



Three years follow up of posterior capsule clarity after Peripheral capsular Re-constructor (Fix-o-flex)

Ahmed Elmassry , MD. PhD.
Professor of Ophthalmology
President of EOS
Alexandria University
EGYPT

Ioannis G Pallikaris, MD.
Professor Of Ophthalmology
Crete University
Greece



ACKNOWLEDGEMENT



Harilaos S Ginis, PhD

Loukia L. Leonidou, MSc

Onourcan Sahin, PhD

Dimitris Liakopoulos, MD, MSc

Shaimaa Elbassiouny MD

Ibtsam Yakout MD

Manos Xylouris, BSc,MD, PhD

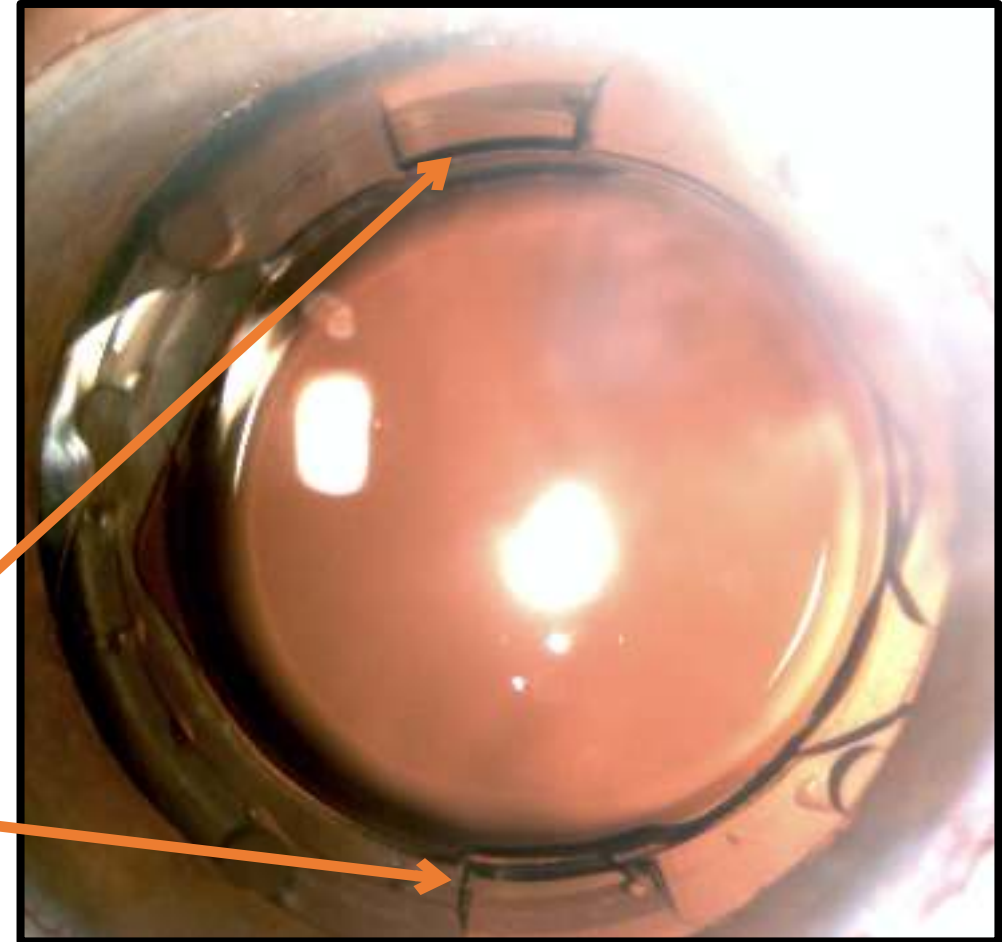
Financial Disclosure:

**The authors of this presentation have received
research funding from EYE-PCR B.V.**

**Authors IP, HG, OS have a patent on the presented
novel implant**

RING SPECIFICATIONS

- ❖ External diameter: 9.8mm
- ❖ 2.4mm incision.
- ❖ Axial thickness: 1.7m.
- ❖ "Retainers" to fasten the optical part of the IOL.

