Customized Corneal Cross-Linking for the Treatment of Myopic Refractive Error: 6-Months Results of a Prospective Clinical Study

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CXL: Background

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

$\rightarrow$ Specific correction of refractive errors
Purpose of the Study

• 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

– Healthy eyes
– Age > 18 years
– BCVA ≥ 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 µm (Pentacam® 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

<table>
<thead>
<tr>
<th>MRSE</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>-1.00 to -1.75</td>
<td>10 J/cm²</td>
</tr>
<tr>
<td>-2.00 to -3.00</td>
<td>15 J/cm²</td>
</tr>
</tbody>
</table>

- Pentacam® data
- Refraction
Treatment Protocol

- 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/cm² irradiation*
  - Pulse interval 1 sec on, 1 sec off
  - Maximum total UVA dose → 15 J/cm²
PiXL Treatment
PiXL Treatment
PiXL Treatment
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)

<table>
<thead>
<tr>
<th>Time</th>
<th>UCVA (LogMAR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preop</td>
<td>0.5</td>
</tr>
<tr>
<td>1 Week</td>
<td>0.22</td>
</tr>
<tr>
<td>1 Month</td>
<td>0.22</td>
</tr>
<tr>
<td>3 Months</td>
<td>0.22</td>
</tr>
<tr>
<td>6 Months</td>
<td>0.1</td>
</tr>
</tbody>
</table>

n = 39
Results: BCVA

- **BCVA stable**

![Graph showing BCVA measurements over time](image-url)

<table>
<thead>
<tr>
<th>Time</th>
<th>BCVA (LogMAR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preop</td>
<td>0.0</td>
</tr>
<tr>
<td>1 Week</td>
<td>0.0</td>
</tr>
<tr>
<td>1 Month</td>
<td>0.0</td>
</tr>
<tr>
<td>3 Months</td>
<td>0.0</td>
</tr>
<tr>
<td>6 Months</td>
<td>-0.1</td>
</tr>
</tbody>
</table>

$n = 39$
Results: Pachymetry

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

<table>
<thead>
<tr>
<th>Time</th>
<th>Pachymetry (µm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preop</td>
<td>558</td>
</tr>
<tr>
<td>1 Week</td>
<td>553</td>
</tr>
<tr>
<td>1 Month</td>
<td>549</td>
</tr>
<tr>
<td>3 Months</td>
<td>547</td>
</tr>
<tr>
<td>6 Months</td>
<td>555</td>
</tr>
</tbody>
</table>

n = 39
Results: Endothelial Cell Count

- **Stable** within the first month

![Graph showing endothelial cell count pre-operation vs. 1 month post-operation](image)

- Preop: 2967 cells/mm²
- 1 Month: 2890 cells/mm²

n = 39
Change in UCVA

• At 3 months…
  – 15 J group $\rightarrow$ > 25 letters
  – 10 J group $\rightarrow$ > 17 letters
Refractive Change

• After 6 months…
  – 15 J group → 1,375 D
  – 10 J group → 1,0 D
PiXL: Conclusion

→ Refractive procedure for moderate myopia (≤ -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!

– Ruhr University Eye Hospital –
Bochum, Germany

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