Aberrometry of Femtosecond Laser vs. Microkeratome Based LASIK

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Financial Disclosure

Received travel related supports and had consultant agreements with IntraLase.
Collaborators

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  - Associate Clinical Professor, University of California, Irvine
  - Vice-President, IntraLase Corporation
I’d like to express my appreciation to the following individuals for their data contribution to this presentation:

- Schallhorn, M.D.; Tanzer, M.D.
- Durrie, M.D.; Kezirian, M.D.
- Jon Dishler, M.D.
Objective

To compare changes following LASIK with a mechanical vs. IntraLase FS keratome

• Objective Wavefront Aberration
• Subjective Manifest Refraction

JCRS Jan. 2005
Methods

• Randomized, Prospective Study (N=18 eyes / 9 patients)
• Inclusion criteria of ≤ 4.00D spherical myopia and < 2.0D astigmatism
• Fellow eyes matched to within 0.75D sphere and 0.5 D cylinder
• Flaps created by IntraLase® and Hansatome® keratomes in fellow eyes
• Compare manifest refraction and optical wavefront aberrations at 10 weeks post-flap only procedure
• Non-Wavefront Guided excimer correction performed 10 weeks after flap creation
• Compare manifest refraction and optical wavefront aberrations at 3 months after excimer laser ablation
• Protocol was approved by WIRB
Methods

• **IntraLase FS™ Femtosecond Laser**
  - 120 µm thickness
  - 8.8 mm diameter
  - 45 degree hinge angle

• **Hansatome**
  - 9.5 mm Ring
  - 160 µm Head

• **Technolas 217A Excimer Laser**
  - 6.5 to 7.0 mm Treatment Zone
  - 3.0 mm Transition Zone
  - Eye Tracker Center of Pupils
  - Treatment based on post-flap refraction

• **Hartmann-Shack Aberrometer**
  - (Wavefront Sciences, Inc., Albuquerque, NM)

• **Statistical Analysis**
  - Wilcoxon signed rank test
Results: 10 Week Post Flap Manifest Refraction

![Graph showing data on Manifest Sphere, Manifest Cylinder, and MRSE for Hansatome and IntraLase.](image_url)

- **Manifest Sphere**
  - Hansatome vs IntraLase
  - Comparison with significant difference at P=0.04

- **Manifest Cylinder**
  - Hansatome vs IntraLase

- **MRSE**
  - Hansatome vs IntraLase

*Note: The graph illustrates the diopters for pre-flap and 10 weeks post-flap conditions for different treatments.*
Results: 10 Week Post Flap
Lower Order Aberrations

![Graph showing comparison between Hansatome and IntraLase for Defocus and Astigmatism](image)

- **Defocus**
  - Hansatome: *P = .004*
  - IntraLase: *P = .008*

- **Astigmatism**
  - Hansatome
  - IntraLase
Results: 10 Week Post Flap Higher Order Aberrations

Individual Zernike Post Hansatome: Trefoil (p=.03), Quadrafoil (p=.03)

Individual Zernike Post IntraLase: No Significant Increases
HANSATOME
RMS=0.72 µm
SD=0.31 µm

INTRALASE
RMS=0.31 µm
SD=0.12 µm

TOTAL RMS
POINT SPREAD FUNCTIONS OF FLAP INDUCED WAVEFRONT CHANGES
Summary of Results: 10 Week Post Flap

• Statistically Significant Changes in Hansatome Group
  – Subjective Spherical Manifested Refraction
  – Objective Wavefront Aberration
    • Defocus (LOA)
    • Total Higher Order Aberrations (HOA)
      – Trefoil
      – Quadrafoil

• Statistically Significant Changes in Intralase Group
  – Objective Wavefront Aberration
    • Defocus (LOA)
Results: UCVA 3 Months Post Excimer Laser Treatment

- One patient excluded from analysis due to epithelial ingrowth in Hansatome eye after re-lift
Results: 3 Months Post Excimer Laser Treatment*

