SCHARIOTH
MACULA LENS
A45SML

THE MAGNIFIER IN THE EYE

THE NEW HOPE FOR PATIENTS WITH DRY AMD

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MACULA
LENS

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MEDICONTUR
Vision of Expertise

WHAT   IS SML?

SML is a bifocal Add-On IOL
with a specifically designed central
optic area providing high addition power
of +10.0D, developed by
Prof. Gabor B. Scharioth.*

SML is intended for monocular implantation
in the better-seeing eye, without affecting distance
vision or visual field.

- Add-on with simple bifocal design

- Central 1.5 mm diameter optical zone with +10D

- Peripheral zone optically neutral

- Combines proven add-on technology

- With sufficient magnification

- Without affecting distance vision or visual field

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SML − Features

01
Implantation site:
ciliary sulcus

02
4 flex haptics
− perfect fit

03
Non-torque design
− rotational stability

04
Square design
− no iris capture

05
Convex-concave
optic − no IOL touch

06
Hydrophilic material
with very low
chromatic aberration
(Abbe 57)

07
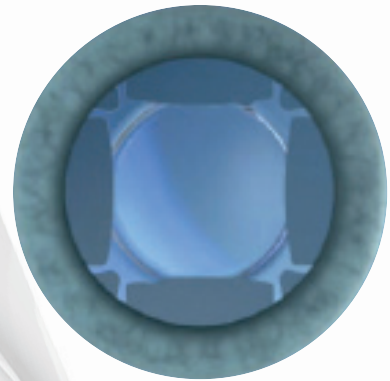Easy and safe
surgery
− through 2.2 mm
incision

08
Round polished
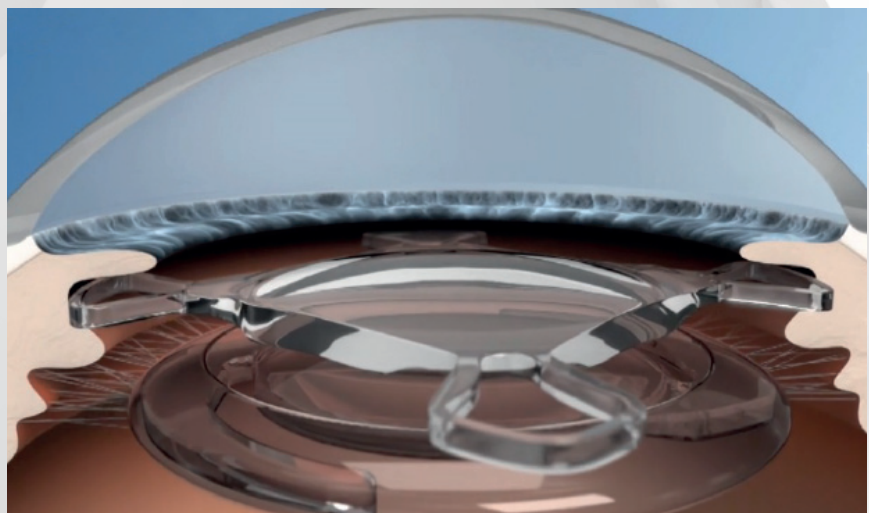edges
− no chafing
effect

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Strengths

- Sufficient magnification

- Easy and safe surgery

- Independent from lens status

- No reduction of visual field

- Not affecting distance vision

- Reversibility

- Affordable

SML is Safe

- **Proven Add-On Platform
  present on the market since 2010; over 2500 pcs implanted**

- SML is stable in the sulcus

- Without IOP elevation

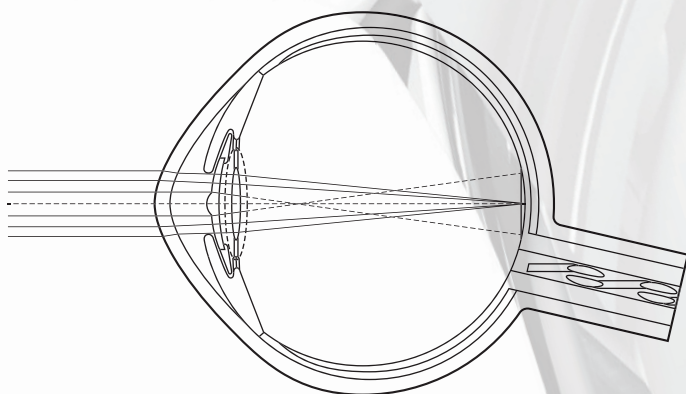- No iris capture possible

- No chafing effect

Using so – called Near Triad Reflex:
miosis – accommodation – convergence

Due to the effect of near vision miosis, the central optical portion – providing the magnified image – will dominate when the patient focuses on near objects only but will not influence far vision significantly when the patient focuses on distant objects through a dilated pupil.
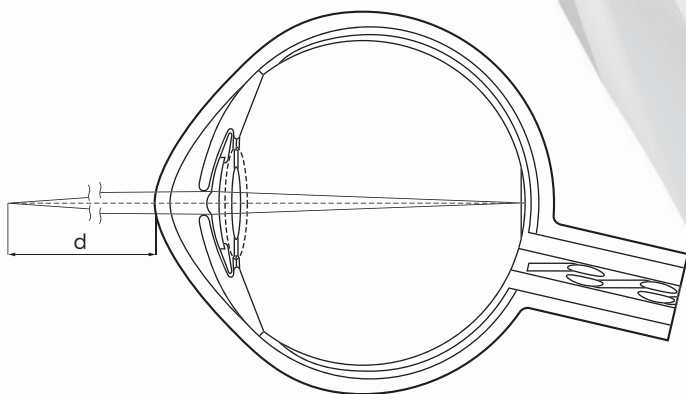
Pict 1: Patient´s eye with dilated pupil

• When the patient focuses on a distant object, the pupil is dilated and there is enough space around the central optical region for light rays passing through the peripheral optical portion of the secondary IOL as well.

• Light rays originating from a distant object that pass through the peripheral optical region and form the image of the distant object on the retina (solid lines) will dominate the patient's perception over light rays passing through the central optical region that do not focus on the retina (dashed lines).

Pict 2: Patient´s eye with constricted pupil

• When the pupil is constricted, light rays are restricted mainly to the central optical region of the secondary IOL, thus providing a magnified image on the macula. This is the case when the patient focuses on a near object, for example reads a newspaper or a price tag, and the pupil is constricted due to the near triad reflex.

• The image thus formed on the retina is magnified compared to the image formed of distant objects. This feature enables the patient's eye to resolve the image in case of AMD as well.

• Due to the relatively high refraction of the central optical region compared to the basic lens power, sharp vision is achieved at a very near distance (d), which is typically about 15 cm.
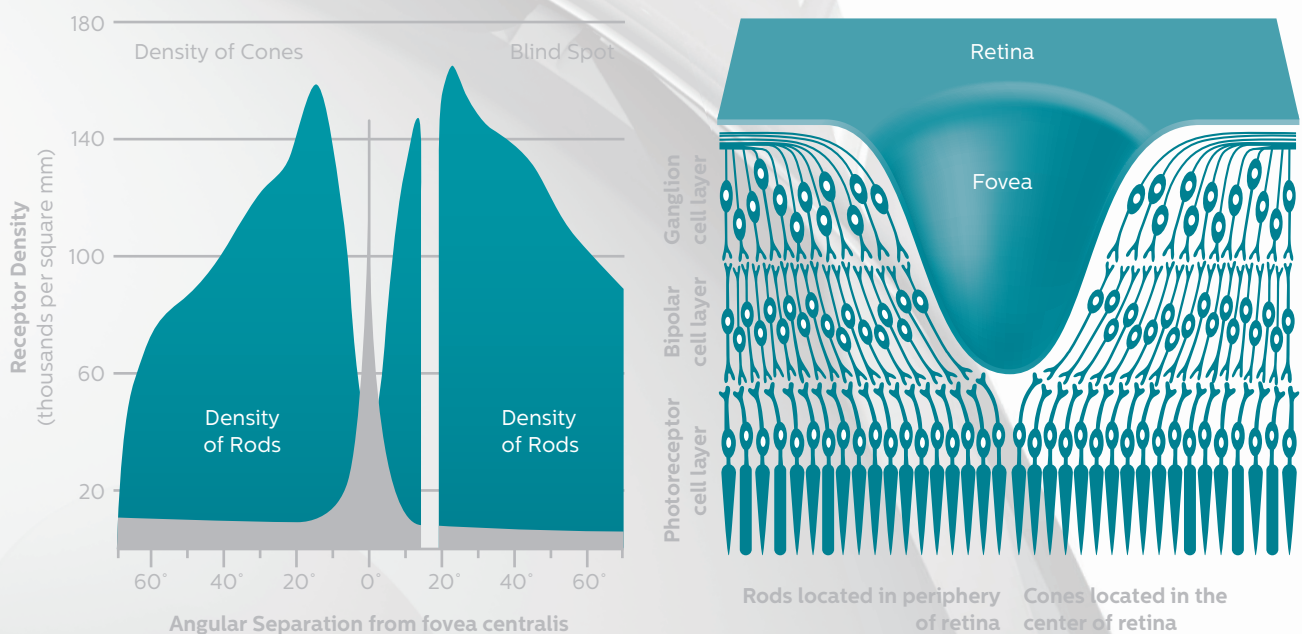
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SML uses the best and most sensitive part of retina
– THE FOVEA – the highest concentration of CONEs.
Both color vision and highest visual acuity is attributed to cones.

