Implantation of Scharioth Macula Lens in AMD: Results of a European Multicenter Clinical Trial

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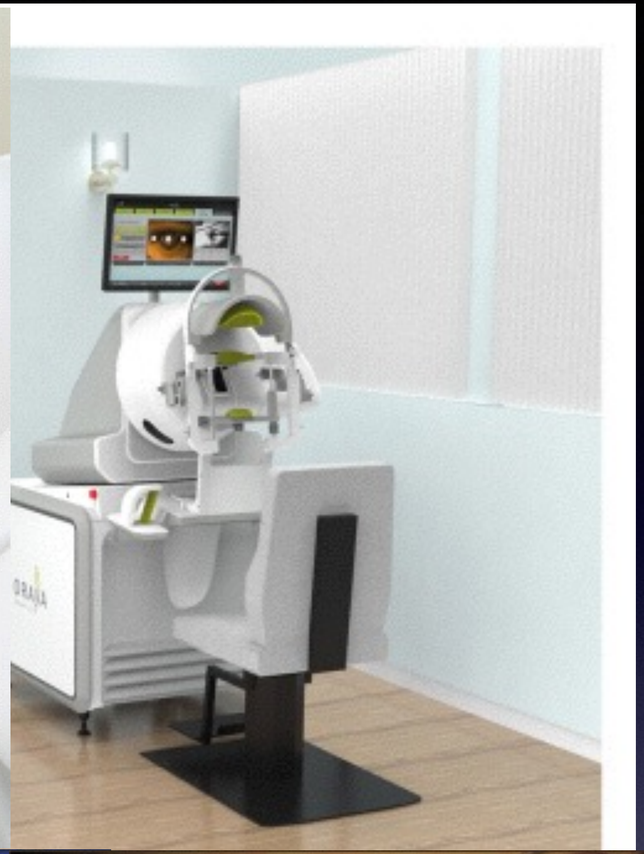
G.Scharioth - inventor of SML - receives royalties from Medicontur Ltd.

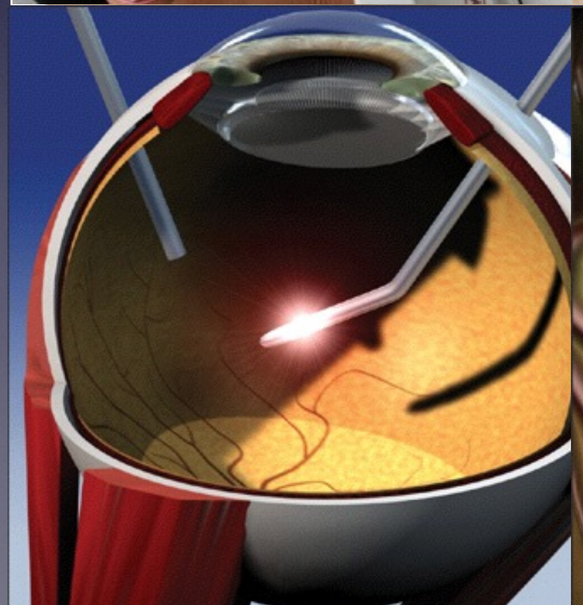
Treatment of neovascular AMD

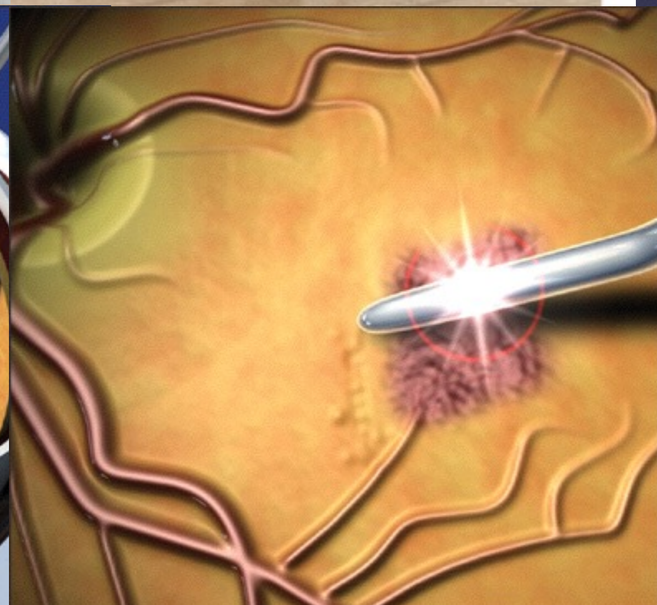
-Intravitreal anti - VEGF therapy

Wet AMD

- ORAYA - Highly focussed low energy X - ray radiation to macula.
- Epimacular brachy therapy



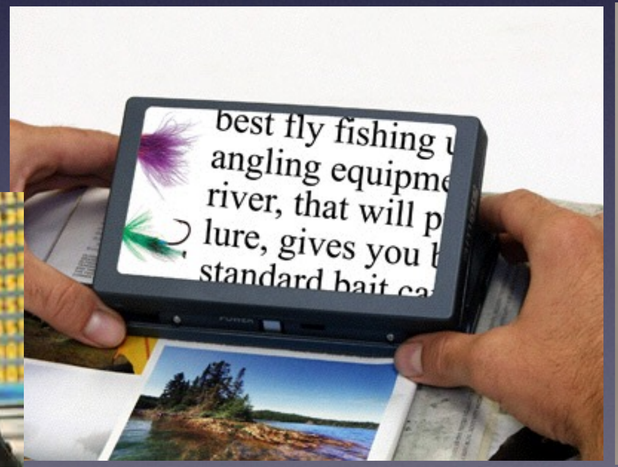




Rehabilitation of vision

Low vision aids

(glasses, magnifiers, loops, electronic devices)

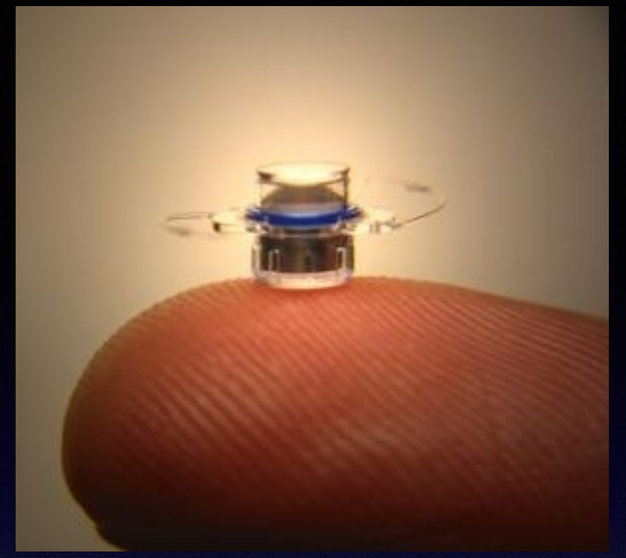


Magnifying IOL's

- Lipshitz implantable miniature telescope
- Lipshitz mirror implant
- IOL VIP System
- iol AMD

