Wavefront-Assisted Real-Time Laser Thermokeratoplasty from PriaVision, Inc

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Current LTK: 
Areas Needing Enhancement

- Surgically Induced Astigmatism
- Regression
- Initial Overcorrection

Intraoperative wavefront + low energy treatments may address some of these concerns
Goal: Make outcomes independent of

- Biology/Physiology/Anatomy,
- Surgery: decentration, fixation, tear film/stromal hydration etc
- Environmental: humidity/temp
- Prior surgery, post: LASIK, LASEK, PRK, LTK, RK etc
Intraoperative Wavefront Sensing

Hartmann-Shack wavefront sensor by Wavefront Sciences, Albuquerque NM

This high resolution and reliable sensor integrated into the Hyperion LTK Laser system
HYPERION™ LTK System
HyperWave Adaptive LTK prototype
HYPERION™ LTK System

HyperWave Adaptive LTK prototype
Initial Experience
Mexico

- Intraoperative Real Time wavefront monitoring (20 patients)
- Low Energy-LTK (100 patients)
- Hyperion modified with Low Energy software
- Hartmann-Shack sensor
  - WaveFront Sciences, Albuquerque, NM
HyperWave Wavefront-LTK System Modes/Capabilities

- **Diagnostic**: measure and display aberrations/refractions/haze/accommodation on the Hyperion even when not treating.

- **Intraoperative**: precise, rapid, & repeatable refraction and high order aberration data feedback of the eye being treated, for real time nomogram refinements by the Hyperion.
What is Intraoperative Wavefront-Assisted LTK?

- Real time (~5-10 Hz) refractions and aberrations (4th order Zernike) monitoring *during LTK* from start to completion of treatment

- Hyperion can adapt/modify ongoing treatment to *precisely control the treatment plan* after each laser pulse
Online Adaptive Wavefront-LTK program benefits

- Immediate postop accuracy to +/- 0.50 D
- Objective measure of high order aberration
- Evolving procedures such as lower energies [potentially lower regression], and astigmatism are easily addressed
- Overcomes variables affecting LTK outcomes example: (age, genetics, anatomy, hydration, surgeon error, manifest refraction errors, stiffness anisotrophy, thickness, pathologies, prior surgeries shrinkage rate uniformity, system calibration, registration, data entry etc)
Why Low Energy LTK?

- Peak temperatures on pig eyes for FDA-like Txs showed > 100 °C
- Desired temperatures are 60 °C - 70 °C
  [collagen shrinkage range from scientific literature]
- Regression rates are expected to reduce with less wound healing cascade induction
- Smoother transition zones
  - Better corneal optics with wavefront analysis
Low Energy LTK

**TEMPERATURE MODEL, PIG EYE**
32.5 mJ/spot [260 mJ/pulse]

**CALCULATED CORNEAL TEMPERATURE**
18 mJ/spot [144 mJ/pulse]
High Energy U.S. FDA Cohort

REFRACTIVE CHANGE vs ENERGY - 1 WEEK POST-OP
HYPEROPAIA Tx. 14 pulses

R² = 0.03
Krueger/Gomez, Jan 26' 03: 20 eyes of 11 patients
Gentle LTK [144 mJ/pulse], Actual delta SE [1 DAY POSTOP] vs Attempted delta SE

\[ R^2 = 0.89 \]

Mean Attempted delta SE: 1.66 D
Mean Actual 1 Day PostOp delta SE: 1.71 D

 Tx pattern: 16 spots
  6mm + 7mm rings
  5 Hz, 144 mJ/pulse

<table>
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<tr>
<th>Desired Correction SE D</th>
<th>0.75</th>
<th>1.00</th>
<th>1.25</th>
<th>1.50</th>
<th>1.75</th>
<th>2.00</th>
<th>2.25</th>
<th>2.50</th>
<th>2.75</th>
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<th>3.50</th>
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<tr>
<td>Pulses per ring # P/R</td>
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<td>34</td>
<td>37</td>
<td>39</td>
<td>41</td>
<td>43</td>
<td>45</td>
<td>48</td>
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<td>52</td>
<td>54</td>
<td>56</td>
<td>59</td>
<td>61</td>
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<tr>
<td>Treat time Secs</td>
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<td>13.6</td>
<td>14.8</td>
<td>15.6</td>
<td>16</td>
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<td>20</td>
<td>20.8</td>
<td>22</td>
<td>22.4</td>
<td>23.6</td>
<td>24.4</td>
</tr>
</tbody>
</table>
Low Energy LTK Nomogram