• Excimer treatment based on 10 weeks post-op refraction
• No enhancement needed on any patient (4 year post-op)
Results: 3 Months Post Excimer Laser Treatment

- Statistically significant change in coma following excimer laser in Hansatome group
- Trend, but not statistically significant change in spherical aberration in both groups
Conclusions

- LASIK flap may induce minimal HOA in the mechanical microkeratome group
- IntraLase™ femtosecond laser flap creation did not cause significant change in the eye’s existing higher-order aberrations
- LASIK flaps may induce changes in sphere and cylinder
- Statistically significant increase in coma from the excimer laser ablation in Hansatome but not IntraLase group (possibly related to better exposure of bed)
Flap Architecture

Does the femtosecond laser create better flap than mechanical keratome?

• Uniform thickness lamellar flap
• Dry stromal bed for consistent excimer laser-tissue interaction … *Diffuse Reflector*?
• Corneal stromal bed smoothness
• Safety of femtosecond laser
  – Interrupted procedures with incomplete flaps
  – Post-operative inflammation
  – Femtosecond laser-tissue interaction.
Better flap architecture = Better visual outcomes?

- Faster visual recovery
- Accurate target correction
- Less surgical and post-op complications
- Excellent final quality of vision
• Randomized, prospective, contralateral eye

• Blade vs IntraLase

• 102 eyes
LASIK Visual Outcome

• Experimental Results: UCVA at 1 Day

![Bar chart showing UCVA at 1 Day for Hansatome (n=88) and IntraLase (n=88). The chart includes cumulative ETDRS Visual Acuity with a p-value of 0.03.]

Hansatome (n=88)  IntraLase (n=88)

% Eyes

Cumulative ETDRS Visual Acuity

p=0.03

Durrie AAO 2004
Higher Order Aberration

- Experimental Results: Higher Order Aberrations at 3 M

- RMS: High
- Coma: *p = 0.015
- Trefoil: *p = 0.096
- Sph: p = 0.478
- Ab: *p = 0.019
- Sec: *p = 0.004
- Astig: *p = 0.019
- Tetrafoil: *p = 0.019

**Hansatome** vs **IntraLase**

Durrie AAO 2004
US NAVY Study
Schallhorn, Tanzer

• Comparison of Visual Outcomes with Femtosecond and Mechanical Keratomes for WFG LASIK
  – Hansatome
  – Amadeus
  – IntraLase
  – VISX excimer laser
  – 300 patients
UCVA – 1 Day

Amadeus
(n=100)

Hansatome
(n=99)

IntraLase
(n=100)

<table>
<thead>
<tr>
<th>Vision</th>
<th>Amadeus</th>
<th>Hansatome</th>
<th>IntraLase</th>
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<tbody>
<tr>
<td>20/12.5</td>
<td>7%</td>
<td>6%</td>
<td>15%</td>
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<tr>
<td>20/16</td>
<td>15%</td>
<td>49%</td>
<td>68%</td>
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<tr>
<td>20/20</td>
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<td>68%</td>
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<tr>
<td>20/40</td>
<td>68%</td>
<td>68%</td>
<td>68%</td>
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I>H&A p<0.001
Clinical Results – 1 Month

<table>
<thead>
<tr>
<th>Instrument</th>
<th>UCVA</th>
<th>MSE</th>
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<tbody>
<tr>
<td>Amadeus (n=94)</td>
<td>90% ± 0.50 D</td>
<td>-0.17 ± 0.35</td>
</tr>
<tr>
<td>Hansatome (n=97)</td>
<td>89% ± 0.50 D</td>
<td>-0.09 ± 0.36</td>
</tr>
<tr>
<td>IntraLase (n=100)</td>
<td>95% ± 0.50 D</td>
<td>+0.04 ± 0.29</td>
</tr>
</tbody>
</table>