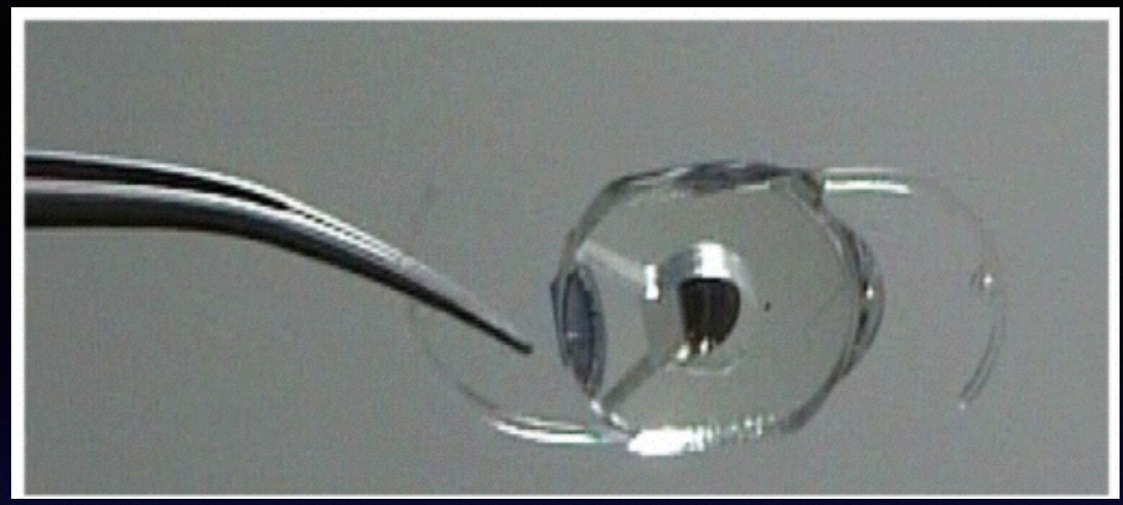
Lipshitz Implantable Miniature Telescope

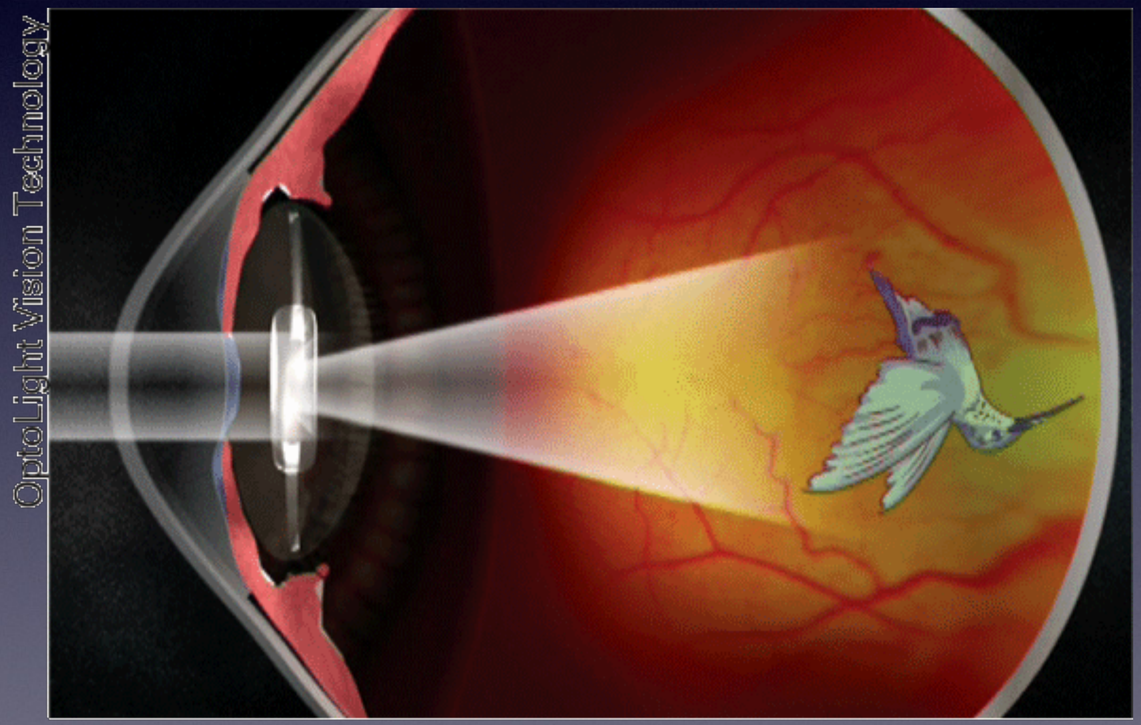
- FDA approval 2010
- 1 large rigid device, positioned within the capsular bag and protrudes through pupil
- Large incision of 12 mm
- Very sensible to decentration
- Visual field affected
- Galilean telescopic effect



Lipshitz Mirror Implant

- Rigid IOL
- 2 miniature mirros in Cassegrain telescopic configuration
- Incision size of 6.5 mm

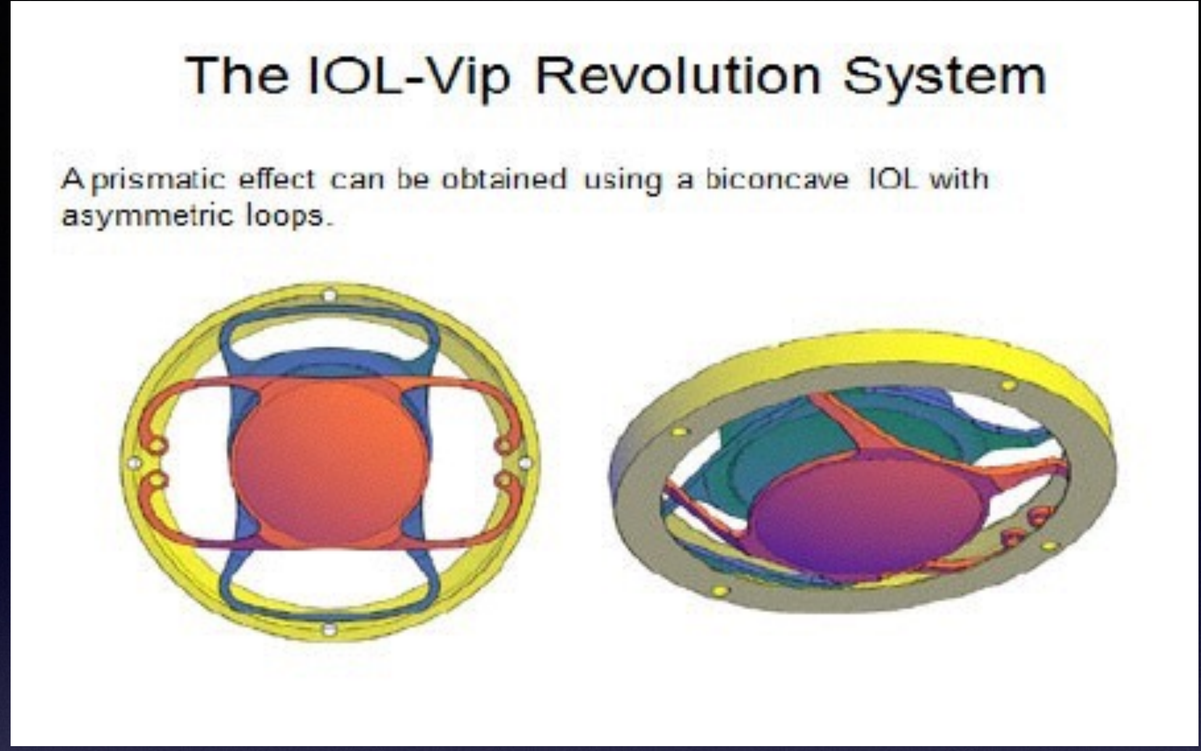




The Lipshitz Macular Implant uses mirrors to enlarge the central part of the visual field.

