5th International Congress of Wavefront Sensing & Optimized Refractive Corrections

February 21-23, 2004 – Whistler, Canada
W. Bruce Jackson, MD
University of Ottawa Eye Institute
The Ottawa Hospital
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5th International Congress of Wavefront Sensing & Optimized Refractive Corrections
Disclosure

- Research funding – VISX
- Consultant – VISX, Perfect Vision 20/20
Laser Vision Correction Of Presbyopia

ADVANTAGES

- Less invasive
- Established and improving LV technology
- Correct refractive error if present
- Customize ablation using wavefront
Laser Vision Correction Of Presbyopia

DISADVANTAGES

- Risk of visual symptoms
- Myope/emmetrope – high expectations
- May have some loss of “quality of vision”
- Dependence on pupil size
Techniques

- Inferior off centered ablations for near
  - Anschütz, Vinciguerra, Bauerberg
Techniques

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- Center Far
  - PARM - Avalos
  - Tamayo

- Center Near
  - Ruiz
  - VISX
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PARM Technique
(Presbyopia Avalos and Rozakis Method)

- G. Avalos 1998 - bilateral LASIK
- Hyperopes 60%, emmetropes 30%
- Enhancements possible (11-21%)
PARM Technique
(Presbyopia Avalos and Rozakis Method)

- Results in > 500 eyes (-4 to +3.5 D)
  - 82% 20/25 or better distance
  - 50% J1, 26% J2/J3 (76% J1-3)
- Keratometry 41-43 D preop – avoid <38 & >48 D (glare, halo, _ VA _ CS)
- Induced astigmatism of 0.50 to 0.75 D
- Agarwal – improved nomogram (B&L)
High Dioptric Power
Peripheral Cornea For Near

- G. Tamayo 2000
- VISX laser and C-cap program _ VSS
- Emmetropic and myopic presbyopes treated
High Dioptic Power
Peripheral Cornea For Near

Results

- Myopia and Presbyopia
  - 94% 20/30 or better and 69% J1 to J3
  - No loss of lines of BSCVA
- Pure Presbyopia
  - 44% 20/25 or better with 56% no change
  - 69% J1-J3
Techniques

- Inferior off centered ablations for near
  - Anschütz, Vinciguerre, Bauerberg

- Center Far
  - PARM - Avalos
  - Tamayo

- Center Near
  - Ruiz (1993)
  - VISX
VISX LASIK MULTIFOCAL
PRESBYOPIA TREATMENTS

Study of Central Near Technique
Sponsored by VISX, Incorporated

The Eye Institute, Ottawa Hospital

Investigators:
- W. Bruce Jackson, M.D.
- George Mintsioulis, M.D.

Study Team:
- Marc Lafontaine, COMT
- Brian Lorimer, COMT
- Lori O’Connor
- Nancy Whyte, RN
Study Design

- Feasibility study designed to allow refinements
- Several cohorts of ~10 eyes each have been treated with incremental improvements to treatment shape
- 60 eyes enrolled to date
Treatment

- Bilateral LASIK treatments
- Wavescan driven hyperopic treatment with a pupil size dependent presbyopic correction
- Amadeus microkeratome
Multifocal LVC Study Design

- Key clinical parameters:
  - Distance: UCVA, BSCVA
  - Near: Distance Corrected VA, BSCVA
  - Manifest Refraction
  - Near addition
  - Contrast acuity, contrast sensitivity
  - Corneal topography, wavefront analysis
Study Population

- 14 eyes of 7 patients
  - Mean age: 54.2 ± 4.1 years
  - Mean MRSE: +2.00 ± 0.97 D
  - Mean add requirement:
    - +2.13 ± 0.19 D
Baseline Parameters

- Analysis cohort:
  - 14 eyes of 7 hyperopic patients:
    - Mean age: 54.2 ± 4.1 years
    - Mean MRSE: +2.00 ± 0.97 D
    - Mean add requirement: +2.13 ± 0.19 D
Distance UCVA Results

- **20/20 or better**
  - Pre-op (n=14): 7%
  - 1 Month (n=14): 7%
  - 3 Months (n=14): 50%
  - 6 Months (n=10): 71%

- **20/25 or better**
  - Pre-op (n=14): 90%
  - 1 Month (n=14): 57%
  - 3 Months (n=14): 93%
  - 6 Months (n=10): 90%

- **20/40 or better**
  - Pre-op (n=14): 93%
  - 1 Month (n=14): 100%
  - 3 Months (n=14): 100%
  - 6 Months (n=10): 29%
Near UCVA Results

