Z-LASIK in a High Volume Refractive Surgery Clinic

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Since Shinagawa LASIK Center was established in October 2004 and from that time through March 2010 we have performed over 700,000 cases.

Shinagawa LASIK Center in Tokyo (70% of operations) and 3 branch clinics in Osaka, Nagoya, and Fukuoka.

We have a total of **144 doctors** (Full-time:43, Part-time:101)

Our clinics perform about 65% of the LASIK procedures in Japan.
Other operations available:
- Surface ablation (PRK, LASEK, EpiLASIK)
- Intracorneal Ring Segment
- Phakic IOL
- Multi-focal IOL
- CK (Conductive Keratoplasty)
- KAMRA® Intracorneal Inlay
Awards

“Ziemer Award 2009 for the highest number of refractive treatments worldwide”

“For the worldwide highest treatment volume on the ALLEGRETTO Wave EYE-Q laser system” (2006 through 2008)

“For the worldwide highest treatment volume in 2009 and for positioning the SCHWIND AMARIS laser in Shinagawa’s premium segment”
Z-LASIK Patient volume at Shinagawa LASIK Center

Z-LASIK using Femto LDV in 88,914 eyes as of February 2010 !!
Prices for Both Eyes

**Intra LASIK**
178,000 Yen (US$1780)

**Z-LASIK**
220,000 Yen (US$2200)

**AMARIS Z-LASIK**
260,000 Yen (US$2600)

- Implementing the latest technologies benefits not only patients but also surgeons. Investment we make must benefit both patients and clinic.
Why use Femto LDV?

- Better visual outcomes: 20/20 vision in 97.7% of cases
- Effects of much lower energy per spot
- Smooth corneal stromal bed with excellent optical quality
- Saves tissue
- Create accurate flaps
- 6 min procedure for both eyes
- Presbyopia treatment
  - AcuFocus Intracorneal Inlay pocket software
    (We started from Aug, 2009)
Improved visual outcomes for 1,000 eyes of 526 patients

- Preop Characteristics (n=1,000 eyes) * Randomized

<table>
<thead>
<tr>
<th></th>
<th>Age</th>
<th>Sph</th>
<th>Cyl</th>
<th>SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean±SD</td>
<td>35.12±7.94</td>
<td>-4.56±2.33</td>
<td>-1.02±0.87</td>
<td>-5.07±2.34</td>
</tr>
<tr>
<td>Range</td>
<td>(18 to 59)</td>
<td>(-11.75 to -4.50)</td>
<td>(-6.25 to 0)</td>
<td>(-12.38 to +4.25)</td>
</tr>
</tbody>
</table>

* Combining LDV with SCHWIND AMARIS
  (SCHWIND eye-tech-solutions GmbH & Co KG, Kleinostheim, Germany)
Clinical Results at 3 months

**MRSE**

* n=1000 eyes

- **±1.00D**: 98.9%
- **±0.50D**: 91.9%
- **±0.25D**: 62.9%
- **0D**: 58.0%

*Shinagawa LASIK Center*
Results: Achieved Correction

UCVA

- 97.7% of the eyes achieved at least 20/20 or better vision after one week and there was no significant reduction in their visual outcomes at 3M.

*n=1000 eyes

Shinagawa LASIK Center
Corneal flap creation with much lower energy per spot

- High-energy spots induce inflammation.
- During ablation, Femto LDV™ uses only 1/50th of the energy of Intra FS60™ per spot.
- By using Femto LDV™, damage to cells is reduced.
- Occurrences of TLS (transient light syndrome) and DLK (diffuse lamellar keratitis) when using Femto LDV™ are reported at very low rates.

The higher pulse energy laser causes increased stromal cell death and the higher pulse energy is related to the occurrence of inflammation.¹
- Observation shows that by using Femto LDV™, more stromal fibers are preserved.

References:
2. Omid Kermani, MD; Uwe Oberheide, PhD. Comparative micromorphologic in vitro porcine study of IntraLase and Femto LDV femtosecond lasers. *J Cataract Refract Surg.* 2008; 34:1393-1399
Corneal flap creation with much lower energy per spot - CONT’

• Summary

Femto LDV is able to make flaps with less energy per pulse than IntraLase. Thus it induces fewer complications, such as inflammation, and also maintains a healthier corneal structure.

This could be marketed as a “Premium” LASIK that is friendlier to patient’s eyes. This creates a strong message for patients and can attract many customers.
Smooth Corneal Stromal Bed

- **Purpose**
  - To evaluate optical quality of the treated eyes

- **Subjects and Methods**
  - The optical quality of the treated eyes was measured using Optical Quality Analysis System (OQAS, Visiometrics, Spain)
  - Measurements were performed at 1 week after the surgery.
  - **Preop Characteristics:**
    Compared with two groups a) Z-LASIK (n=208) b) IntraLASIK (n=209)

