Sulcoflex® Platform: 
A journey through supplementary IOLs and 12 years of clinical history

M. Amon

Head: Academic Teaching Hospital of St. John
Chair: Sigmund Freud University; Vienna

Financial disclosure:
Alcon
Bausch & Lomb
Geuder
Johnson & Johnson
Morcher
Rayner: Inventor of Sulcoflex
Zeiss Meditec
Material and Design
Surgery
Results
Conclusion
Material and Design: The History of Sulcoflex®
Uveal and Capsular Biocompatibility of Intraocular Implants

Hydrophilic Rayacryl: HEMA-MMA copolymer
long term experience (>20 a)

Superb uveal biocompatibility


Additive IOLs available

Cristalens Reverso®  Rayner Sulcoflex®  1st Q®
„Exotic“ IOLs:

Morcher: Extended depth of focus-IOLs
iOLAMD Eyemax®: Magnification x 1.3 (hyperaspheric optic)
1st Q® SML
“off label” IOLs

production stopped: HumanOptics MS 714 PB®

“off label” ICL
anterior vaulting

Correction of residual refractive error in pseudophakic eyes with the use of a secondary piggyback toric implantable collamer lens; J.Cat.Refract.Surg. 26/19; 766-769; 2010
The History of Sulcoflex®

- 1991 first publication on uveal and capsular biocompatibility
- 1998 idea and invention of a single-piece hydrophilic add-on IOL
- 2000 contact and cooperation with Rayner to design Sulcoflex
- 2004 first prototype
- 2007 worlds first implantation of Sulcoflex
- 2007 first presentation at ESCRs
- 2008 toric, multifocal and multifocal/toric (bifocal, refractive) IOLs
- 2018 worlds first implantation of the new trifocal Sulcoflex

Cellular invasion on hydrogel- and poly(methyl methacrylate) implants. An in vivo study
Uveal and capsular Biocompatibility of Intraocular Implants
M. Amon. J. Cat. Refract. Surg. 27/2; 178-179; 2001
Sulcoflex: a new IOL concept for the pseudoephakic eye
Cadaver Eye Study:

- appropriate sulcus fixation
- appropriate centration
- minimal interaction with uveal tissue
- minimal interaction with in-the-bag IOL
Optical bench study:

- same reflections from additional interfaces
- two IOLs similar optical quality to single IOL
- additional lightloss less than 1%

Effect of interface reflexion in pseudophakic eyes with an additional refractive intraocular lens
Jens Schrecker, Katja Zoric, Arthur Messner, Timo Eppig
J Cat Refract Surg; 38/8; 1650-1656
Results: Rayner Sulcoflex®

- n: 200 eyes/ 12 years follow-up
- refr. mf, toric, mf/t, monofocal
- LFCM: < than after phaco
- Iris trauma: 0
- Pigment dispersion syndrome: 0
- Interlenticular opacification: 0

Kahraman G, Amon M "Sulcoflex: A new supplementary intraocular lens for pseudophakic refractive errors
Results: Rayner Sulcoflex®

- positive iris-distance: 100%
- positive central optic-distance: 100%
- optic capture: 0
- pupil ovalisation: 0
- UCVA: 0.9
- refraction: +/- 0.25dpt

Kahraman G, Amon M "Sulcoflex: A new supplementary intraocular lens for pseudophakic refractive errors"
Centration Study: Rayner Sulcoflex®

Decentration compared to the center of the pupil in mm
max. decentration capsular bag: 1,05 mm
max. decentration sulcus: 0,6 mm
Statistically significant better centration of ciliary sulcus fixated IOLs

Specific indications
“Dynamic refraction”

- pediatric cataract
  (refractive exchange of supplementaty implant RESI)
- silicone oil
- corneal/scleral alteration
Conclusion after 12 years

Supplementary IOLs are effective for secondary enhancement of the surgical result and for primary “Duet implantation”

They represent a reversible or exchangeable technology for the future
Next step: create first diffractive trifocal add-on IOL

RayOne® Trifocal has fewer rings on the IOL optic surface for reduced potential visual disturbances and improved night vision.

