Visual performance and contrast sensitivity with a new hydrophobic asymmetric–refractive extended-depth-of-focus (EDOF) IOL

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Purpose:

To evaluate the visual acuity for distance, intermediate and near vision as well as contrast sensitivity after implantation of a new hydrophobic asymmetric-refractive extended depth of focus (EDOF)IOL.

Setting:

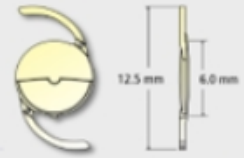
All implantations and follow-ups were performed at the AUGENTAGESKLINIK Lockwitzgrund and AUGENZENTRUM Fetscherplatz in Dresden, Germany

Our clinic has no financial interest in the trial results.

Study design:

- Prospective
- 20 patients (bilateral)
- Follow ups: 1-7 d, 4-6 w, 3 + 6 + 12 m
- Endpoints: VA, SR, Defocus curve, CS, PCO + patient satisfaction

One-piece posterior chamber lens for extended depth of focus and high contrast sensitivity with aspherical surface and blue light filter

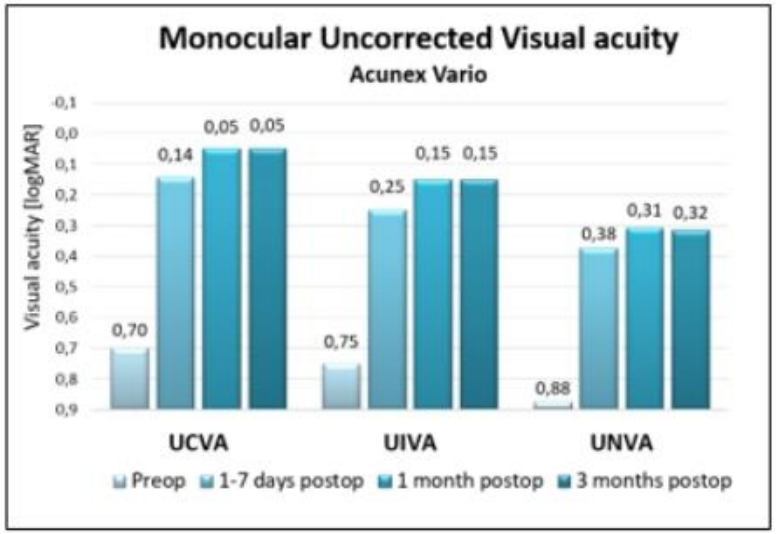


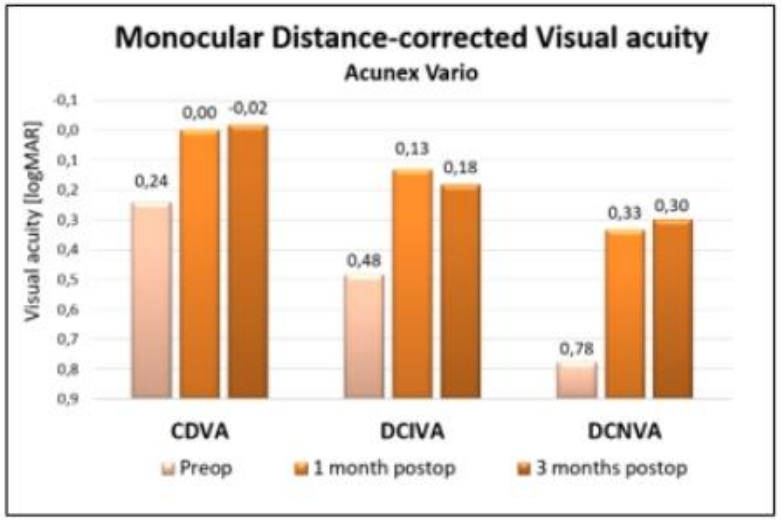
Product	ACUNEX® VARIO AN6V
Type	Foldable one-piece EDOF-IOL for capsular bag fixation
Optic Size	6.0 mm
Overall Length	12.5 mm
Haptic Angulation	0°
Optic Design	Biconvex Sector_shaped nearvision segment - anterior: +1.5D Aspherical surface - posterior Spherical aberration free
IOL Design	C-Loop haptic Optic and haptics with square edges, posterior 360° continuous barrier effect
Material	Hydrophobic glistening-free acrylate UV absorbing and additional blue light filter
Available Diopters	SE +10.0D to +30.0D (0.5D)
Refrative Index	1.54 @ 35°
Estimated A-Factor (nominal)	119.1
Sterilization	Gamma sterilization
Storage	Supplied at 0.9 % saline solution, storage at room temperature not > 43°C (110°F)
Recommended Incision Size	≥ 2.0 mm

