



**IVCRC.net**  
International Vision Correction  
Research Center Network



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## Stability of Lens Position of the FEMTIS® FB-313 after Femtolaser-Assisted Capsulotomy: Interim Results of FEMTIS Multicentered Study

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Relevant Financial Disclosures:

Oculentis<sup>1,2,3</sup> Alcon<sup>1,2,3,4</sup> AMO<sup>1,2,3,4</sup> Carl Zeiss Meditec<sup>1,2,3</sup> Physiol<sup>1</sup> Hoya<sup>1,2,3</sup>  
1 = Research Grants; 2 = Travel Expenses; 3 = Lecture Fees; 4 = Consulting

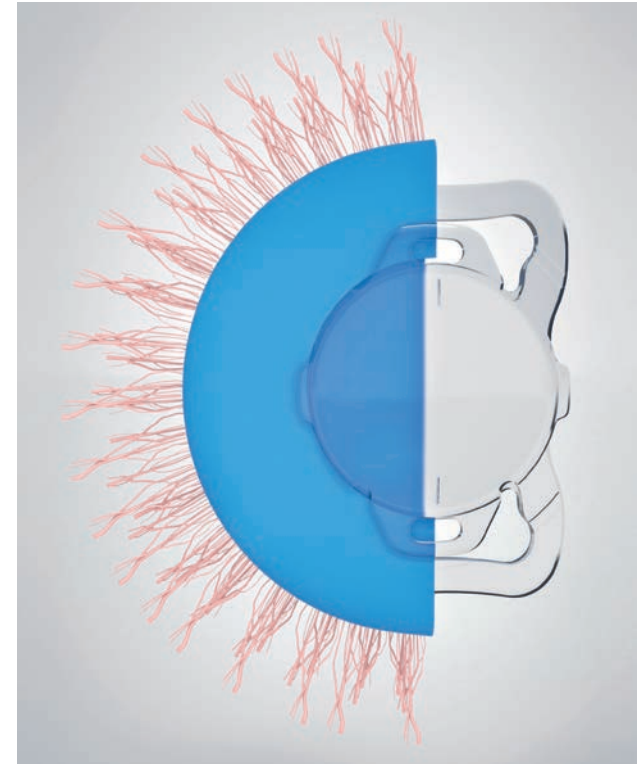
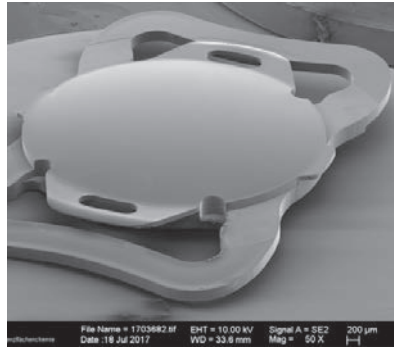
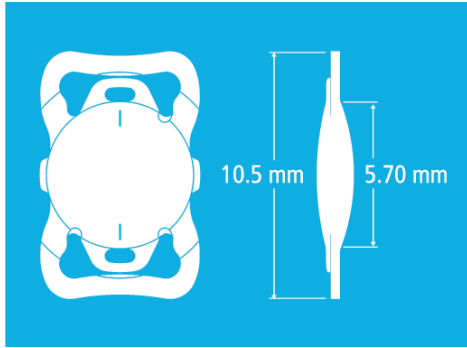


**LISBON2017**  
7-11 OCTOBER

XXXV CONGRESS of the ESCRS

FIL - Feira Internacional de Lisboa, Portugal  
This Congress has been awarded 36 CME credits

# FEMTIS FB-313 G IOL



Type	Foldable one-piece acrylic IOL for easy fixation in the capsulorrhexis
Optic Size	5.7 mm
Overall Length	10.5 mm
Haptic Angulation	0°
Optic Design	Biconvex Aspherical surface - posterior
Design	Optic and haptics with stepped square edges, posterior 360° continuous barrier effect
Material	HydroSmart® - a copolymer, consisting of acrylates with hydrophobic surface, UV absorbing
Available Diopters	+15.0D to +30.0D (0.5D)

