

Extensive experience from prospective observational registry and retrospective long-term (2-9 years) clinical evaluation

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Author have any financial or proprietary interest on this presentation.

Two key sources of WIOL-CF data

CNOR = Czech National Observational Registry

- Implantations 09/2012 – 04/2014
 - Only SRK/T formula used
 - Standard cataract surgery
- 12 centers
- Binocular implantation
- Prospective, 6-months follow-up

WOLF = WIOL-CF Long-Term Follow up

- Implantations 2005-2011
 - Different formulas for calculation used
 - Standard cataract surgery
- 3 centers
- Binocular or monocular implantation
- Retrospective, patients invited for ophthalmology examination if implantation at least 2 years ago

Different setting and follow-up

CNOR

- 136 eyes, 68 patients (39 male, 29 female)
- Mean age 62.2 years, (48-82 years), 6 months follow-up
- Indication – cataract without any other ophthalmic pathology, corneal astigmatism < 1.25 cylD
- Key parameters: VA in all distances, contrast sensitivity, optical phenomena, satisfaction

WOLF

- 52 eyes; 40 patients (26 male, 14 female, 12 binocular and 28 monocular implantations)
- Mean age at long term follow-up 64.5 years (47-80), surgery at least 2 years ago; mean follow-up 5.6 years (2-9 years), total WIOL-CF experience of 292 „eye-years“
- Indication – cataract, other ophthalmic pathologies present at long term follow-up (diabetic retinopathy etc.)
- Key parameters: accommodation, transparency, VA, optical phenomena, subjective satisfaction, social functioning

What means VA = logMAR 0.2 at 40 cm?

- Practical tool included in the programme leaflet:

LUNCHTIME SYMPOSIUM

Symposium Program	logMAR 0.50*
September 14, 13:00 to 14:00	logMAR 0.30*
ExCel. Capital Suite 2	logMAR 0.25*
Boxed Lunch Included	logMAR 0.20*

Bioanalogic WIOL-CF[®]: Functional Principles and Practical Guidance to Optimize Clinical Outcomes

Moderated by J. Güell, Spain

Stable and consistent visual acuity results even after 2-9 years from implantation

Far

UCDVA (dec)	CNOR	WOLF
Mean (SD)	0.95 (0.14)	0.98 (0.09)