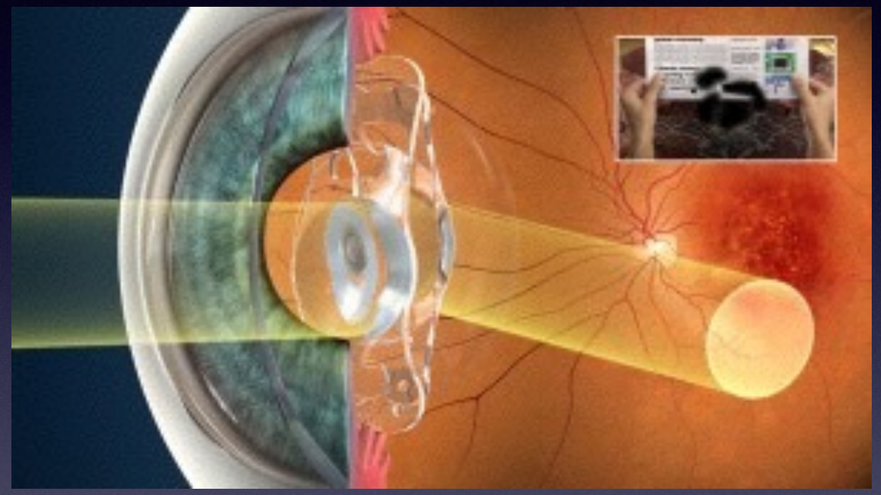
IOL Revolution
Lenspecial Italy

- EU launch 2012
- 2 thick rigid PMMA IOL
- 1 high powered biconcave IOL and 1 high powered biconvex IOL are positioned within a separately implanted silicone gutter inside the capsular bag
- Large incision of 8 mm
- Visual field affected
- Galilean telescopic effect



iol AMD

- 2 hydrophobic IOLs
- one in bag, one in sulcus
- 3 mm incision
- Galelian telescope

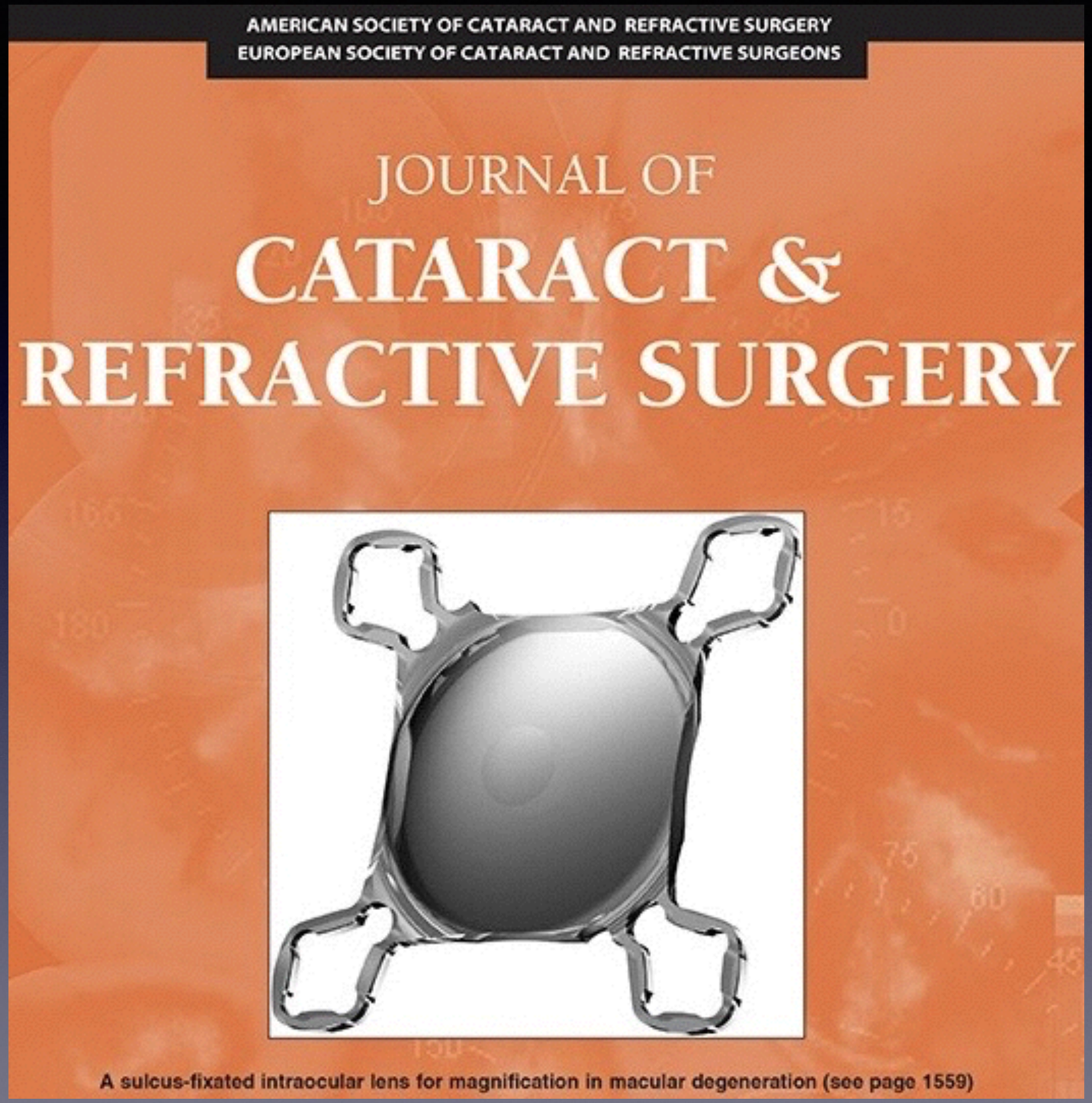


Downsides of current tech.

- large incision
- difficult surgery
- could affecting distance vision
- affect visual field
- only in combination with cataract surgery
- limited magnification of intraocular Galilean telescope
- high cost
- limited reversibility

