Sulcoflex® trifocal:
An adaptive solution towards DIVA
(Distance Independent Visual Ability)

M. Amon

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

Worlds first implantation:
30. 7. 2018
Duet-implantation: 40 eyes
implantation in pseudophakic eye: 40 eyes (ongoing)
EU Trial: 68 eyes

bilateral surgery
follow-up: 6 months
single surgeon
postop refraction: 0
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®
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 world’s first implantation of Sulcoflex
- 2007 first presentation at ESCRs
- 2008 toric, multifocal and multifocal/toric (bifocal, refractive) IOLs
- 2018 world’s 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

Sulcoflex: a new IOL concept for the pseudophakic eye
Cadaver Eye Study:

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

Effect of interface reflection in pseudophakic eyes with an additional refractive intraocular lens
Optical bench study:

- equal reflections from additional surfaces/interface
- similar optical quality of two IOLs as compared to single IOL
- additional lightloss less than 1%

Jens Schrecker, Katja Zoric, Arthur Messner, Timo Eppig
J Cat Refract Surg; 38/8; 1650-1656; 2011
Ramin Khoramnia et al.
ESCRS, Paris 2019
Results: Rayner Sulcoflex®

- n: 200 eyes/13 years follow-up
- refr. mf, toric, mf/t, monofocal
- LFCM: < than after phaco
- iristrauma: 0
- pigmentdispersion: 0
- interlenticular opacification: 0

Results: Rayner Sulcoflex®

- positive iris-distance: 100%
- positive central optic-distance: 100%
- optic capture: 0
- pupil ovalisation: 0
- UCVA: 0.9
- refraction: +/- 0.25dpt
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 suplementaty 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
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
## 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>
</tr>
</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>
</tr>
<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>
</tr>
<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 3.0 mm pupil</strong></td>
<td>14%</td>
<td>14.3% (Ave.)</td>
<td>12%</td>
<td>11%</td>
</tr>
<tr>
<td><strong>Light Energy Split 3.0 mm pupil</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>
</tr>
</tbody>
</table>
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
Visual Acuity

Decimal visual acuity (mean +/- SD)

CDVA pre, CDVA, UDVA, UIVA, UNVA

RayOne trifocal

Tecnis Symfony, AT LISA tri
Binocular Defocus Curve
Surgery
IOL calculation for secondary implantation

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

- postop ametropia within +/- 7 D:
  hyperopia:
    sph. equivalent x 1.5
  myopia:
    sph. equivalent x 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
Results
Standard prä-op Test für Kataraktpatienten

Optische Biometrie

Zusätzliche prä-op Tests für IC-8™ IOL Patienten:

- Mesopische Pupillengröße < 6.0 mm
- Test Dominates Auge: es sollte keine ausgeprägte Dominanz vorliegen
- Manifeste Refraktion (max. Pluskorrektur, keine Auto-refraktion)
- Unkorrigierter und fernkorrigierter Visus
  - Fernen (UCDVA, BCDVA)
  - Nähe (40 cm) (UCNVA, BCNVA)

Optional prä-op Tests für IC-8 IOL Patienten:

- Potentieller Visus nach OP

Duet-implantation
Binocular defocus curve

Decimal visual acuity (mean ± SD) vs. level of defocus (dpt)

RayOne tri
Sulcoflex tri
Secondary enhancement

Option of “finetuning” with 0.25 dpt steps
All patient should get detailed information about potential dysphotopsia
The case
U. P.: wish of spectacle independance; female, 72a

1. visit (august 2018):

heterochromia, no uveitis, normal posterior segment

od: well centered IOL (Acrysof SA 60; 2015); secondary cataract
VA: +0.75sph +0.5cyl/140    0.8

os: cortical cataract
VA: +0.75sph    0.6
U. P.: wish of spectacle independance; female, 72a

surgery:

september 2018

os: uneventful Duet-procedure with Sulcoflex trifocal (0dpt plus trifocality)
U. P.: whish of spectacle independance; female, 72a

1 week later, september 2018

od: secondary enhancement with +1.5dpt Sulcoflex trifocal; incision at steep axis: 140 degrees

YAG capsulotomy performed 4 weeks after Sulcoflex implantation
U. P.: wish of spectacle independance; female, 72a

Last visit (March 2019):

OU: well centered IOLs, no pigment dispersion, no interlenticular opacification, good iris/IOL clearance, no central IOL contact

VA: OD: sc 1.25; Jg 1

VA: OS: sc 1.25; Jg 1

Spectacle independance, halos acceptable
Conclusion

• Excellent visual acuity results across all distances
• Results are comparable to trifocal “in the bag“ IOLs at least

But:

• Supplementary IOLs offer an adaptive option
Conclusion

Option of finetuning (0.25 dpt)
Option of specific selection of IOL-combination (asphericity, torus, material for bag-IOL,…)
Option of exchange for future IOL-solutions
Reversibility, exchangeability: wider spectrum of indications
Increased explantation-rate due to different technology
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

Biometricalical surprise
Sophisticated
Adjustable
Flexible
Effective