AMERICAN ACADEMY OF OPHTHALMOLOGY®

AAO 2022 gather

PO307

The effect of fs-laser lentotomy on accommodation amplitude and clarity of the presbyopic crystalline lens

Omid Kermani MD | Artemis Augenklinik am Neumarkt, Köln

Georg Gerten MD | Artemis Augenklinik am Neumarkt, Köln

Uwe Oberheide PhD | Institut für Optik und Elektronik, TH Köln

Heike Sievert | ROWIAK GmbH Hannover

Holger Lubatschowski PhD | ROWIAK GmbH Hannover

Financial Disclosure

AAO 2022 gather

Presenter:
Omid Kermani*

Shareholder*
ROWIAK GmbH, Hannover

Co-author:
Georg Gerten*
Holger Lubatschowski*
Heike Sievert (none)
Uwe Oberheide (none)

Objective

- To demonstrate improvement in near vision (reading ability) in patients with age-related near vision loss (presbyopia) after treatment with a femtosecond laser (ROWIAK GmbH, Hannover).
- Prospective, randomized, exploratory study to investigate efficacy and safety; EUDAMED No: CIV-14-12-013004

Endpoints

- Improvement of accommodation width by ≥+1D
- Improvement of near visual acuity by at least 2 lines
- Optic properties of the crystalline lens (scattering, opacification)
- Assessment of complications (glare, change UCVA and BCVA)

Methods and Materials

- OCT guided sub-µJ fs.-laser decompression of the lens nucleus
- 12 radial lesions (= compression joints; width 200 – 600 µm)
- Clear central optical zone 2.0 mm to 5.2 mm
- Total treatment zone diameter determined by safety zone (700µm) to epithelial fibers
- Treatment time 1 – 3 min
- Variation of laser parameters was covered by 9 treatment arms

Volume of nucleus (L=40 mm, r=15 mm):

$V = \pi r^2 \times L$

The nucleus is to be compressed in radius by ***w*** so that its length increases by ***s*** (e.g. **s** = 80 µm corresponds to 1 D)

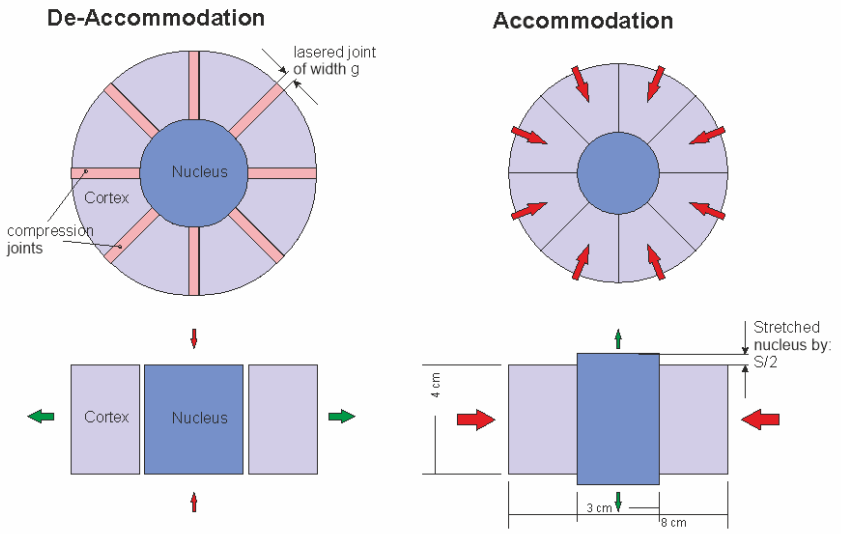
$V = \text{const.} = p\, r^2 \times L = p\,(r-\boldsymbol{w})^2 \times (L+\mathbf{s})$