I>A p=0.04
I>H p<0.01
Change in 25% Contrast Acuity (3 Month)

Mean Difference:
+0.03 LM (loss)
-0.01 LM (gain)
-0.04 LM (gain)

I>H p=0.04
I>A p<0.001
H>A p=0.02

Amadeus (n=94)
Hansatome (n=92)
IntraLase (n=100)
Conclusions US Navy Study

• WFG LASIK approach favors IntraLase
  – Better clinical results
  – Faster visual recovery with faster return to flight status
  – Improved mesopic low contrast visual acuity (QOV)

• No significant differences in overall higher order aberrations (HOA) based on keratome used
  – Amadeus induces more spherical aberration
  – Both Amadeus and Hansatome induce more horizontal coma compared to IntraLase
Lamellar Structure of the Cornea

Peripheral fibers contribute to strength
- Minimize cutting deeper fibers
Microkeratome cut

- Lamellar structure of the cornea
- Microkeratome cuts deep in periphery with poor diameter and centration control
- Variability in central thickness across different flaps (standard deviation)
- Also significant variability regionally within a flap
- Confirms earlier studies using regional subtraction pachymetry

Image provided by Jon Dishler, MD
IntraLase cut

Lamellar structure of the cornea
• IntraLase cuts thin planar flap with precise depth, diameter and centration control
IntraLase Flap

- minimal variability in central thickness across different flaps (standard deviation)
- minimal variability regionally within the flap
- confirms earlier studies performed with regional subtraction pachymetry and histology

Image provided by Jon Dishler, MD
Dry Stromal Bed

- Diffuse reflector
- Less variation in tissue hydration
Clinical Experience

- 300 lasers installed worldwide
- 50 in Asia
- 500,000 LASIK flaps performed
- US – 20% of LASIK flaps done with IL
Safety Considerations

- **Interrupted procedures**
  - Incomplete flaps
  - Button hole flaps
- **Post-operative inflammation**
  - Diffuse lamellar keratitis (DLK)
    - Laser energy related?
    - Limited course with proper treatment
  - Transient light sensitivity (TLS)
- **Femtosecond laser-tissue interaction**
  - Effects on endothelial cells
    - Not a problem in animal study
  - Effects on other intraocular pigmented cells
- **Further clinical experience and study will be helpful to further show the safety of the femtosecond laser**
IntraLase FS30™
30 kHz Femtosecond Laser

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# Laser Settings

<table>
<thead>
<tr>
<th>Aspect</th>
<th>15 kHz</th>
<th>30 kHz</th>
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<tbody>
<tr>
<td>Thickness</td>
<td>110</td>
<td>110</td>
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<tr>
<td>Diameter</td>
<td>9.3</td>
<td>9.3</td>
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<tr>
<td>Raster Energy</td>
<td>1.5 μJ</td>
<td>0.9 μJ</td>
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<tr>
<td>Spot Separation</td>
<td>10/10μµ</td>
<td>9/9μµ</td>
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<tr>
<td>Sidecut Energy</td>
<td>1.2 μJ</td>
<td>0.5 μJ</td>
</tr>
<tr>
<td>Total Time</td>
<td>59 secs</td>
<td>36 secs</td>
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Discussion 15KHz vs. 30KHz

- Tighter spot separation → Better quality of corneal dissection → Easy to lift the flap
  - Bottros, ASCRS 2005
  - Tran, World Cornea Congress V and ASCRS 2005
- Decrease energy per pulse → Decrease total energy in stromal bed and sidecuts → Less gap at sidecuts → Less chance for epithelial ingrowth and less potential inflammation
  - Foulkes, ASCRS 2005
- Faster treatment time for better patient comfort → Less risks for transient anterior segment ischemia? → Less potential inflammation
No difference in stromal bed smoothness between blade and IL 15 kHz
Significantly smoother bed with IL 30 kHz
THANK YOU FOR YOUR ATTENTION

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