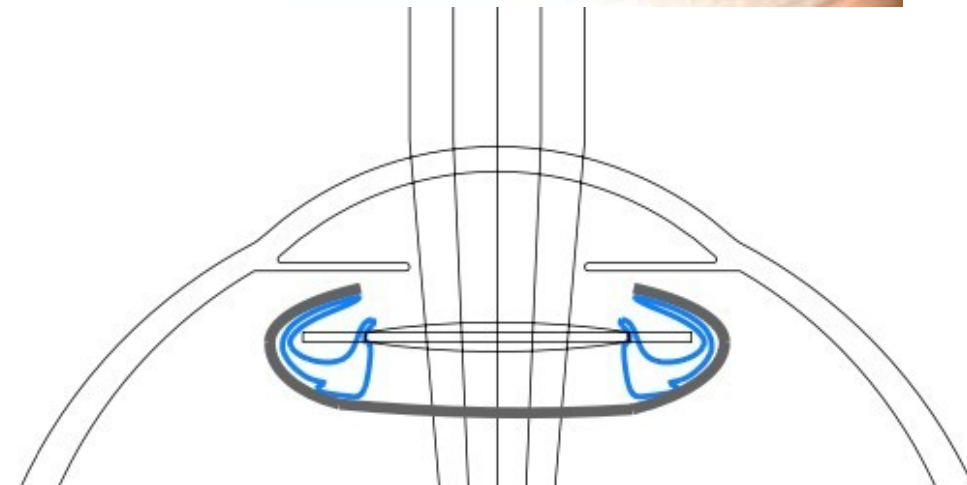


The **fixOflex** ring is inserted in the capsule following **phacoemulsification** and **prior to IOL implantation**.

- ❖ Maintains an open capsule while restoring its anatomical shape.
- ❖ Features **retainers** to secure and center the optic of the IOL

Hypothesis under clinical investigation:

- ❖ The ring leads to a more predictable **IOL position** in the eye (axial and transverse) (ELP)
- ❖ The ring **reduces the formation of PCO** acting as a mechanical barrier.
- ❖ **Refractive outcomes** will be more stable post-operatively.