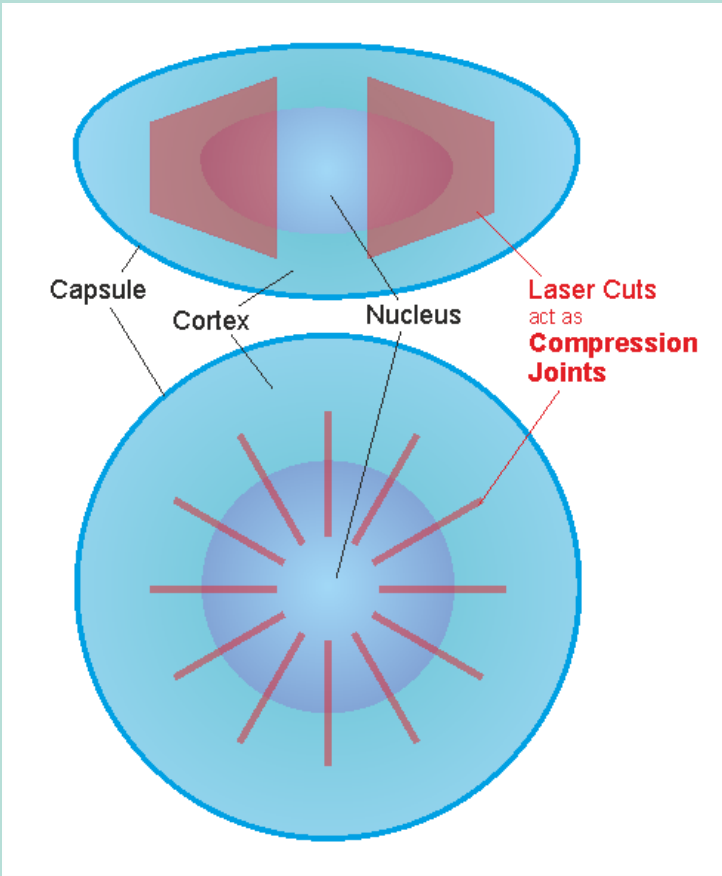
necessary compression:

$\boldsymbol{w} = r\,\{\,1- \text{SQRT}\,[L/(L+\mathbf{s})]\,\}$

for **s = 0,24 mm** (3 dpt) follows w = 45 µm !

So the pie pieces have to move inwards by only 45 µm to change 3 D on the lens





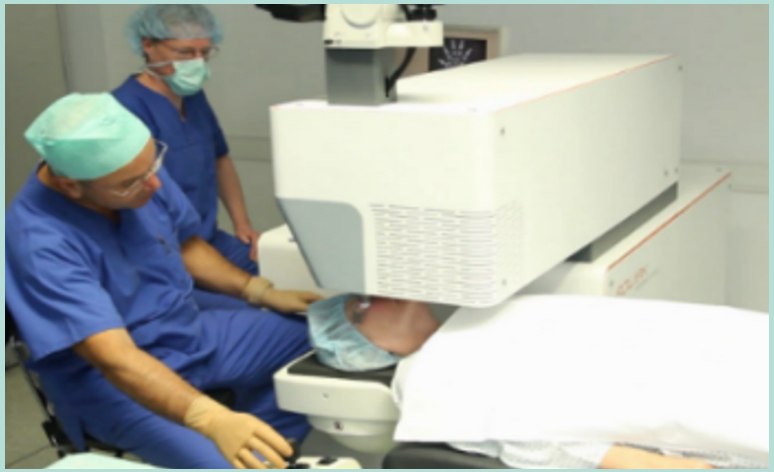
35 Patients (58 Eyes)

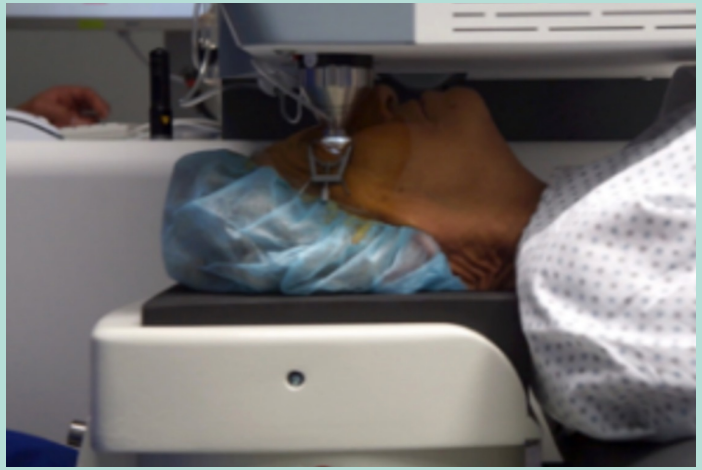
Exclusion criteria:

- Equal to those for Refractive Lens Exchange (RLE)

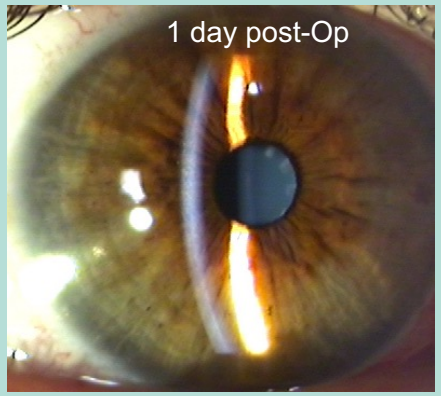
Inclusion criteria:

