



# Customized Corneal Cross-Linking

RUB

for the Treatment of Myopic Refractive Error:  
*6-Months Results of a Prospective Clinical Study*



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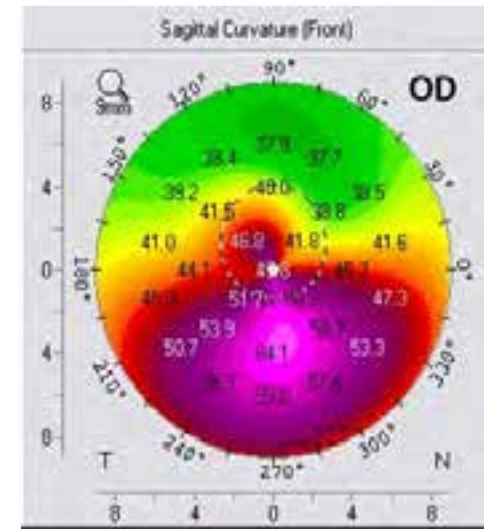
**– Ruhr University Eye Hospital –  
Bochum, Germany**



# CXL: Background

- Established for *treatment of keratoconus*
- Flattening of  $K_{\max}$  postOP
  - Flattening in the area that was weakest
  - Steepening in the superior cornea

→ *Specific correction of refractive errors*





# Purpose of the Study

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- To evaluate...

- Safety
- Efficacy

...of **photorefractive intrastromal corneal collagen cross-linking (PiXL)** using the **KXL II System (Avedro Inc.)\***

- Treatment of **myopic refractive** errors in **healthy eyes** by using...

- **UVA 365 nm wavelength light source** with programmable illumination pattern
- **Riboflavin**



\* The Mosaic / KXL II device and the PiXL procedure are not available in the United States.



# Study Design

- ***Prospective evaluation*** for the ***treatment of myopia*** in ***healthy eyes***
- Duration → ***12 month***
- Visits: screening, day of surgery, 1 day, 1 week, 1, 3, 6 und 12 month postoperatively
- ***40 eyes*** in 2 groups
- ***Phakic*** and ***pseudophakic*** eyes



# Inclusion Criteria

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- ***Healthy eyes***
- ***Age > 18 years***
- ***BCVA  $\geq$  0,6 logMAR (equal to 20/80)***
- ***Myopia***
  - ***Group 1: MRSE -1,0 D to -1,75 D, cyl. max. -0,75 D***
  - ***Group 2: MRSE -2,0 D to -3,0 D, cyl. max. -0,75 D***



# Exclusion Criteria

- ***Keratoconus***
- ***Pachymetry < 475  $\mu\text{m}$  (Pentacam<sup>®</sup> HR)***
- ***Aphakic*** eyes, pseudophakic eyes with an ***IOL without UV-filter*** or eyes with ***anterior chamber IOL***
- ***Vitamin C*** supplements (within 1 week preop)
- ***Cataract surgery*** → less than ***3 month ago***
- Corneal implants or ***previous corneal refractive surgery***



# Treatment Plan

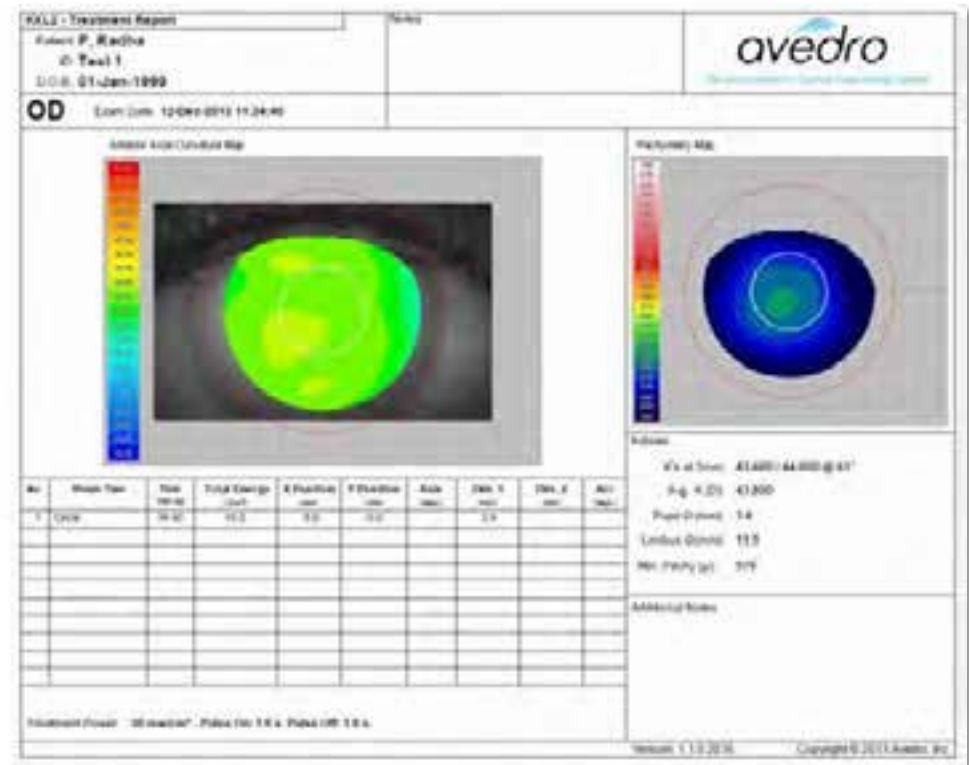


## Myopia:

4 mm circular spot  
centered on corneal vertex

| MRSE           | Dose                 |
|----------------|----------------------|
| -1.00 to -1.75 | 10 J/cm <sup>2</sup> |
| -2.00 to -3.00 | 15 J/cm <sup>2</sup> |

- Pentacam<sup>®</sup> data
- Refraction







# Treatment Protocol

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- Topical anesthesia
- **Epithelial removal** (hockey knife):
  - 4 mm treatment zone
  - 1 mm margin required around edge of treatment zone
- **10 minutes Riboflavin pre-soak**
  - Vibex Rapid: 0.1% Riboflavin with HPMC
  - 2 drops every minute
- Rinse with BSS prior to irradiation
- Instill additional BSS every 1 minute during irradiation
- **30mW/cm<sup>2</sup> irradiation**
  - Pulse interval 1 sec on, 1 sec off
  - Maximum total UVA dose → 15 J/cm<sup>2</sup>







# PiXL: Setting OR

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# PiXL Treatment

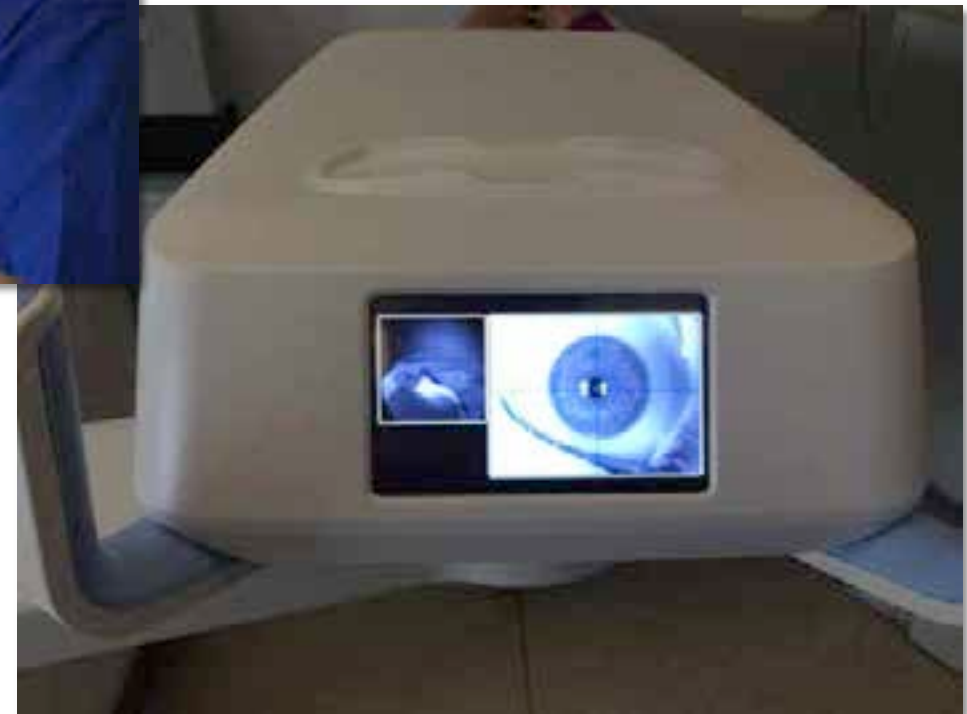
RUB





# PiXL Treatment

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# PiXL Treatment

RUB







# Eyetracking





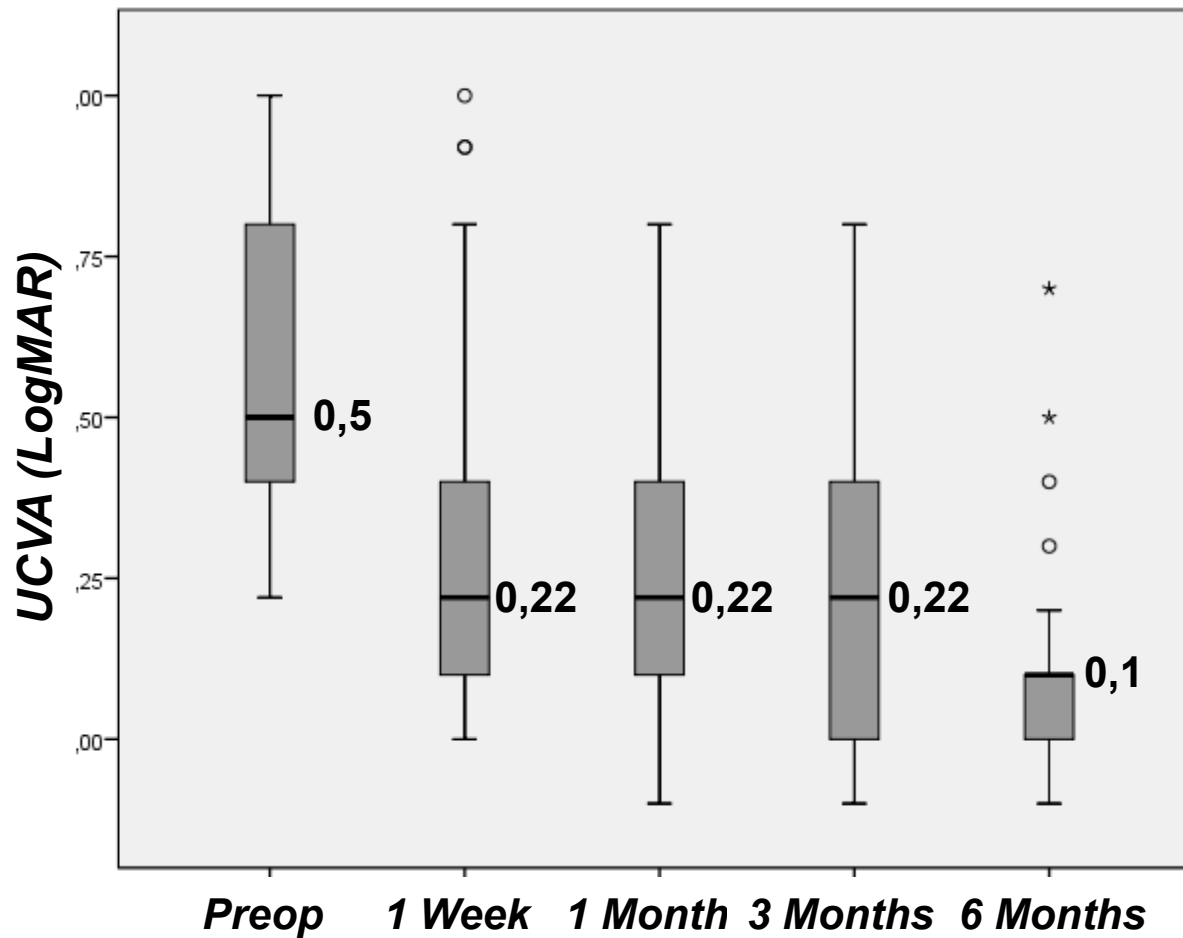
# Results: Study Collective



- ***First treatment:***
  - 15. October 2014
- ***Treatments so far:***
  - 20 surgeries → 19 bilateral treatments and 1 unilateral treatment
  - Total: 39 eyes
    - 38 phakic eyes
    - 1 pseudophakic eye
- ***Study collective:***
  - 14 female, 6 male
  - Age → 20 – 60 years (median: 31 years)



# Results: UCVA



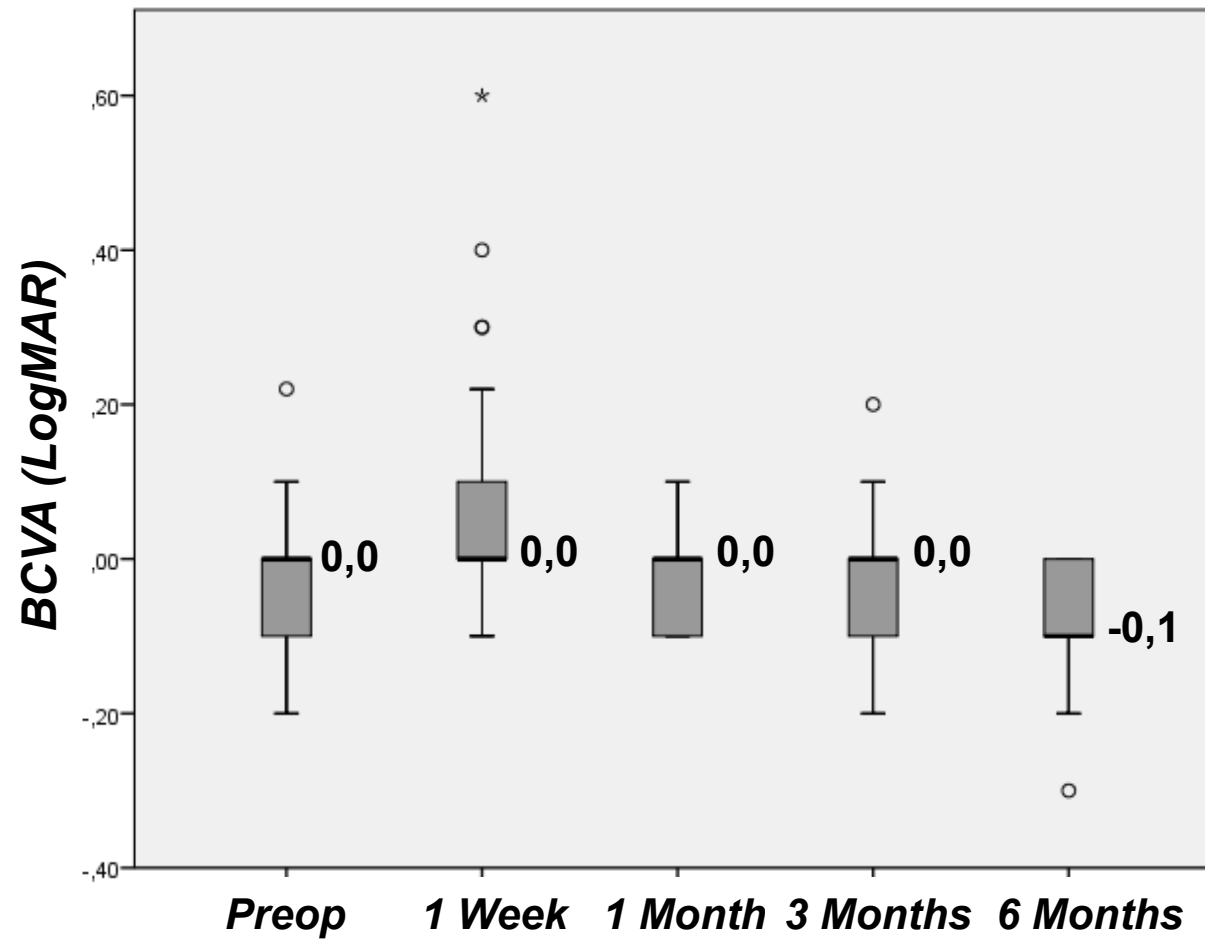
- **Significant increase of UCVA**
- **Few deviations from target refraction (emmetropia)**

n = 39





# Results: BCVA

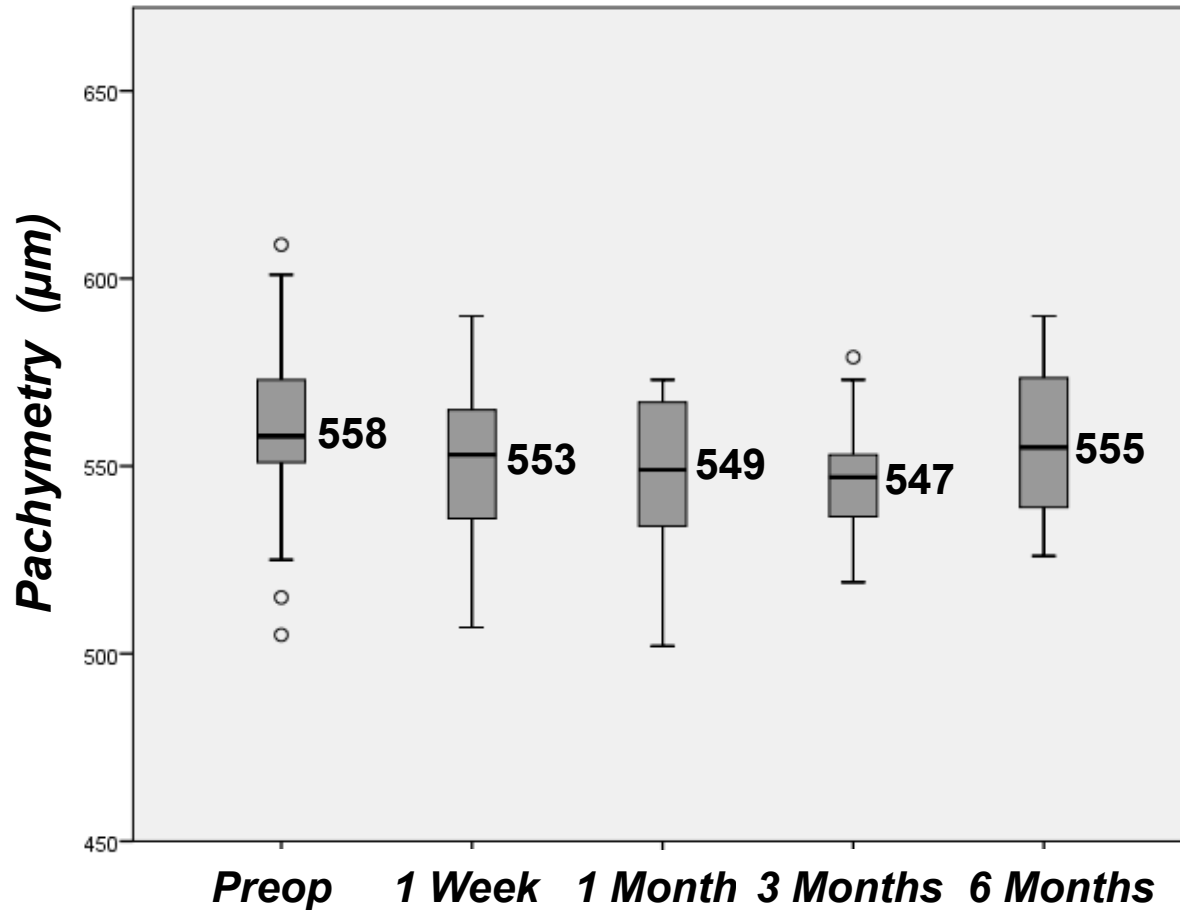


- *BCVA stable*

n = 39



# Results: Pachymetry

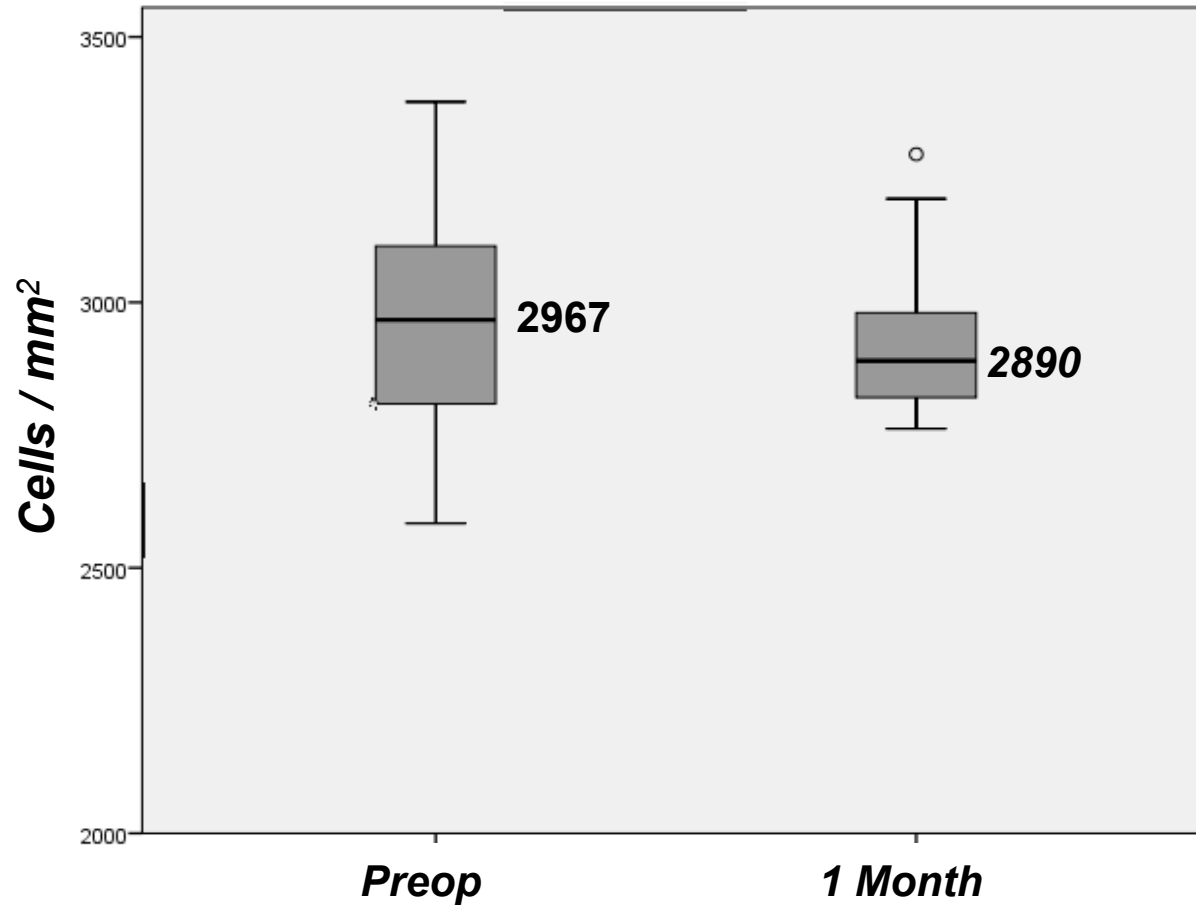


- Slight **decrease of corneal thickness** within **3 months** postop
- After **6 month** → **initial pachymetry**

n = 39



# Results: Endothelial Cell Count

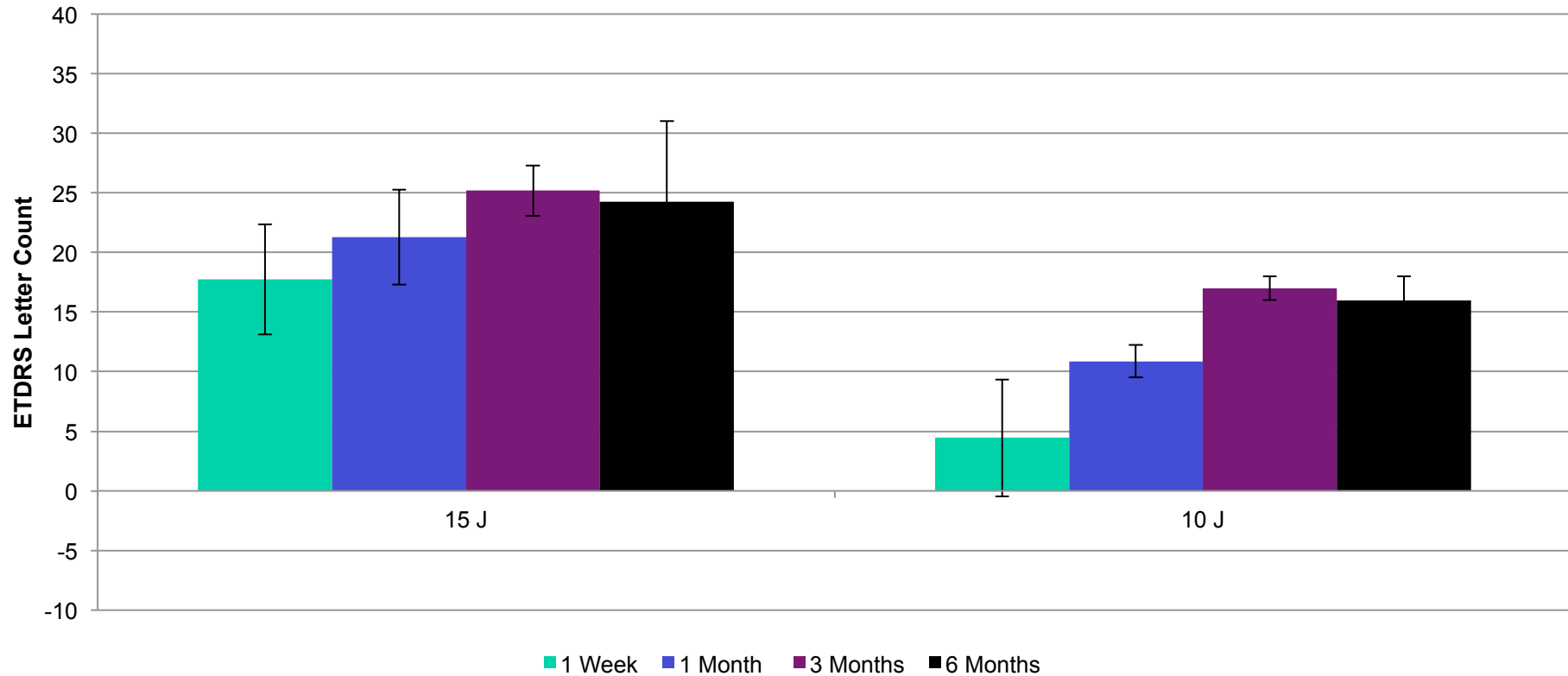


- **Stable** within the **first month**

n = 39



# Change in UCVA

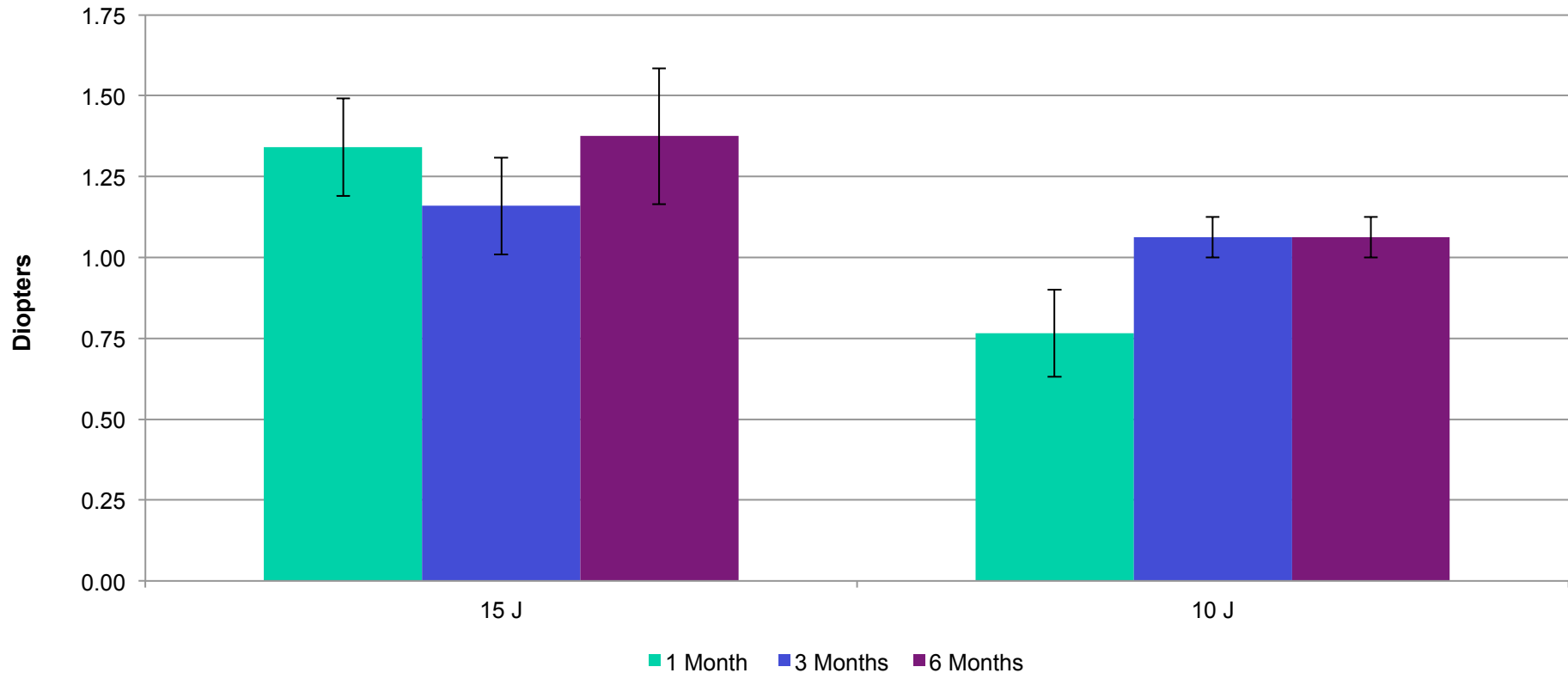


- **At 3 months...**
  - **15 J group → > 25 letters**
  - **10 J group → > 17 letters**



# Refractive Change

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- **After 6 months...**
  - **15 J group → 1,375 D**
  - **10 J group → 1,0 D**



# PiXL: Conclusion

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- **Refractive procedure for moderate myopia** ( $\leq -3,0$  D) in **healthy eyes**
- **No tissue ablation**
- **Long-term stability unknown → initial results after 6 months promising**
- Upcoming treatment modality  
→ **transepithelial / astigmatism**



**Thank you for your**  
**kind attention!**



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