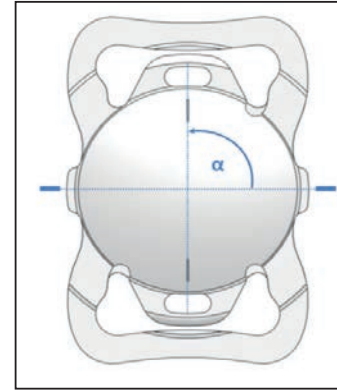
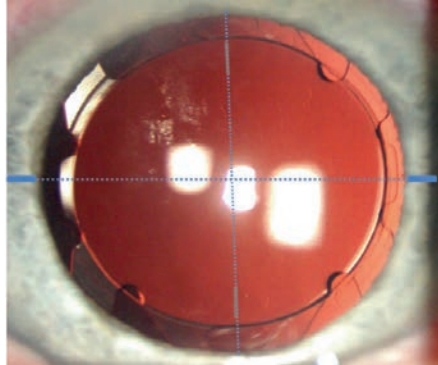


# Study Design

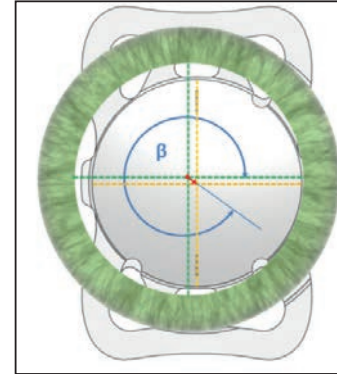
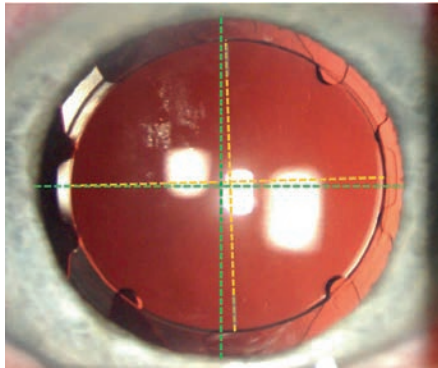
- International trial with 8 clinics in Germany, GB, Spain, Andorra
- 360 eyes (preferred bilateral)
- Study visits: Preop, Surgery and postop 1-7 d, 6-8 w, 6 m, 12 m
- Cataract in both eyes
- Exp. postop. Corneal astigmatism  $< 1.0$  D
  
- Main endpoints:
  - decentration
  - rotation
  - tilt
  - distance iris - IOL
  - subjective refraction
  - visual acuity
  - PCO } via image analysis
  
- Reading center (image analysis): IVCRC, Dept. of Ophthalmology, University of Heidelberg  
IWR, Dept. of applied Mathematics