Percentage of eyes

- J1 or better
- J2 or better
- J3 or better

**Pre-op (n=14)**
- J1 or better: 0%
- J2 or better: 43%
- J3 or better: 100%

**1 Month (n=14)**
- J1 or better: 7%
- J2 or better: 64%
- J3 or better: 100%

**3 Months (n=14)**
- J1 or better: 7%
- J2 or better: 64%
- J3 or better: 79%

**6 Months (n=10)**
- J1 or better: 7%
- J2 or better: 100%
- J3 or better: 100%
# Refractive Outcome

<table>
<thead>
<tr>
<th>Mean ± s.d. (Diopters)</th>
<th>1 Month (n=14)</th>
<th>3 Months (n=14)</th>
<th>6 Months (n=10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MRSE</td>
<td>-0.15 ± 0.31</td>
<td>-0.13 ± 0.37</td>
<td>-0.13 ± 0.24</td>
</tr>
</tbody>
</table>

- Accurate, stable refractive results
Near VA Results with Distance Correction*

* No eye requires distance correction at 6 Months post-op
Simultaneous Uncorrected Distance and Near Vision

<table>
<thead>
<tr>
<th>% of eyes</th>
<th>Near</th>
<th>J2</th>
<th>J3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distance</td>
<td>20/25</td>
<td>20/25</td>
<td></td>
</tr>
<tr>
<td>3 Months</td>
<td>57%</td>
<td>71%</td>
<td></td>
</tr>
<tr>
<td>6 Months</td>
<td>90%</td>
<td>90%</td>
<td></td>
</tr>
</tbody>
</table>

Simultaneous uncorrected distance and near vision achieved in majority of eyes
Simultaneous Distance and Near Vision

Uncorrected near vision

J11
J9
J7
J5
J3
J1

Uncorrected distance vision

20/12.5 20/20 20/32 20/50 20/80 20/125

90% achieve target of improved distance and near vision

Target outcome 20/25 & J3 or better

Pre
6M
Corneal Topography Shape Analysis

- Standard Topography Axial Power map shows central steepening
- Example: Subject ID# 14117 3M post-Wavefront-guided Presbyopia Tx
Corneal Topography Shape Analysis

- Proprietary software calculates “tissue lens” removed
- Shows power gradient within optical zone area
- Example:
  - Subject ID#14117
  - 3.0 diopter measured central add

- Subject ID# 14117 (OS)
- Visual outcome at 3M post-op: 20/16 distance, J1+ near
Questionnaire Results

Satisfaction with vision at 6 Months (n=10)

- Satisfied/Very Satisfied
  - Vision in Daylight: 100%
  - Vision at Night: 100%
  - Near Vision (bright): 100%

- Not Sure
  - Vision in Daylight: 70%
  - Vision at Night: 0%
  - Near Vision (bright): 0%

- Somewhat Dissatisfied
  - Vision in Daylight: 0%
  - Vision at Night: 0%
  - Near Vision (bright): 0%

- Very Dissatisfied
  - Vision in Daylight: 0%
  - Vision at Night: 0%
  - Near Vision (bright): 0%
Spectacle Independence

Spectacle Use 6M Post-op

% of eyes

No Correction

Uses Correction

Reading
Computer Work
Cheque Writing
Driving (Day)
Driving (Night)
Recreation
Safety Summary

- At 6 months post-op, n=10

- **Distance Vision**
  - No significant (>1 line) loss of high or low contrast visual acuity with correction
  - Some glare/ halo problems reported
  - No ghosting or double images

- **Near Vision**
  - No significant (>1 line) loss of visual acuity with correction
  - Vision quality better in bright lighting
Case Report
WaveScan Hyperopic-Presbyopic Treatment

Pre op RE

Manifest = +1.5 DS x 0.75 DC x 10°
Distance acuity = 0.62 LogMAR (20/80)
Near acuity = 0.90 LogMAR (J7)
Distance corrected Near = 0.78 LogMAR (J6)
Case Report

WaveScan Hyperopic-Presbyopic Treatment

3 Month Results RE

Manifest = -0.25 DS x 0 DC

Distance acuity = -0.4 LogMAR (20/20 +2)

Near acuity = 0.36 LogMAR (J2)

Distance corrected Near = 0.48 LogMAR (J3)
High Order WaveScan of Presbyopic Correction

Aspheric shape with a central myopic zone
Multifocal Ablation For Presbyopia

CONCLUSIONS

- Still in development
- Multiple approaches
- Results are promising - many happy pts
- Myopic patients the biggest challenge
Thank You