- Presbyopic patients with clear lens (no cataract), with the desire for refractive lens exchange (RLE) were eligible for the study
- Residual accommodation < 2D
- Myopia > -2D
- Hyperopia
- Dilated pupil size ≥ 7 mm
- Age ≥ 45 years (mean 52±5 years)
- Informed consent
- Declaration of Helsinki conform

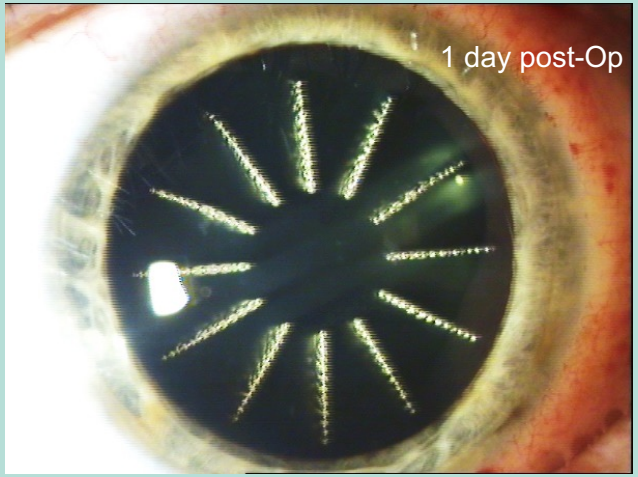


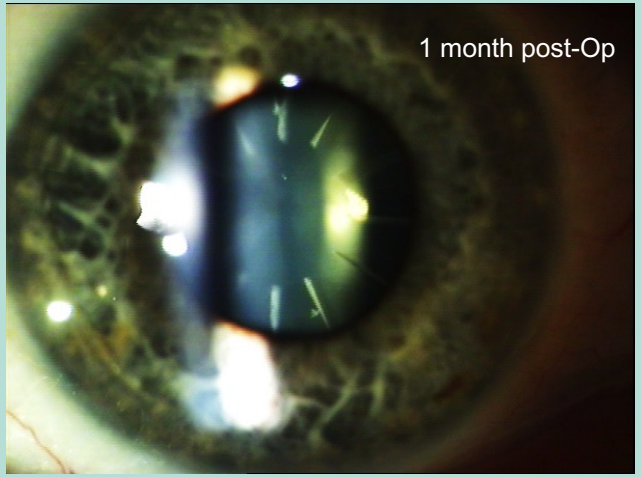


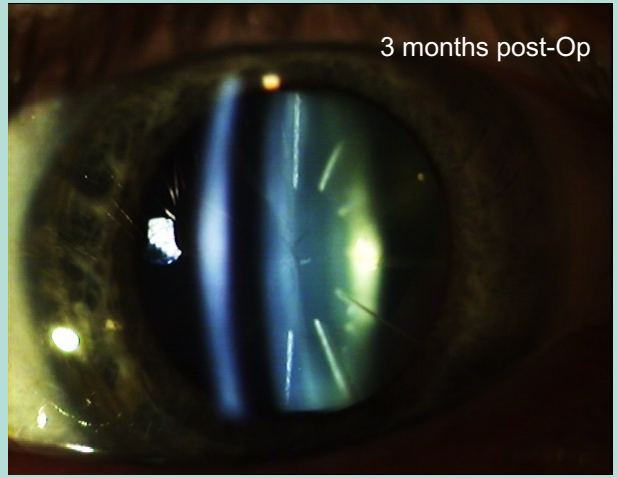
Clinical Results



- Laser lesions fade but remain as „scars“ within the nucleus
- No opacification of the non-affected crystalline lens in the observation period (up to 12 months)
- No signs of inflammation
- IOP remains stable

