

OPEN-CAPSULE DEVICE FOR PCO PREVENTION

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Dr. Kleinmann is a consultant for Hanita Lenses, Israel

Conclusions of rabbit study phase 1

- ◆ Encouraging PCO prevention results for both hydrophilic and hydrophobic ring materials
- ◆ No significant difference between hydrophilic and hydrophobic IOLs
- ◆ Our results suggested primary PCO prevention due to inhibition of Soemmering's ring formation indicating suppression of cell proliferation and not only a mechanical blockage

Animal trial
(prototype)

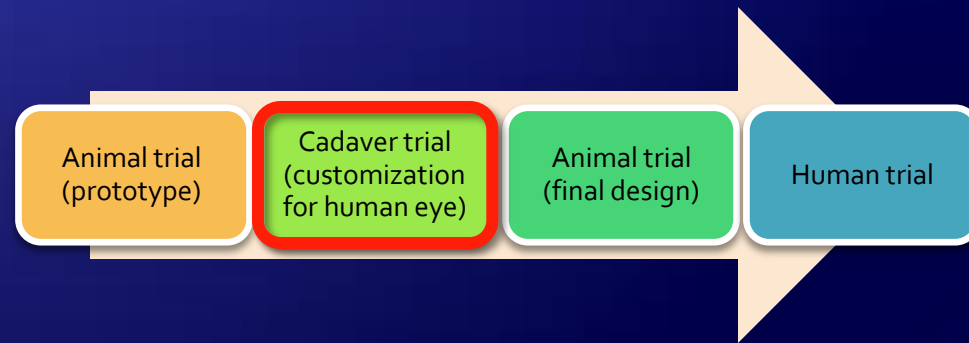
Cadaver trial
(customization
for human eye)

Animal trial
(final design)

Human trial

Conclusions of Cadaver study

- ◆ Ring diameter of 9.5 mm was found to fit all capsular bag sizes of eyes tested with no ovalization or deformation
- ◆ Future steps: To simplify the insertion of the IOL haptics into the ring groove



Remaining questions

1. Do the side windows assist in PCO prevention?
The windows induce fluid flow, however function as a passage for the cells.
2. What wall geometry will be more efficient in PCO prevention - vertical or round?
3. How to simplify the insertion of the IOL haptics into the ring groove?

Animal trial
(prototype)

Cadaver trial
(customization
for human eye)

Animal trial
(final design)

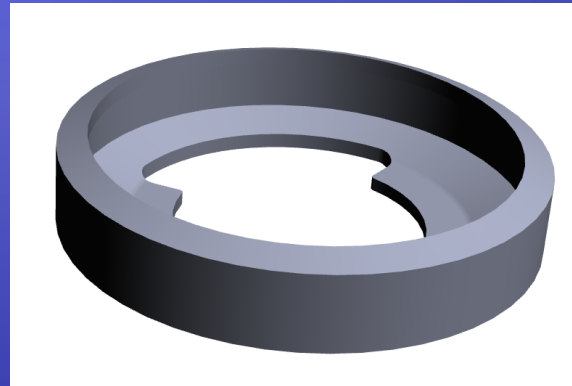
Human trial

New designs



Design 1

- Vertical wall for capsular bend enhancement
- Extensions for IOL positioning
- Windows for fluid flow



Design 2

- Vertical wall for capsular bend enhancement
- Extensions for IOL positioning



Design 3

- Round wall for capsular adhesion
- No posterior rim for easing the IOL positioning

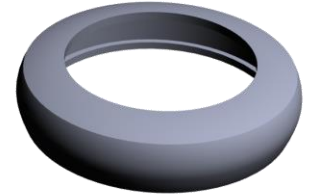
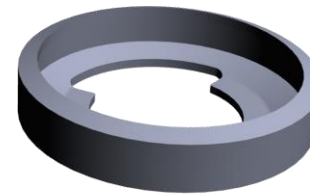
Comparison to previous design

Previous design

- ◆ Outer diameter: 11 mm
- ◆ Wall height: 1.5 mm

Current designs

- ◆ Outer diameter: 10.5 mm
- ◆ Wall height: 1.7 mm



Rabbit trial - Methods

- ◆ 18 NZW rabbit eyes were divided into three groups and implanted, after lens removal, as following:

	N (eyes)	Ring	IOL
Group 1	7	Design 1	SeeLens AF
Group 2	7	Design 2	SeeLens AF
Group 3	7	Design 3	SeeLens AF

- ◆ Tested groups were compared to control group of previous study (same study setting, rabbit species, rabbit age and weight):

	N (eyes)	Ring	IOL
Control	6	-	SeeLens AF

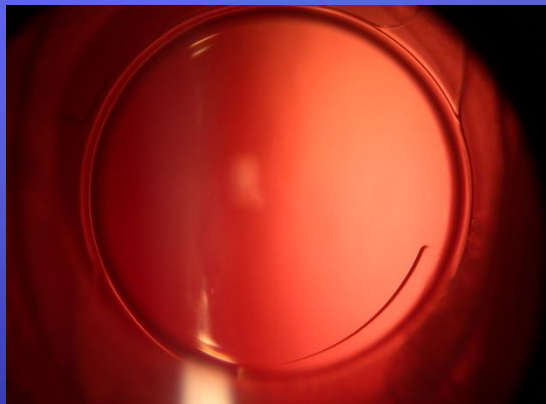
Rabbit trial - Methods

- ◆ Following tests were performed:
 - ◆ Slit Lamp and Miyake Apple evaluation at 6 weeks
 - ◆ Histopathological evaluation (ongoing)

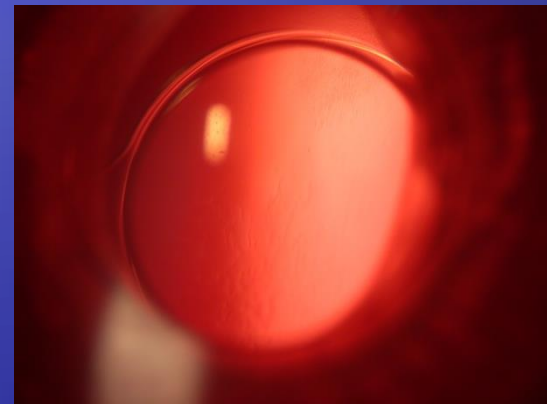
Results - implantation

- ◆ Implantation of the ring still requires manipulations, and is to be optimized
- ◆ Insertion of IOL haptics into the ring groove was easy in all designs
- ◆ In design 3 the IOL was more prone to tilt due to the absence of the posterior rim
- ◆ In designs 1 and 2 the extensions are to be elongated to eliminate risk of IOL misalignment

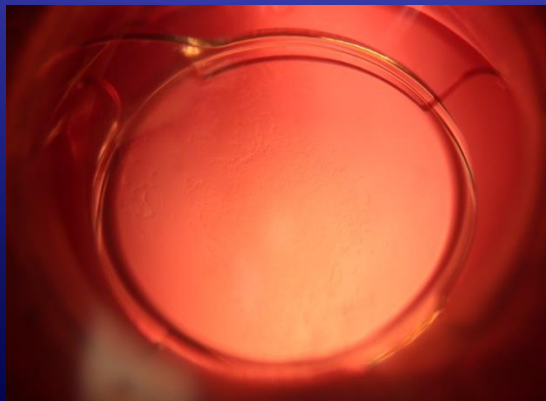
Results - 6 weeks



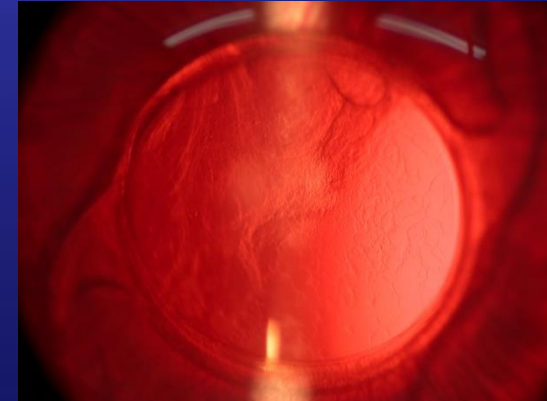
Average
PCO score:
0.67



Average
PCO score:
1.43



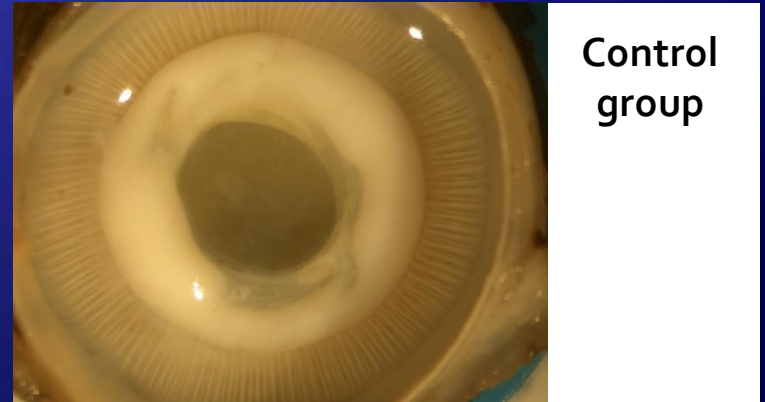
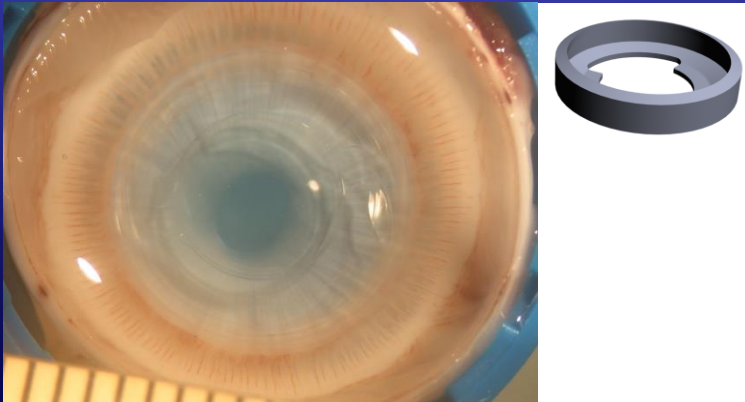
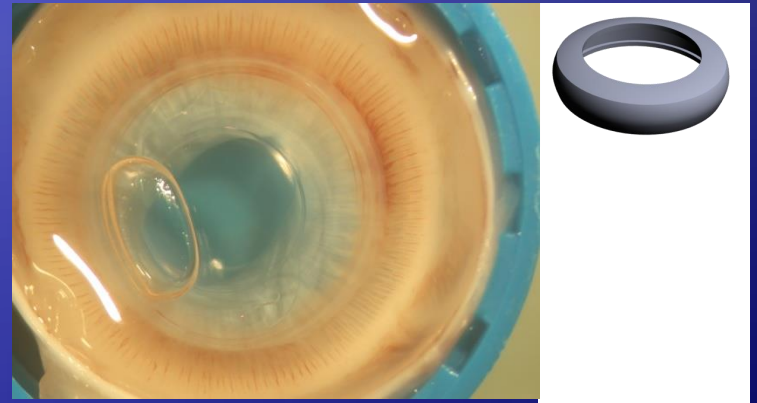
Average
PCO score:
1.43



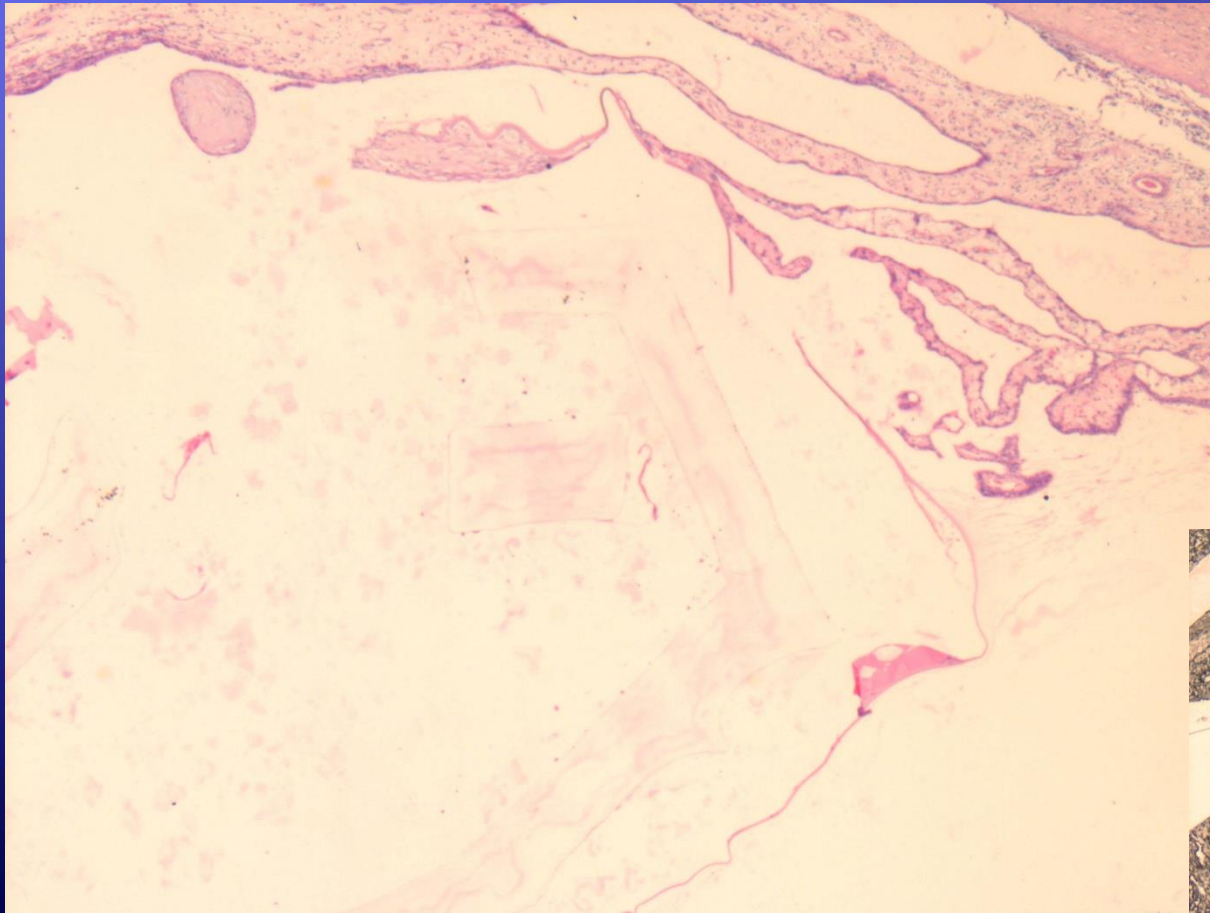
**Control
group**

Average
PCO score:
3.25

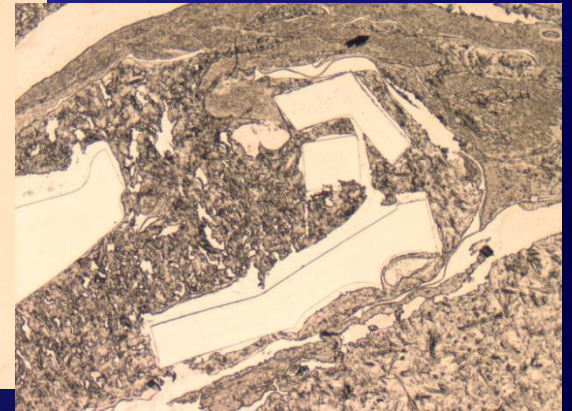
Results - 6 weeks



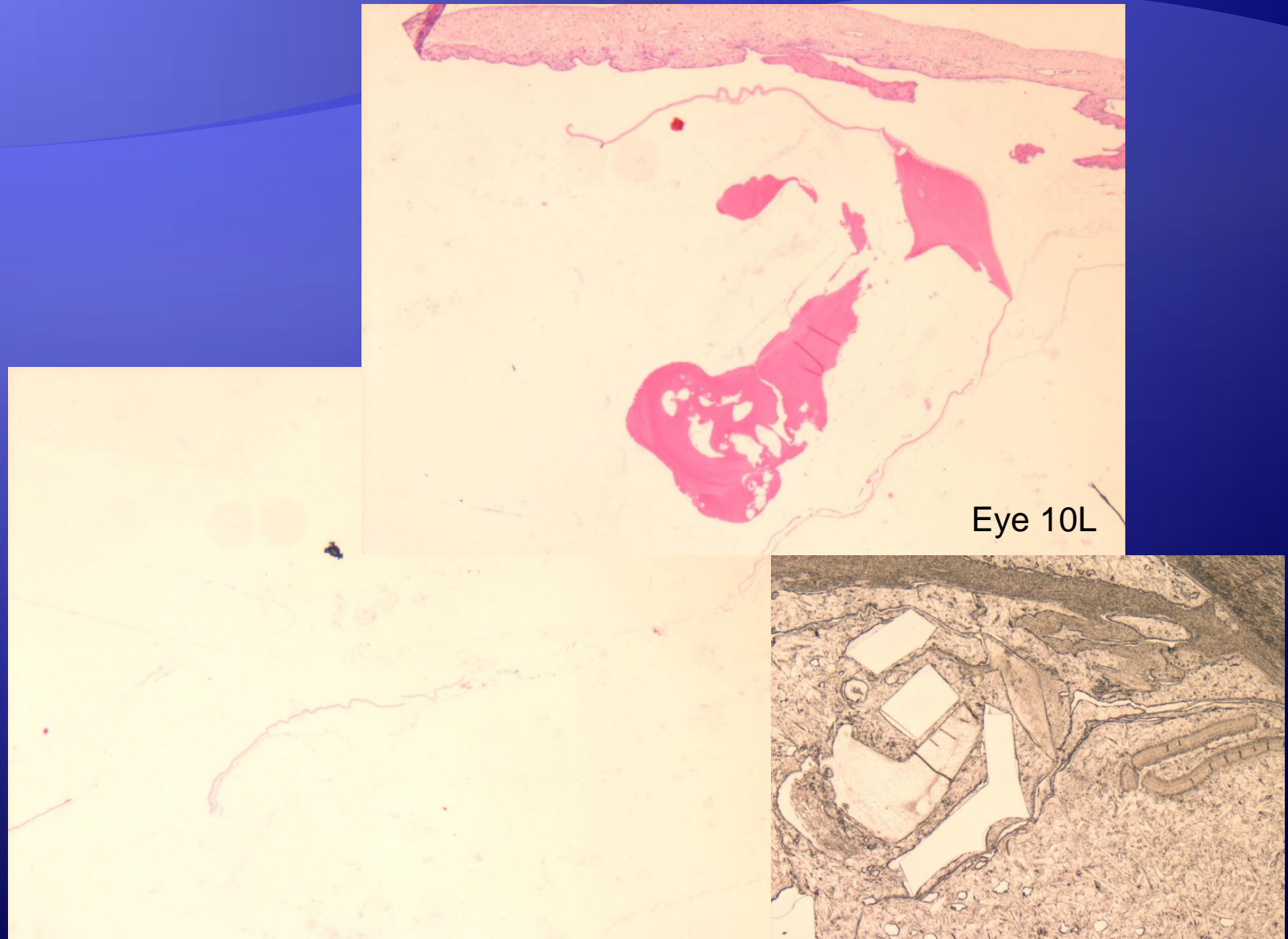
Histology – design 1



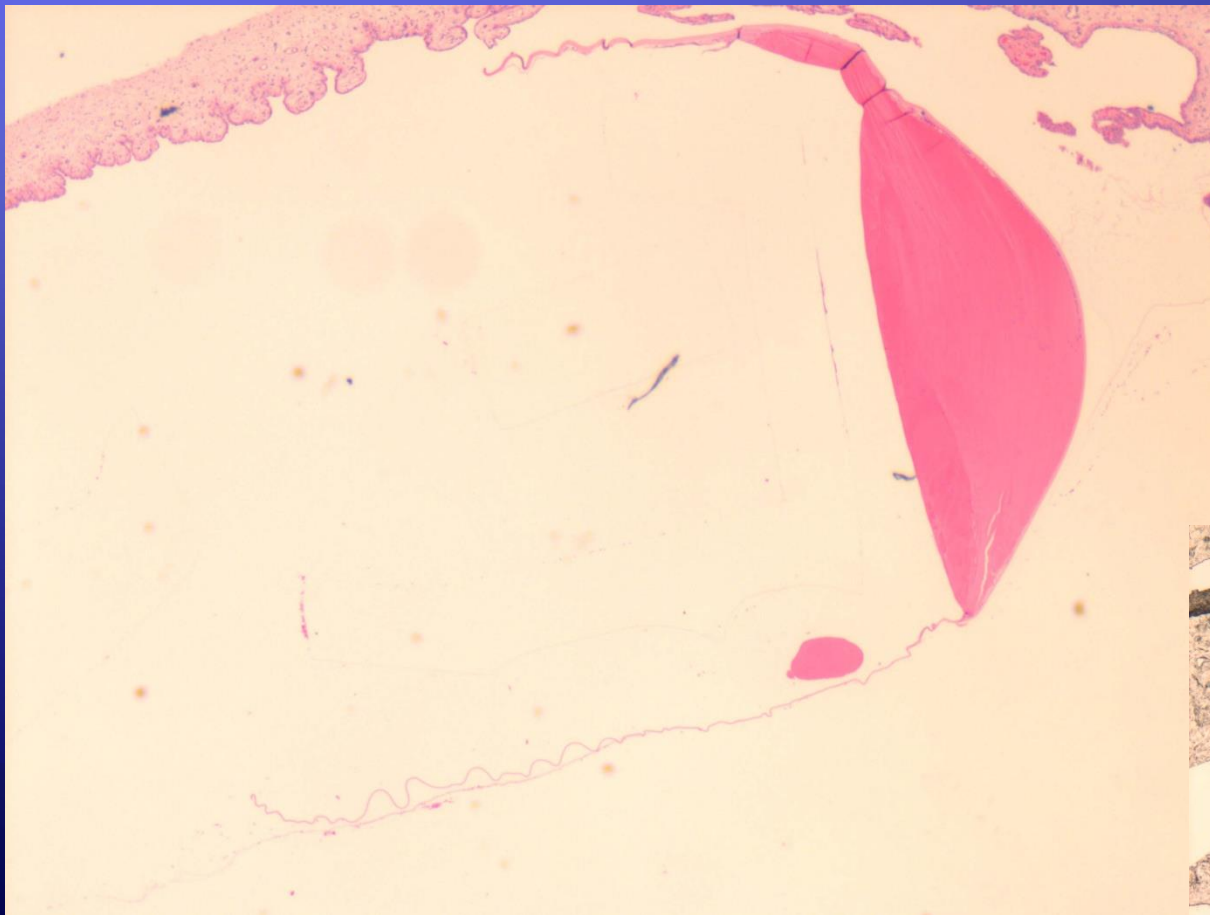
Eye 8R



Histology – design 1



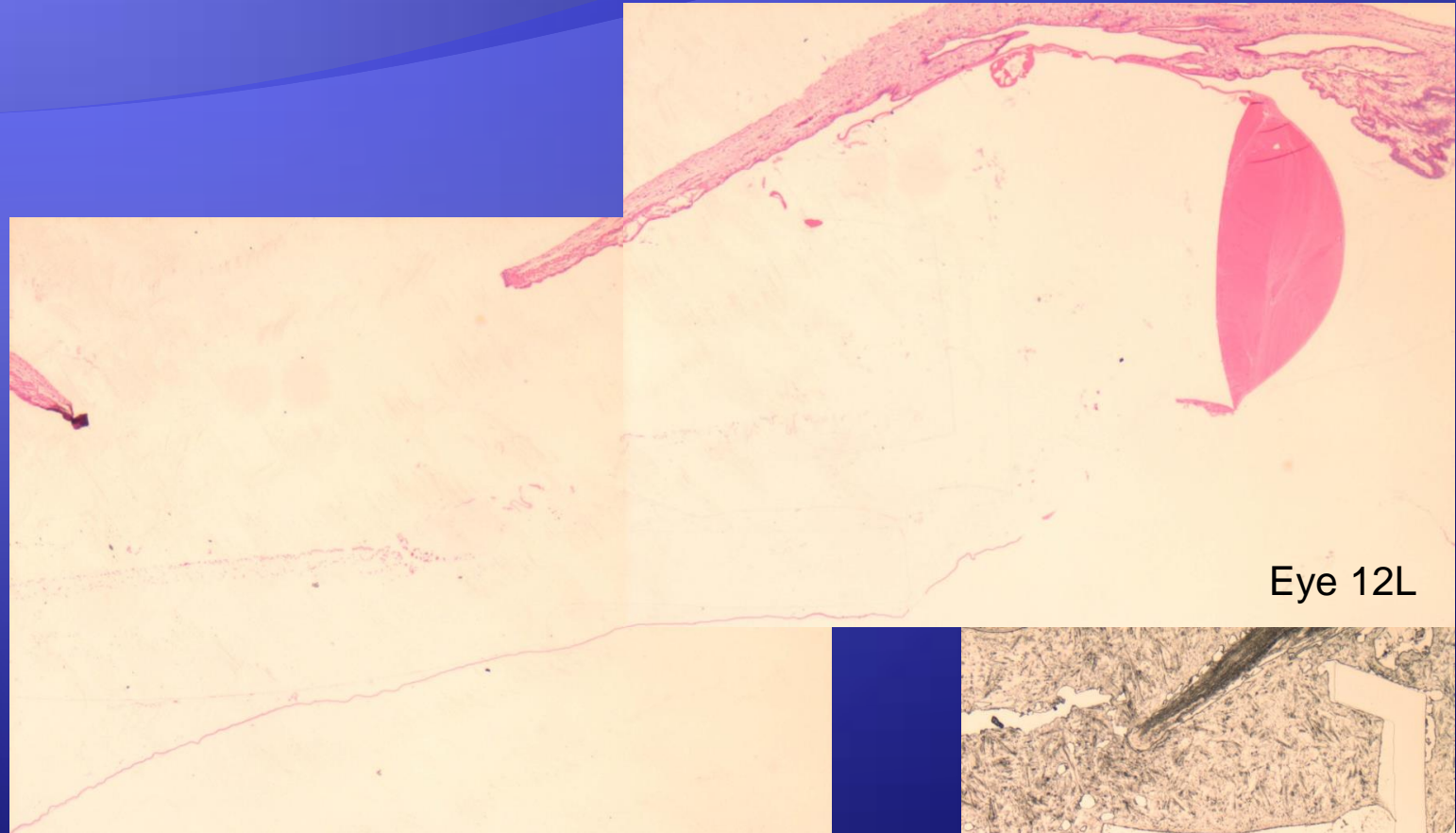
Histology – design 2



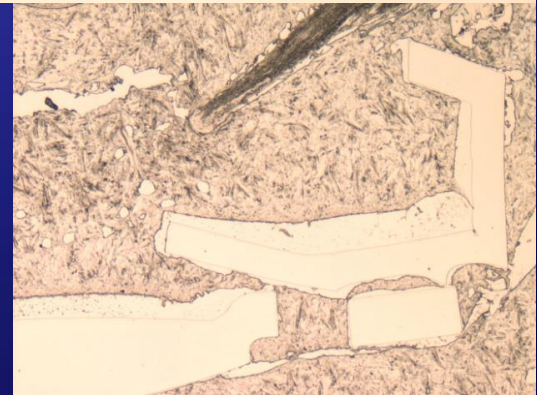
Eye 11R



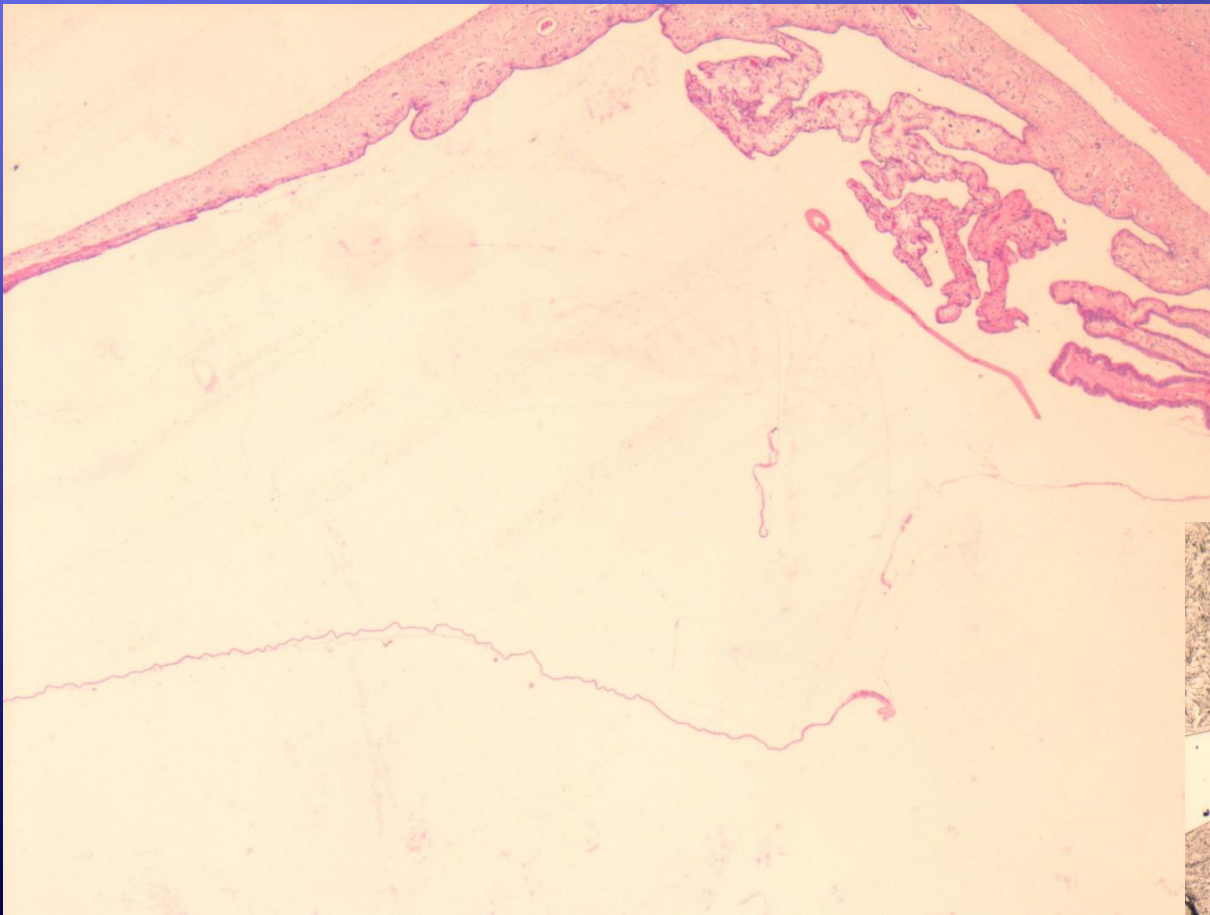
Histology – design 2



Eye 12L



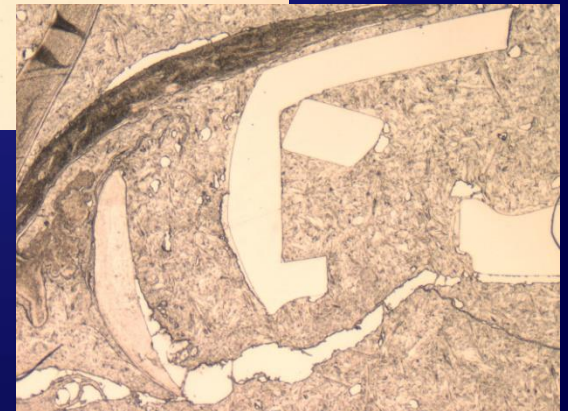
Histology – design 3



Eye 9L



Histology – design 3



Summary

- ◆ Ring of design 1 was proven to be most effective in prevention of PCO
- ◆ Soemmering ring protrusions were observed in histology and the slit lamp imaging, however were not observed in Miyake-Apple view.

Conclusions

1. The side windows were proven to assist in prevention of PCO
2. No significant difference was seen between vertical and circular wall designs
3. The problem of insertion of IOL into the ring groove was successfully resolved, however the implantation of the ring is still to be optimized

Thank you!