Features:
- 16 diffractive steps / rings
- 4.5 mm diffractive zone
- > 4.5 mm monofocal, distance

Benefits:
- Reduces visual disturbances
- Developed to be less dependent on pupil size or lighting conditions
- Improves distance vision in mesopic condition
Surgery
IOL calculation for secondary implantation

- R-vergence formula:
  - sph. equivalent of ametropia, K-values, ACD

- postop ametropia within +/- 7 D:
  - hyperopia:
    - sph. equivalent $\times 1.5$
  - myopia:
    - sph. equivalent $\times 1.2$
IOL calculation for Duet-procedure

- In the bag IOL: monofocal, toric/monofocal
  any IOL-type (IOL neutral aspheric)
  emmetropia ("closest minus")

- Sulcoflex: distance 0 dpt

- Routine biometry, no change of any constant
Initial Trial: Duet-implantation

Worlds first implantation:
30. 7. 2018
Duet-implantation: 40 eyes
implantation in pseudophakic eye: 40 eyes (ongoing)

bilateral surgery
follow-up: 6 months
single surgeon
postop refraction: 0

EU Trial: 68 eyes
Binocular defocus curve

RayOne tri
Sulcoflex tri
**Conclusion**

- Excellent visual acuity results across all distances
- All patients were satisfied with their distance, intermediate and near vision
- No surgical and postop-complications
- Preliminary data of EU-studie support our data
- Results are comparable to trifocal “in the bag“ IOLs at least

But:

- Supplementary IOLs offer an adaptive option
Secondary enhancement

Option of “finetuning“ with 0.25 dpt steps
All patient should get detailed information about potential dysphotopsia
Conclusion

Option of finetuning (0.25 dpt steps)
Option of specific IOL-combination:
  asphericity, torus, material for bag-IOL,…

Need of futurefixation:
in case of toric IOL rotation

Option of exchange for future IOL-solutions
Early explantation: photopic phenomena, fine-tuning
Late explantation: AMD, DME,…
Conclusion

Main indications today:

In phakic patients: Multifocal Duet-implantation

In pseudophakic patients: Multifocal enhancement Biometricalal surprise
Sophisticated
Adjustable
Flexible
Effective
Cadaver Eye Study:

▪ appropriate sulcus fixation
▪ appropriate centration
▪ minimal interaction with uveal tissue
▪ minimal interaction with in-the-bag IOL

Werner L., ESCRS 2011 Istanbul
Effect of interface reflection in pseudophakic eyes with an additional refractive intraocular lens
A REVIEW OF RESULTS AFTER IMPLANTATION OF A SECONDARY INTRAOCULAR LENS TO CORRECT RESIDUAL REFRACTIVE ERROR AFTER CATARACT SURGERY: K. GUNDERSEN ET AL.; CLINICAL OPHTHALMOLOGY; 11, 1791-1796; 2017

M. Amon; 2015
Centration Study: Rayner Sulcoflex®

Decentration compared to the center of the pupil
max. decentration capsular bag: 1.05 mm
max. decentration sulcus: 0.6 mm

Statistically significant better centration of ciliary sulcus fixated IOLs

Comparison of optical performance and patient satisfaction with an Extended Range of Vision IOL and a trifocal IOL: A randomized prospective study

Guenal Kahraman
Franz Prager
Barbara Wetzel
Clemens Bernhart
Michael Amon

Dept. of Ophthalmology Academic Teaching Hospital of St. John
Sigmund Freud Private University
Vienna, Austria
Image Quality of 6 different IOLs

Through Focus Image Quality Bench Test Data, 50 lp/mm, ISO Model Eye, White Light (Halogen 440 - 755 nm), in Aqueous
# Comparison of Trifocal Technology

<table>
<thead>
<tr>
<th></th>
<th>PhysIOL FineVision</th>
<th>Zeiss AT LISA Tri</th>
<th>Alcon PanOptix</th>
<th>Rayner Trifocal</th>
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</thead>
<tbody>
<tr>
<td><strong>Diffractive Technology</strong></td>
<td>Diffractive Apodized Trifocal across full optic surface</td>
<td>Diffractive Trifocal up to 4.34 mm thereafter bifocal</td>
<td>Diffractive Trifocal up to 4.5 mm thereafter monofocal</td>
<td>Diffractive Trifocal up to 4.5 mm thereafter monofocal</td>
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<tr>
<td><strong>Diffractive Steps</strong></td>
<td>26 diffractive steps</td>
<td>29 diffractive steps 0.0 D</td>
<td>15 diffractive steps</td>
<td>16 diffractive steps</td>
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<tr>
<td><strong>Diffractive Orders</strong></td>
<td>0, 1, 2</td>
<td>0, 1, 2</td>
<td>0, 2, 3 (non-sequential)</td>
<td>1, 0, 1</td>
</tr>
<tr>
<td><strong>Light Loss</strong></td>
<td>14%</td>
<td>14.3% (Ave.)</td>
<td>12%</td>
<td>11%</td>
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<tr>
<td><strong>Light Energy Split</strong></td>
<td>49% D / 18% I / 34% N</td>
<td>50% D / 20% I / 30% N</td>
<td>42% D / 24% I / 22% N (includes 12% light loss)</td>
<td>52% D / 22% I / 26% N</td>
</tr>
<tr>
<td><strong>Reading Distance</strong></td>
<td>37.5 cm 75.0 cm</td>
<td>40.0 cm 80.0 cm</td>
<td>42.0 cm 60.0 cm</td>
<td>37.5 cm 75.0 cm</td>
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Comparison of Trifocal Technology