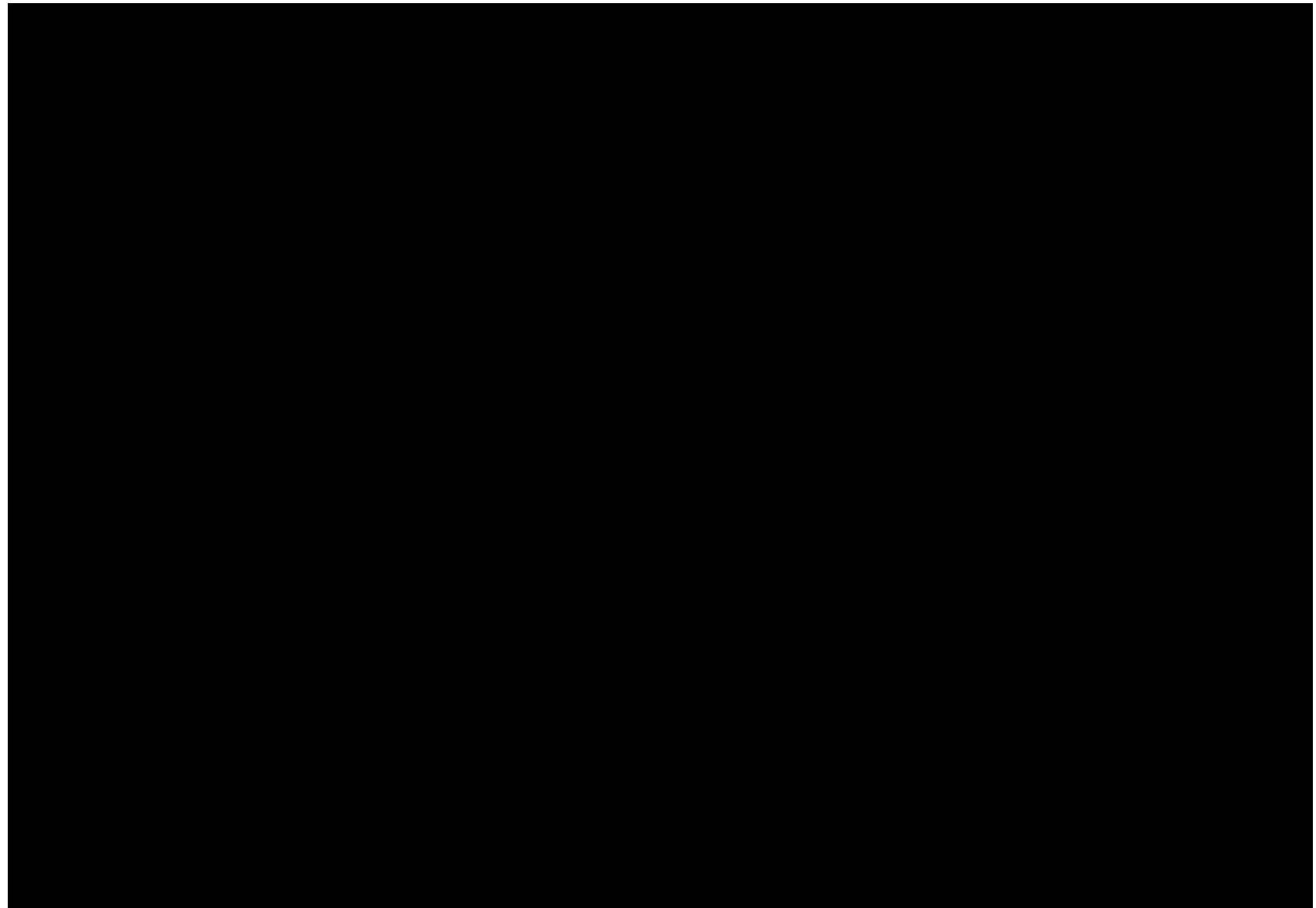
PATIENTS AND METHODS

- ❖ **120 patients**, presented for cataract treatment.
- ❖ Mean age : **64.13** yo (SD 8.34, range: 43 to 88 yo)
- ❖ Cataract grade (LOCS III): 1 to 3
- ❖ Standard IOL calculation (**Tecnis, ZCB00**, Lenstar Biometry, Heigis formula).
- ❖ **Followup: 1 day, 1 week, 1 month, 3 months 6 months and 1 year. And now three years**

Surgical observations:

- ❖ Mean time duration for ring implantation was 1.29 minutes (SD 0.31) (**1min 17sec**)
- ❖ In 5 patients (6.9%) the ring required additional manipulations for centration. In one case the IOL was implanted behind the ring.

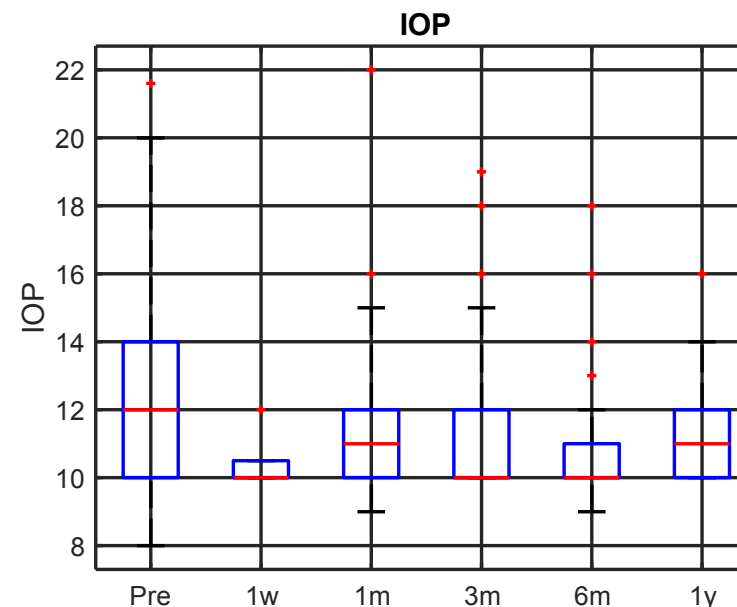
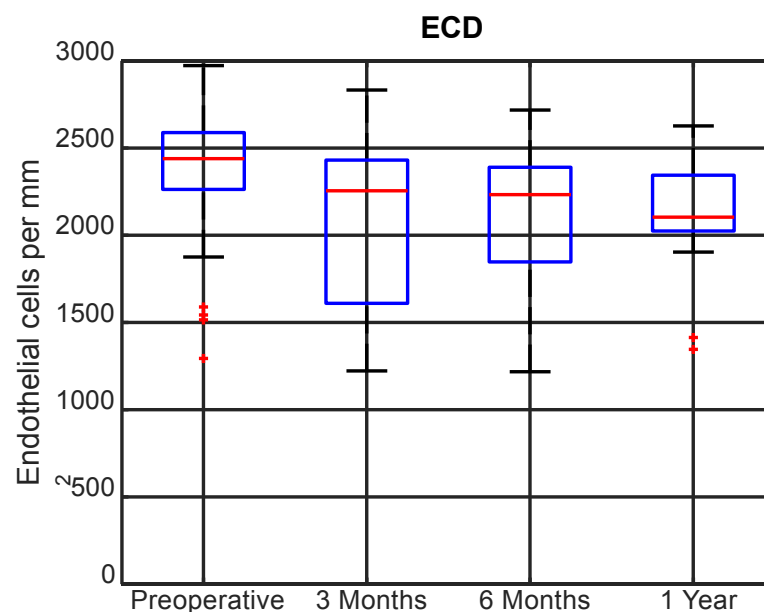