# Image analysis

IOL rotation



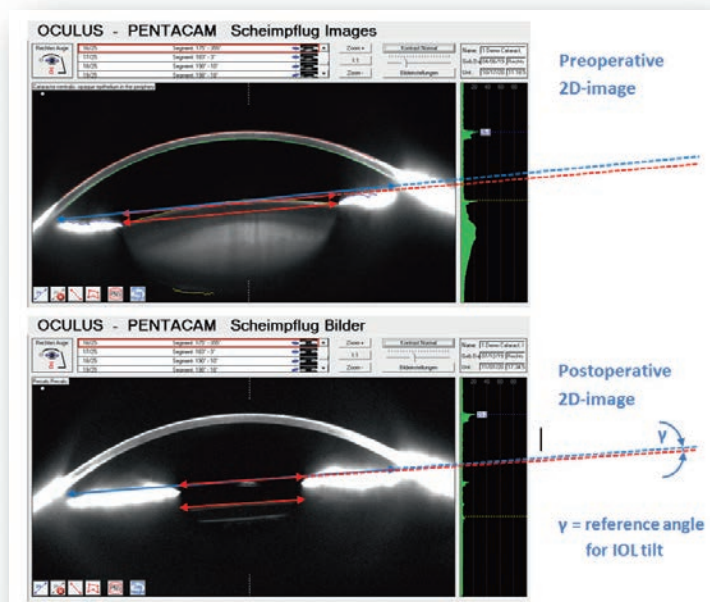
IOL decentration



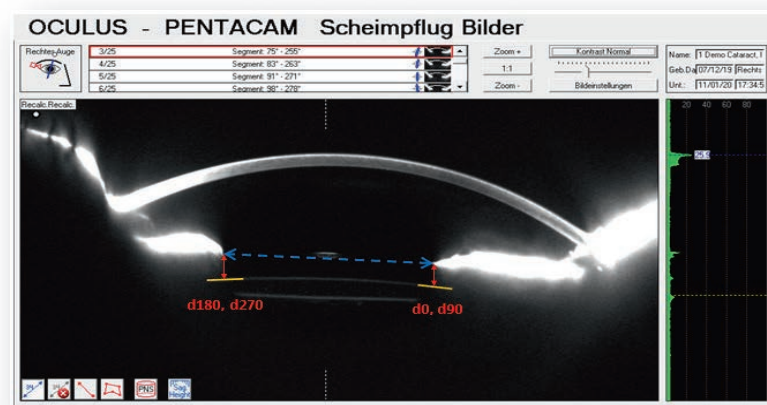


# Image analysis

## IOL Tilt



## Distance IOL to Iris





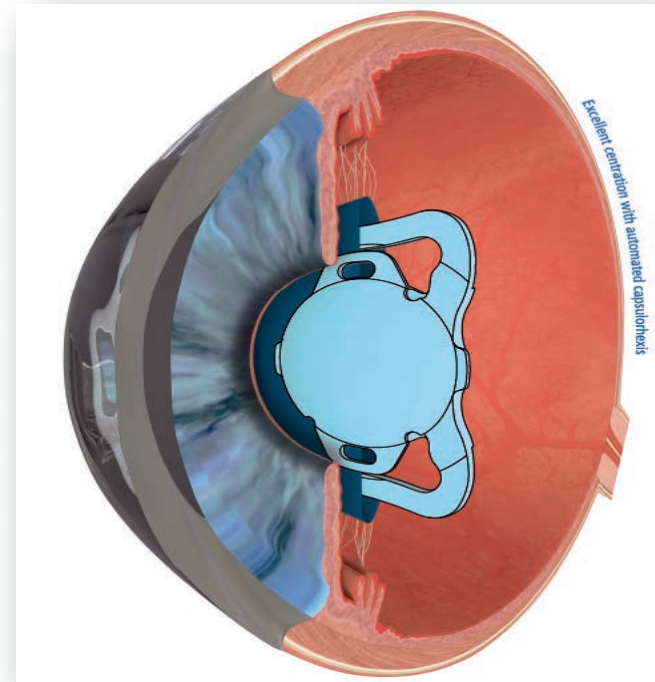
# Preoperative patient demographics

<b>Eyes (n)</b>	<b>294</b>	<b>Patients (n)</b>	<b>156</b>	<b>Follow up completion (eyes)</b>	
<b>Gender (n)</b>					
Female	<b>87</b>	(55.77 %)		Preoperative	294
Male	<b>69</b>	(44.23 %)			
<b>Age (y)</b>				Surgery	282
Mean $\pm$ SD	<b>72.26</b>	$\pm$ 7.64		Postop. 1-7 Days	279
<b>UDVA (logMAR)</b>				Postop. 6-8 Weeks	254
Mean $\pm$ SD	<b>0.57</b>	$\pm$ 0.29		Postop. 6 Month	184
<b>SE (D)</b>				Postop. 12 Month	84
Mean $\pm$ SD	<b>+0.27</b>	$\pm$ 2.36			
<b>Sphere(D)</b>					
Mean $\pm$ SD	<b>+0.63</b>	$\pm$ 2.33			
<b>Cylinder (D)</b>					
Mean $\pm$ SD	<b>-0.74</b>	$\pm$ 0.52			
<b>CDVA (logMAR)</b>					
Mean $\pm$ SD	<b>0.25</b>	$\pm$ 0.18			



# Surgical characteristics

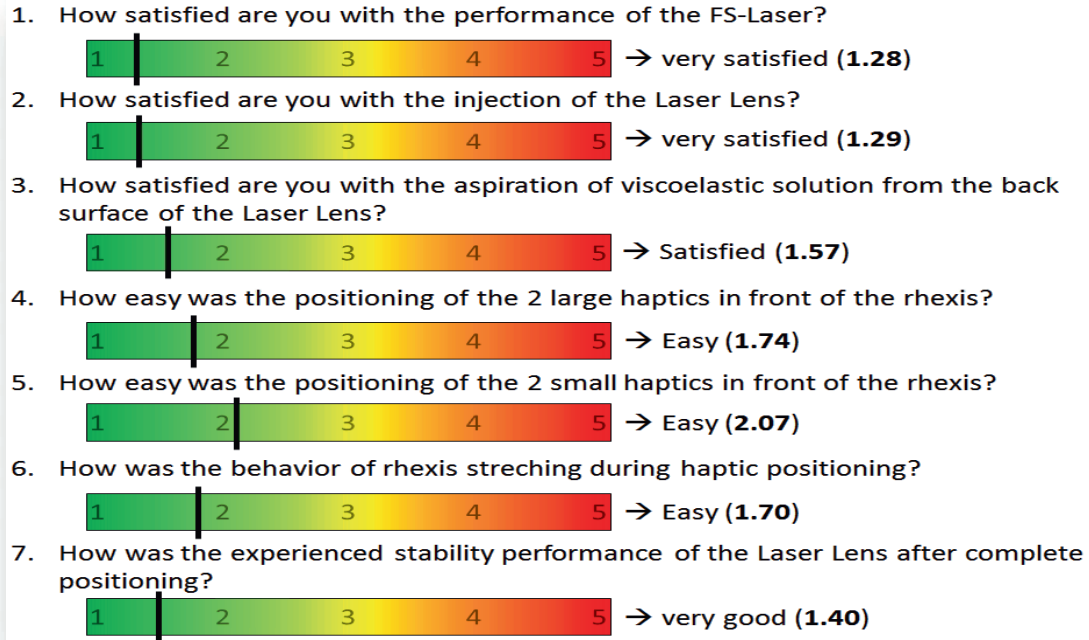
<b>IOL power (D)</b>	<b>20.33 ± 2.42</b>
<b>Capsulorhexis size (mm)</b>	<b>4.95 ± 0.11</b>
<b>Incision size (mm)</b>	<b>2.42 ± 0.33</b>
<b>Surgery time (min)</b>	<b>12.32 ± 6.44</b>





# Results - Investigator questionnaire

(grading: 1 = best ; 5 = worst regarding school marks)

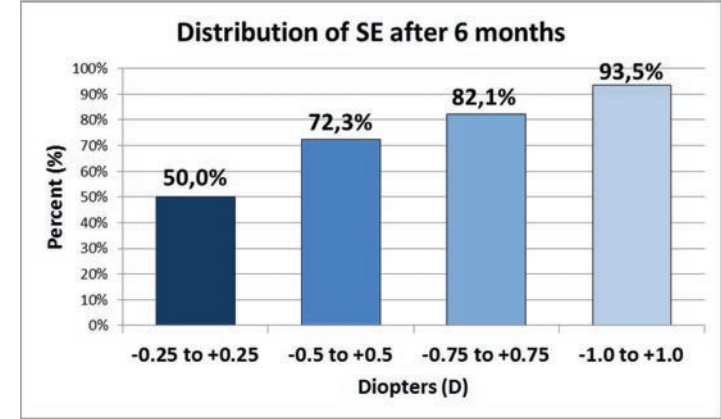
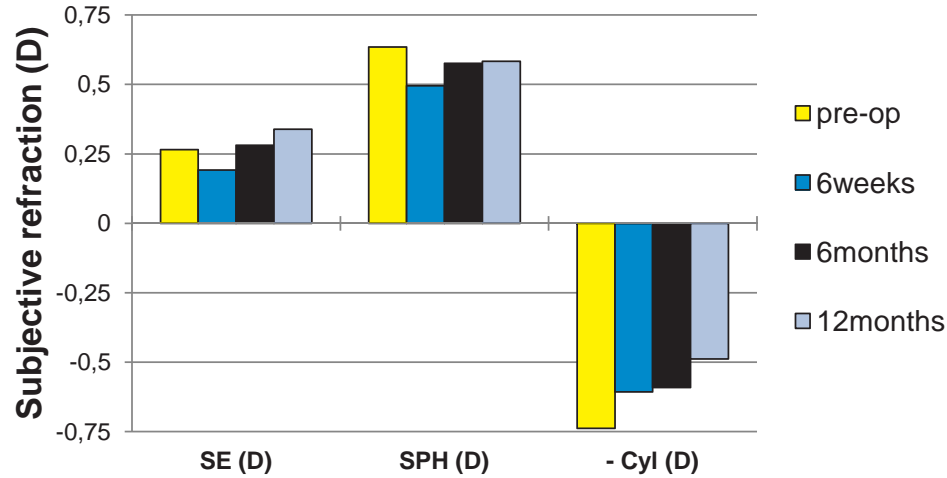






# Results - Predictability

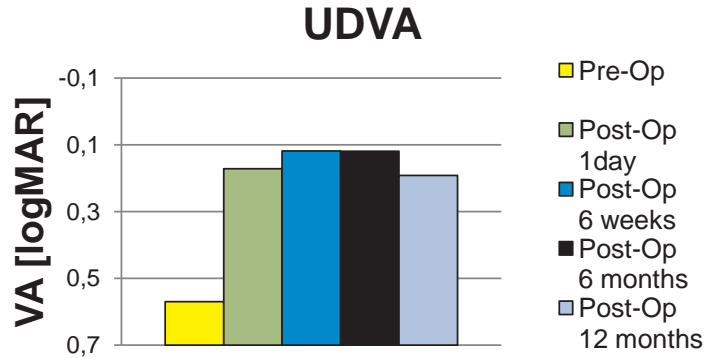
## Subjective refraction



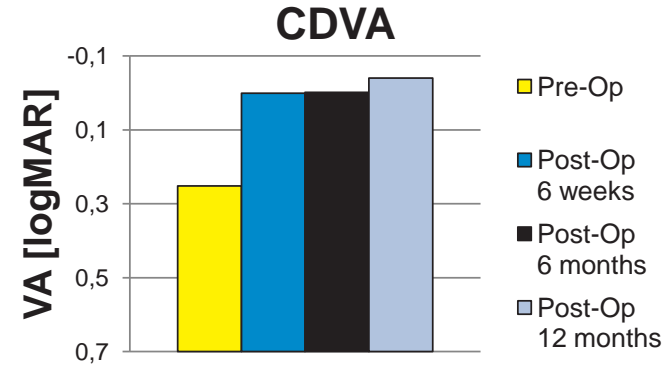
- A-constant optimization



# Results - Visual Acuity



- Slightly decreasing after 12 month
- Reasonable of hyperopic shift



- However increased after 12 month
- Probably due to exact IOL centration



# Results - IOL Rotation

(Published study results)

Source: Becker KA, Auffarth GU, Völcker HE; Measurement method for the determination of rotation and decentration of intraocular lenses; Der Ophthalmologe [01 Jun 2004, 101(6):600-603]

→ **Mean IOL-rotation =  $5.3^\circ \pm 1.4^\circ$  after 6 months**

Source: Ioannis T Tsinopoulos, Konstantinos T Tsaousis, Dimitrios Tsakpinis, Nikolaos G Ziakas, and Stavros A Dimitrakos ; Acrylic toric intraocular lens implantation: a single center experience concerning clinical outcomes and postoperative rotation; Clin Ophthalmol. [2010; 4: 137–142]

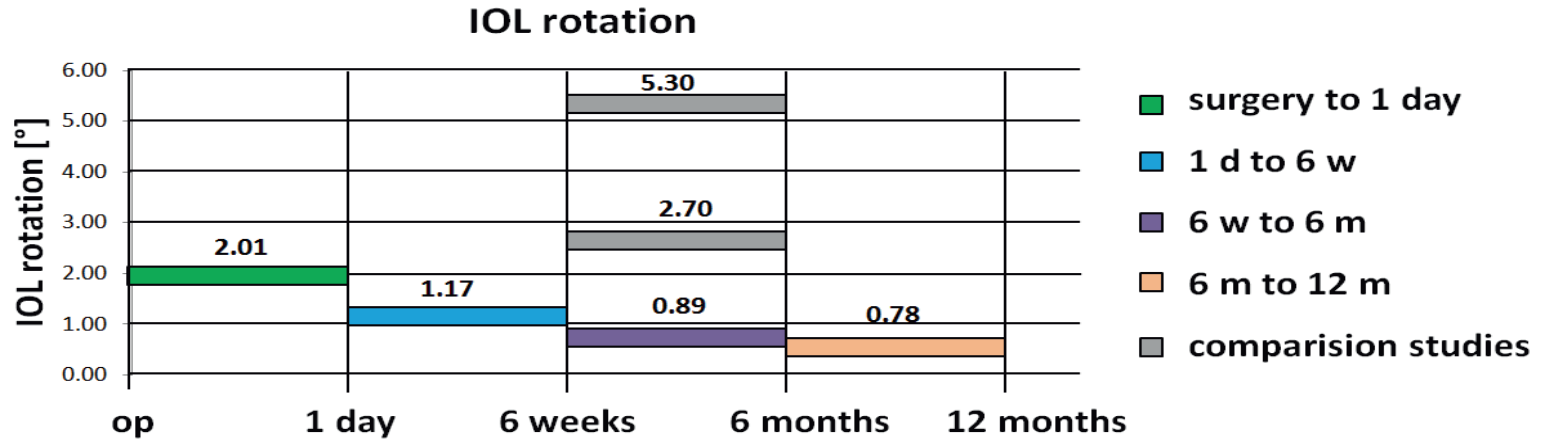
→ **Mean IOL-rotation =  $2.7^\circ \pm 1.5^\circ$  after 6 months**

Source: Draschl P, Hirnschall N, Luft N, Schuschitz S, Wiesinger J, Rigal K, Findl O.; Rotational stability of 2 intraocular lenses with an identical design and different materials.; [J Cataract Refract Surg. 2017 Feb;43(2):234-238]

→ **Mean IOL-rotation =  $2.4^\circ \pm 1.85^\circ$  for the hydrophilic IOL**

→ **Mean IOL-rotation =  $1.6^\circ \pm 1.61^\circ$  for the hydrophobic IOL**

# Results - IOL Rotation



- Low rotation behaviour
- Minimal value compared to published studies



# Results - IOL Decentration

(Published study results)

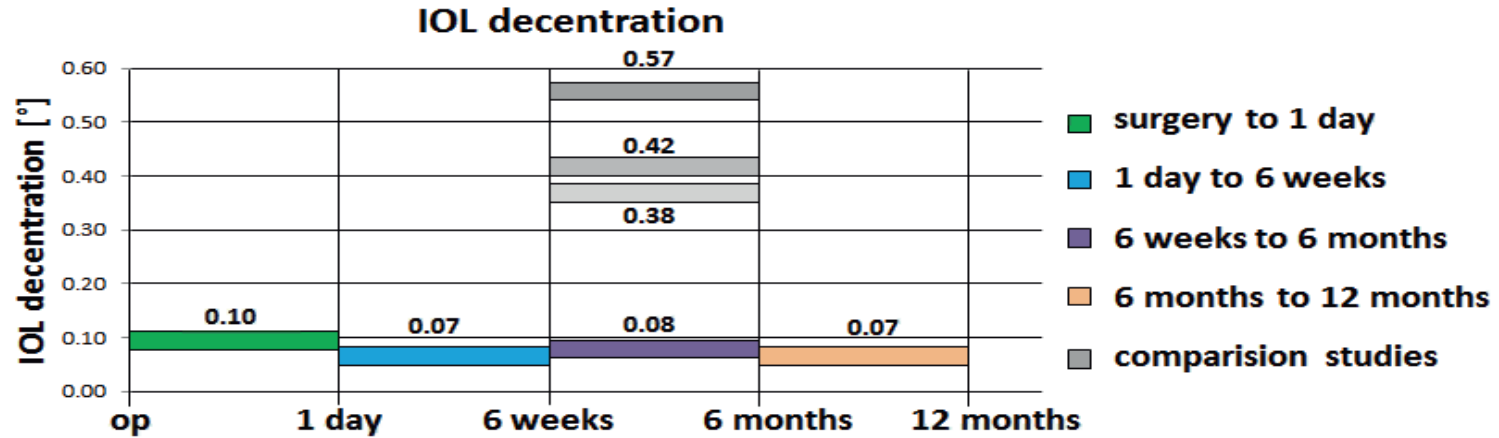
Source: Findl O, Hirschall N, Draschl P, Wiesinger J.; Effect of manual capsulorhexis size and position on intraocular lens tilt, centration, and axial position; [J Cataract Refract Surg. 2017 Jul;43(7):902-908]

- Mean IOL decentration **0.38** ± 0.23 mm (control group)
- Mean IOL decentration **0.40** ± 0.21 mm (Rhexis 4.5 mm - 5.5 mm)
- Mean IOL decentration **0.17** ± 0.08 mm (Rhexis under 4.5 mm)

Source: Do-HyungLeeMD, PhD, Soo-CheolShinOD, Choun-KiJooMD, PhD; Effect of a capsular tension ring on intraocular lens decentration and tilting after cataract surgery; [JCRS Vol. 28, Issue 5, May 2002, Pages 843-846]

- Mean IOL decentration **0.42** ± 0.17 mm (IOL with CTR)
- Mean IOL decentration **0.57** ± 0.16 mm (IOL)

# Results - IOL Decentration



- Low decentration behaviour
- Minimal value compared to published studies



# Results - IOL Tilt

(Published study results)

Source: Ale JB; Intraocular lens tilt and decentration: a concern for contemporary IOL designs; [Nepal J Ophthalmol. 2011 Jan-Jun;3(1):68-77.]

→ **Average tilt 2°- 3°**

Source: U. Mester, T. Sauer, H. Kaymak; Decentration and tilt of a single-piece aspheric intraocular lens compared with the lens position in young phakic eyes; [J Cataract Refract Surg. 2009 Mar;35(3):485-90.]