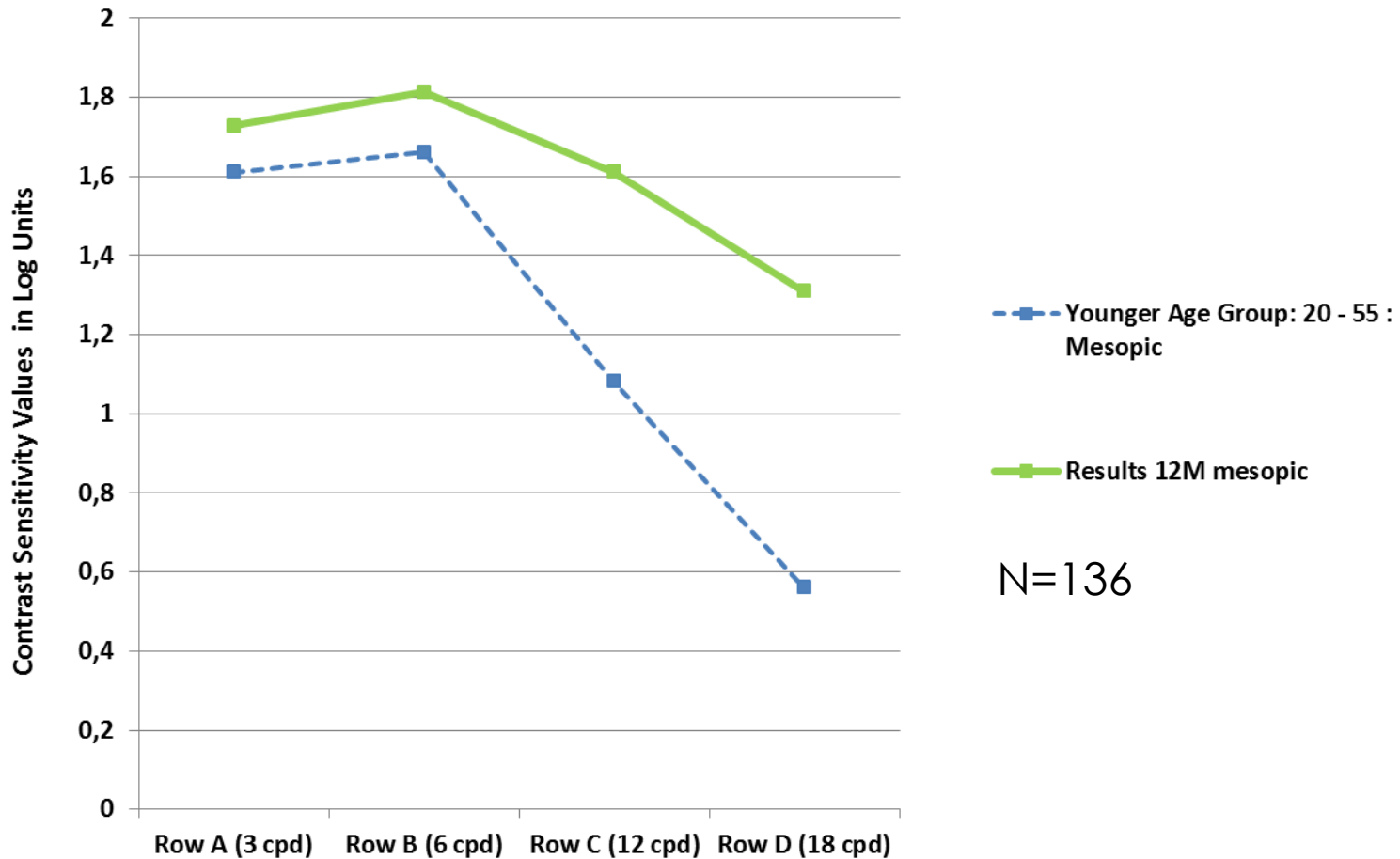
Intermediate 70cm

UCIVA (logMAR)	CNOR	WOLF
Mean (SD)	0.15 (0.14)	0.06 (0.17)

Near 40cm

UCNVA (logMAR)	CNOR	WOLF
Mean (SD)	0.29 (0.15)	0.28 (0.17)

CNOR: Mesopic contrast sensitivity values above young population norm consistently confirmed



CNOR: True accommodation substudy

Objective

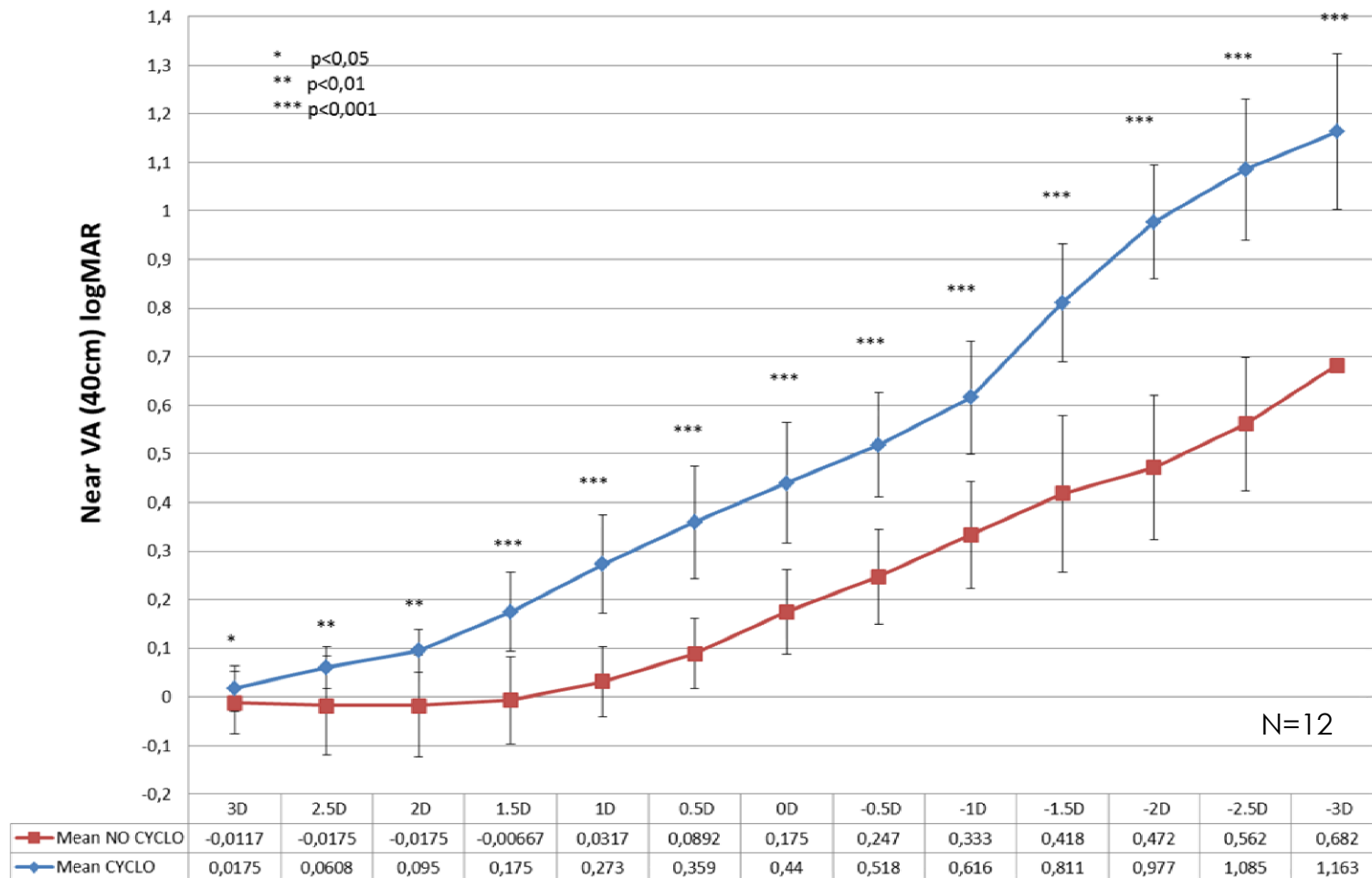
- Differentiate the magnitude of true accommodation and pseudo-accommodation mechanisms of WIOL-CF action in clinical investigation

Methodology

- Influence of pseudo-accommodation was eliminated by use of 3 mm pinhole occluder
- Magnitude of true accommodation was proven by difference of near defocus curves with and without cycloplegia (elimination of effect of ciliary muscles)

Results

Defocus curve- Near (40cm) VA



Defocus curves significantly differed in all points of defocus curves ($p < 0,05$). The differences of measurements with and without cycloplegia show true accommodation in the range of approximately 1.5 diopters.

WOLF: iTrace aberrometry



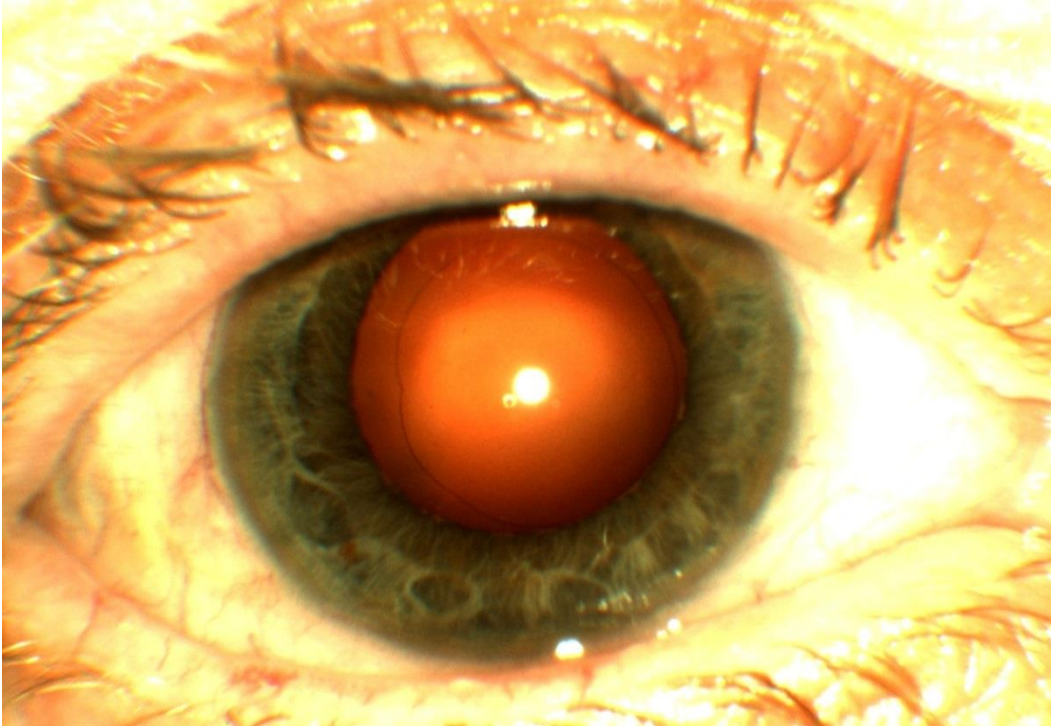
- Evaluation of difference map far / near (33cm)

73% of eyes show change in refraction which correspond to accommodation (IOL shape change)

	Mean (D)	Max	Min	SD
Accommodation volume	4.42	10.3	1.2	1.7
Peak accommodation	3.09	7.3	1.7	1.03
Mean change of SE	0.82	1.85	-0.42	0.55

WOLF: Enduring transparency of lens

Example - 8 years after implantation

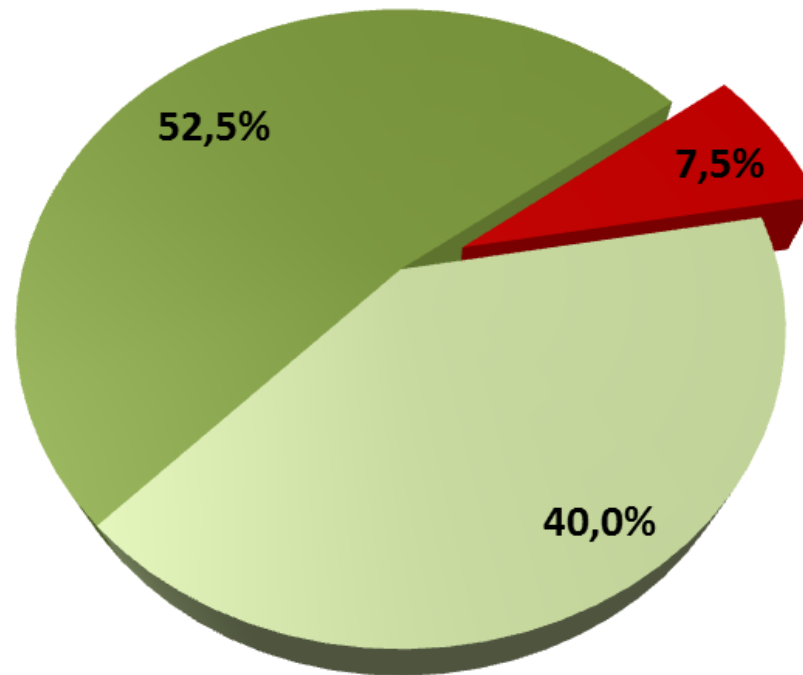


- None from examined lens shows changes in sense of accumulation of deposits, calcifications, fogging, glistenings, etc.
- Incidence of YAG capsulotomy \approx 5% in 2 years