1:28

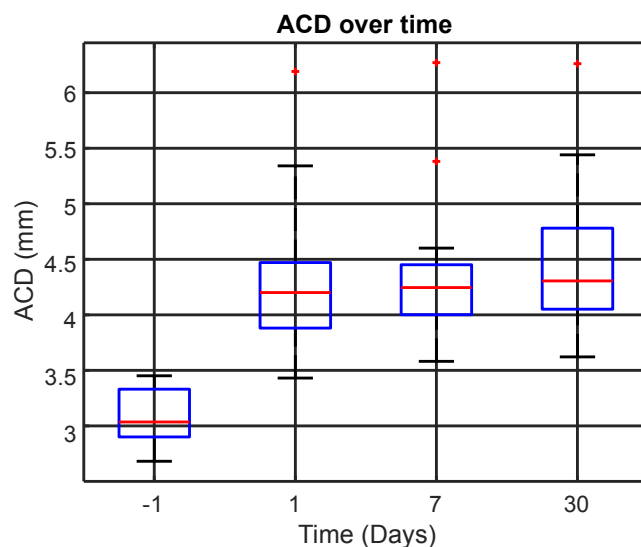


Endothelial cells and IOP



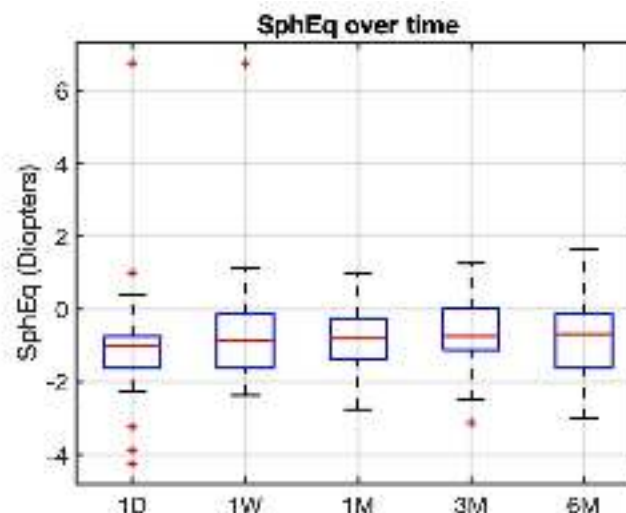
- **Endothelial cell loss** was within normal limits, as expected after standard phacoemulsification surgery.
- **No anterior chamber reaction** and postoperative intraocular pressure changes were observed.
- **No serious adverse events** were reported.
- **No PCO has been reported ONE year after surgery.**