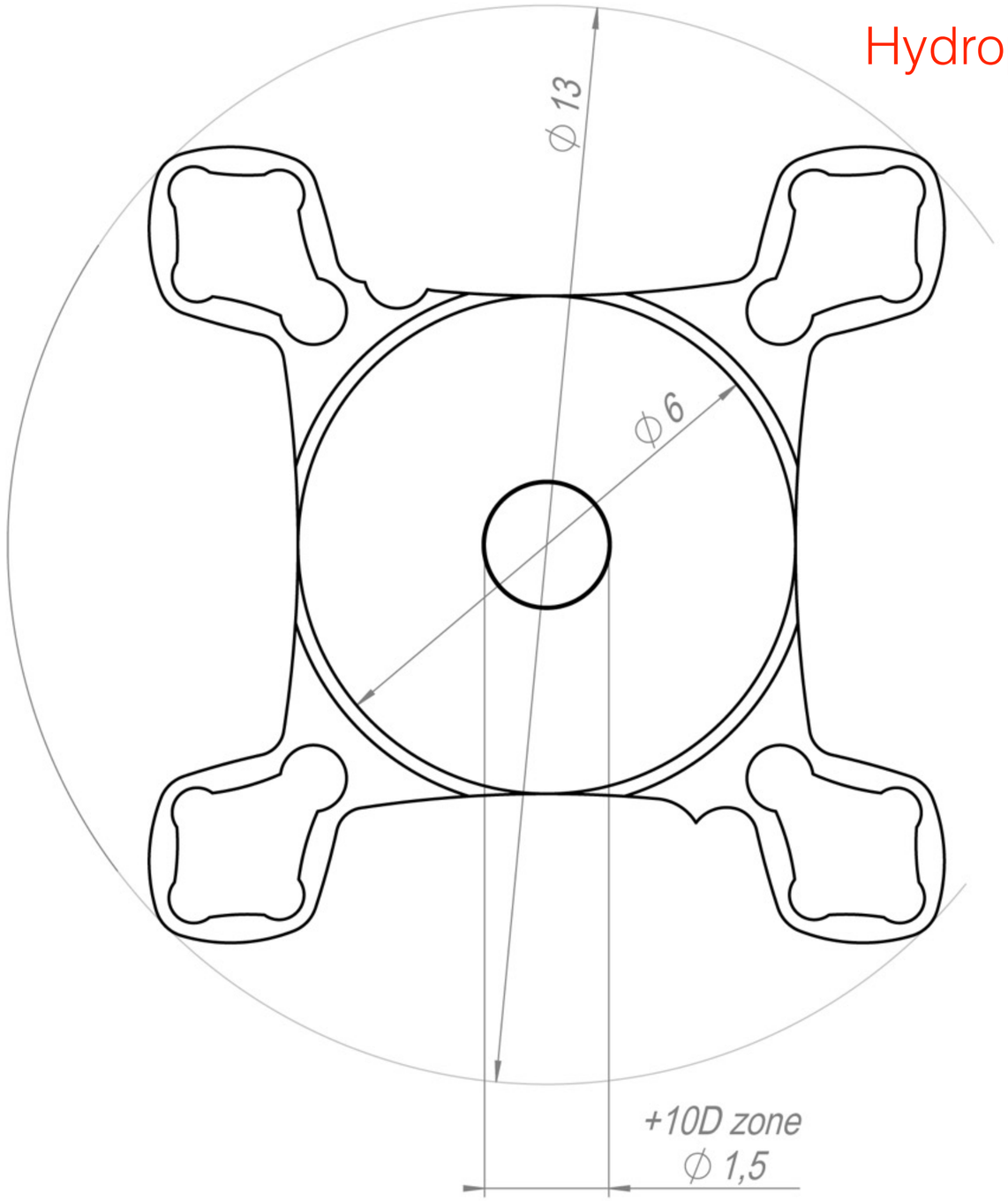
Aim of a new technology

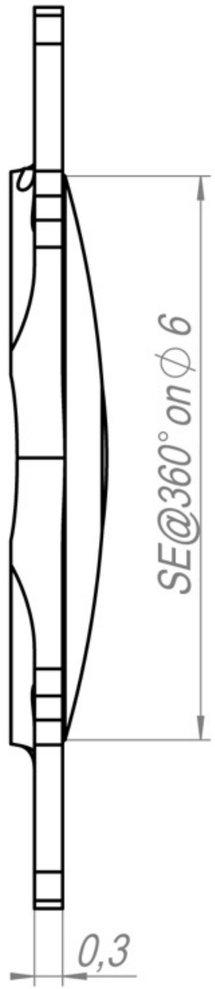
- sufficient magnification
- easy and safe surgery
- independent from lens status
- no reduction of visual field
- not affecting distance vision
- Reversible
- Affortable


AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY
EUROPEAN SOCIETY OF CATARACT AND REFRACTIVE SURGEONS
JOURNAL OF
CATARACT &
REFRACTIVE SURGERY
A sulcus-fixated intraocular lens for magnification in macular degeneration (see page 1559)