WOLF: Glare/Halo

92% of the WOLF-CF patients is free from serious / disturbing optical phenomena

40% of the patients is completely free of any optical phenomena



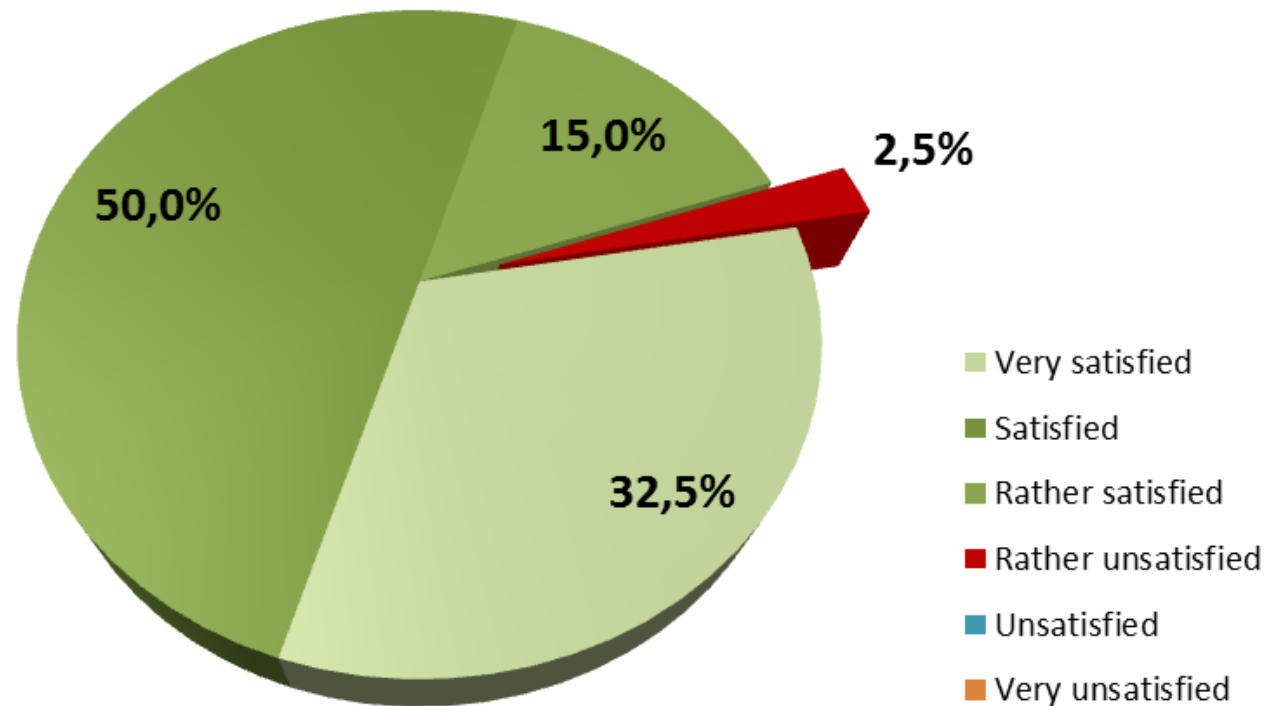
WOLF
N=40

None Mild Serious/Disturbing

WOLF: High long-term subjective satisfaction

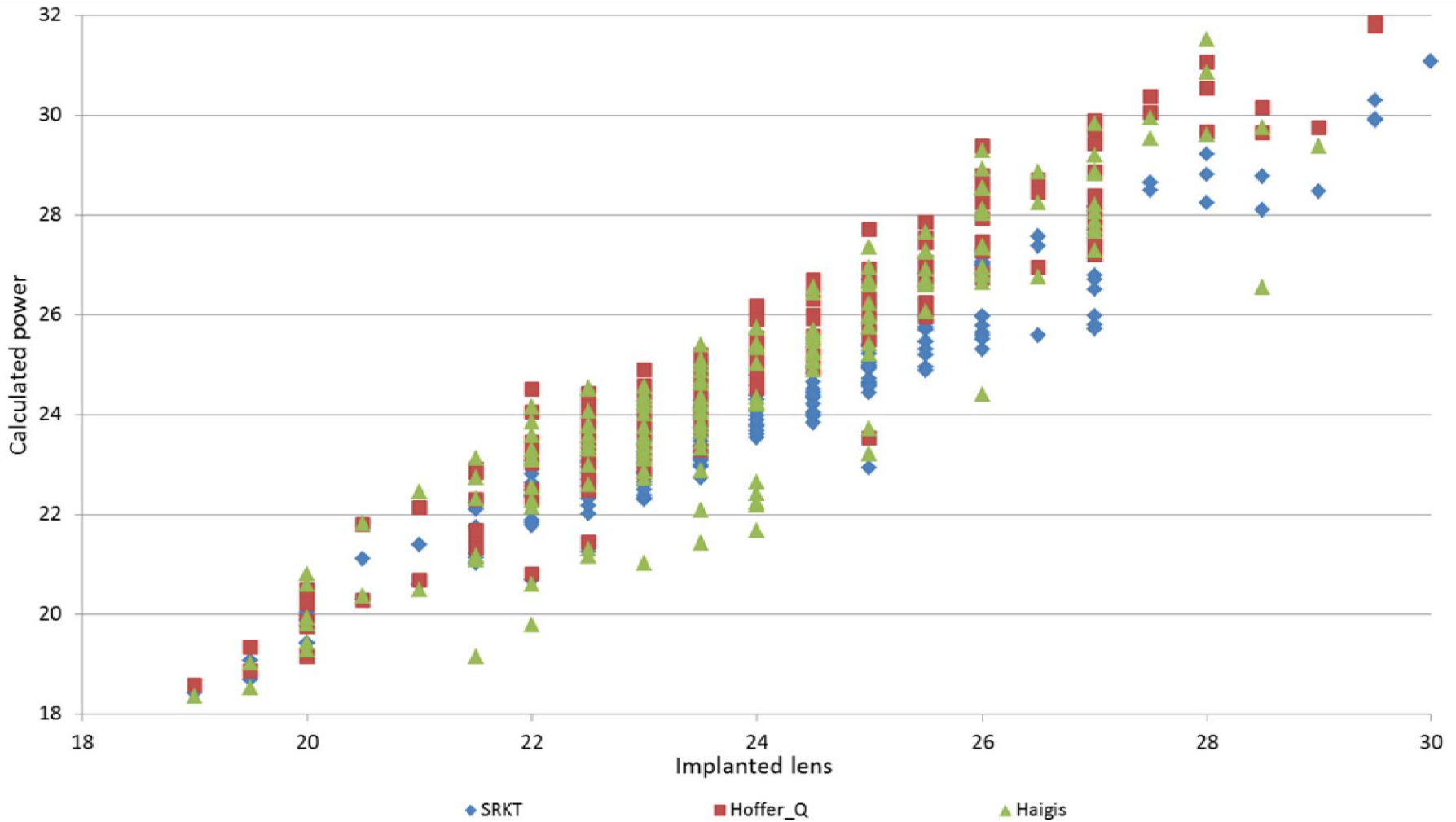
97% of WOLF-CF patients express long-term subjective satisfaction

- High level of „social functioning“ and „self-sufficiency“ scored in NEI-VFQ 25 by 99 and 98 points from 100



WOLF
N=40

CNOR: IOL calculation formulas accuracy analysis



Conclusions

- Accommodation mechanism of WIOL-CF action proven clinically in the study of precisely defined methodology
- Very favorable visual acuity outcomes proven in both large group of patients (68 patients, 136 eyes) as well as in long-term follow up (individually 2-9 years, in total 292 eye-years of experience)
- Critical aspects of visual function proven to last unchanged for long-term (transparency, visual acuity, accommodation)
- Low level of serious/disturbing optical phenomena, very high level of „social functioning“ and „self-sufficiency“ scored in long-term follow-up
- Exceptional contrast sensitivity confirmed
- Opportunities for further improvement identified:
 - Near visual acuity mean and variability
 - Use of Haigis formula for IOL calculation
 - Use of polyfocality „reserve“ for improvement of near vision
 - Potential for binocular optimization
 - Optimization of surgery technique (capsulorhexis, OVD)
 - Correction of pre-operative and/or induced astigmatism
 - Refractive surgery settings, adequate pre-op diagnostics and patient selection