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)

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

EU Trial: 68 eyes
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 ECRS
- 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 reflelection in pseuophakic eyes with an additional refractive intraocular lens
Optical bench study:

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

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: 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
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 supplementary 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
**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</strong></td>
<td>14%</td>
<td>14.3% (Ave.)</td>
<td>12%</td>
<td>11%</td>
</tr>
<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>
</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

![Graph showing visual acuity measurements for different lenses and conditions.](image-url)
Binocular Defocus Curve

Decimal visual acuity (mean +/- SD)

Level of defocus (dpt)

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
Duet-implantation
Binocular defocus curve

RayOne tri
Sulcoflex tri
Secondary enhancement

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

**RESULTS – VISUAL ACUITY**

<table>
<thead>
<tr>
<th>Visual Acuity</th>
<th>Cumulative % of Eyes</th>
</tr>
</thead>
<tbody>
<tr>
<td>UDVA</td>
<td>6%</td>
</tr>
<tr>
<td>CDVA</td>
<td>35%</td>
</tr>
<tr>
<td>UIVA</td>
<td>9%</td>
</tr>
<tr>
<td>DC/VA</td>
<td>12%</td>
</tr>
<tr>
<td>UNVA</td>
<td>24%</td>
</tr>
<tr>
<td>DCNVA</td>
<td>50%</td>
</tr>
</tbody>
</table>

N= 68 eyes 1 month postop
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)

RESULTS – PATIENT SATISFACTION

N= 68 eyes
1 month postop
RESULTS – PATIENT SATISFACTION

Spectacle Independence- Do you wear spectacles for distance/intermediate/near vision?

N= 68 eyes
1 month postop

% of eyes

Distance

97%

94%

76%

3%

6%

0%

24%

Intermediate

94%

6%

0%

20%

Near

76%

24%

0%

0%

Never

Sometimes

Often

Always

Distances
RESULTS – PATIENT SATISFACTION

How satisfied are you with your near/intermediate/distance and overall vision? (Likert Scale Scoring)

N= 68 eyes
1 month postop

Distance
Intermediate
Near
Overall

Extremely satisfied
Satisfied
Neutral
Dissatisfied
Extremely Dissatisfied

% of Eyes

47%
41%
53%
41%
50%
47%
35%
53%
3%
12%
12%
6%
0%
0%
0%
0%
0%
0%

Distance
Intermediate
Near
Overall

Extremely satisfied
Satisfied
Neutral
Dissatisfied
Extremely Dissatisfied

% of Eyes

47%
41%
53%
41%
50%
47%
35%
53%
3%
12%
12%
6%
0%
0%
0%
0%
0%
0%

Distance
Intermediate
Near
Overall

Extremely satisfied
Satisfied
Neutral
Dissatisfied
Extremely Dissatisfied

% of Eyes

47%
41%
53%
41%
50%
47%
35%
53%
3%
12%
12%
6%
0%
0%
0%
0%
0%
0%

Distance
Intermediate
Near
Overall

Extremely satisfied
Satisfied
Neutral
Dissatisfied
Extremely Dissatisfied

% of Eyes

47%
41%
53%
41%
50%
47%
35%
53%
3%
12%
12%
6%
0%
0%
0%
0%
0%
0%

Distance
Intermediate
Near
Overall

Extremely satisfied
Satisfied
Neutral
Dissatisfied
Extremely Dissatisfied

% of Eyes

47%
41%
53%
41%
50%
47%
35%
53%
3%
12%
12%
6%
0%
0%
0%
0%
0%
0%

Distance
Intermediate
Near
Overall

Extremely satisfied
Satisfied
Neutral
Dissatisfied
Extremely Dissatisfied

% of Eyes

47%
41%
53%
41%
50%
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
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
Conclusion

Main indications today:

In phakic patients: **Multifocal Duet-implantation**

In pseudophakic patients: **Multifocal enhancement Biometricalal surprise**
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,…
Sophisticated, Adjustable, Flexible, Effective