Aug 2015

Hydrophilic - 25% water



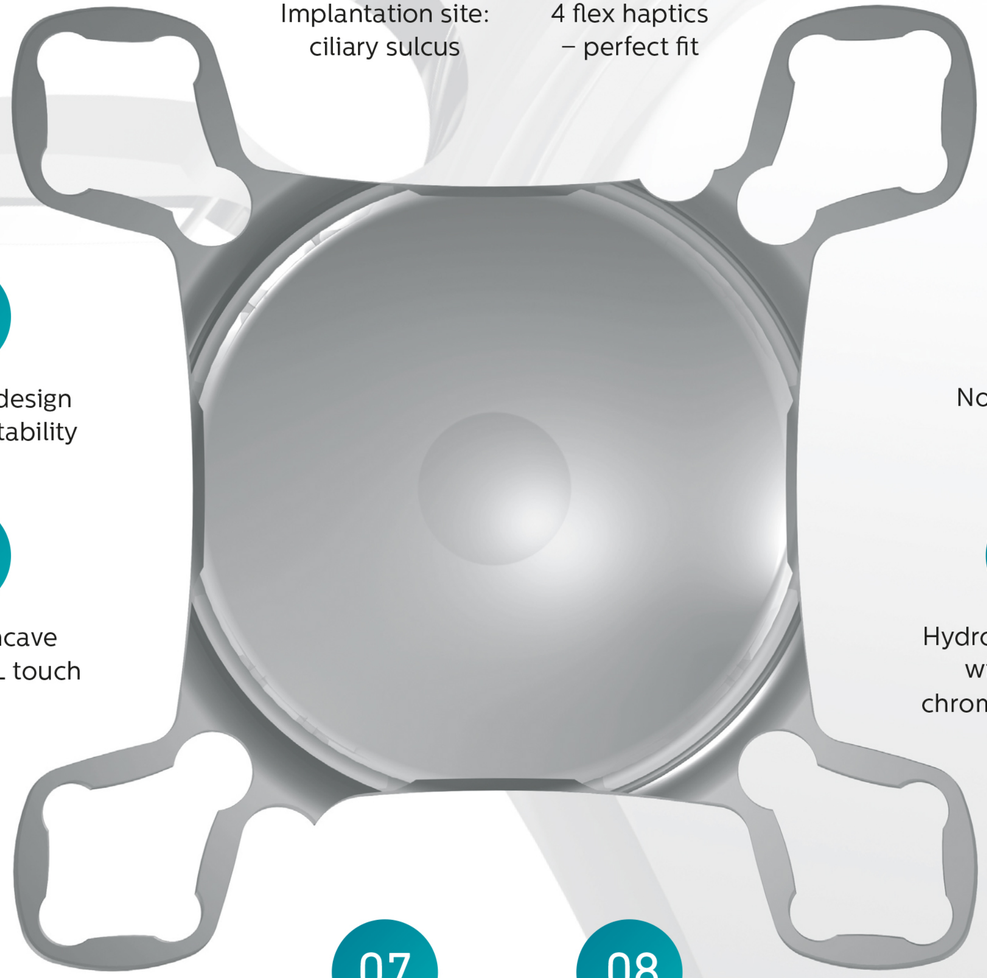


01

Implantation site: ciliary sulcus

02

4 flex haptics – perfect fit



03

Non-torque design – rotational stability

04

No iris capture

05

Convex-concave optic – no IOL touch

06

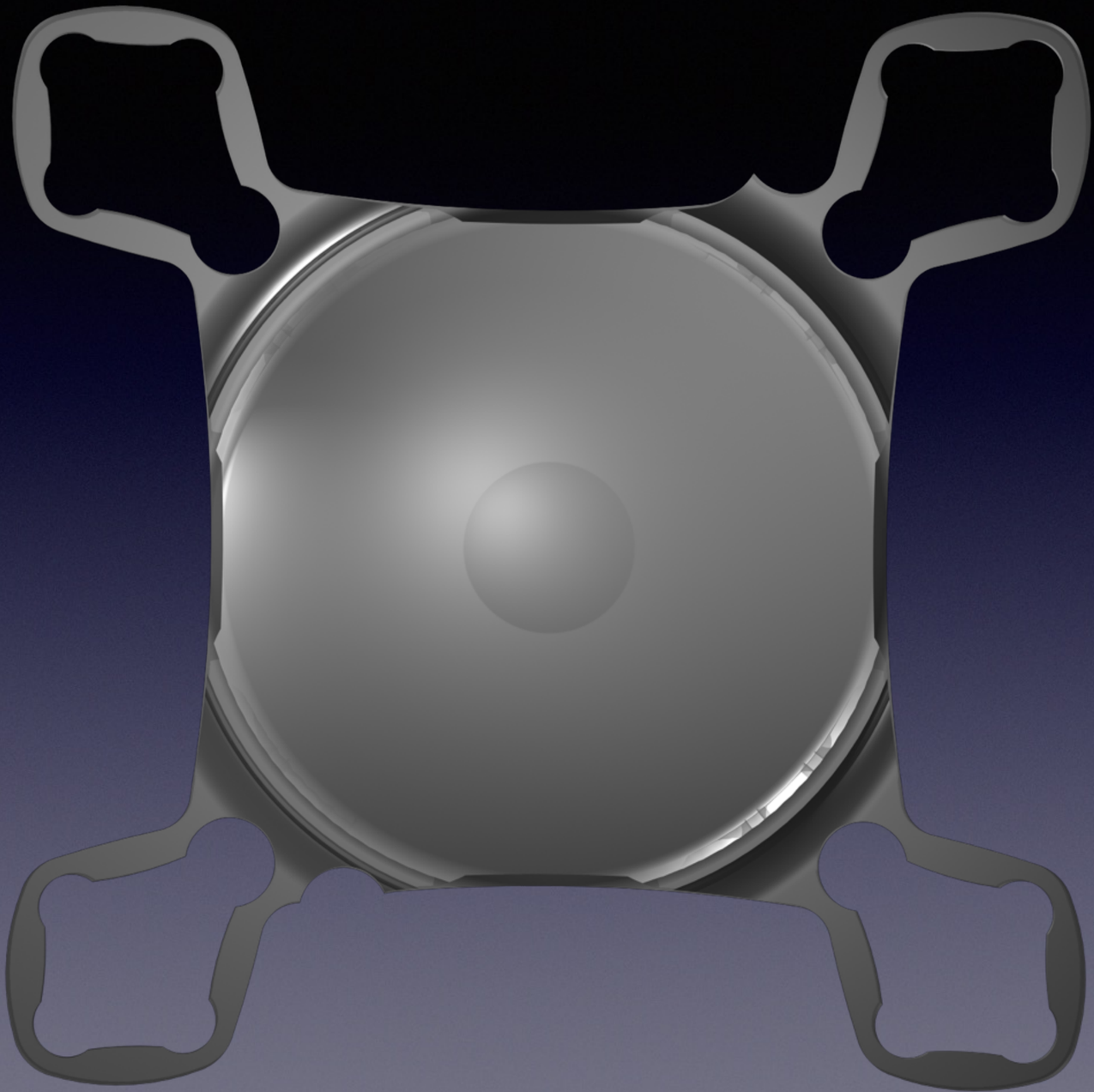
Hydrophilic material with very low chromatic aberration (Abbe 58)

07

Easy and safe surgery – through 2.2 mm incision

08

Smooth polished edges – no chafing effect



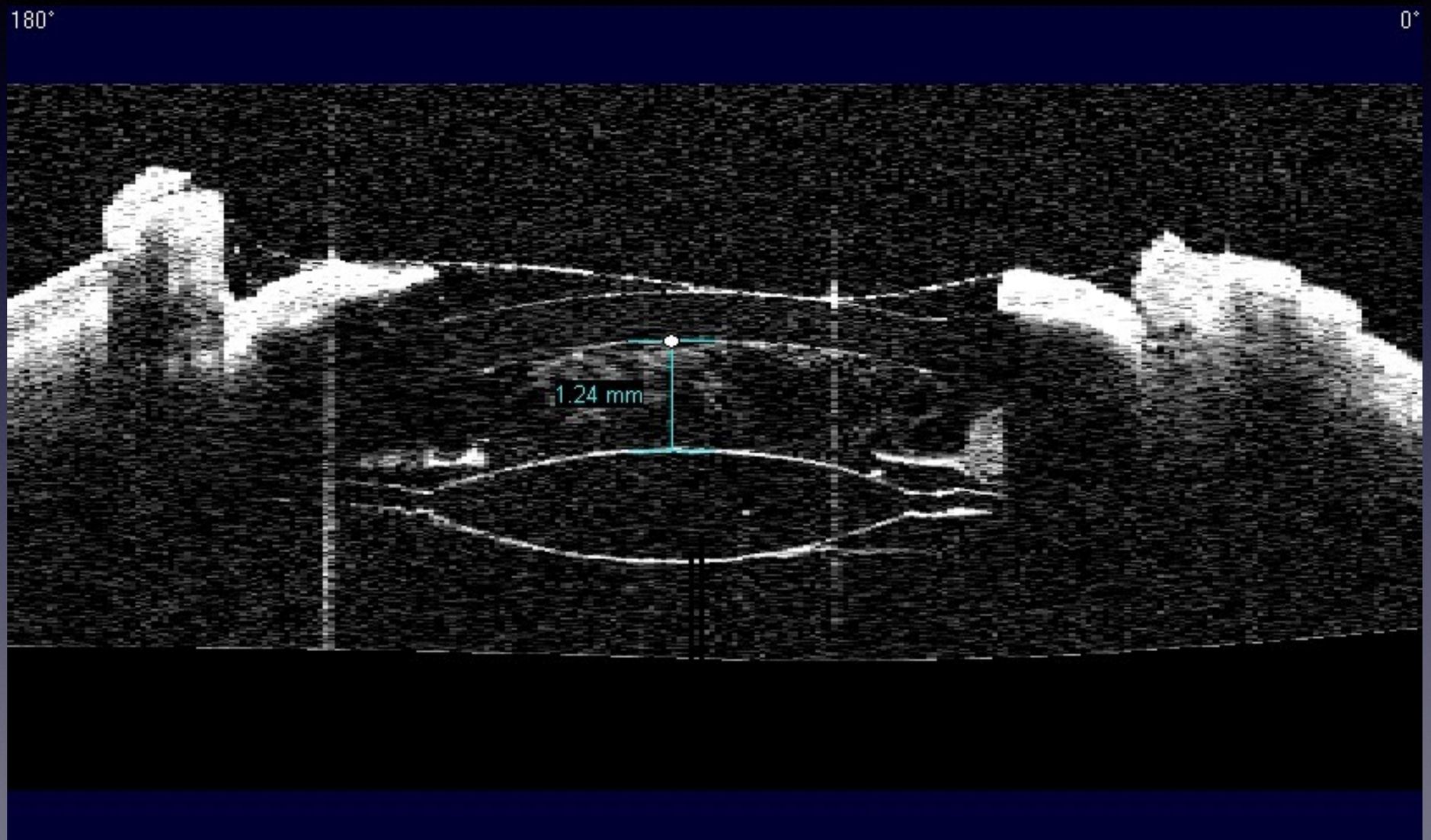
ZEISS

Visante™ OCT
ANTERIOR SEGMENT IMAGING

S/W Version: 1.2.0.1 Patient ID: Gender: Unknown Age: 0

Anterior Segment Single

OD OS



6 countries across Europe

Sept 2016
(facts so far)

- 6 countries
- 7 centrers
- 60 eyes (planned)
- 35 eyes* (implanted)

35

eyes/patients

F/M (35)

23/12

AGE

77.8

(65-94)