PhysiOL FineVision

Zeiss AT LISA Tri

Alcon PanOptix

Rayner RayOne Trifocal
PhysIOLOne Fine Vision

Zeiss AT LISA Tri

Alcon PanOptix

Rayner RayOne Trifocal

All trademarks are property of their respective owners.
Competitor Source: Respective owners published marketing materials, Rayner test data held on file.
### USAF 1951 target charts

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<th>Distance</th>
<th>Intermediate 80cm</th>
<th>Near 40cm</th>
<th>Distance</th>
<th>Intermediate 80cm</th>
<th>Near 40cm</th>
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<td><strong>RayOne Trifocal</strong></td>
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- **3.0 mm pupil size**
- **4.5 mm pupil size**
Visual Acuity

Decimal visual acuity (mean +/- SD)

- CDVA pre
- CDVA
- UDVA
- UIVA
- UNVA

RayOne trifocal

- Tecnis Symfony
- AT LISA tri
Binocular Defocus Curve

Decimal visual acuity (mean +/- SD) vs. Level of defocus (dpt)

Decimal visual acuity vs. Level of defocus for Tecnis Symfony and AT LISA tri.
EU TRIAL: CLINICAL RESULTS - SULCOFLEX TRIFOCAL

Multicentre evaluation assessing Visual acuity, contrast, defocus and patient satisfaction in pseudophakic patients with bilaterally implanted supplementary Sulcoflex Trifocal intraocular lenses

Prospective pilot study in pseudophakic patients

- Multicentre, 7 sites in Europe
- Multi-surgeon 7 surgeons
- Total of 68 eyes (34 patients)
FIRST RESULTS AND VISUAL PERFORMANCE

68 eyes (34 patients) underwent bilateral Sulcoflex Trifocal implantation

End Measures:

- Post operatative Subjective Refraction (SE, Sph, Cyl)
- Monocular and Binocular VA (LogMar):
  - Uncorrected Distance (UCVA) and Best Corrected Distance Visual Acuity (CDVA)
  - Uncorrected Near (UNVA) and Distance Corrected Near Visual Acuity (DNVA)
  - Uncorrected Intermediate (UIVA) and Distance Corrected Intermediate Visual Acuity (DNVA)
  - Contrast sensitivity with F.A.C.T charts
  - Defocus curve from -4.00 D to +2.00 D
  - Patient satisfaction with a self-administered questionnaire (Likert Scale)
  - Complications/AE

EXCLUSION CRITERIA:

- Previous ocular surgery
- Regular corneal astigmatism greater than 0.75 D
- Irregular astigmatism and corneal opacities
- Glaucoma with impairment of GCL and RNFL
- Macular diseases
RESULTS – SUBJECTIVE REFRACTION

- All eyes were within ±1.00 D of emmetropia and 94% of eyes were within ±0.50 D
RESULTS – VISUAL ACUITY

- All patients achieved Monocular UDVA of 0.1 LogMAR or better,
- 94% of patients achieved Monocular UIVA (70cm) of 0.1 LogMAR or better.
- 91% of patients achieved Monocular UNVA (40cm) of 0.1 LogMAR or better.
Post-op photopic contrast sensitivity was similar compared to pre-op in pseudophakic eyes
Post-op mesopic contrast sensitivity was lower compared to pre-op in pseudophakic eyes at higher spatial frequency (> 6 cycle/degree)
Do you find the following phenomena disturbing and troublesome? (Likert Scale Scoring 0 to 4)

N= 68 eyes
1 month postop

Halo
% of Eyes

Glares
% of Eyes

Starburst
% of Eyes

Dysphotopic Phenomena Scores

No
Hardly
Somewhat
Quite
Highly

N= 68 eyes
1 month postop
Spectacle Independence - Do you wear spectacles for distance/intermediate/near vision?

RESULTS – PATIENT SATISFACTION

N= 68 eyes
1 month postop

% of eyes
Never
Sometimes
Often
Always
Distances

Distance
97%
3%
0%
0%

Intermediate
94%
6%
0%
0%

Near
76%
0%
0%
0%

N= 68 eyes
1 month postop
How satisfied are you with your near/intermediate/distance and overall vision? (Likert Scale Scoring)

RESULTS – PATIENT SATISFACTION

N = 68 eyes
1 month postop
Female: U. P.; 72a

Oktober 2015: uneventful IOL implantation both eyes

September 2018: uneventful, bilateral secondary enhancement

VA right eye: 0.7 (secondary cataract); Jg 1; YAG capsulotomy scheduled

VA left eye: 1.0; Jg 1