Conventional Vs Customized Excimer Laser Ablation: A Clinical Trial

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Sao Paulo
Brazil - 2004
Study Design and Demographics

- Prospective, randomized, one eye – conventional – contralateral eye custom.
- LadarVision, 6.5 mm ablation diameter (myopia and myopic astigmatism)
- Six months of follow-up
- Age
  - 22 to 53 years (average 32.1 years)
- Total of 45 Patients
Demographics

Spherical Equivalent

- **Conventional**
  - -1,25 to 6,13 D
  - Average = -2,80 D
  - PRK = 17 eyes
  - Lasik = 28 eyes

- **Custom**
  - -1,00 to -6,50 D
  - Average = -2,79 D
  - PRK = 15 eyes
  - Lasik = 30 eyes
PRK

- Conventional
  - Spherical Equivalent: -1.25 to -2.88 D
  - Average = -1.80
  - 17 eyes

- Custom
  - Spherical Equivalent: -1.25 to -3.25 D
  - Average = -1.83
  - 15 eyes
Lasik

- **Conventional**
  - Spherical Equivalent
    - -1,50 to -6,13 D
  - Average = -3,79
  - 28 eyes

- **Custom**
  - Spherical Equivalent
    - -1,00 to -6,50 D
  - Average = -3,62
  - 30 eyes
Spherical Equivalent

PRK

Spherical Equivalent

PRK

Preop  1M  3M  6M

PRK Conv
PRK Custom
Spherical Equivalent
Lasik

Preop  | 1M  | 3M  | 6M  
---|---|---|---
-4  | -3  | -2  | -1  
0  

Lasik Conv
Lasik Custom
PRK
Cycloplegic SE x Target

**Conventional PRK**
- 1M: 76.5%
- 3M: 94.1%
- 6M: 70.5%

- +/- 0.50: 23.5%
- +/- 1.00: 5.9%
- +/- 0.50: 29.4%

**Custom PRK**
- 1M: 80.0%
- 3M: 86.6%
- 6M: 100.0%

- +/- 0.50: 20.0%
- +/- 1.00: 13.3%
- +/- 1.00: 0.0%
Lasik
Cycloplegic SE x Target

Conventional Lasik

<table>
<thead>
<tr>
<th></th>
<th>1M</th>
<th>3M</th>
<th>6M</th>
</tr>
</thead>
<tbody>
<tr>
<td>+/-.50</td>
<td>92.8%</td>
<td>81.5%</td>
<td>85.2%</td>
</tr>
<tr>
<td>+/-1.00</td>
<td>7.2%</td>
<td>18.5%</td>
<td>14.8%</td>
</tr>
</tbody>
</table>

Custom Lasik

<table>
<thead>
<tr>
<th></th>
<th>1M</th>
<th>3M</th>
<th>6M</th>
</tr>
</thead>
<tbody>
<tr>
<td>+/-.50</td>
<td>73.3%</td>
<td>80.3%</td>
<td>83.3%</td>
</tr>
<tr>
<td>+/-1.00</td>
<td>26.7%</td>
<td>20.7%</td>
<td>16.6%</td>
</tr>
</tbody>
</table>
UCVA
PRK 1M

UCVA PRK 1M

Conv PRK
Custom PRK

<table>
<thead>
<tr>
<th>Vision</th>
<th>Conv PRK</th>
<th>Custom PRK</th>
</tr>
</thead>
<tbody>
<tr>
<td>20/15</td>
<td>0.00%</td>
<td>9.00%</td>
</tr>
<tr>
<td>20/20 or &gt;</td>
<td>9.00%</td>
<td>42.80%</td>
</tr>
<tr>
<td>20/25 or &gt;</td>
<td>85.60%</td>
<td>88.70%</td>
</tr>
<tr>
<td>20/30 or &gt;</td>
<td>92.74%</td>
<td>88.70%</td>
</tr>
</tbody>
</table>
UCVA
PRK 6M

UCVA PRK 6M

- 20/15: Conv PRK 7.70%, Custom PRK 9.00%
- 20/20 or >: Conv PRK 69.20%, Custom PRK 90.90%
- 20/25 or >: Conv PRK 99.99%, Custom PRK 99.99%
- 20/30 or >: Conv PRK 76.90%, Custom PRK 79.90%

Legend:
- Conv PRK
- Custom PRK
UCVA Lasik 1M

UCVA Lasik 1M

- 20/15: 0.00%
- 20/20 or >: 3.57%
- 20/25 or >: 69.23%
- 20/30 or >: 67.87%
- 96.15%
- 85.67%
- 100%
- 96.37%

