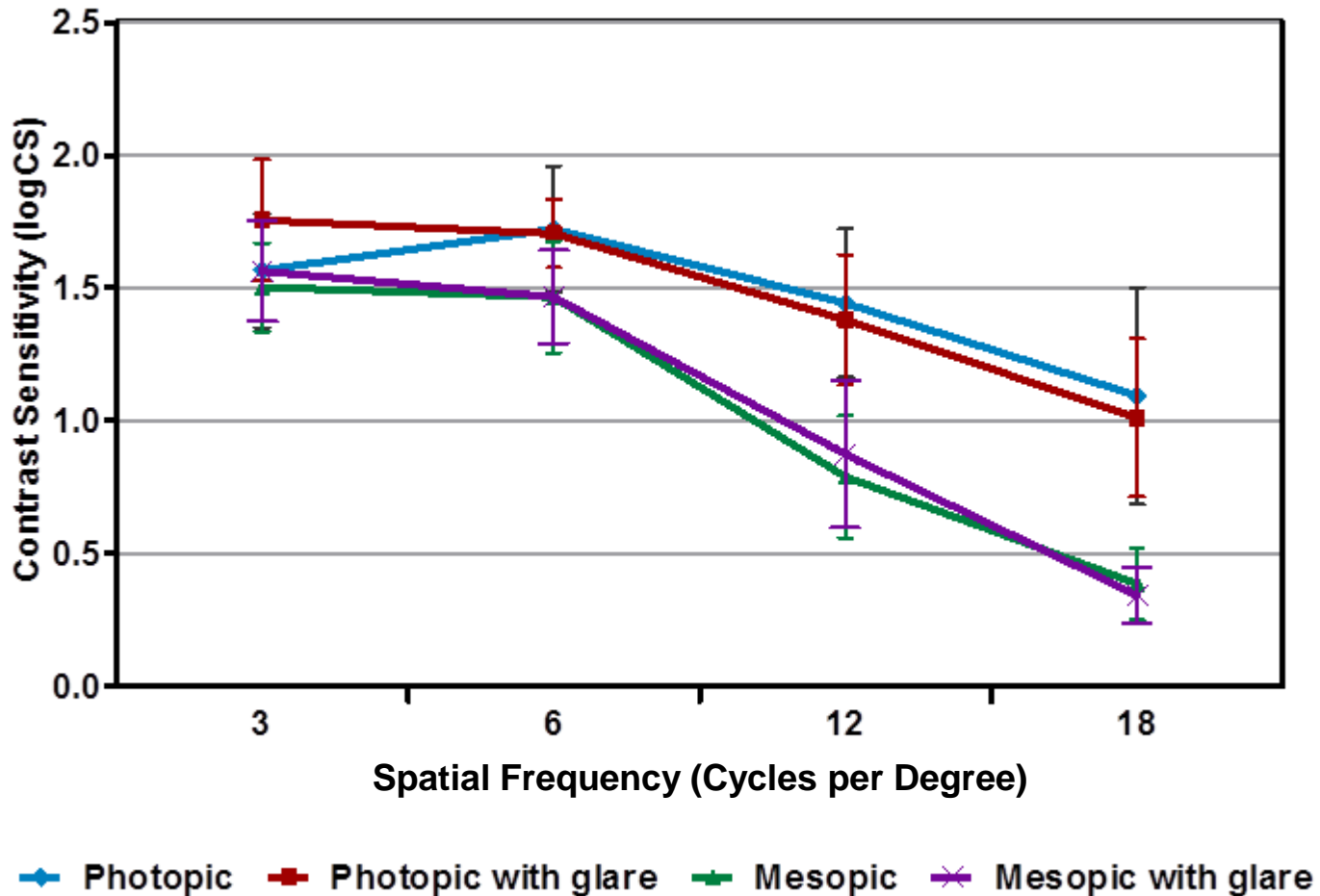
Binocular best corrected defocus curve at 3 months



Clinical Outcomes from Our institution

- **Contrast Sensitivity**

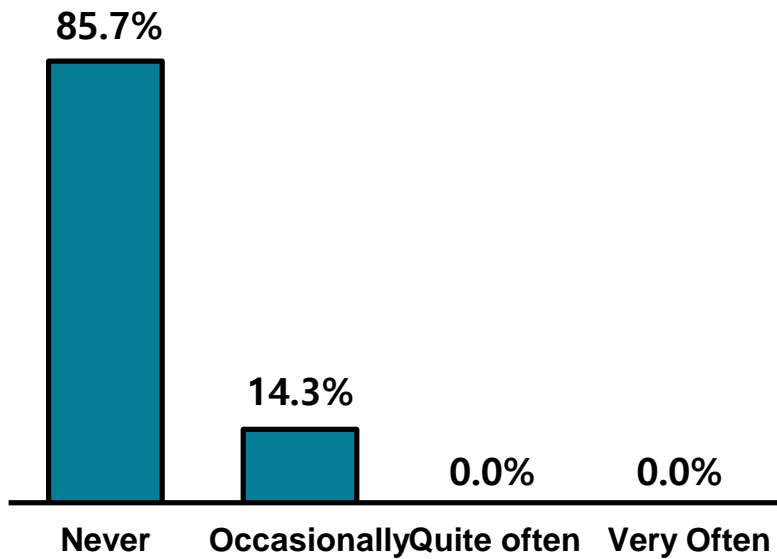
Post-operative contrast sensitivity scores at 3 months