Inclusion Criteria

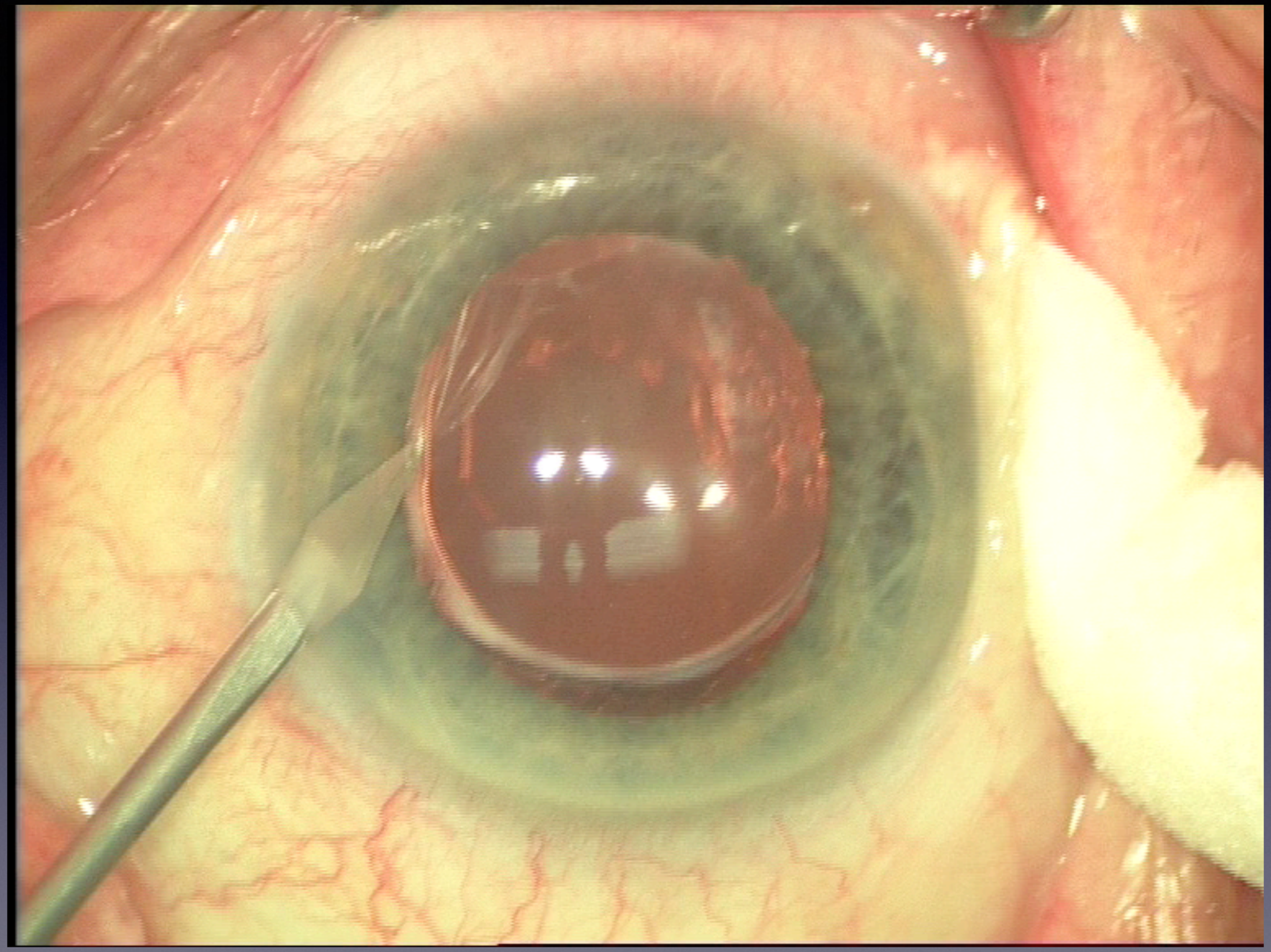
- Age > 55 yrs
- Pseudophakic eyes with dry / inactive wet AMD
- CDVA of 0.4 Decimal (6/15, 20/50) to 0.1 Decimal (6/60, 20/200) ETDRS chart.
- Pre operative CNVA: measured at 40 cms with a +2.5 D near vision add and measured at 15 cams with a + 6 D near vision add.
- **An improvement of CNVA by 3 or more lines**

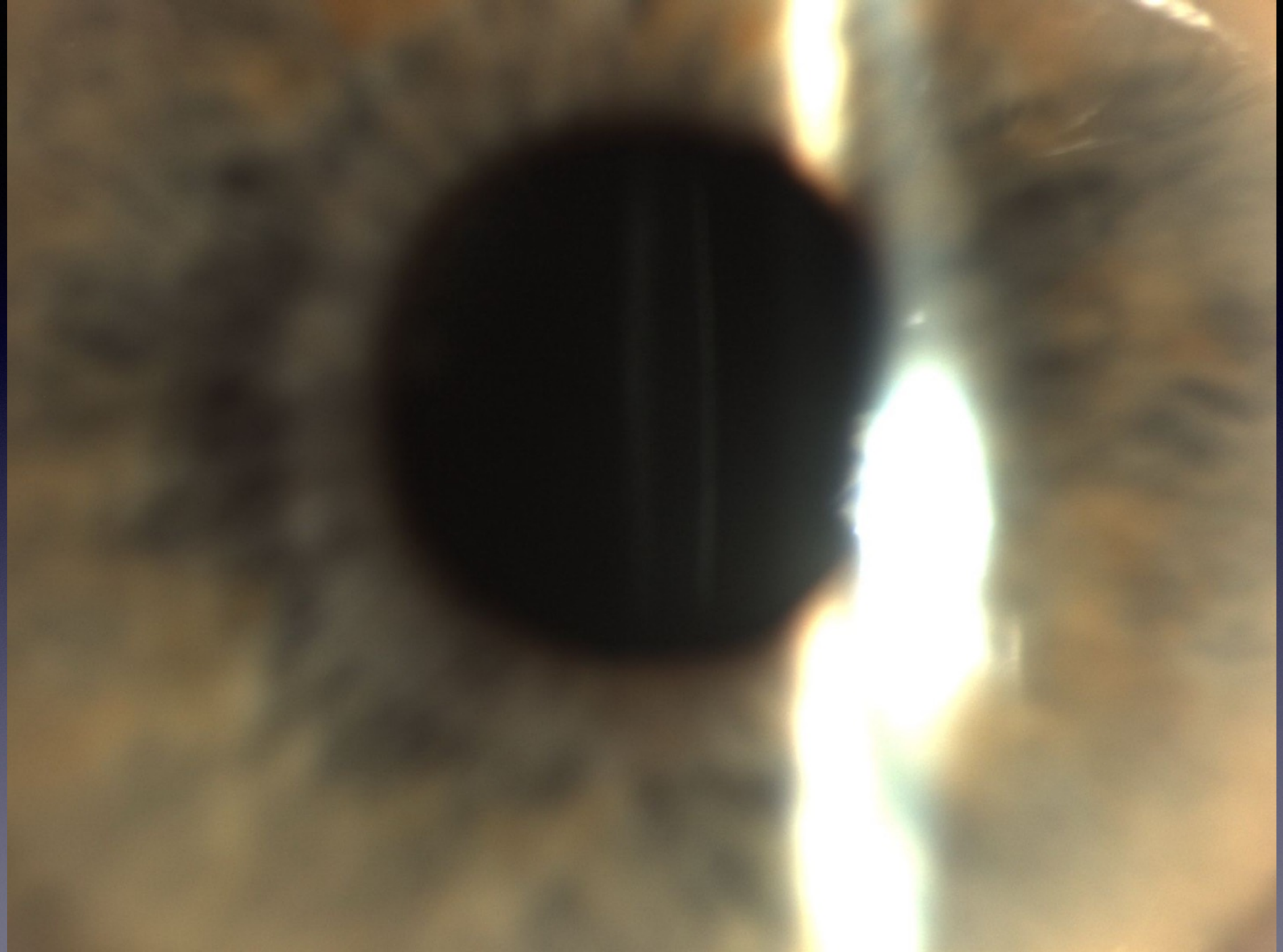

after Stroke

Standarised self illuminated ETDRS near vision chart

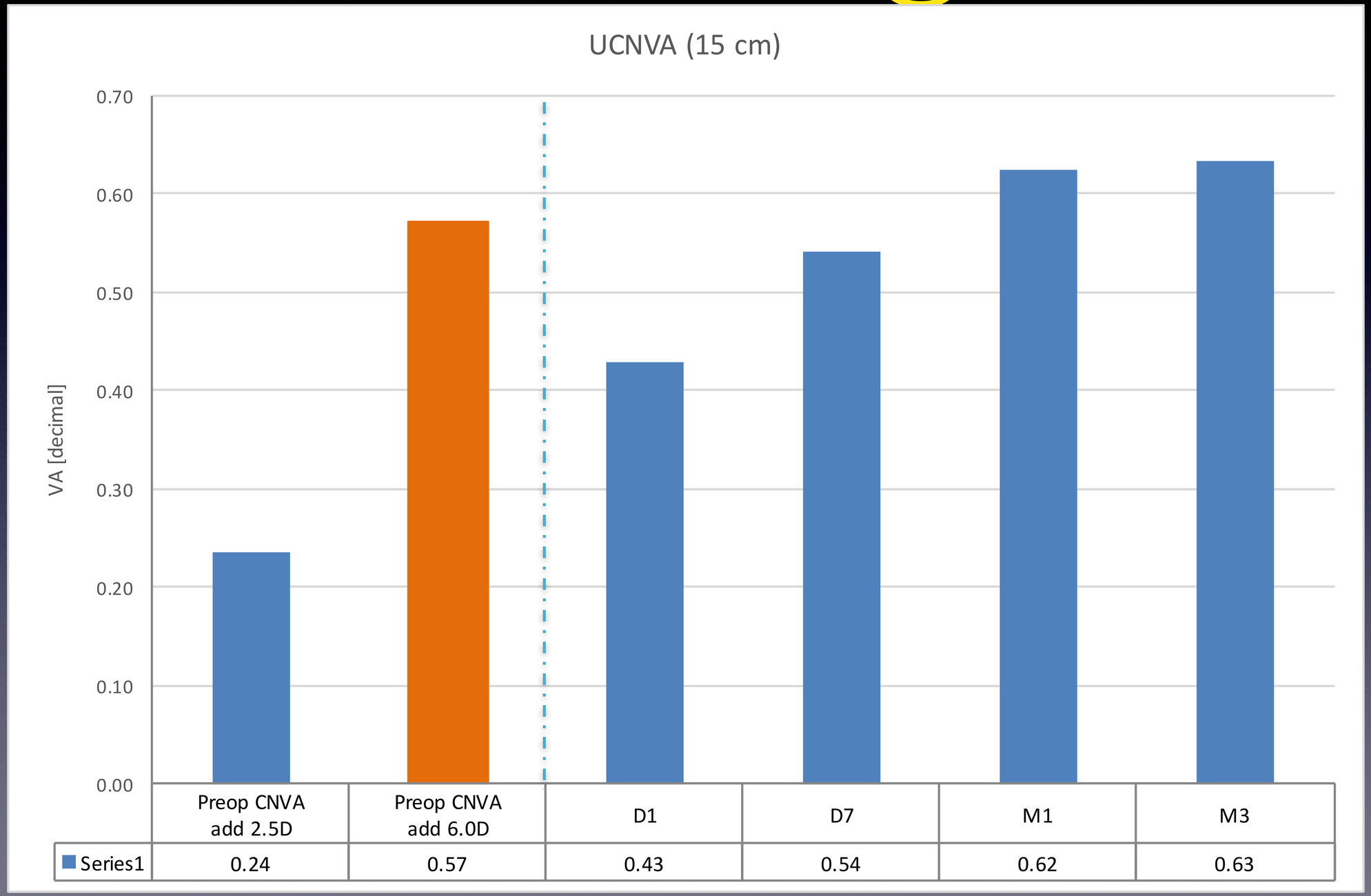
Exclusion Criteria

- Active wet AMD
- Severe Zonulopathy
- Iris neovascularisation
- Uveitis
- ACD < 2.8 mm from endothelium
- Previous complicated cataract surgery