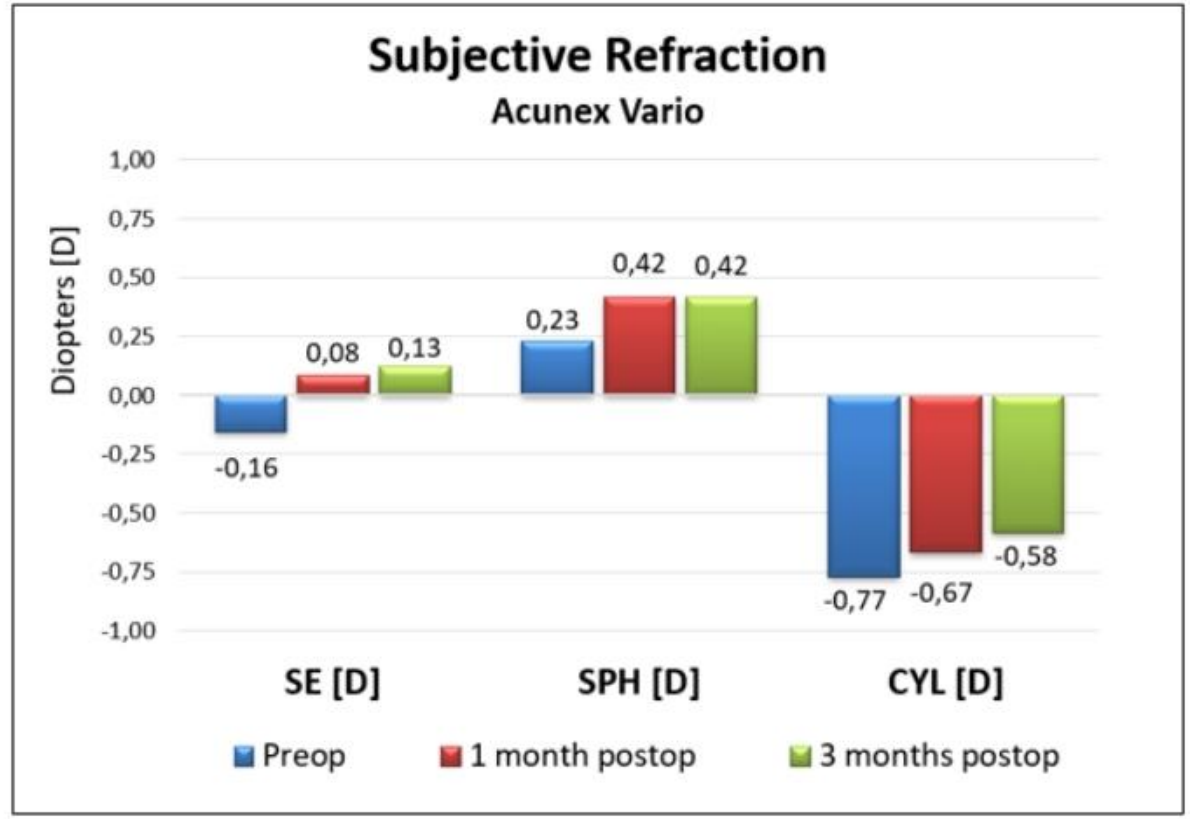
aspheric
EDOF
blue light filter
Glistening-free

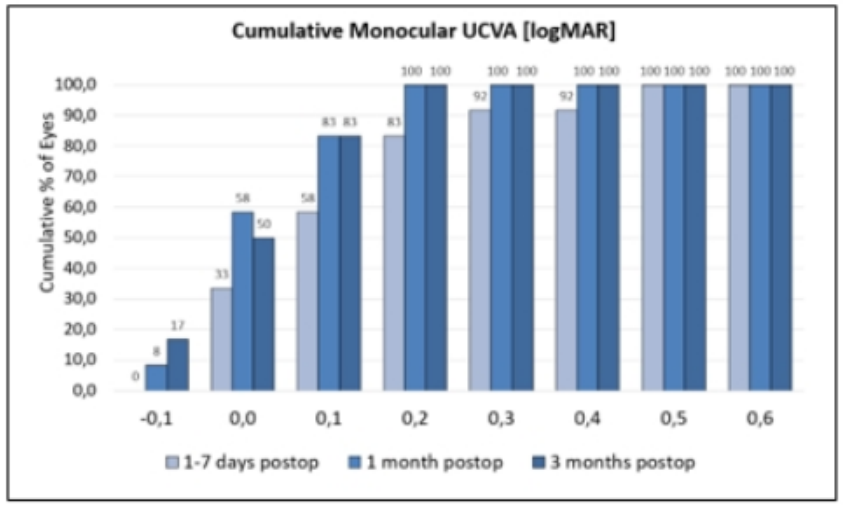
Inclusion criteria:
- Cataract or CLE
- Patient age 40 to 80 years
- Expected postop. astigmatism ≤ 0.75 dpt
- Pupil diameter ≥ 3 mm and max. ≤ 6mm
- Pupil decentration < 0.8 mm (Center Shift)

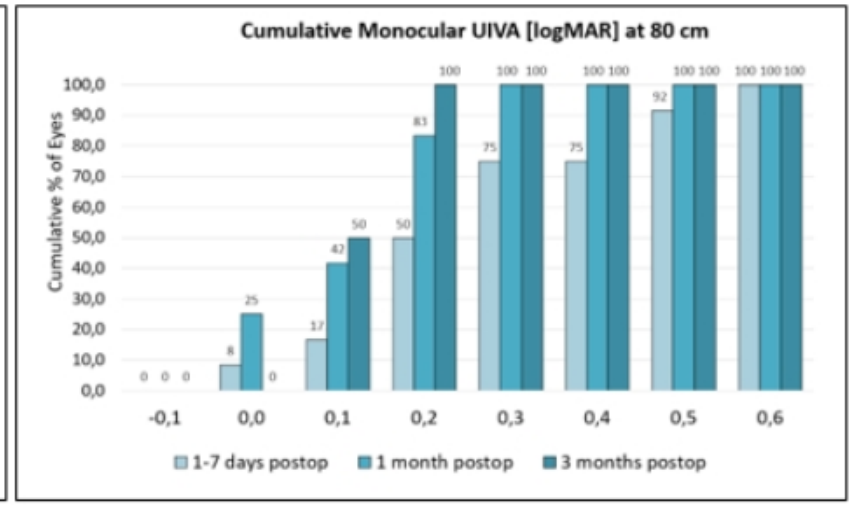
Exclusion criteria:
- Amblyopia
- Strabismus
- Irregular astigmatism
- Diabetic mellitus
- Previous refractive or glaucoma surgery
- VA potential 0.3 logMAR or worse

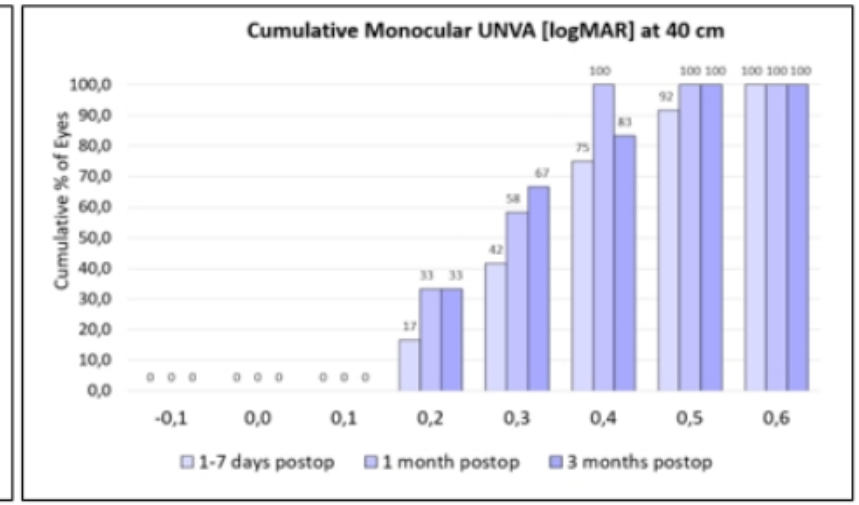

Monocular Uncorrected Visual acuity
Acunex Vario
Visual acuity [logMAR]
-0,1
0,0
0,1
0,2
0,3
0,4
0,5
0,6
0,7
0,8
0,9
0,70
0,14
0,05
0,05
0,75
0,25
0,15
0,15
0,88
0,38
0,31
0,32
UCVA
UIVA
UNVA
Preop
1-7 days postop
1 month postop
3 months postop

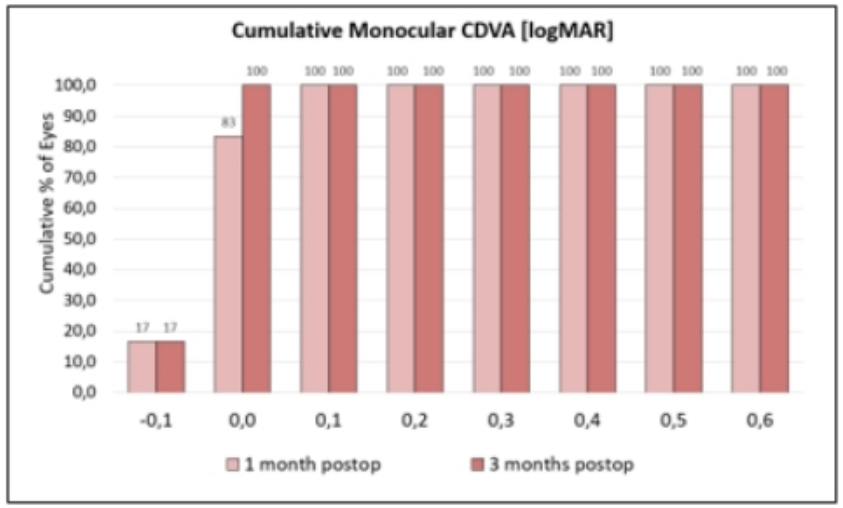

Monocular Distance-corrected Visual acuity
Acunex Vario
Visual acuity [logMAR]
-0,1
0,0
0,1
0,2
0,3
0,4
0,5
0,6
0,7
0,8
0,9
0,24
0,00
-0,02
0,48
0,13
0,18
0,78
0,33
0,30
CDVA
DCIVA
DCNVA
Preop
1 month postop
3 months postop

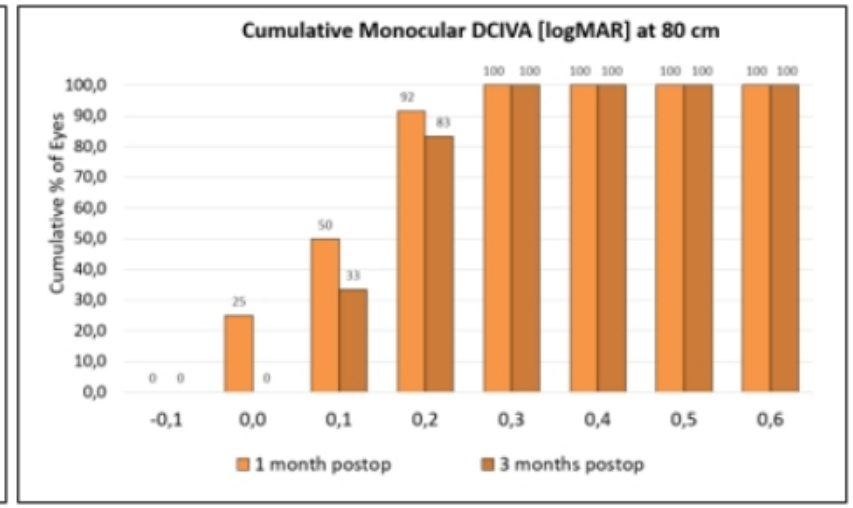

Subjective Refraction
Acunex Vario
Diopters [D]
1,00
0,75
0,50
0,25
0,00
-0,25
-0,50
-0,75
-1,00
-0,16
0,08
0,13
0,23
0,42
0,42
-0,77
-0,67
-0,58
SE [D]
SPH [D]
CYL [D]
Preop
1 month postop
3 months postop

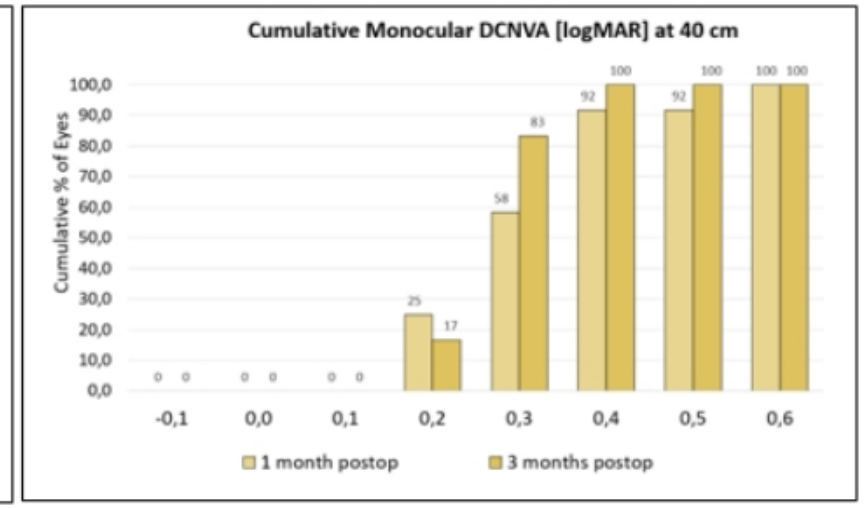

Cumulative Monocular UCVA [logMAR]
Cumulative % of Eyes
100,0
90,0
80,0
70,0
60,0
50,0
40,0
30,0
20,0
10,0
0,0
-0,1
0,0
0,1
0,2
0,3
0,4
0,5
0,6
1-7 days postop
1 month postop
3 months postop

