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IntraLase® Corp.
Clinical Studies Fact Sheet

Clinical data validates IntraLase as a superior technology for creating corneal flaps to initiate the LASIK procedure, providing a level of safety and predictability never-before-available to the LASIK surgeon.

IntraLase Improves Visual Outcomes

"Randomized Prospective Clinical Study of LASIK: IntraLase Laser versus Mechanical Keratome," 2004

Author: Daniel S. Durrie, M.D.

Methodology: Randomized, prospective, contralateral, study of 88 patients (176 eyes) undergoing bilateral LASIK, each eye randomized for flap creation with IntraLase or the leading microkeratome (Hansatome). Patients in first arm underwent Custom LASIK, while those in the second arm received Standard LASIK.

Key Findings: Clinically and statistically significant visual acuity improvements were seen in the IntraLase-treated eyes. IntraLase-treated eyes resulted in better visual acuity than the microkeratome-treated eyes. Additionally, results for eyes receiving Standard LASIK with IntraLase outperformed those in eyes receiving Custom LASIK with a microkeratome. Clinically and statistically significant contrast sensitivity improvements were seen in IntraLase-treated eyes at 1, 3 and 6-months postoperative.
Post-operative Uncorrected Visual Acuity (UCVA) 20/16 or better:

Custom Treatment Study (N=51):

- Day-one: IntraLase vs. Hansatome: **45** vs. **29** percent
- One week: IntraLase vs. Hansatome: **43** vs. **31** percent
- One month: IntraLase vs. Hansatome: **67** vs. **51** percent
- