

# CORNEA COLD® VS OPTISOL-GS

## A COMPARATIVE STUDY OF A NEW HYPOTHERMIC STORAGE MEDIUM USING A NOVEL METHOD TO CALCULATE THE OVERALL QUALITY OF THE CORNEA



*Mohit Parekh*

SIBO – Societa Italiana Banca degli Occhi, L'aquila, Italy  
24<sup>TH</sup> November 2012

### Disclosure

The authors from FBOV have no conflict of interests. EUROBIO is the manufacturer of Cornea Cold and has potential conflict of interest.

# Topics

*Determining overall quality of the cornea*

- *Thickness*
- *Transparency*
- *Viable Endothelial Cell Density (VECD)*
- *Morphology*
- *Overall quality*
- *Epithelium*

*Cornea Cold<sup>®</sup> VS Optisol-GS*



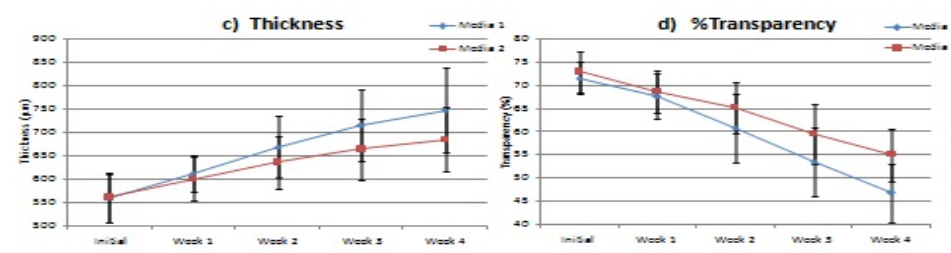
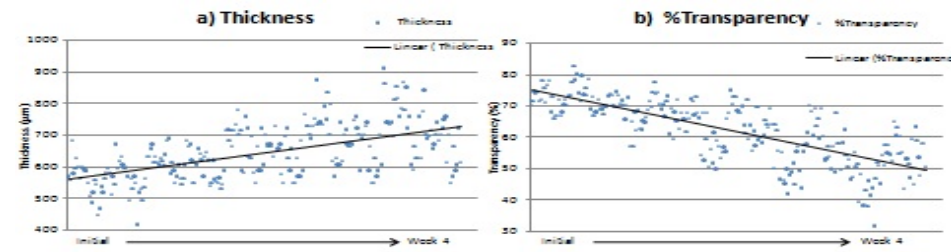
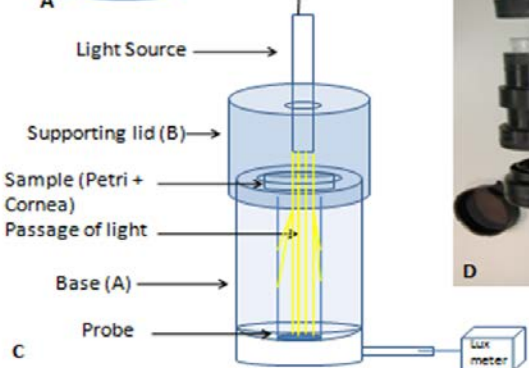
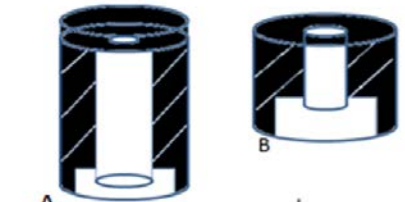
# OQ - Thickness



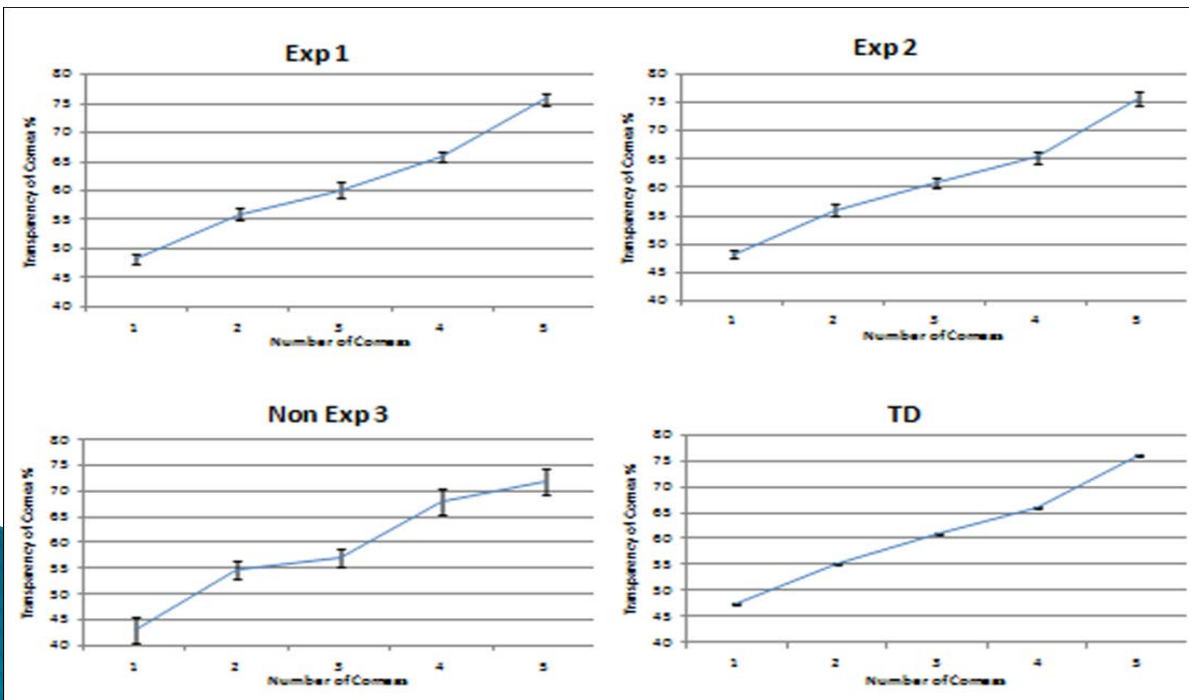
Evaluation	Score
540.1 – 550 – 560	4
530.1 – 540 and 560.1 – 570	3.75
520.1 – 530 and 570.1 – 580	3.5
510.1 – 520 and 580.1 – 590	3.25
500.1 – 510 and 590.1 – 600	3
490.1 – 500 and 600.1 – 610	2.75
480.1 – 490 and 610.1 – 620	2.5
470.1 – 480 and 620.1 – 630	2.25
460.1 – 470 and 630.1 – 640	2
450.1 – 460 and 640.1 – 650	1.75
440.1 – 450 and 650.1 – 660	1.5
430.1 – 440 and 660.1 – 670	1.25
420.1 – 430 and 670.1 – 680	1
410.1 – 420 and 680.1 – 690	0.75
400.1 – 410 and 690.1 – 700	0.5
390.1 – 400 and 700.1 – 710	0.25
<390 - >710	0

Gianni Salvalaio *et al.* Cheratoplastica lamellare e anteriore: determinazione dello spessore dei lenticoli Corneali. Ottica fisiopat 2010; XV: 43-51

# OQ - Transparency



Parekh MN, *et al.* A New Device To Measure The Objective Values For Transparency Of The Donor Cornea. ARVO meeting, May 2012.



Evaluation	Score
0-20	0
21-25	0.25
25.1-30	0.5
30.1-35	0.75
35.1-40	1
40.1-45	1.25
45.1-50	1.5
50.1-55	1.75
55.1-60	2
60.1-65	2.25
65.1-70	2.5
70.1-75	2.75
75.1-80	3
80.1-85	3.25
85.1-90	3.5
90.1-95	3.75
95.1-100	4

# OQ - Viable Endothelial Cell Density

$$V_M = \frac{(\%CM \times CA) + (\%PM \times PA)}{TA}$$

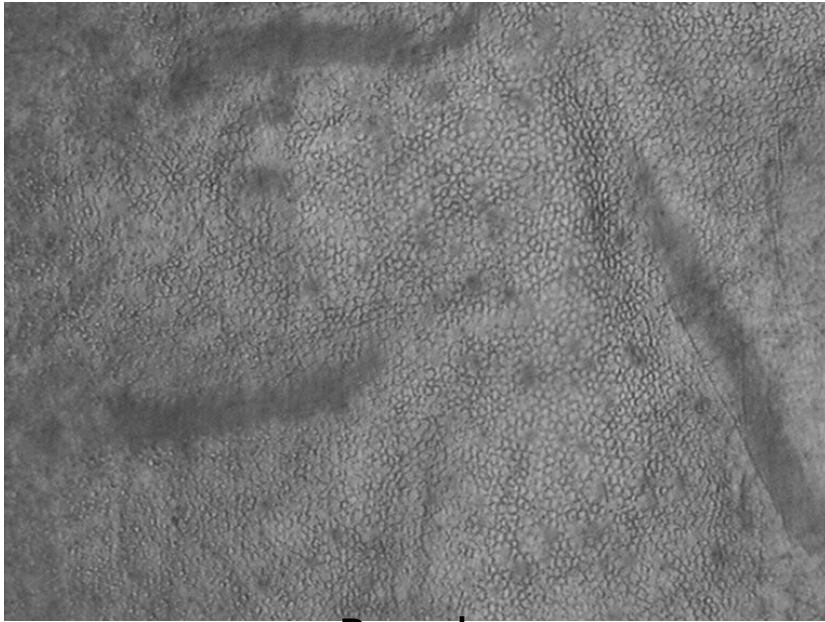
Where,  
 CA = Optic zone  
 PA = Outside optic zone



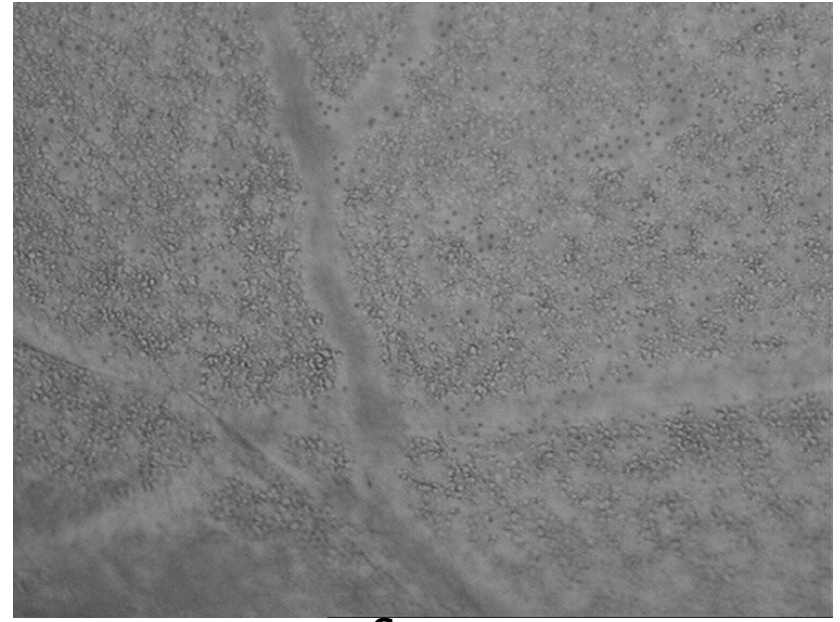
•Parekh, M., *et al.* A Simplified Technique for In situ Excision of Cornea and Evisceration of Retinal Tissue from Human Ocular Globe. *J. Vis. Exp.* (64), e3765, DOI: 10.3791/3765 (2012). [PMID: 22733120]

$$VECD = \frac{\left[ \text{VisECD} - \frac{\text{VisECD} \times \left[ \frac{(\%CM \times CA) + (\%PM \times PA)}{TA} \right]}{100} \right]}{1000 \text{ (for OQ)}}$$

# OOQ - Morphology



Regular



Severe

Parameter	Evaluation	Score
<b>Morphology</b>	Regular	4
<i>Intercellular Borders</i>	Regular - Mild	3.5
<i>Polymorphism</i>	Mild	3
<i>Dystrophy</i>	Mild - Moderate	2.5
<i>Degeneration</i>	Moderate	2
	Moderate - Severe	1.5
	Severe	1
	Severe - poor	0.5
	Poor	0

$$\text{Morphology} = \frac{\text{IB} + \text{P} + \text{Dy} + \text{De}}{4}$$

Picture courtesy:  
Domenico Amato *et al*, Pre-cut donor tissue  
for Descemet stripping automated  
keratoplasty: anterior hinged lamella on  
versus off. Br J Ophthalmol 2010;94:519-522

# Overall quality of the cornea

OQ- M

OQ- Th

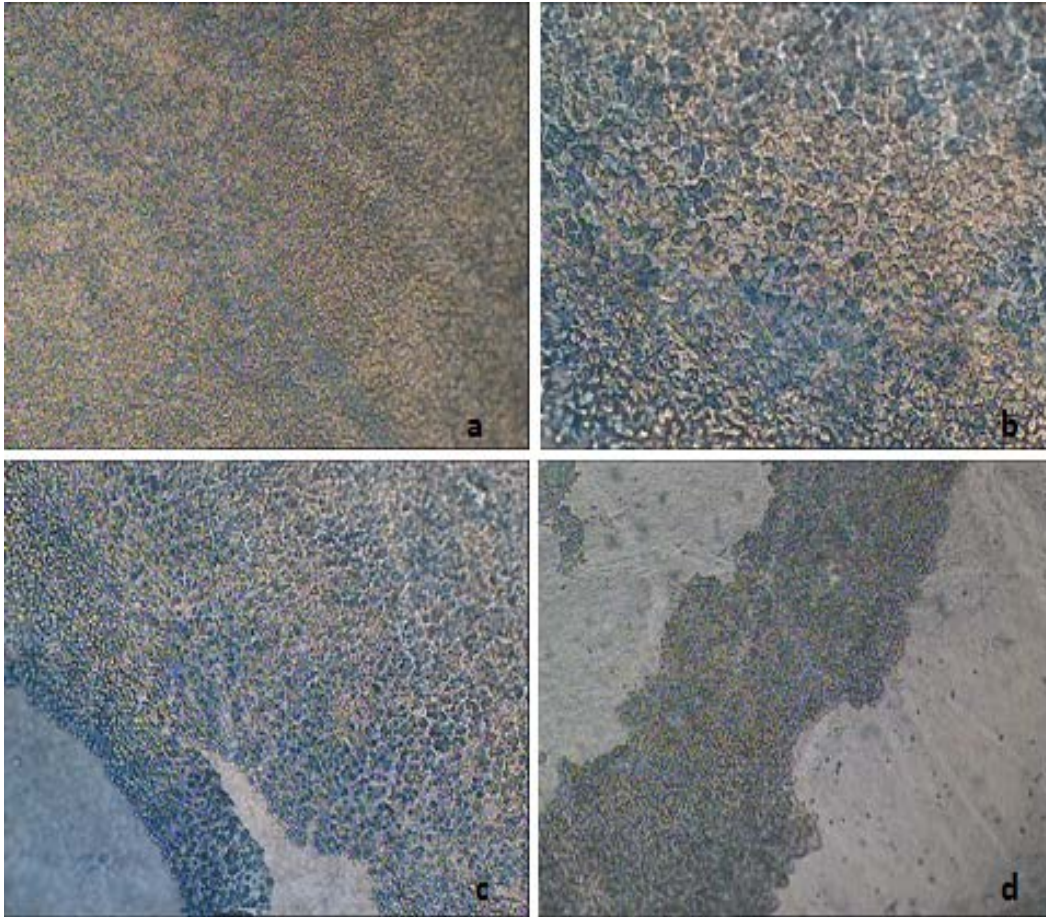
OQ- Tr

OQ- VECD

$$\left[ \frac{IB + P + Dy + De}{4} \right] + \left[ (\text{Epithelial layer} - \text{Endothelial layer}) \times 19 \right] + \left[ \frac{\text{Sample} \times 100}{\text{Blank}} \right] + \left[ \frac{V_{ECD} - \left[ \frac{V_{ECD} \times \left[ \frac{(\%CM \times CA) + (\%PM \times PA)}{TA} \right]}{100} \right]}{1000} \right]$$

OQ =

# OOQ - Epithelium



Evaluation	Score
0-20	0
20.1-25	0.25
25.1-30	0.5
30.1-35	0.75
35.1-40	1
40.1-45	1.25
45.1-50	1.5
50.1-55	1.75
55.1-60	2
60.1-65	2.25
65.1-70	2.5
70.1-75	2.75
75.1-80	3
80.1-85	3.25
85.1-90	3.5
90.1-95	3.75
95.1-100	4

A) 50X: intact integrity with 50% mortality,

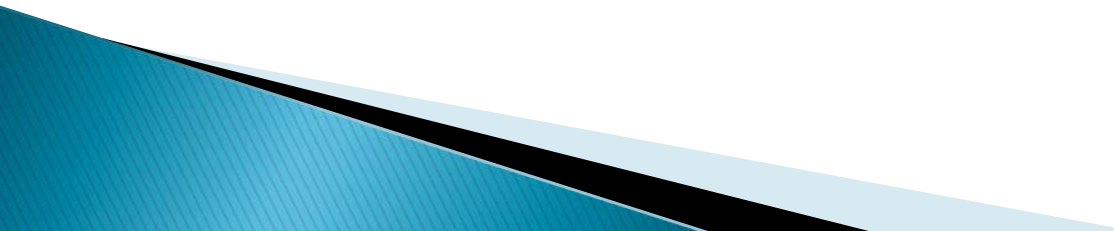
B) 200X: Regular – Mild morphology due to few cells not in the shape as the others,

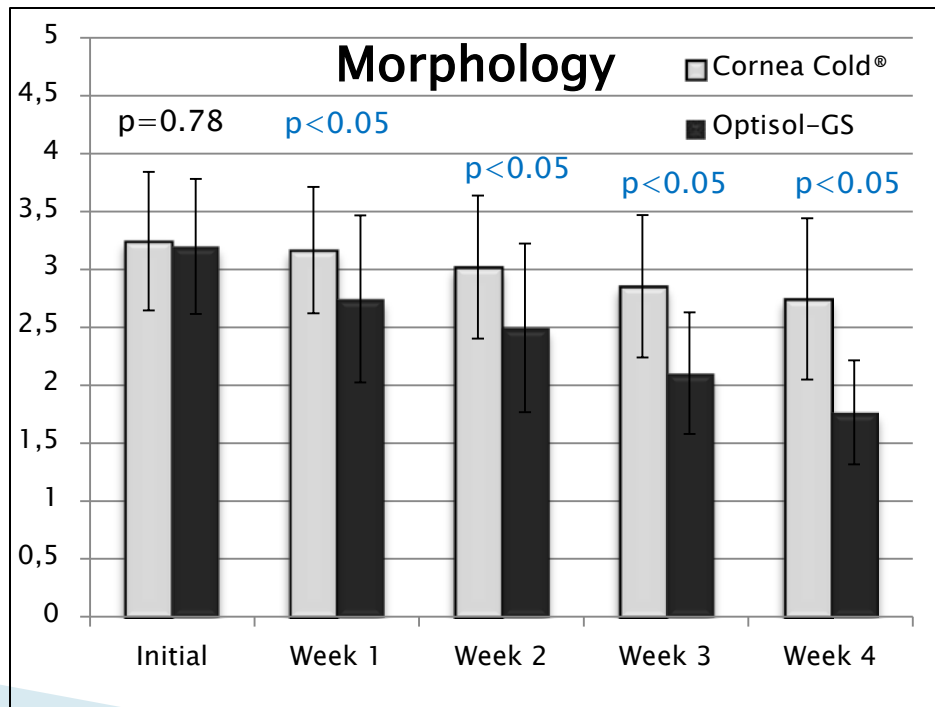
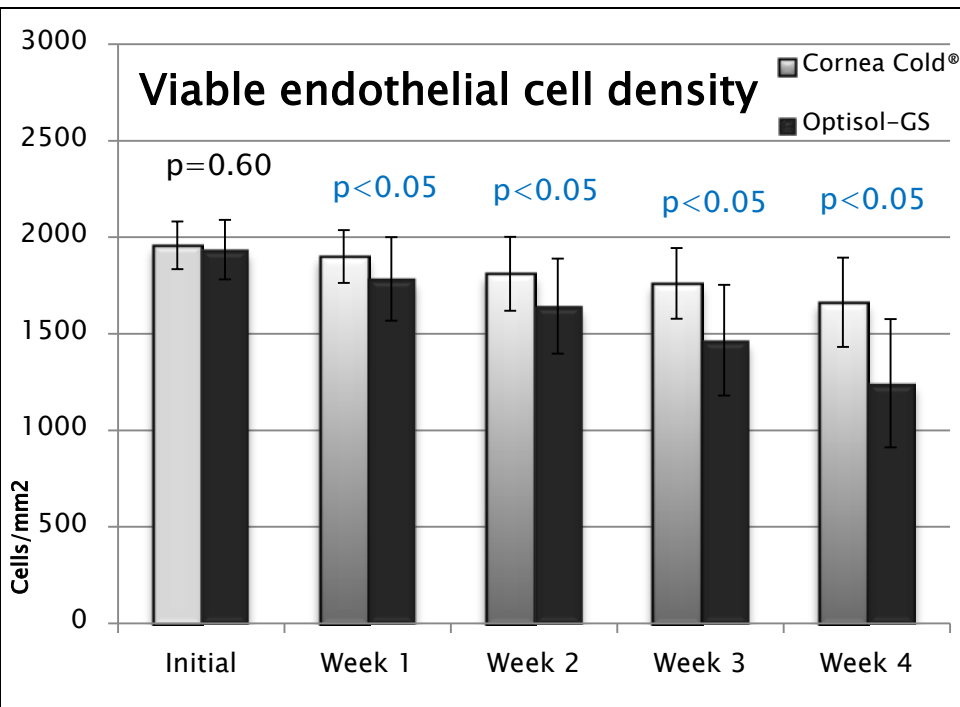
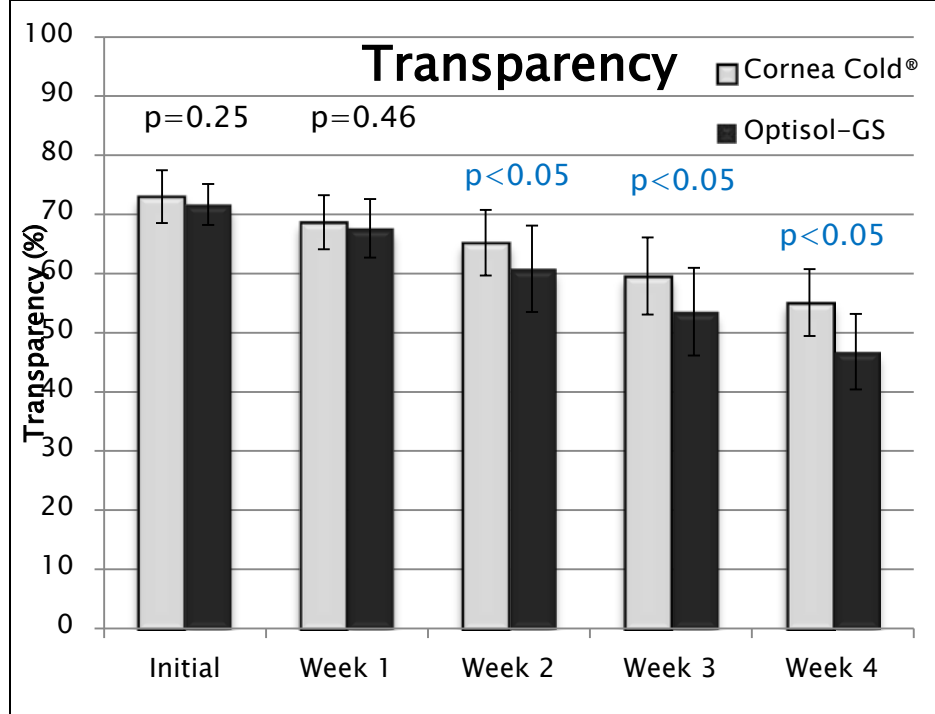
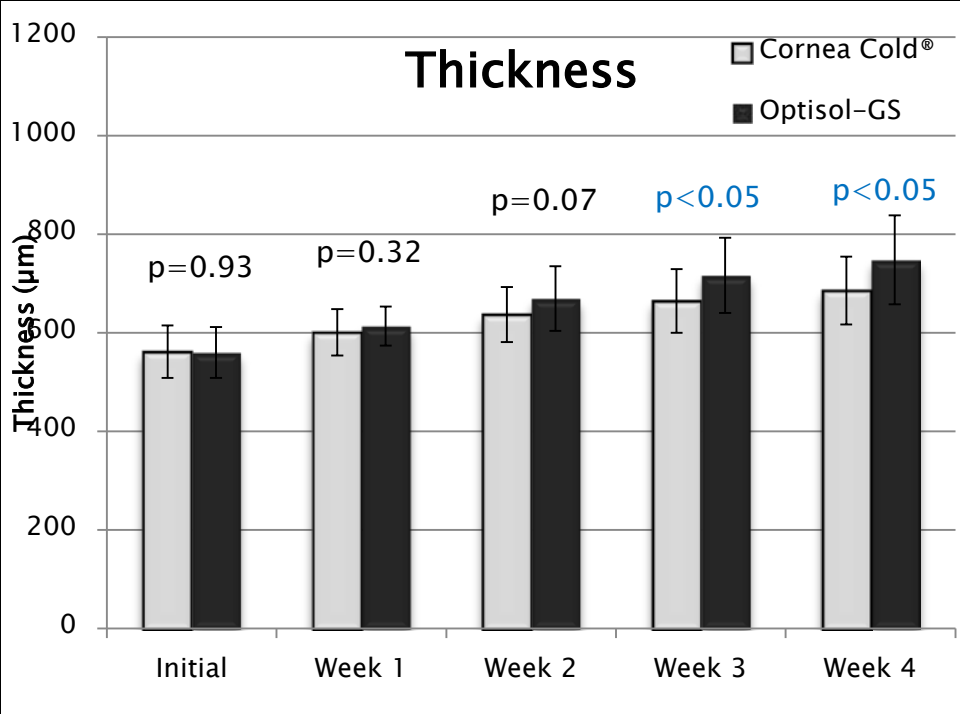
C) 100X: the epithelial integrity is lost with 80% mortality,

D) 50X: 40% cell integrity.

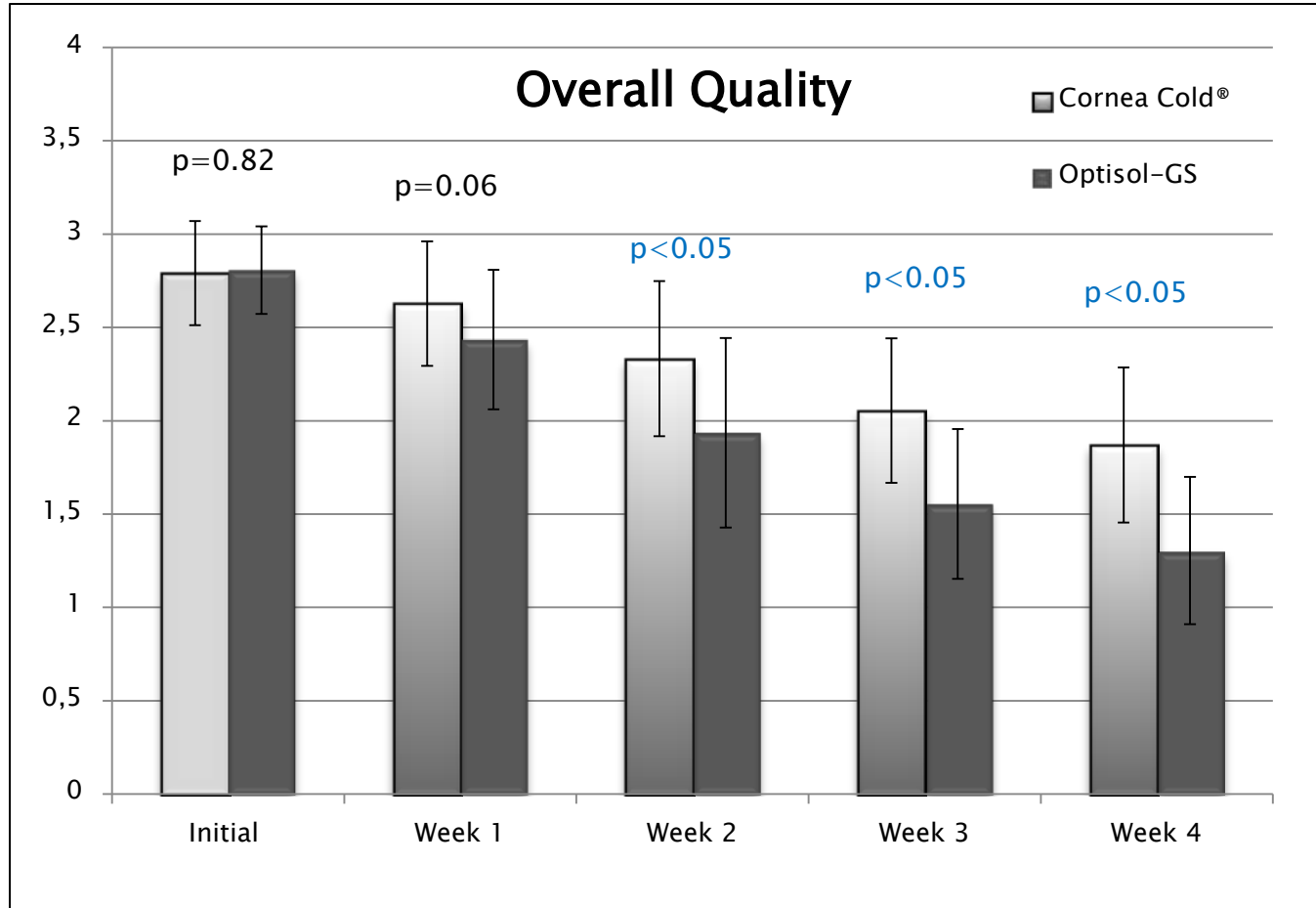


# Cornea Cold® Vs Optisol-GS

- 24 pairs of human donor corneal tissues suitable for research
  - Interchange of right and left eye corneas equally
  - 4 phases – 1 open and 3 blinded (masked observers)
  - Data and analysis were obtained every 7<sup>th</sup> day up to 4 weeks
- 



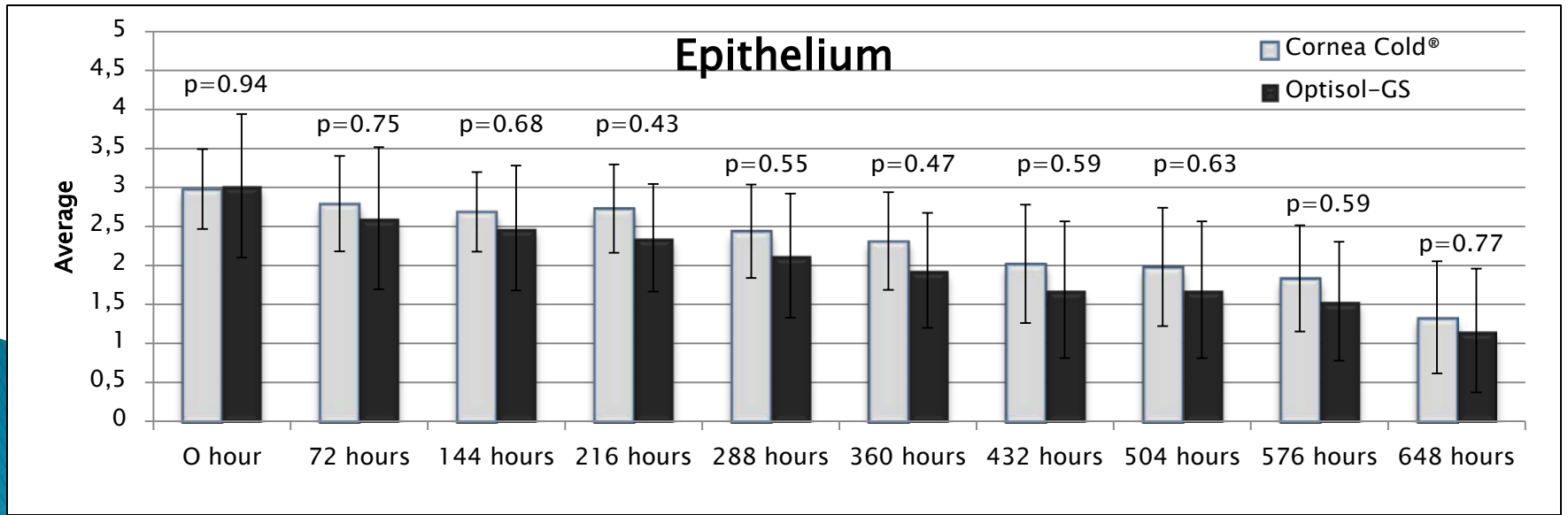
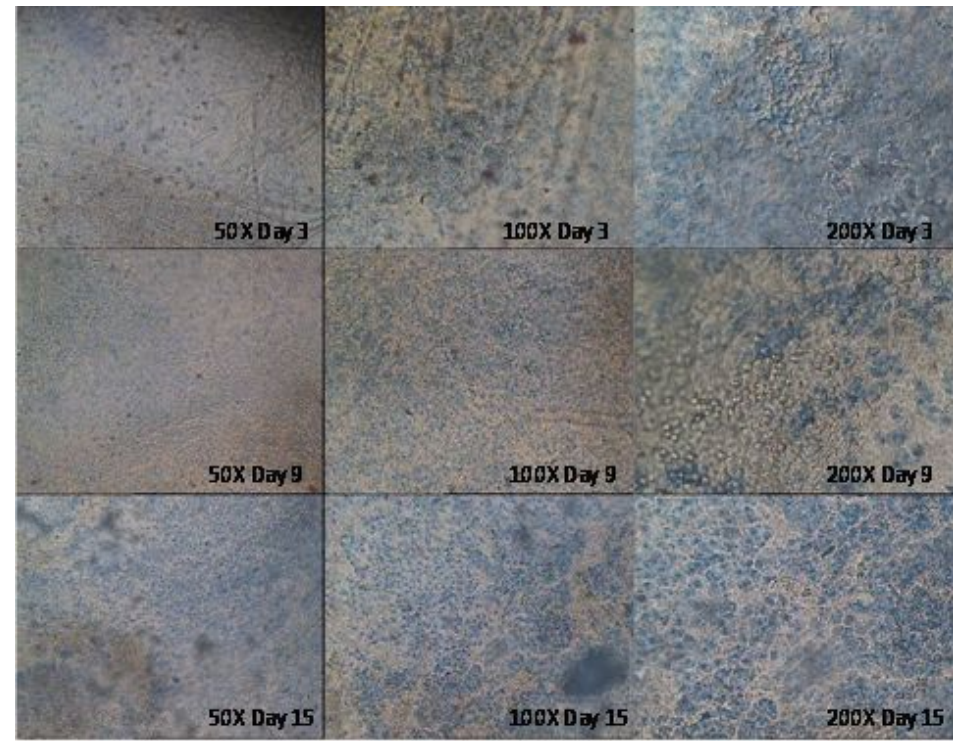
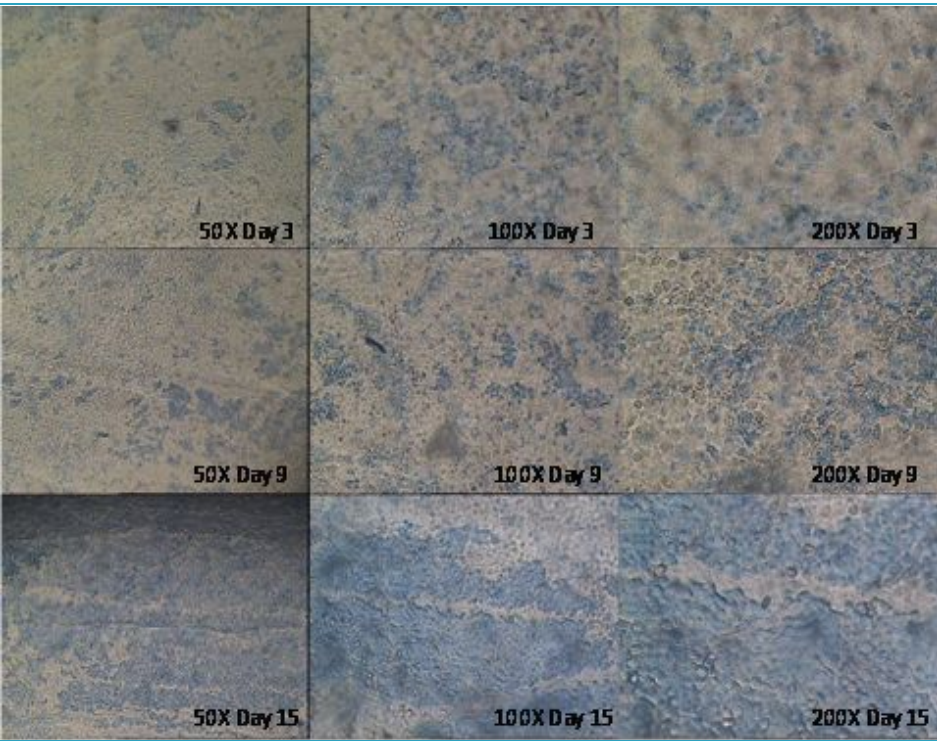
# Overall Quality



Cornea Cold®

# Epithelium

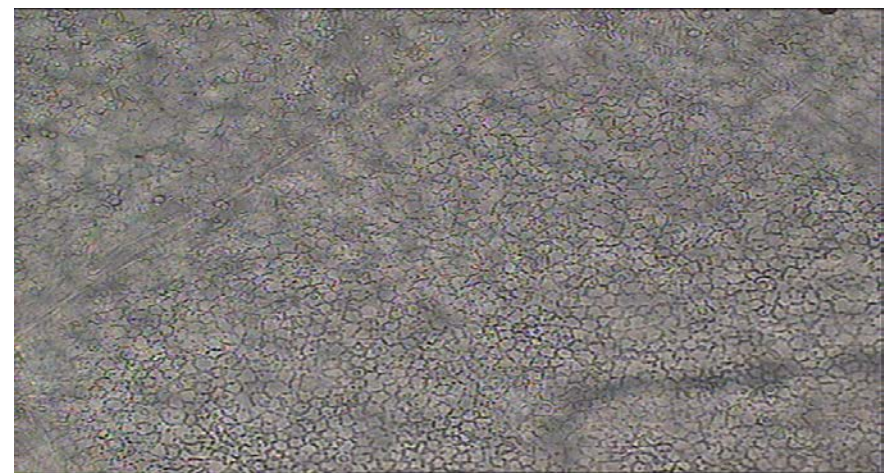
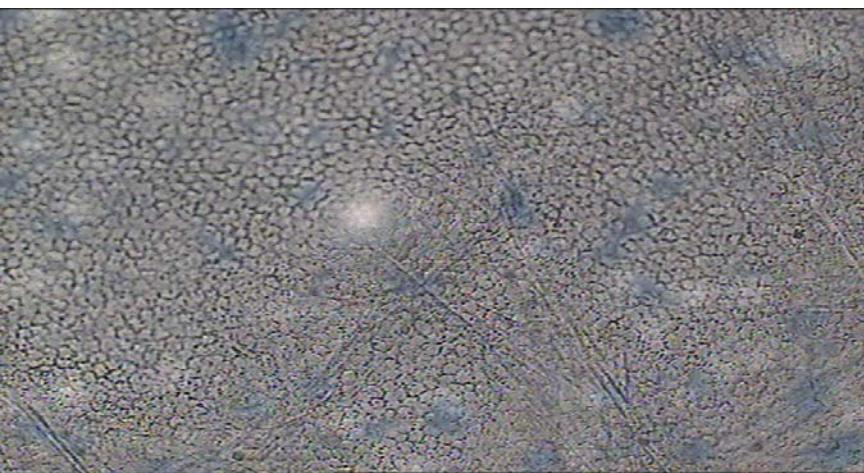
Optisol-GS



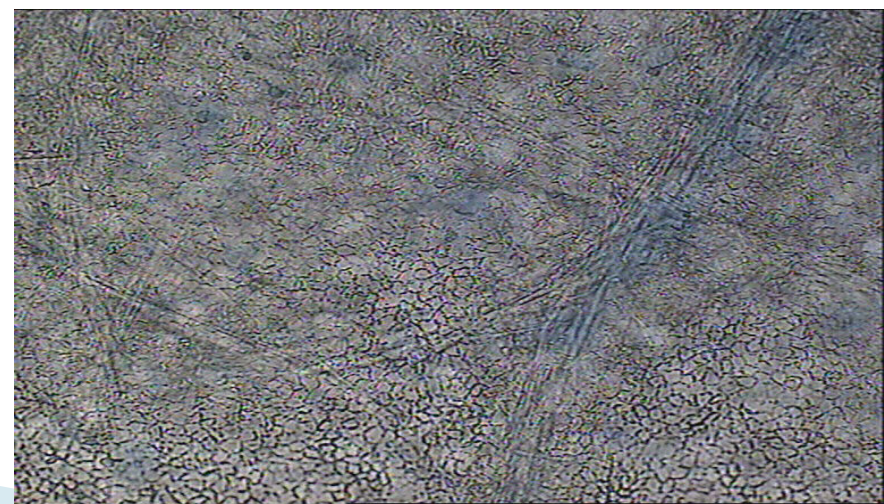
Optisol-GS

Cornea Cold®

Initial



Week 2



Week 4

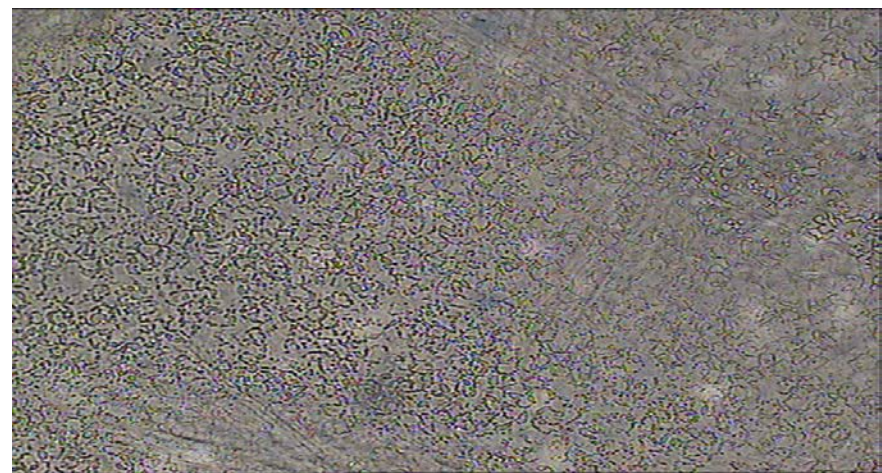
Optisol-GS

Cornea Cold®

Initial



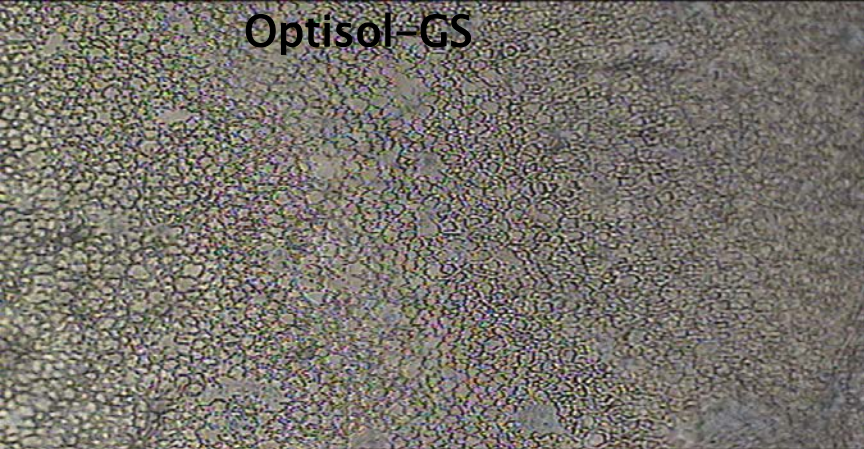
Week 2



Week 4

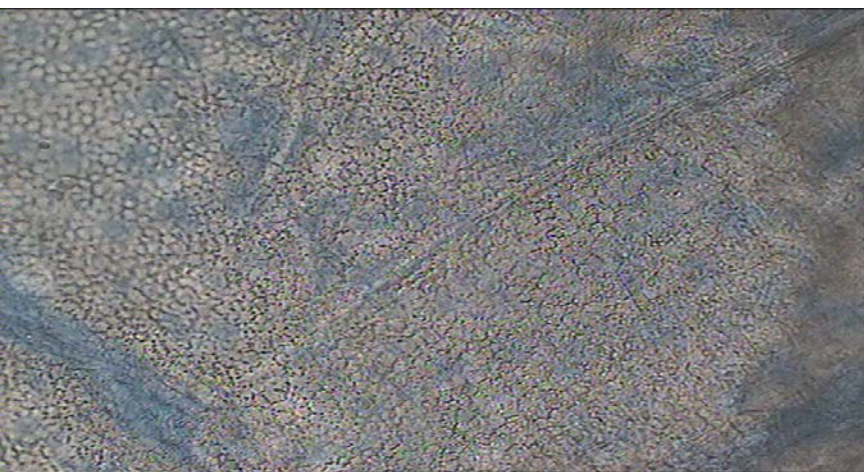
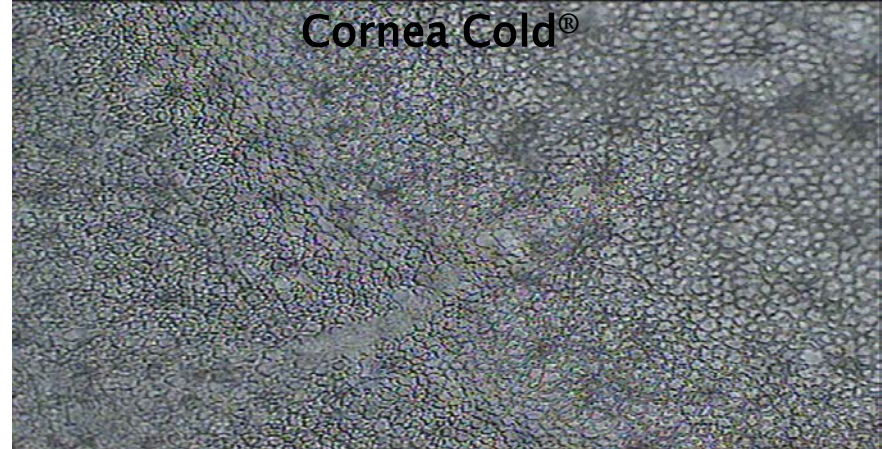


Optisol-GS

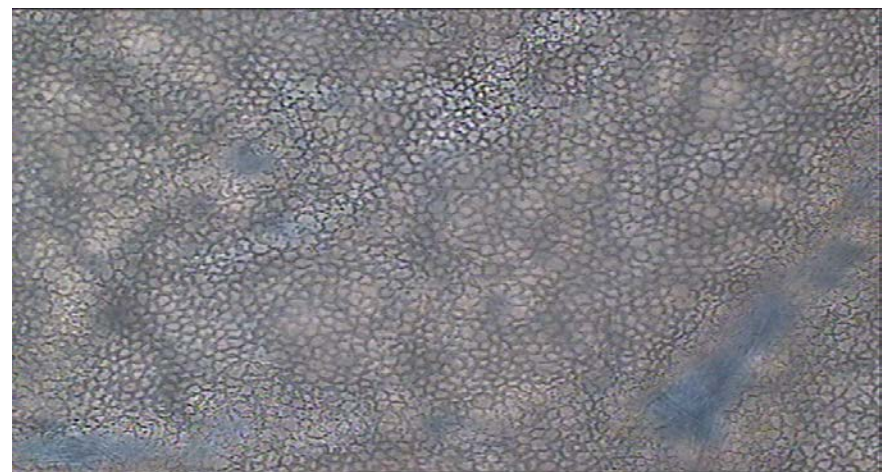


Initial

Cornea Cold®



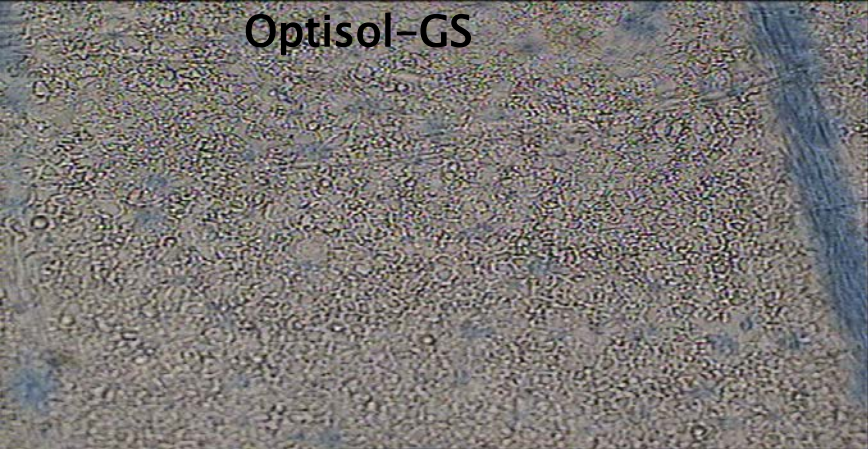
Week 2



Week 4

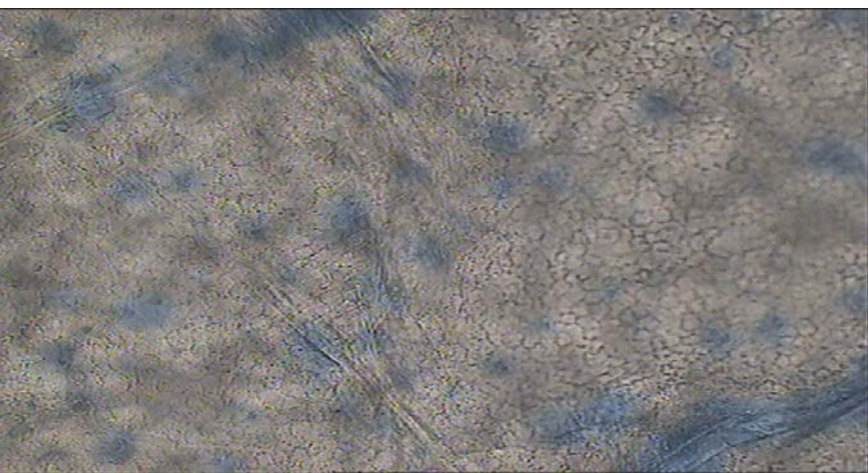


Optisol-GS

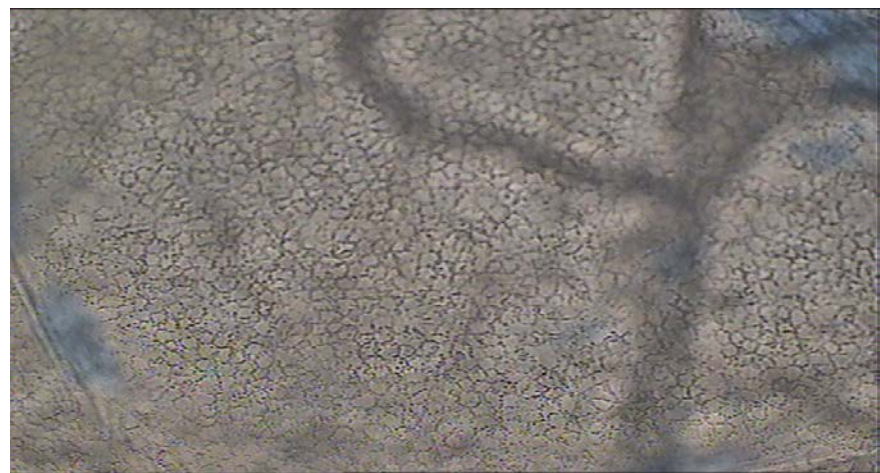


Initial

Cornea Cold®



Week 2



Week 4





# Central Mortality

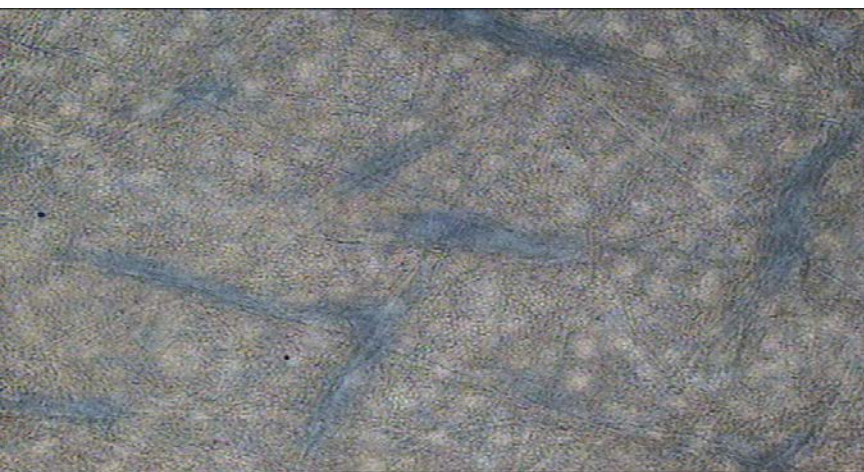
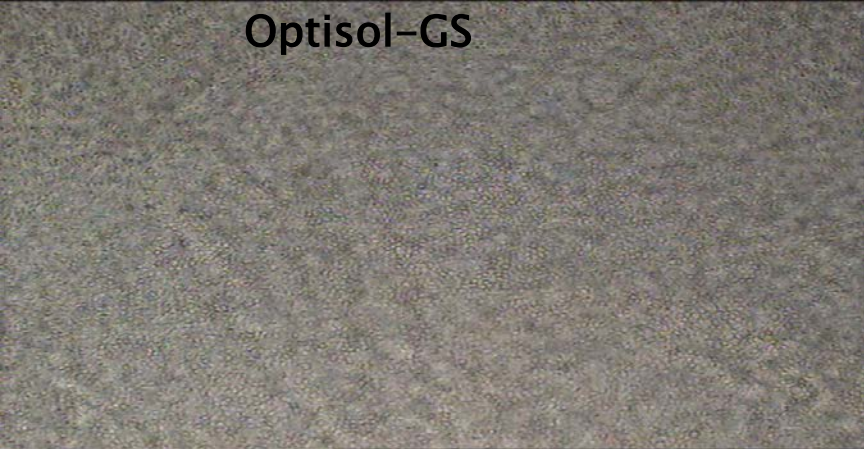
Optisol-GS

Cornea Cold®

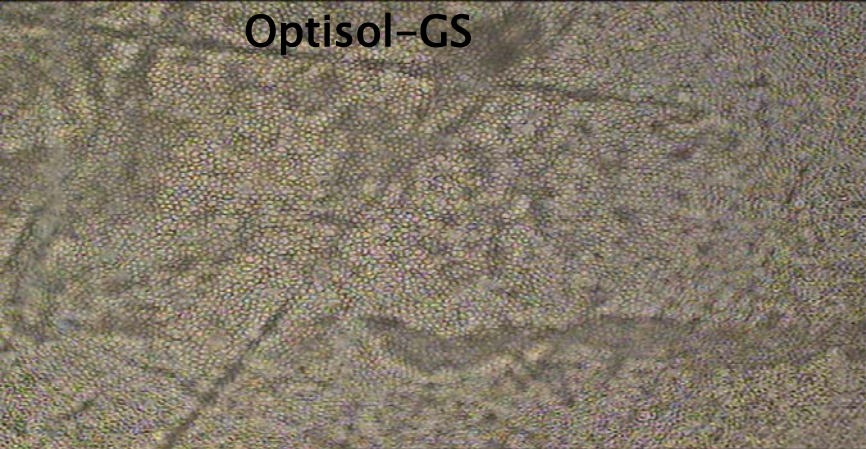
Initial

Week 2

Week 4

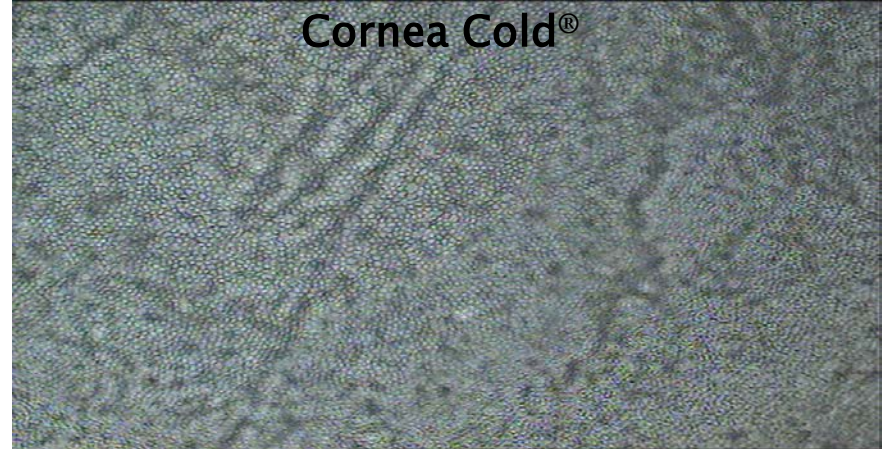


Optisol-GS

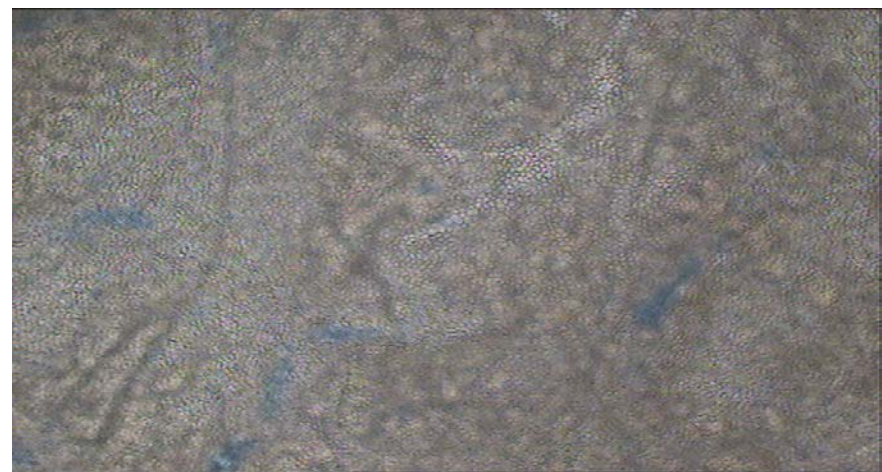


Initial

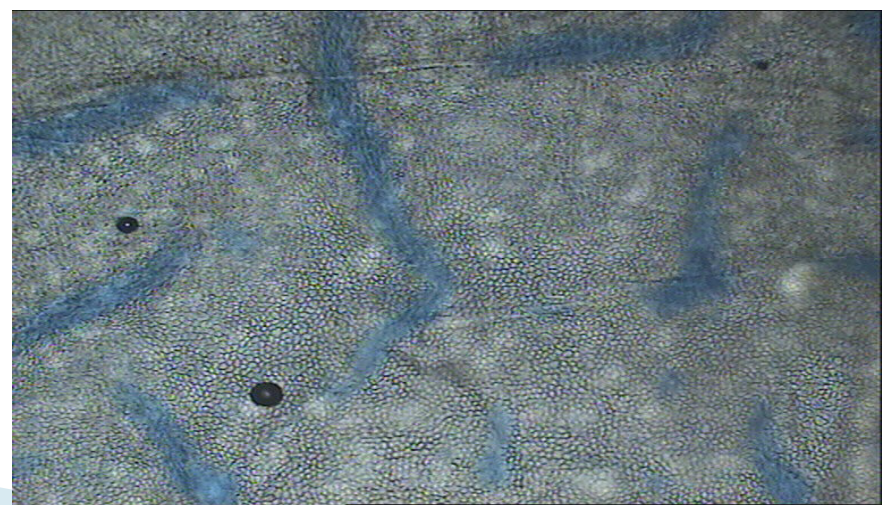
Cornea Cold®



Week 2

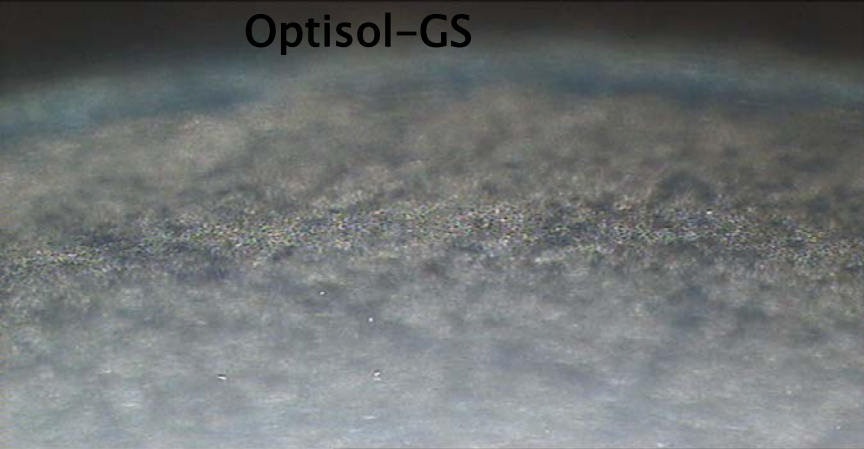


Week 4



# Peripheral Mortality

Optisol-GS

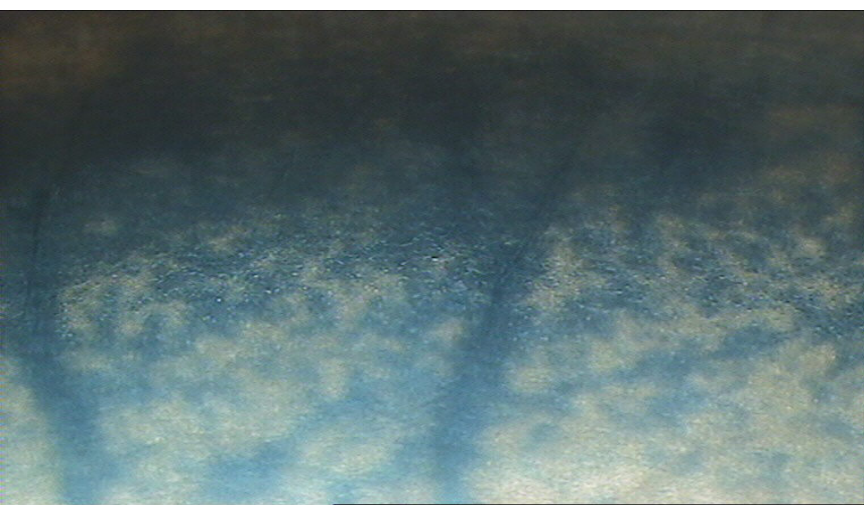


Initial

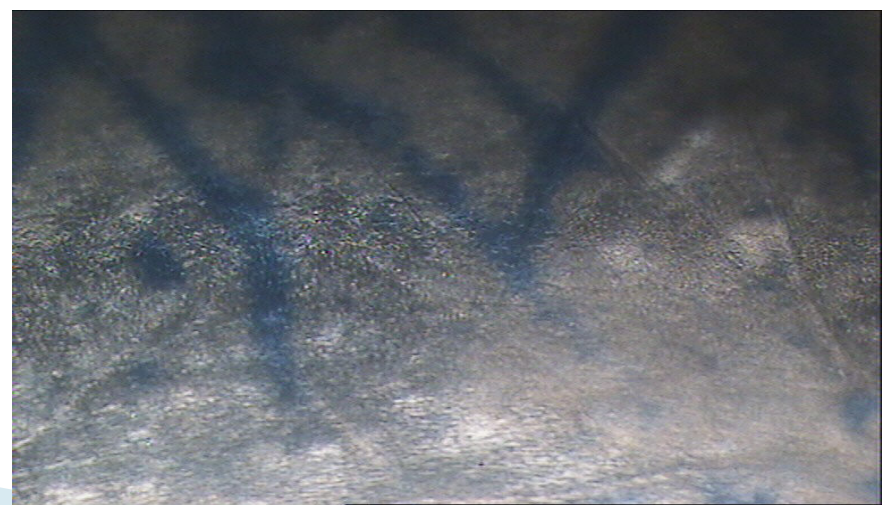
Cornea Cold®



Week 2



Week 4



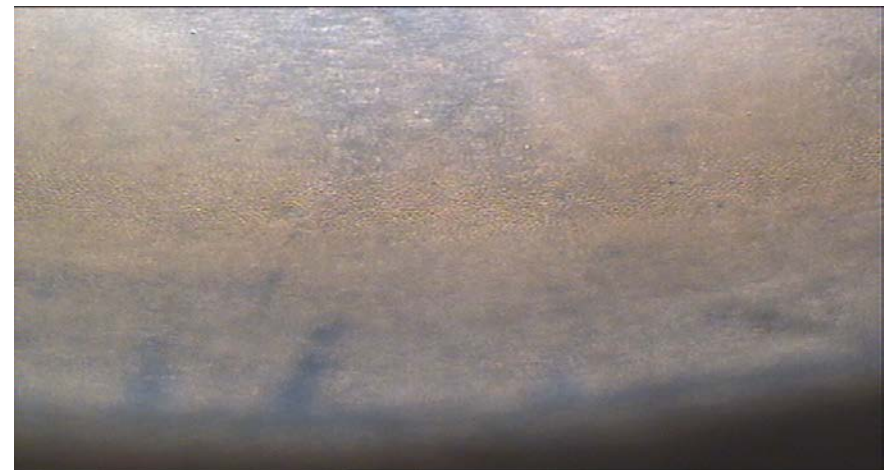
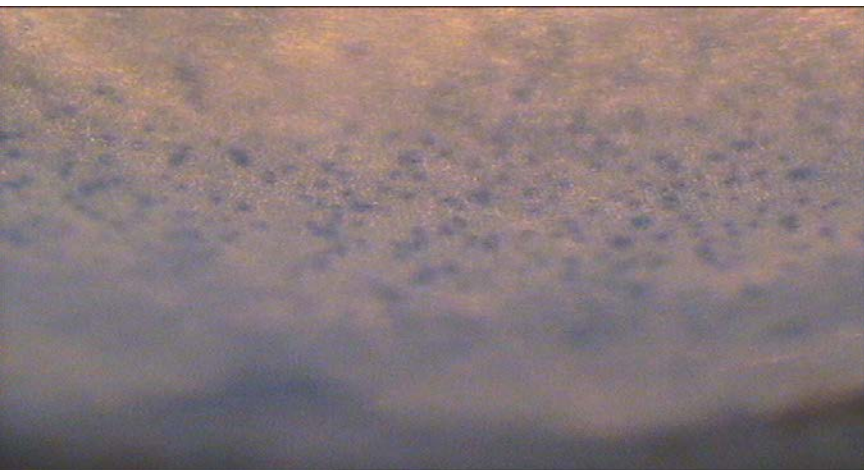
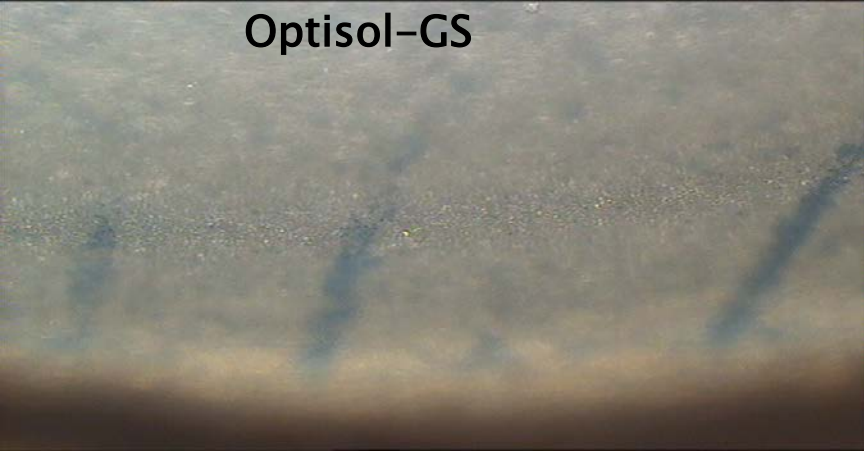
Optisol-GS

Cornea Cold®

Initial

Week 2

Week 4



# Take Home Message

- The parameters selected for determining the OQ can be used by the eye banks without changing their current protocols by using their standards and converting those subjective analysis into objective values as described.
  - Overall quality formula can be modified and used in the current eye banking protocols for increasing the value and standards of the donation and bio banking.
  - Cornea Cold<sup>®</sup> storage medium can preserve the donor corneal tissues for  $\leq 21$  days.
  - Longer preservation time can permit higher flexibility, evaluation accuracy, more effective surgical manipulation due to clarity and quality for corneal transplantation and ease of transportation.
  - Future prospects - to learn the clinical outcomes using Cornea Cold<sup>®</sup>
- 