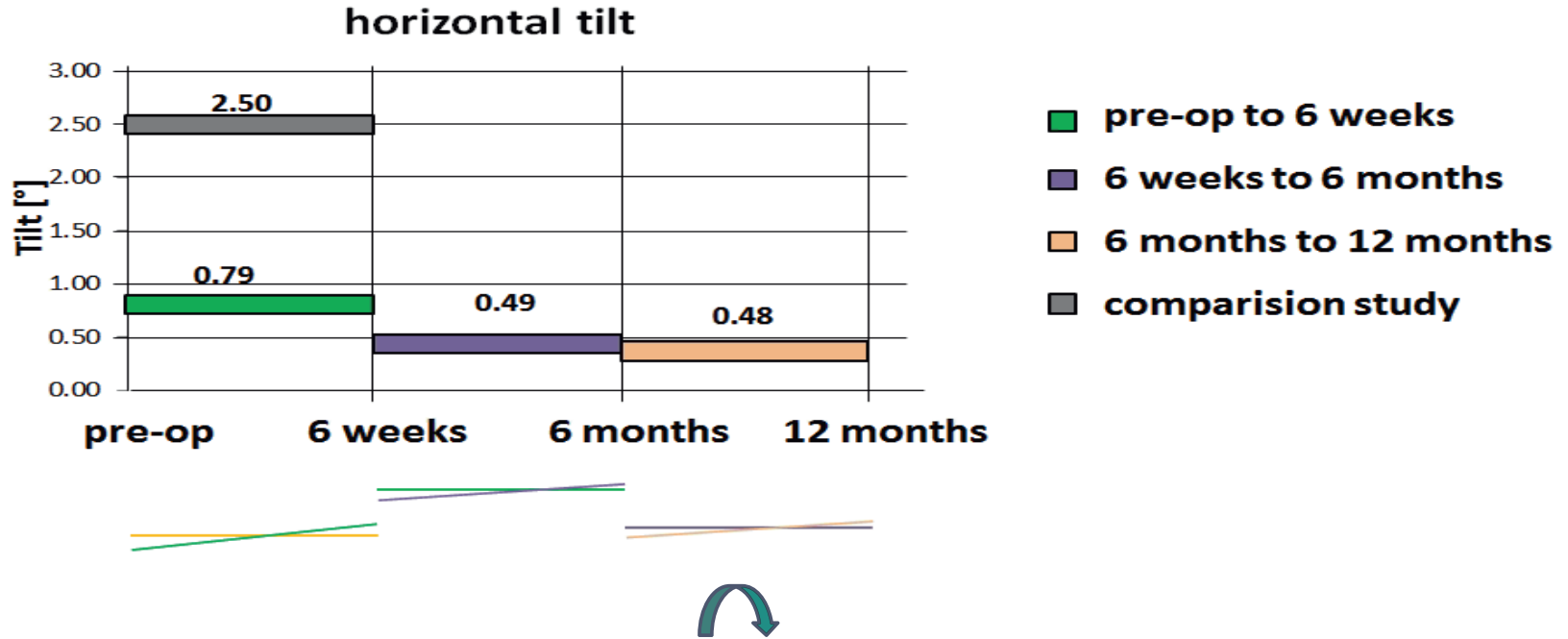
→ **Horizontal tilt 2.50°**

→ **Vertical tilt 3.10°**

Source: Martin Baumeister, MD, Jens Bühren, MD, Thomas Kohlen, MD; Tilt and decentration of spherical and aspheric intraocular lenses: Effect on higher-order aberrations; [J Cataract Refract Surg. Volume 35, Issue 6. June 2009, Pages 1006-1012]