- 144 mJ/pulse, 8 spots/ring
- ~10 pulses/Diopter/ring, 2 rings - 6mm/7mm
- Delta S.E. range from 0.75 D to 5.00 D, [corresponds from 22 to 60 pulses per ring]
- Tx time from 10 secs to 25 secs
- No pause between rings (reduces 8 secs)
- ALLWET technique immediate pretreat:
  - Anesthetic/dilate: drops 3X 1 min apart
  - Lid speculum
  - Liquid wash: chilled BSS for 30 secs
  - Wipe quickly with Merocel
  - Eye fixated and centered
  - Treatment pulses started
**WF-LTK clinicals shown to date**

- Intraoperative wavefront measurements and recordings don’t interfere with standard LTK.
- Integrated unit shows remarkable stability and high correlations to manifest refraction.
- Sphere/Cylinder/Axis and 4th order Zernikes computed with existing software.
- Ensures pathway to software-driven outcomes endpoint [obviates the need for a specific preset nomogram]
- Use for Hyperopia, Astigmatism, Presbyopia
Gentle LTK [144 mJ/pulse] Online WF monitoring data

$R^2 = 0.76$
Sph Eq (Diopters)

Time (seconds)

R² = 0.89
R² = 0.85
R² = 0.96
Sph Eq (Diopters)

Time (seconds)

$R^2 = 0.74$
1 day:
- Avg delta SE attempted: 1.66 D,
- Avg delta SE actual: 1.71 D,

Avg preOp UCVA (logMAR): 20/100,
Avg postOp UCVA (logMAR): 20/35,
mean H.O.A. increased only 25% postoperatively

Patient Satisfaction Questionnaire: “very happy”.
20 eyes of 11 patients

Gentle LTK [144 mJ/pulse], UCVA LogMAR [PreOp - 1 DAY PostOp]

Mean UCVA PreOp: 20/100
Mean UCVA PostOp 1 Day: 20/35

Tx pattern: 16 spots
6mm + 7mm rings
5 Hz, 144 mJ/pulse
Gentle LTK [144 mJ/pulse], Surgically Induced Astigmatism Vector Analysis [1 DAY POSTOP]

Mean SIA 1 Day: 0.6 D, StdDev: 0.7 D

Tx pattern: 16 spots
6mm + 7mm rings
5 Hz, 144 mJ/pulse

1 DAY PostOp SIA
46yo, +1.00 D sph, 64 pulses,
46 yo, +1.0-2.0 X 90, 64 pulses

Patient 36182 OS

January 2003

LTK/COAS prototype
46 yo, +1.0 -2.0 x 90, 64 pulses

PriaVision Low Energy LTK

Patient: 36182 OS
Machine: LE-LTK/COAS prototype
Date: January 2003

PriaVision Confidential
Intraoperative Capabilities

Intraoperative System: All Diagnostic system capabilities plus:

- **Automatic Tx shutoff at specified WR endpoint convergence** to +/- 0.25 D

- **Automatic Tx shutoff at specified WR divergence limits** [S.I.S./S.I.A.]

- **Automatic restart of Tx when WR limit exceeded** to correct user prioritized [Zernike] aberration order
  - Cylinder over Sphere
  - Spherical Aberration over Coma
Adaptive LTK is based on Continuous [200 msecs] Progressive Approximation of the Tx plan using dynamic aberration monitoring [4th order Zernikes] and Gentler pulse energies.

Applications of Adaptive LTK:
Precise Sphere

Precise Cylinder
Adaptive LTK is based on Continuous [200 msecs] Progressive Approximation of the Tx plan using dynamic aberration monitoring [4th order Zernikes] and Gentler pulse energies.

Applications of Adaptive LTK:

Spherical Aberration [4-5 mm diameter]
Adaptive LTK is based on Continuous [200 msec] Progressive Approximation of the Tx plan using dynamic aberration monitoring [4th order Zernikes] and Gentler pulse energies.

Applications of Adaptive LTK:
- Precise Vertical Coma
- Precise Trefoil
Conclusion

- Wavefront-Assisted low energy LTK allows for refined outcomes and intraoperative monitoring
- Real-time feedback helps for dynamic treatment modification
- Adaptive LTK with closed loop treatment control introduces the next paradigm for real-time wavefront customized correction
Thank you