Receptor Density (thousands per square mm)

180 — Density of Cones   Blind Spot
140
100
60
Density of Rods   Density of Rods
20

60° 40° 20° 0° 20° 40° 60°

Angular Separation from fovea centralis

Retina

Fovea

Ganglion cell layer
Bipolar cell layer
Photoreceptor cell layer

Rods located in periphery of retina   Cones located in the center of retina

Cones are concentrated in the fovea. Both color vision and highest visual acuity is attributed to cone cells.
During visual examination of small details, light is focused onto the fovea centralis.
Rods are absent from the fovea but abundant elsewhere in the retina. They are responsible for night vision, our most sensitive
motion detection, and our peripheral vision.

Thus, with non-foveal/macular regions of the retina we can detect motion and contours under scotopic conditions but
CANNOT READ IN THE DARK. That is why SML does not deflect light away from the fovea.

SML, by MAGNIFICATION, uses the rest of the damaged FOVEA
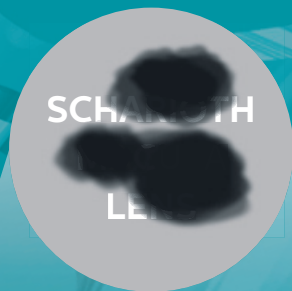– the best and most sensitive part of the retina – to enable reading.

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Mode of Action: MAGNIFICATION

MAGNIFICATION
(about 2-times)

Dark spots covering the text represent damaged macular areas. The SML magnifies the text approximately 2 times but the size of the dark spots remains the same because the SML does not magnify the damaged parts of macula. Thus the SML enables patients with AMD to read the text.

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Enlargement by zooming

With SML
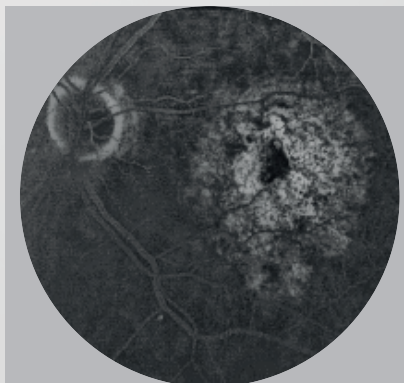
Without SML

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For whom is SML recommended?

- SML targets solely pseudophakic patients with advanced DRY AMD, offering them a convenient, simple and safe solution to restore their near vision impaired by AMD.

- SML – New Technology focuses on patients with advanced stage AMD but it might be helpful for patients with other macular diseases as well, e.g. myopic maculopathy, diabetic maculopathy or hereditary retinal diseases.

- Two thirds of patients with advanced AMD and visual acuity of 0.3 or less are pseudophakic – these patients might benefit from SML.