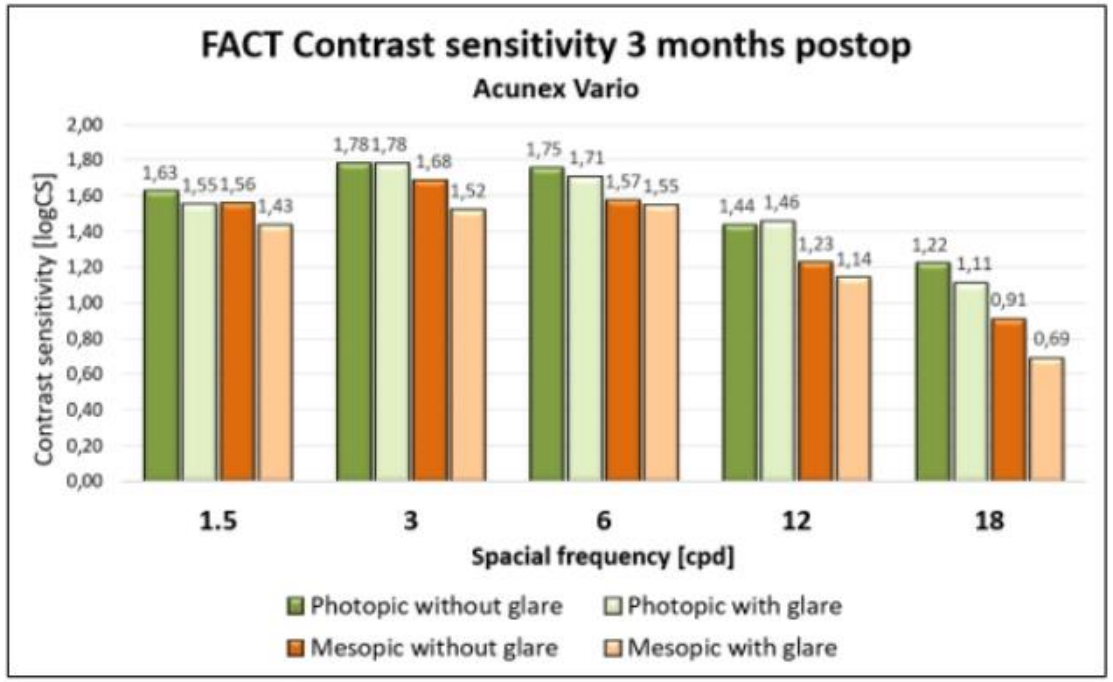

Cumulative Monocular UIVA [logMAR] at 80 cm
Cumulative % of Eyes
100,0
90,0
80,0
70,0
60,0
50,0
40,0
30,0
20,0
10,0
0,0
-0,1
0,0
0,1
0,2
0,3
0,4
0,5
0,6
1-7 days postop
1 month postop
3 months postop