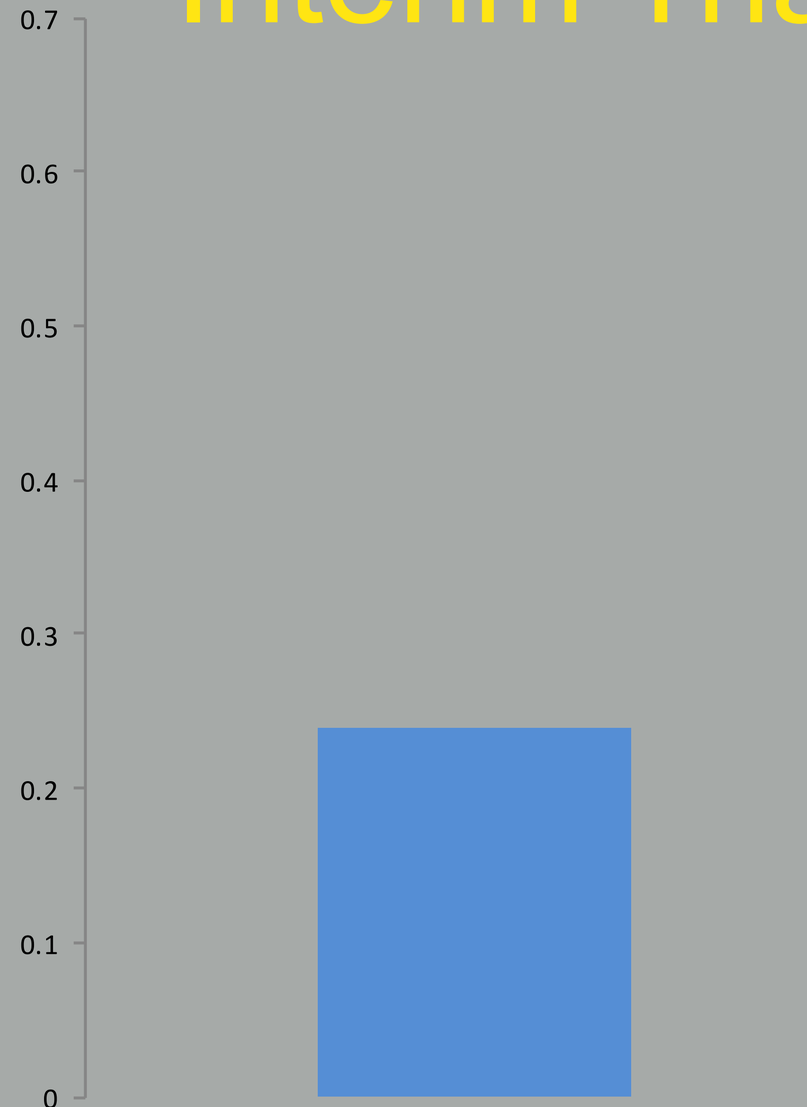




Interim Trial Results @ 3months

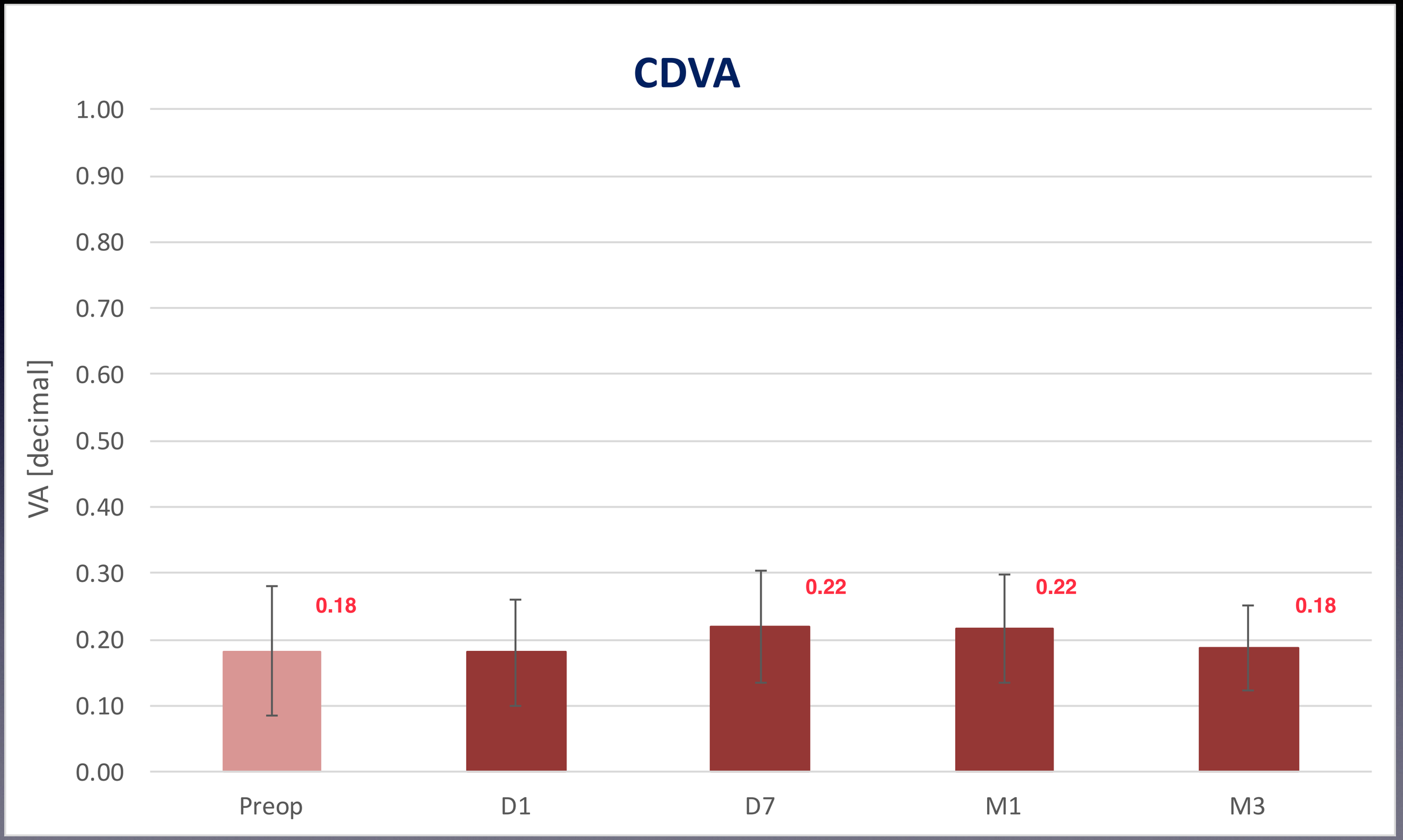


Interim Trial Results @ 3months

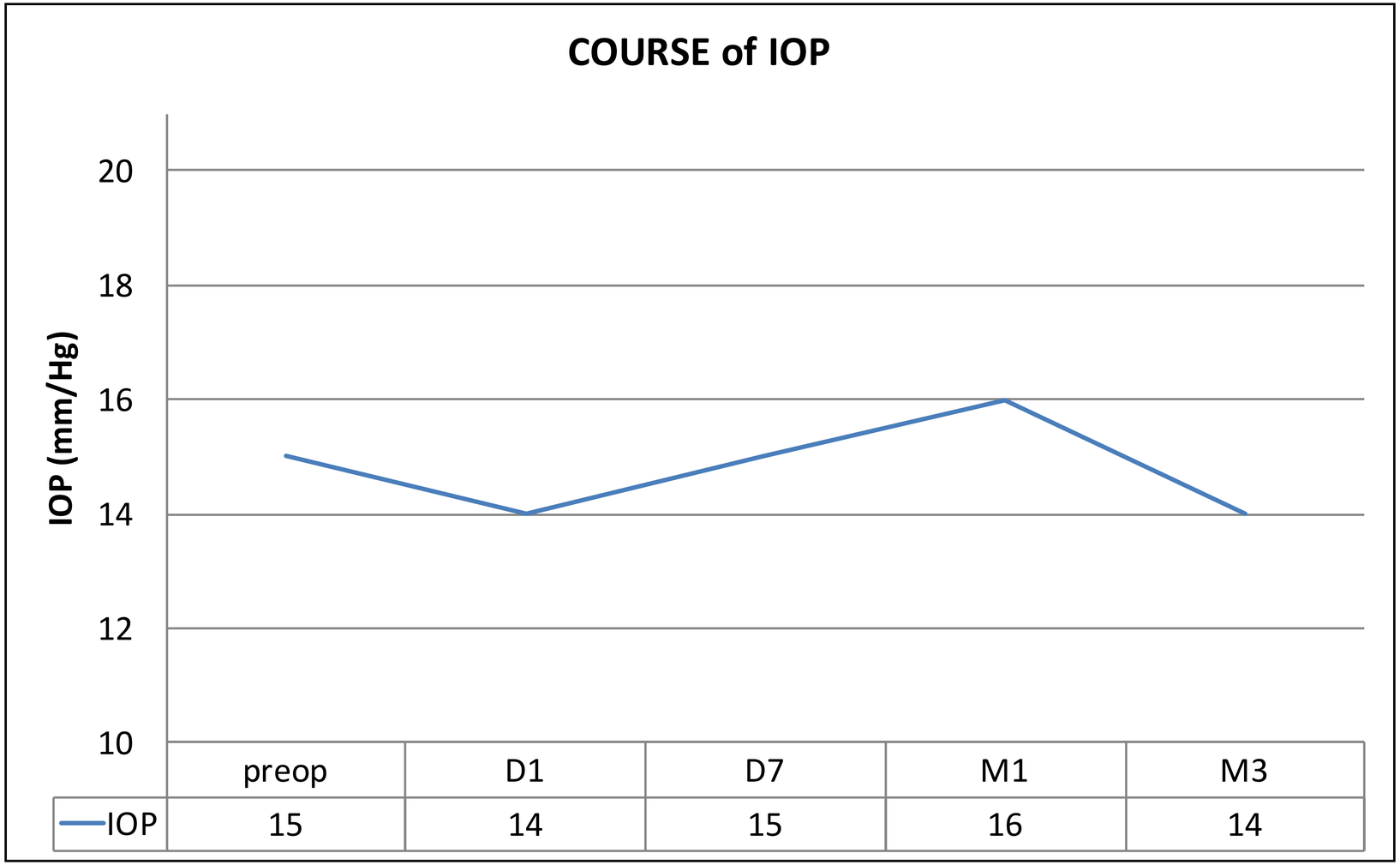


NVA Preoperative
+2.5/40cm

NVA Postoperative
SML/15cm


CDVA
VA [decimal]
1.00
0.90
0.80
0.70
0.60
0.50
0.40
0.30
0.20
0.10
0.00
0.18
0.22
0.22
0.18
Preop
D1
D7
M1
M3

SML - Results


COURSE of IOP
IOP (mm/Hg)
20
18
16
14
12
10
preop
D1
D7
M1
M3
IOP
15
14
15
16
14

Complications

SIDE EFFECTs	No of EYEs	%	Comments
Distance Vision issues Halos/Glares	3	9.7%	2 explanted
IOP increase	-		
Dislocation	-		
Chafing effect	-		
Iris capture	-		
Vitreous loss (during implantation)	1	2.4%	Not effect on VA
Vision Field loss	-		

Conclusions

- SML seems to increase NV without affecting DV
- Pt selection is the key
- Post op visual training