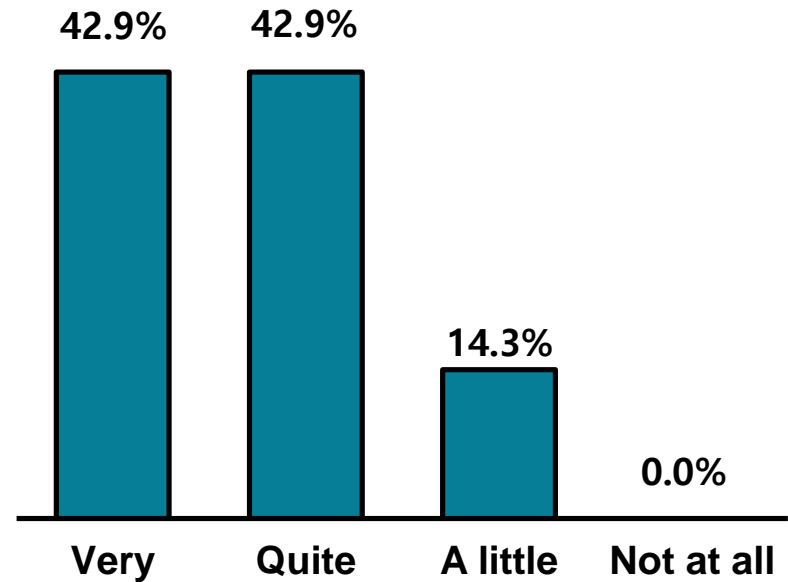
Clinical Outcomes from Our institution

- **Satisfaction and Quality of Vision**

Spectacle Usage at 3 months



Satisfaction with uncorrected vision at 3 months



Clinical Outcomes from Our institution

- Satisfaction and Quality of Vision**

Satisfaction with near, intermediate, far vision at 3 months

Satisfaction with vision at		N=7	
		n	%
Near	Very	3	42.9%
	Quite	2	28.6%
	A little	2	28.6%
	Not at all	0	0.0%
Intermediate	Very	4	57.1%
	Quite	1	14.3%
	A little	2	28.6%
	Not at all	0	0.0%
Far	Very	4	57.1%
	Quite	2	28.6%
	A little	1	14.3%
	Not at all	0	0.0%
Overall	Very	4	57.1%
	Quite	1	14.3%
	A little	2	28.6%
	Not at all	0	0.0%

Clinical Outcomes from Our institution

- Satisfaction and Quality of Vision**

Quality of Vision at 3 months

Visual Quality causing discomfort		N=7	
		n	%
Glare	Never	5	71.4%
	Occasionally	2	28.6%
	Quite often	0	0.0%
	Very often	0	0.0%
Halo	Never	6	85.7%
	Occasionally	1	14.3%
	Quite often	0	0.0%
	Very often	0	0.0%
Starbutst	Never	6	85.7%
	Occasionally	1	14.3%
	Quite often	0	0.0%
	Very often	0	0.0%
Hazy vision	Never	7	100.0%
	Occasionally	0	0.0%
	Quite often	0	0.0%
	Very often	0	0.0%
Blurred vision	Never	7	100.0%
	Occasionally	0	0.0%
	Quite often	0	0.0%
	Very often	0	0.0%

Visual Quality		N=7	
		n	%
Distortion	Never	6	85.7%
	Occasionally	1	14.3%
	Quite often	0	0.0%
	Very often	0	0.0%
Double Vision	Never	7	100.0%
	Occasionally	0	0.0%
	Quite often	0	0.0%
	Very often	0	0.0%
Fluctuation	Never	5	71.4%
	Occasionally	1	14.3%
	Quite often	0	0.0%
	Very often	1	14.3%
Focusing Difficulties	Never	7	100.0%
	Occasionally	0	0.0%
	Quite often	0	0.0%
	Very often	0	0.0%
Difficulty judging Distance or Depth perception	Never	7	85.7%
	Occasionally	0	14.3%
	Quite often	0	0.0%
	Very often	0	0.0%

Clinical Outcomes from Our institution

- **Adverse events**

Adverse Events		N=14	
		n	%
Cumulative	Cystoid macular edema (CME)	0	0
	Hypopyon	0	0
	Endophthalmitis	0	0
	Lens dislocation	0	0
	Pupillary block	0	0
	Retinal detachment	0	0
	Secondary surgical intervention (SSI)	0	0
Persistent	Corneal stroma edema	0	0
	Cystoid macular edema	0	0
	Iritis	0	0
	Raised IOP requiring treatment	0	0

Complications	N=14	
	n	%
PCO	0	0
Posterior Capsule Striae	0	0

Summary

- At 3 months of surgery, far, intermediate, and near vision correction were effective.
- Overall, the satisfaction of the patient after surgery was fairly satisfied to very satisfied.
- Patients with visual discomfort often present, but the results were good in overall.
- No adverse events for 3 months after surgery.



THANK YOU

PRECIZON[®] NVA
Aspheric Presbyopic IOL