Surgery may be performed simultaneously with cataract surgery, but preferably cataract surgery should be done first and following a repeated postoperative VA testing, SML can be implanted later on if the patient is still dissatisfied.

THE SML IS POTENTIALLY SUITABLE FOR A LARGE PERCENTAGE OF EYE SURGEONS.
NO EXTENSIVE TRAINING IS REQUIRED. THERE IS NO LEARNING CURVE.

DRY AMD with pathological changes in the retinal pigment epithelium (RPE) and Bruch's membrane (a collagen-rich extracellular matrix between the RPE and choroidal vasculature) including the presence of ophthalmoscopically visible focal yellow deposition of acellular, polymorphous debris called drusen between the retinal pigment epithelium and Bruch's membrane.

Patient with AMD implanted with SML

85 old male, single eyed, after 13 intravitreal injections. SML implanted in 2014. Preop BCDVA 0.12, Radner 12 (40 cm and 15 cm). Postop 4 weeks BCDVA 0.12, Radner 4 (sc in 15 cm) Courtesy of Prof. Gabor B. Scharioth.
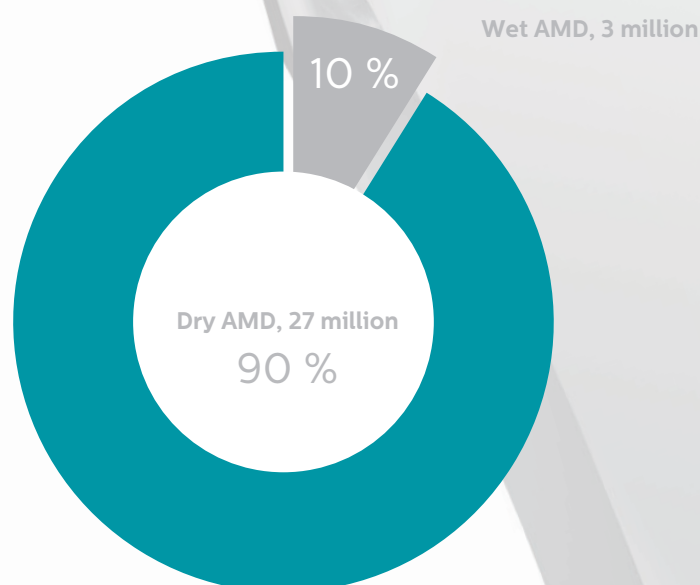
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Almost 30M people worldwide suffer from AMD

Age-related macular degeneration (AMD) affects 8.7 % of the world's population and is the most common cause of irreversible blindness in both developed and developing countries, particularly in people older than 60 years.

Its prevalence is likely to increase as a consequence of
– Growth of elderly populations
– Environmental factors

- Cataract and pseudophakia are the most common eye conditions to be associated with AMD

- Two thirds of patients with advanced AMD and visual acuity of 0.3 or less are pseudophakic
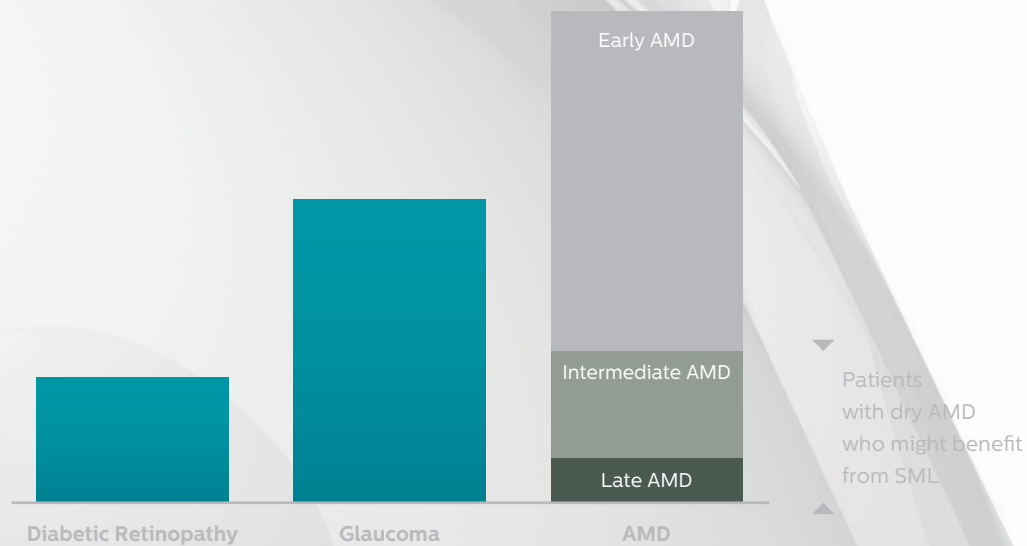   – these patients might benefit from SML