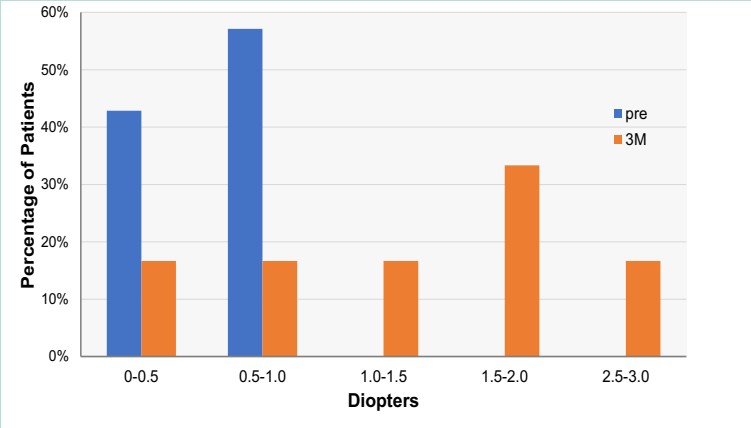




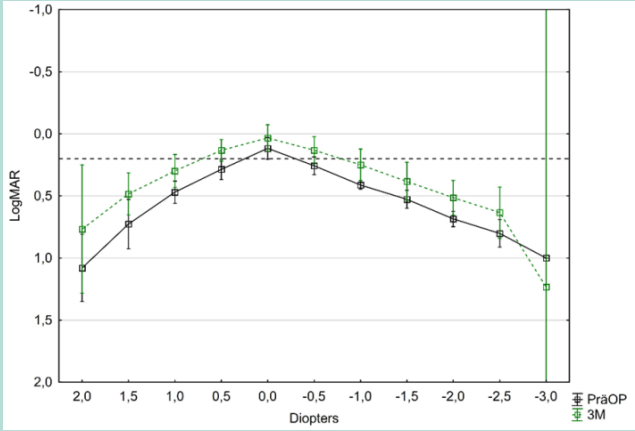


Refractive Results

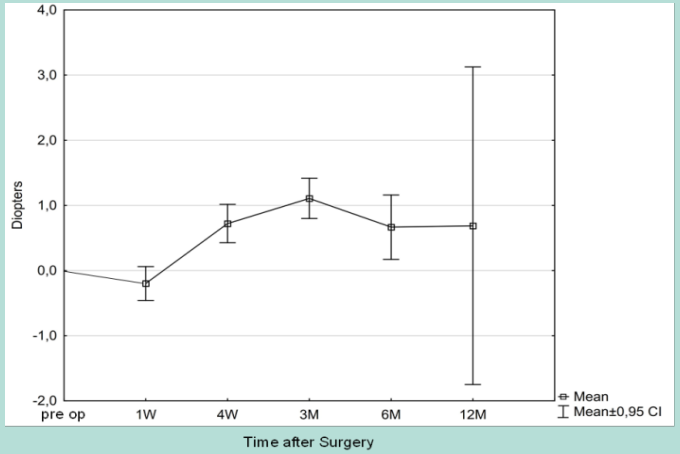
- Accommodation amplitude **before surgery (blue)** and **after three months (orange)** for patients who had accommodation amplitude of < 1.0 dpt before surgery (n=12)



- Defocus curve of patients with **less than 1.0 dpt** (n=12) of accommodation amplitude before surgery (mean ±0.95 confidence interval) pre op (black) and 3 months after surgery (green)



- Post surgical follow-up of subjective refraction with baseline 0 dpt preoperatively (mean ±0.95 confidence interval).



Discussion

The expected improvement of subjective and objective (Casio, Topcon Japan) accommodation (primary endpoint) after laser treatment could not be proved.

The hyperopic shift, that was noted could be traced back (FE simulation) to flattening of the polar lens radii, confirming an unintended biomechanical effect of the treatment.

The fs.-laser treatment had no negative effect on photic BCVA. However, the laser treatment led to an increase in glare and a decrease of contrast sensitivity in the treated patients.

All laser lesions faded over time leaving a fine scar in the nucleus. Up to 12 months post-Op none of the eyes developed progression of lens opacification (cataract).

No other severe complications were noted.

Conclusion

Fs.-laser presbyopia reversal by setting radial decompression areas in the lens nucleus improved subjective and objective accommodation amplitude of 1.0 dpt and more in eyes with residual accommodation amplitude ≤ 1,0 dpt. The effect was accompanied by an unintended hyperopic shift as well indicating a biomechanical response of the crystalline lens to the treatment. Within the follow-up period of up to 12 months best corrected visual acuity was not reduced (no cataract formation) but patients suffered from glare and reduced contrast sensitivity due to the remnants of the laser lesions.

References

- Burd, H. J.; Wilde, G. S. (2016): Finite element modelling of radial lentotomy cuts to improve the accommodation performance of the human lens. In: Graefe's archive for clinical and experimental ophthalmology 254 (4), S. 727–737. DOI: 10.1007/s00417-016-3296-z.
- Hahn, Jan; Fromm, Michael; AL Halabi, Fedaa; Besdo, Silke; Lubatschowski, Holger; Ripken, Tammo; Krüger, Alexander (2015): Measurement of Ex Vivo Porcine Lens Shape During Simulated Accommodation, Before and After fs-Laser Treatment. In: Invest. Ophthalmol. Vis. Sci. 56 (9), S. 5332. DOI: 10.1167/iovs.14-16185.
- Gerten, G.; Ripken, T.; Breitenfeld, P.; Krueger, R. R.; Kermani, O.; Lubatschowski, H.; Oberheide, U. (2007): In vitro and in vivo investigations on the treatment of presbyopia using femtosecond lasers. In: Ophthalmologe, S. 40–46.