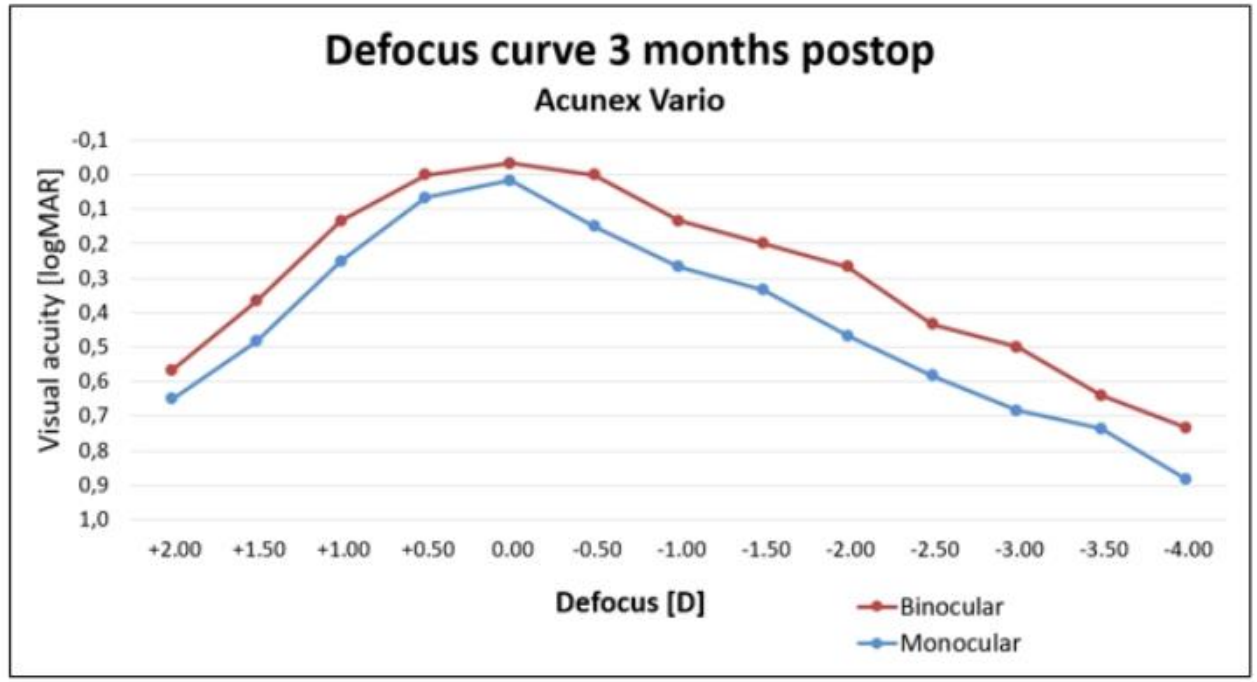

Cumulative Monocular UNVA [logMAR] at 40 cm
Cumulative % of Eyes
100,0
90,0
80,0
70,0
60,0
50,0
40,0
30,0
20,0
10,0
0,0
-0,1
0,0
0,1
0,2
0,3
0,4
0,5
0,6
1-7 days postop
1 month postop
3 months postop


Cumulative Monocular CDVA [logMAR]
Cumulative % of Eyes
100,0
90,0
80,0
70,0
60,0
50,0
40,0
30,0
20,0
10,0
0,0
-0,1
0,0
0,1
0,2
0,3
0,4
0,5
0,6
1 month postop
3 months postop


Cumulative Monocular DCIVA [logMAR] at 80 cm
Cumulative % of Eyes
100,0
90,0
80,0
70,0
60,0
50,0
40,0
30,0
20,0
10,0
0,0
-0,1
0,0
0,1
0,2
0,3
0,4
0,5
0,6
1 month postop
3 months postop


Cumulative Monocular DCNVA [logMAR] at 40 cm
Cumulative % of Eyes
100,0
90,0
80,0
70,0
60,0
50,0
40,0
30,0
20,0
10,0
0,0
-0,1
0,0
0,1
0,2
0,3
0,4
0,5
0,6
1 month postop
3 months postop


FACT Contrast sensitivity 3 months postop
Acunex Vario
Contrast sensitivity [logCS]
2,00
1,80
1,60
1,40
1,20
1,00
0,80
0,60
0,40
0,20
0,00
1,63 1,55 1,56 1,43
1,78 1,78 1,68 1,52
1,75 1,71 1,57 1,55
1,44 1,46 1,23 1,14
1,22 1,11 0,91 0,69
1.5
3
6
12
18
Spacial frequency [cpd]
Photopic without glare
Photopic with glare
Mesopic without glare
Mesopic with glare


Defocus curve 3 months postop
Acunex Vario
Visual acuity [logMAR]
-0,1
0,0
0,1
0,2
0,3
0,4
0,5
0,6
0,7
0,8
0,9
1,0
+2.00 +1.50 +1.00 +0.50 0.00 -0.50 -1.00 -1.50 -2.00 -2.50 -3.00 -3.50 -4.00
Defocus [D]
Binocular
Monocular

Results:

Post-op uncorrected distance and intermediate acuity were 0.2 logMAR or better for all patients. Near visual acuity was at least 0.4 logMAR or better in all cases. All eyes were within +/-0.5 D deviation from target SE. The evaluations regarding contrast sensitivity shows mean logCS values > 1.0 for spatial frequencies 1.5, 3, 6 and 12 cpd under photopic and mesopic light conditions without glare and for photopic light conditions with glare.

Conclusions:

Patients can benefit from EDOF for far and intermediate distances with the Acunex Vario IOL. Contrast and predictability was excellent and comparable with monofocal IOLs.