AMD can be generally divided into two types:
Dry AMD (90–95 %) and Wet AMD (10–15 %)

Wet AMD, 3 million

10 %

Dry AMD, 27 million

90 %

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AMD is the leading cause of visual impairment in western countries

The most common causes of blindness in developed countries

Early AMD

Intermediate AMD

Late AMD

Patients
with dry AMD
who might benefit
from SML

Diabetic Retinopathy   Glaucoma   AMD

Treatment of AMD

There have been significant advances in the management of exudative (wet) AMD with the introduction of anti–angiogenesis therapy, and patients now have effective treatment options that can prevent blindness and, in many cases, restore vision.

BUT

CURRENTLY THERE IS NO DRUG AVAILABLE FOR DRY AMD
AND TREATMENT POSSIBILITIES ARE LIMITED TO
LOW VISION REHABILITATION (LOW VISION AIDS AND LOW VISION INTRAOCULAR IMPLANTS)
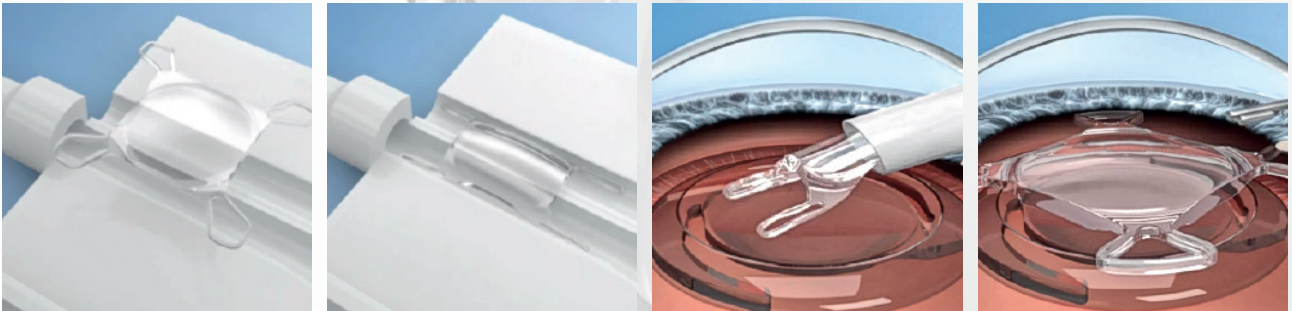
SML – New Technology focuses on patients with advanced stage AMD but might be helpful also for patients with other macular diseases as well, e.g. myopic maculopathy, diabetic retinopathy or hereditary retinal diseases.

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SML – Surgery

- Using highly advanced modern surgical techniques

- Easy implantation: feasible for standard cataract surgeons, accessible to every cataract surgeon

- Microincision (2.2 mm)

- SML is placed in the sulcus

- The procedure takes only 10 minutes

- Pseudophakic patients

- SML is implanted MONOCULARLY in DOMINANT (better-seeing) EYE

Which patients are suitable for SML?