→ **Mean IOL tilt 2.89°**

# Results - IOL Tilt

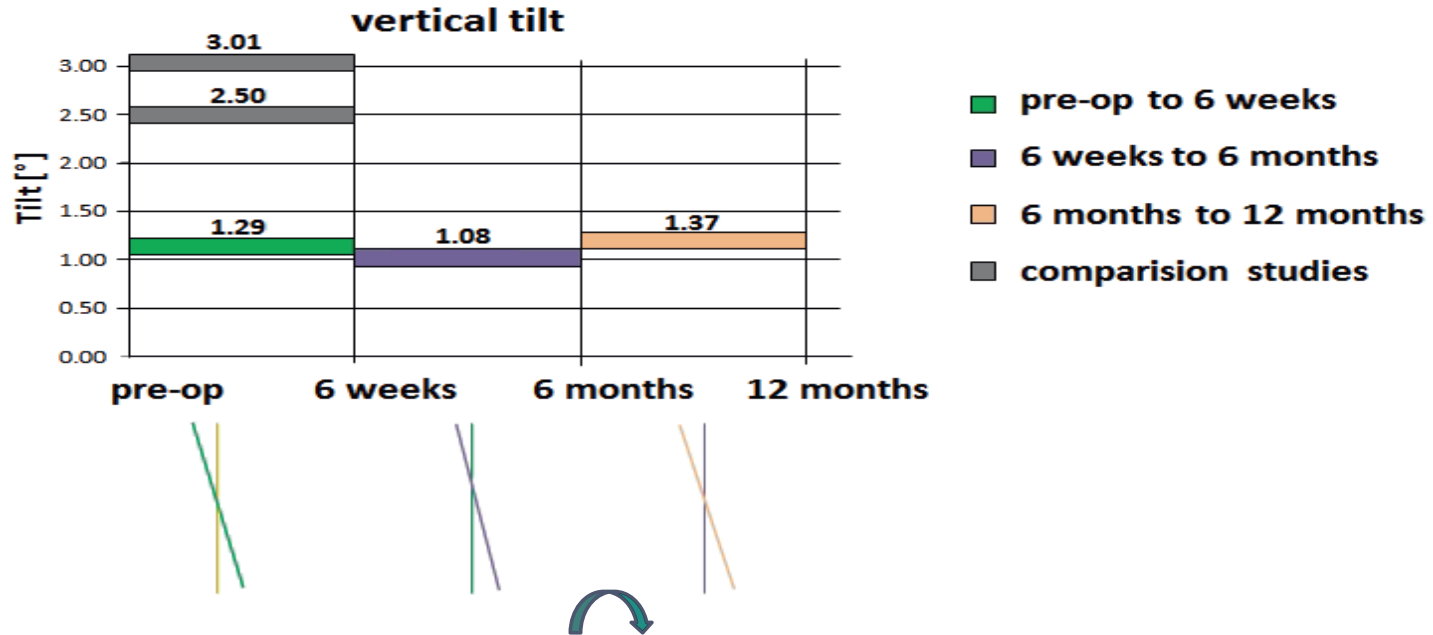


- Low horizontal Tilt behaviour
- Minimal value compared to published studies





# Results - IOL Tilt



- Low horizontal Tilt behaviour
- Minimal value compared to published studies



# Results - PCO

(Published study results)

Source: Muñoz G, Albarrán-Diego C, Ferrer-Blasco T, Sakla HF, García-Lázaro S.; Visual function after bilateral implantation of a new zonal refractive aspheric multifocal intraocular lens.; [J Cataract Refract Surg. 2011 Nov;37(11):2043-52. doi: 10.1016/j.jcrs.2011.05.045.]

- PCO grading of 64 eyes after 6 months
- 59 eyes (92.7 %) **grade 0 - 1**
- 4 eyes (6.3 %) **grade 3**
- 1 eye (1.5 %) **grade 4**

Source: Schriefl SM, Leydolt C, Stifter E, Menapace R.; Posterior capsular opacification and Nd:YAG capsulotomy rates with the iMics Y-60H and Micro AY intra-ocular lenses: 3-year results of a randomized clinical trial.; [Acta Ophthalmol. 2015 Jun;93(4):342-7.]

- PCO grading after 3 years
- **1.9 ± 1.7** group 1
- **1.7 ± 2.2** group 2



# Results - PCO

(Published study results)

Source: Leydolt C, Schartmüller D, Schwarzenbacher L, Schranz M, Schriefl S, Menapace R.; omparison of posterior capsule opacification development with 2 single-piece intraocular lens types; [J Cataract Refract Surg. 2017 Jun;43(6):774-780. doi: 10.1016/j.jcrs.2017.06.005.]

- YAG capsulotomy rate after 3 years
- IOL-Group A = **16.4%**
- IOL-Group B = **6.0%**

# Results - PCO

## PCO grading

0 – none visible at all

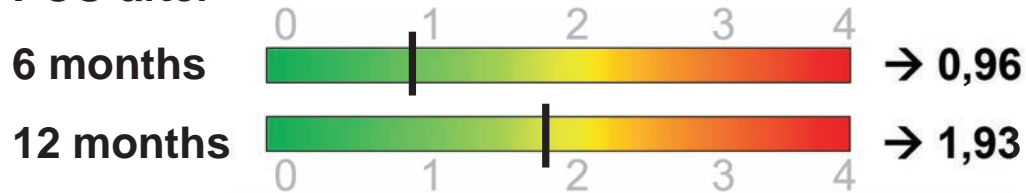
1 – visible but none reaching to IOL optic edge

2 – slightly over IOL optic edge

3 – well inside IOL optic but visual axis clear

4 – across visual axis

## PCO after



➤ Currently 3 YAG treatments (2 after 6 month, 1 after 12 month)

# Conclusions

## FEMTIS IOL