Results

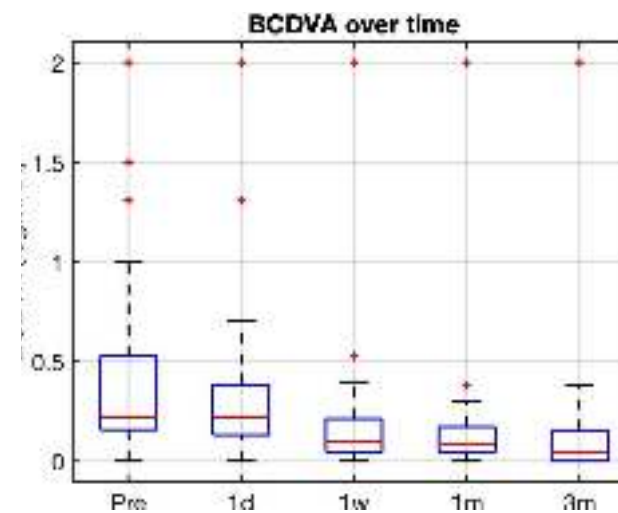


Mean pACD: 4.45 mm (SD 0.70)

Difference between pACD at 1 month and day 1 was not statistically significant ($p=0.021$) indicating a stable postoperative lens position



Mean Spherical Equivalent refraction at 3 Months follow-up: -0.69D (SD 1.13)



Mean BCDVA logMAR at 3 Months follow-up: 0.12 (SD 0.3)



Alexandria Study: Three-Year Follow-Up of Cataract Patients with fix-O-flex™

To present the clinical outcomes and observations from
a **three-year postoperative** follow-up of **68 patients**
who underwent implantation of (Tecnis ZCB00 IOL,
J&J, NJ with **the fix-O-flex™** and compared to a control
group who received conventional cataract surgery.

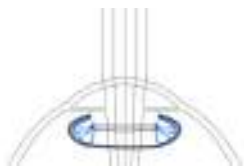




Alexandria Study: Three-Year Follow-Up of Cataract Patients with fix-O-flex TM

- ✓ endothelial cell density and loss (ECD and ECL)
- ✓ posterior capsular opacification (PCO)





Results

Postoperative Refractive outcomes

Uncorrected Visual Acuity (LogMAR)- 1Y and 3Y:

- **fixOflex™ group:**
 - 1Y: $0,13 \pm 0,11$
 - 3Y: $0,18 \pm 0,18$
- **Control Group:**
 - 1Y: $0,11 \pm 0,13$
 - 3Y: $0,13 \pm 0,17$

Corrected Distance Visual Acuity (LogMAR):

- **fixOflex™ group**
 - 1Y: $0,13 \pm 0,11$
 - 3Y: $0,18 \pm 0,18$
- **Control Group:**
 - 1Y: $0,06 \pm 0,09$
 - 3Y: $0,09 \pm 0,14$

Spherical equivalent over time (D):

- **fixOflex™ group**
 - 1Y: $0,85 \pm 0,94$
 - 3Y: $0,87 \pm 0,73$
- **Control Group:**
 - 1Y: $-0,59 \pm 0,67$
 - 3Y: $-0,55 \pm 0,78$

Intraocular Pressure:

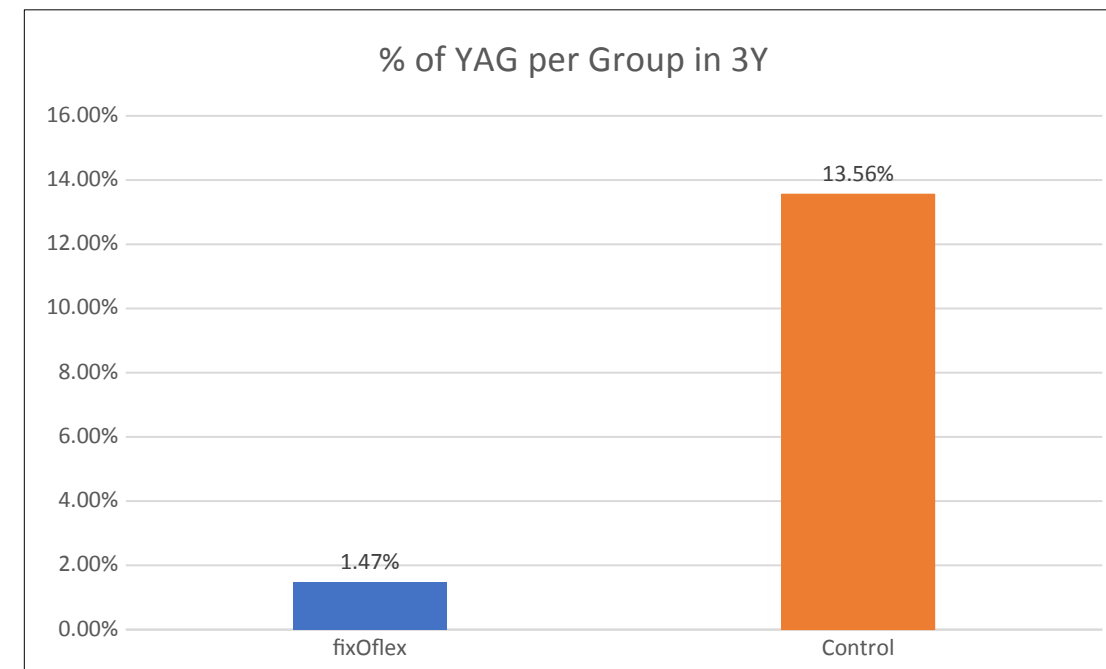
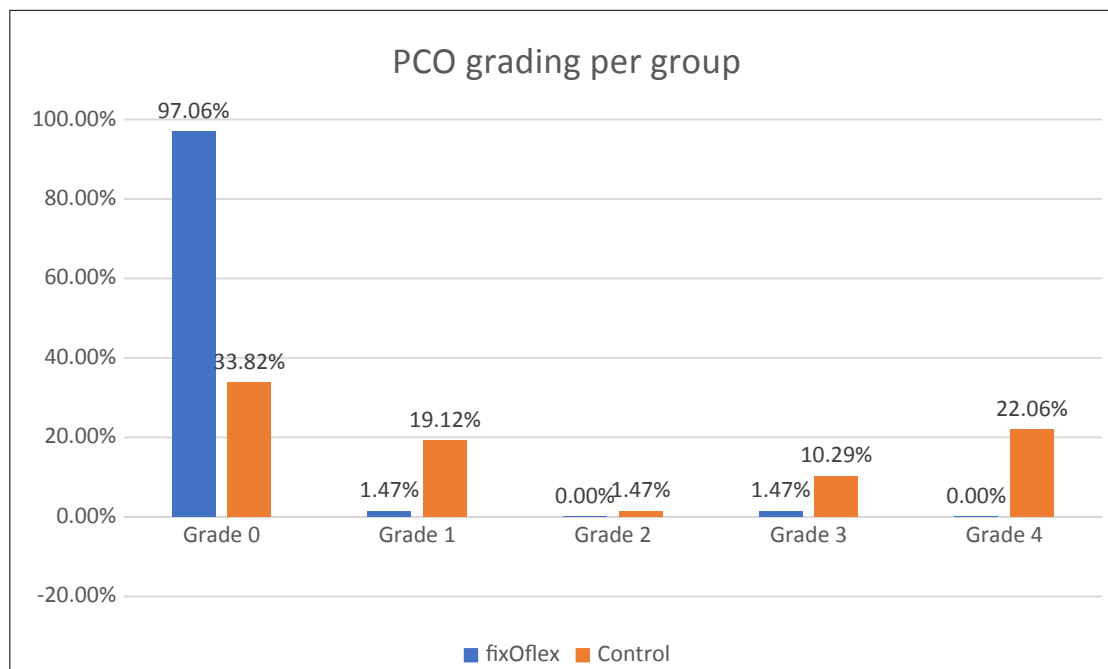
- **fixOflex Group:** The mean preoperative IOP was 13.73 ± 3.1 mmHg, while 3 years after the operation was slightly declined to $12,41 \pm 2.66$ mmHg
- **Control Group:** The mean preoperative IOP was $13.12 \pm 3,55$ mmHg, while 3 years after the operation was 13.60 ± 2.75 mmHg

Endothelial Cell Density and loss 3Y after the operation:

- **fixOflex Group:**
 - Mean ECD $2032,20 \pm 450,10$ cells/mm²,
 - Mean ECL: $-386,53 \pm 338,51$ or 14,78%
- **Control Group:**
 - Mean ECD $2049,31 \pm 481,87$ cells/mm²,
 - Mean ECL: $-338,63 \pm 370,39$ or 16,09%



Posterior Capsular Opacification and Nd:YAG laser



During the three-year postoperative period, **2.94% (2 out of 68)** of the FixOflex™ patients developed **PCO**. In contrast, two-thirds of the control group patients exhibited PCO, with **32.35%** of these cases being clinically significant.