Legend:
- Conv Lasik
- Custom Lasik
UCVA Lasik 3M

- 20/15: 13.00% Conv Lasik, 7.69% Custom Lasik
- 20/20 or >: 58.20% Conv Lasik, 61.49% Custom Lasik
- 20/25 or >: 83.20% Conv Lasik, 80.69% Custom Lasik
- 20/30 or >: 87.36% Conv Lasik, 99.89% Custom Lasik
UCVA Lasik 6M

UCVA Lasik 6M

- 20/15: 9.00%
- 20/20 or >: 61.90%
- 20/25 or >: 90.80%
- 20/30 or >: 95.30%
- 99.80%

Conv Lasik
Custom Lasik
Scattergram
PRK + Lasik (6M)
Safety/Efficacy - PRK

Conventional x Custom - PO 6 M

- Loss - 1 line: 13% (Conventional), 8% (Custom)
- No change: 81% (Conventional), 77% (Custom)
- Gain - 1 line: 6% (Conventional), 15% (Custom)

Visual acuity

n of eyes

0% 20% 40% 60% 80% 100%

Safety/Efficacy - PRK
Safety/Efficacy - LASIK

Safety/efficacy - Lasik
Conventional x Custom - PO 6 M

Visual Acuity

<table>
<thead>
<tr>
<th>Loss</th>
<th>Conventional</th>
<th>Custom</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss - 2 lines</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Loss - 1 line</td>
<td>15%</td>
<td>10%</td>
</tr>
<tr>
<td>No change</td>
<td>85%</td>
<td>79%</td>
</tr>
<tr>
<td>Gain - 1 line</td>
<td>0%</td>
<td>10%</td>
</tr>
</tbody>
</table>
PRK - HOA

Conventional PRK
HOA

Preop: 0.4
6M: 0.61 (+52.5%)

Custom PRK
HOA

Preop: 0.43
6M: 0.63 (+46.5%)
PRK - Coma

**Conventional PRK Coma**
- Preop: 0.24
- 6M: 0.28 (+16.7%)

**Custom PRK Coma**
- Preop: 0.24
- 6M: 0.38 (+14%)
PRK – Spherical Aberration

Conventional PRK Spherical Aberration

0.17

0.41 (+141.2%)

Spher Aber

Preop

6M

Custom PRK Spherical Aberration

0.17

0.33 (+94.1%)

Spher Aber

Preop

6M
Lasik - HOA

Conventional Lasik
HOA

0.43
1.17 (+172%)

Preop
6M

Custom Lasik
HOA

0.43
0.68 (+58.1%)

Preop
6M
Lasik - Coma

Conventional Lasik

Coma

0.22

0.47 (+113.6%)

Custom Lasik

Coma

0.22

0.29 (+24.1%)
Lasik – Spherical Aberration

**Conventional Lasik Spherical Aberration**

- **Preop:** 0.22
- **6M:** 0.96 (+336%)

**Custom Lasik Spherical Aberration**

- **Preop:** 0.23
- **6M:** 0.44 (+91.3%)
Date: 
Test Distance: 3 meters
System Used: F.A.C.T
Snellen Functional Acuity: Right: 20/25 Left: 20/25
Comments: Soft contact lenses in OS

Contrast vision Test developed by Arthur P. Ginsburg Ph.D. Licensed under U.S. Patent #4,365,873 and 5,414,479 by Visumetrics Corp. F.A.C.T is a registered trademark of Stereo Optical Co., Inc.
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Contrast Sensitivity

Stimuli C6 - PRK

Conventional x Custom

Pos - preop

n of eyes

-6 -5 -4 -3 -2 -1 0 +1 +2

0 0.5 1 1.5 2 2.5
Contrast Sensitivity

Stimuli E18 - PRK
Conventional x Custom
Contrast Sensitivity

Stimuli C6 - LASIK
Conventional x Custom

Pos - preop

n of eyes

-4 -3 -2 -1 0 +1 +2

0 1 2 3 4 5 6 7

Contrast Sensitivity

n of eyes
Contrast Sensitivity

Stimuli E18 - LASIK
Conventional x Custom

n of eyes

Pos - preop

-5 -4 -3 -2 -1 0 +1 +2

n of eyes
5th International Congress of Wavefront
Sensing & Optimized Refractive Corrections
February 21-23, 2004 – Whistler, Canada