- Any patient with DRY STAGE AMD complaining about near vision difficulties

- Other conditions may include diabetic retinopathy, myopic retinopathy, hereditary retinal diseases

- Distance vision better than 0.05 (ETDRS, decimal)

- Motivated patient

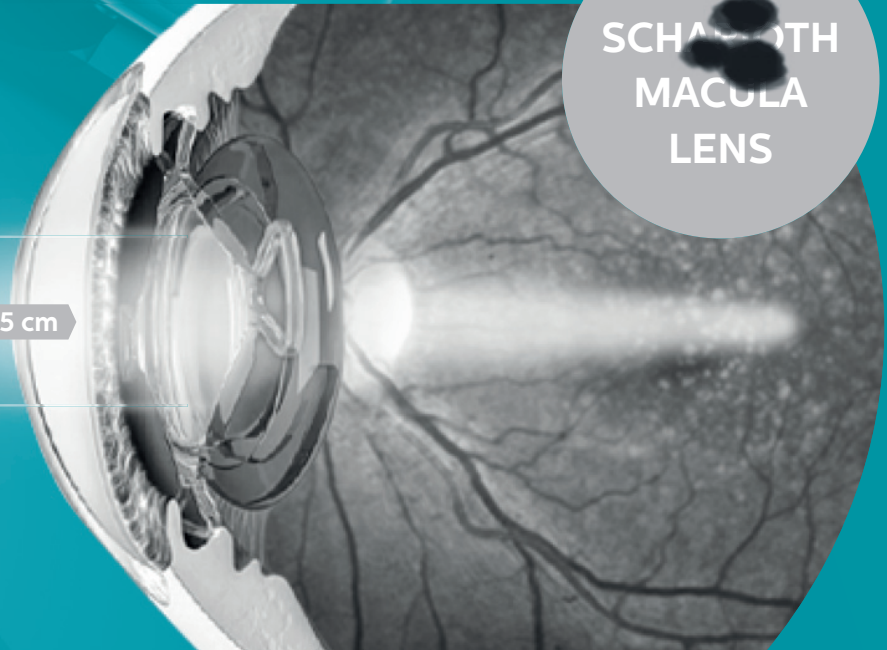- PSEUDOPHAKIC PATIENTS or patients who are candidates for cataract surgery

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SML: Magnifier in the EYE

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Reading distance 15 cm

Advantage of SML

Magnifying IOL system works, but not widely adapted because of

- Large incision
- Difficult surgery
- Might affect distance vision
- Affects visual field
- Only in combination with cataract surgery
- Limited magnification of intraocular Galilean telescope
- High cost
- Contraindicated in single-eyed patients (?)
- Limited reversibility

SML – New Technology focused on patients with advanced stage AMD

- Microincision (2.2 mm)
- Easy and safe surgery
- Distance vision not affected
- Visual field not affected
- May be implanted in pseudophakic or in patients or those who are candidates for cataract surgery
- Affordable (significantly lower cost)
- May be implanted in single-eyed patients
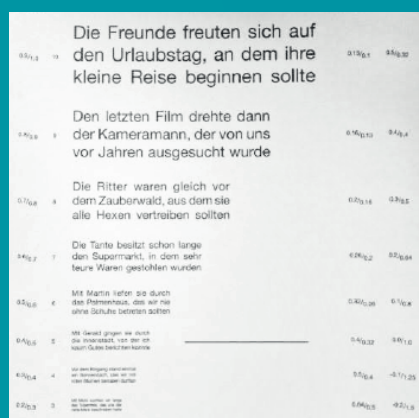- Reversible

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What kind of preoperative tests are needed for SML indication?

Simple preoperative SML candidate tests

- **Near vision at 40 cm (+2.5D) vs 15 cm (+6.0D)**

- **Patient should understand the principle of reduced reading distance and feel improvement of near vision with +6.0**

- **PSEUDOPHAKIC PATIENT**

SML IS POTENTIALLY SUITABLE FOR A LARGE PERCENTAGE OF EYE SURGEONS. NO EXTENSIVE TRAINING IS REQUIRED. THERE IS NO LEARNING CURVE.