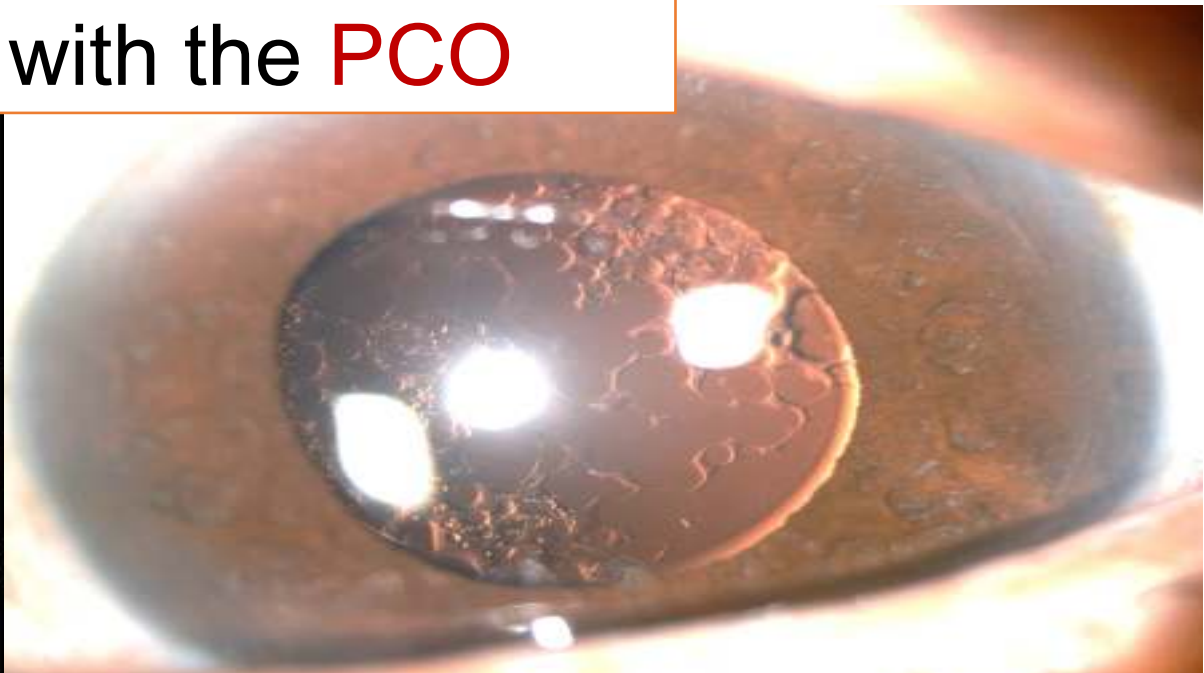
During the three-year postoperative period only **1.47%** of the patients with the FixOflex™ device, **required Nd:YAG** posterior laser capsulotomy, compared to **13.56%** of the control group patients.



I tracy for the eye with the Ring



I trace for the eye with the PCO





Conclusions

- ❖ The Fix-O-flex ring provides an **open capsule space** for IOL implantation.
- ❖ **Anterior chamber depth and refraction** were stable postoperatively.
- ❖ The ring implantation appears to be a **safe and quick additional step** of the surgery, with short learning curve.
- ❖ Limited **intraoperative complications** observed were mainly related to the position of the ring and/or the IOL after implantation and were dealt with minor manipulations.
- ❖ **No serious adverse events were reported.**





Conclusions

The Fix-O-flex ring provides clear posterior capsule after three years follow up (open capsule space Concept for IOL implantation).



THANK YOU



In collaboration with:



INTERNATIONAL CONGRESS OF THE
EGYPTIAN
OPHTHALMOLOGICAL SOCIETY

EOS
2025

Save the Date
7-9 MAY
INTERCONTINENTAL
CITYSTARS, CAIRO, EGYPT

eos-egypt.org



YouTube channel: @Dr.AhmedElmassry