<table>
<thead>
<tr>
<th>Group</th>
<th>Age (Mean±SD)</th>
<th>Sph (Mean±SD)</th>
<th>Cyl (Mean±SD)</th>
<th>MRSE (Mean±SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>a) Z-LASIK (n=218)</strong></td>
<td>29.52±5.16</td>
<td>-4.42±2.28</td>
<td>-0.76±0.66</td>
<td>-4.80±2.35D</td>
</tr>
<tr>
<td><strong>Range</strong></td>
<td>(20 to 39)</td>
<td>(-11.75 to -0.50)</td>
<td>(-3.25 to 0)</td>
<td>(-12.00 to -0.50)</td>
</tr>
<tr>
<td><strong>b) IntraLASIK (n=209)</strong></td>
<td>29.50±5.34</td>
<td>-4.18±2.08</td>
<td>-0.84±0.71</td>
<td>-4.60±2.12D</td>
</tr>
<tr>
<td><strong>Range</strong></td>
<td>(20 to 39)</td>
<td>(-10.00 to -0.25)</td>
<td>(-4.00 to -0.25)</td>
<td>(-10.00 to -0.50)</td>
</tr>
</tbody>
</table>
Both femtosecond lasers have made great technological advances and achieve good results. While only using 1/50th of the energy per spot, Femto LDV™ results in an OSI value that is not significantly different from that of Intra FS60™. Both Femto LDV™ and Intra FS60™ generated smooth corneal stromal beds. 

**Results of both group at 1 week**

<table>
<thead>
<tr>
<th></th>
<th>UCVA</th>
<th>BCVA</th>
<th>MRSE</th>
<th>OSI</th>
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<tbody>
<tr>
<td>a) Z-LASIK</td>
<td>20/12.5</td>
<td>20/12.5</td>
<td>-0.22±0.29D</td>
<td><strong>0.86±0.52</strong></td>
</tr>
<tr>
<td>(n=218)</td>
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<tr>
<td>b) IntraLASIK</td>
<td>20/12.5</td>
<td>20/12.5</td>
<td>-0.22±0.31D</td>
<td><strong>0.84±0.47</strong></td>
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<td>(n=209)</td>
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**OSI (Objective Scatter Index) value shows the analyzed optical quality**

*OSI value is a parameter which allows objective evaluation of intraocular scattered light. It is calculated by evaluating the amount of light on the outside of the double-pass image in relation to the amount of light on the center of it. The higher the OSI value, the higher the level of intraocular scattering. (Reference: Visiometrics) 

**Summary**

- Both femtosecond lasers have made great technological advances and achieve good results.
- While only using 1/50th of the energy per spot, Femto LDV™ results in an OSI value that is not significantly different from that of Intra FS60™.
- Both Femto LDV™ and Intra FS60™ generated smooth corneal stromal beds.
In IntraLase operations for cases with corneal opacity we have to make thicker flaps at a deeper corneal layer to prevent cold spot creation. In our prospective study using Femto LDV™, flaps were created without difficulty even for eyes with heavy opacity. There were no complications such as button hole or tearing.

- **Femto LDV** is a safe and effective method for flap creation.
- For patients with heavy corneal opacity, the flaps created are thinner than those created using other Femto second lasers (Table 1).
- No cold spots were created (Table 2).
- This results in saving more corneal tissue.

### Table 1

<table>
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<th>LDV (n=200)</th>
<th>FS60 (n=200)</th>
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<tbody>
<tr>
<td>Mean Flap Thickness (µm)</td>
<td>90</td>
<td>108.80 ± 6.84</td>
</tr>
</tbody>
</table>

* Saves approximately 18.8µm of corneal tissue.

### Table 2

<table>
<thead>
<tr>
<th></th>
<th>LDV (n=200)</th>
<th>FS60 (n=200)</th>
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<tbody>
<tr>
<td>Cold spots (eyes)</td>
<td>0</td>
<td>27</td>
</tr>
</tbody>
</table>

* No cold spots were found during the operations with LDV.
Summary

For patients with corneal opacity, LDV is able to save more tissue and thus any follow-on surgeries are safer.
Normal settings for flap creation using Femto LDV are typically 90 or 110 µm. Our clinic has been using 100µm PPs on a regular basis and the results have been quite good.

12 patients (24 eyes) using 100µm PPs
The setting for flap creation was 100µm for these patients. The mean flap thickness was 106.88±7.35µm (Table 1).

10 patients (20 eyes) using 90µm PPs
The setting for flap creation was 90µm for the patients. The mean flap thickness was 91.90±6.00µm (Table 2).

**Summary**

The range of error was acceptable and this setting is effective for flap creation.
Advantages of Femto LDV

- Femto LDV incurs fewer complications due to the ease of flap-positioning and flap-lifting.
- Doctors don’t have to ask the patients to reposition or move to another operating room.

Completed 00:05:07 in both eyes
Conclusion

- Femto LDV represents a great technological advance and Z-LASIK provides better visual outcomes for patients.
- Much lower energy per spot reduces the occurrence of inflammation and stromal cell death.
- The smooth corneal stromal bed created has excellent optical quality.
- Saves tissue for patients with corneal opacity.
- Accurate flap creation.
- 6 min procedure for both eyes
  - Surgeons can handle large patient volumes
  - An operation in short time is better for patient.
- Presbyopia treatment
  - Great potential for emmetropic presbyopic patients
  - Ametropic patients (SIM-LASIK) in the future.
Thank you.

Shinagawa LASIK Center