Testing by Radner reading chart
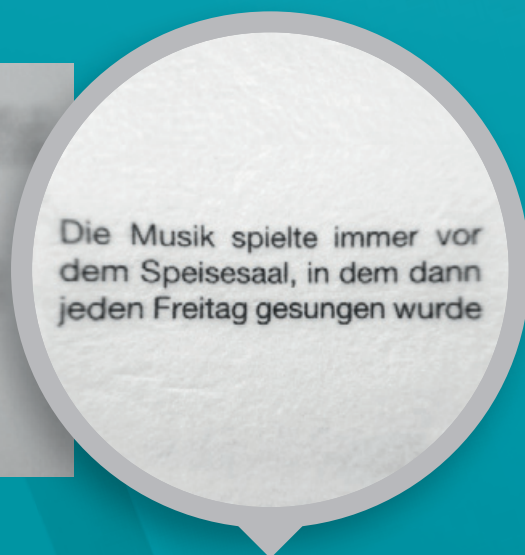

At 40 cm

At 15 cm

Simulating SML (at 15 cm)

SML in Life – self-contained patient

Patient using reading glasses

Patient using low vision aid

Patient using SML

The SML is not recommended in any of the following conditions:

- WET AMD (active/exudative stage)
- Zonulopathy, subluxation, aphakia
- Progressive glaucoma
- Active iris neovascularisation
- Shallow ACD

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Clinical evaluation assessing safety and efficacy of SML

AIM: To assess safety and efficacy of SML

DESIGN
- Pilot study
- Prospective
- Interventional (single group assignment)
- 2 centers

STUDY PLACE
- Prof. Gabor B. Scharioth (8 patients), Recklinghausen, Germany
- Prof. Pavel Rozsival (3 patients), Hradec Kralové, Czech Republic

INTERVENTION
- 11 pseudophakic patients/11 eyes
- Monocular implantation
- Eyes with DRY AMD
- Follow-up: 3-6 months (between September 2013 - March 2015)

INVESTIGATION
Preoperative
- BCDVA, BCNVA; simulation − NVA with addition of +6D from 15 cm distance
- Biomicroscopic examination; IOP
- Fundus examination, FAG

Postoperative
- BCDVA, UNVA,
- Biomicroscopic examination; IOP
- Fundus examination, FAG

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Pilot clinical evaluation proved the concept of SML

Outcomes of the study:

- There was NO reduction in visual acuity

- Distance visual acuity was NOT affected

- Near vision improved in 11 eyes (tested with Radner reading chart)

- One patient out of 11 did not have improvement of NVA due to very low BCDVA before surgery (0.05; ETDRS)

- Most patients are able to read (newspaper)

- No complications related to surgery or implant occurred during follow–up period

- Overall satisfied patients

Patient	Preoperative BCDVA (ETDRS decimal)	Postoperative BCDVA (ETDRS decimal)	Pre BCNVA (add +3.0D) (RADNER CHARTS)	Pre BCNVA @ 15 cm (+6.0 D) (RADNER CHARTS)	Post UCNVA @15 cm (SML) (RADNER CHARTS)
1*	0.4	0.4	6	4	1
2*	0.12	0.12	13	11	8
3*	0.4	0.4	5	3	1
4*	0.05	0.05	13	13	13
5*	0.16	0.16	11	8	5
6*	0.2	0.2	11	8	4
7*	0.1	0.1	11	8	7
8*	0.5	0.5	7	4	3
9**	0.3	0.3	9	5	1
10**	0.3	0.3	13	5	5
11**	0.3	0.3	8	1	1
MEAN	0.257	0.257	9.727	6.36	4.36

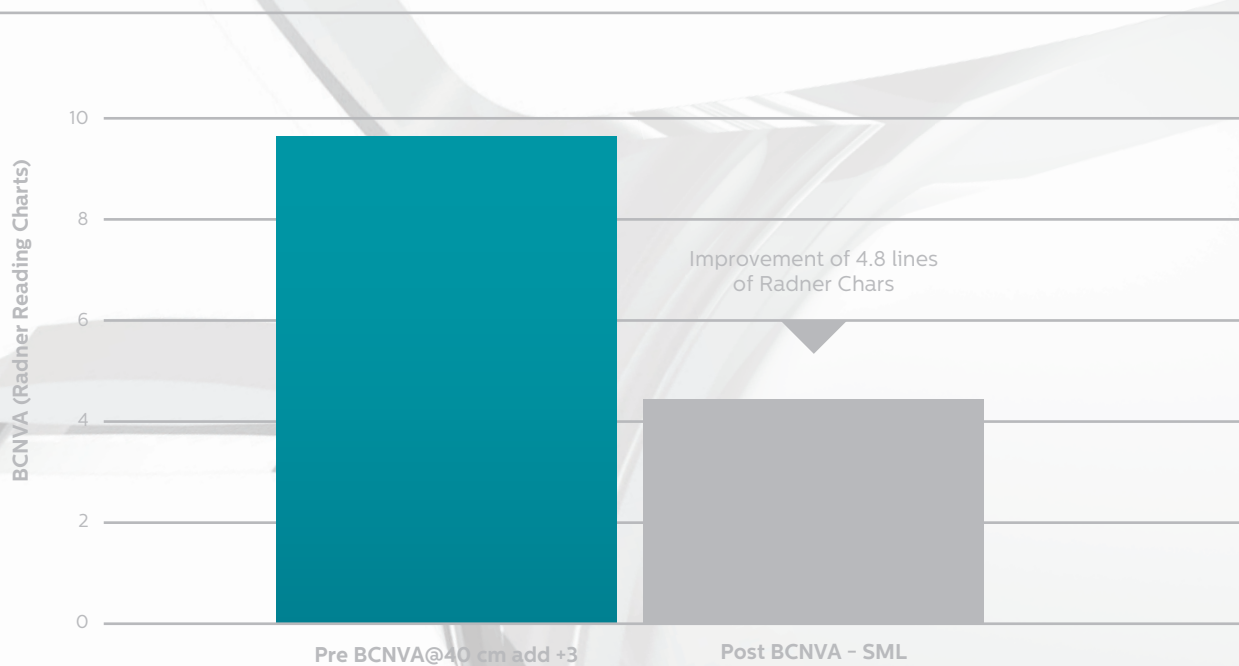**DISTANCE VISION NOT AFFECTED**   **SIGNIFICANT IMPROVEMENT OF NEAR VISION**

Graph shows significant improvement of mean near visual acuity – improvement of 4.4 lines of Radner Charts in patients after implantation with SML compared to patients before surgery.

*Data published by Prof. Gabor B. Scharioth; ESCRS, London 2014; ** Data published by Prof. Pavel Rozsival, Live surgery, Prague, 2015.*
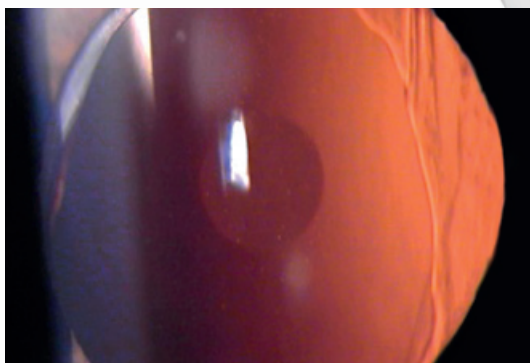
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MEAN BCNVA

Improvement of 4.8 lines
of Radner Chars

BCNVA (Radner Reading Charts)

10

8

6

4

2

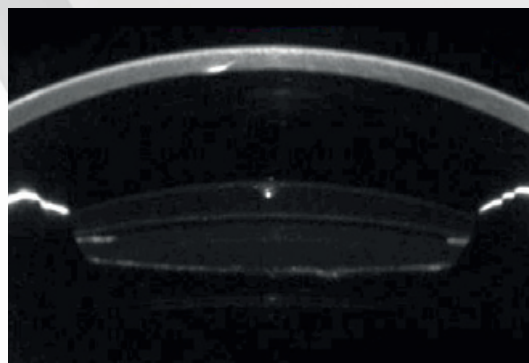0

Pre BCNVA@40 cm add +3

Post BCNVA – SML

Significant improvement of mean near visual acuity – improvement of 4.4 lines of Radner Charts
in patients after implantation with SML compared to with patients before surgery.

Accurate and stable implant position

Postoperative image in retro-illumination,
demonstrating excellent centration
of Scharioth Macula Lens; note central "raindrop"
(diameter 1.5 mm).

Scheimpflug image of anterior segment,
perfect positioning of Scharioth Macula Lens;
note clear space between the two lenses.
Courtesy of Prof. Gabor B. Scharioth.

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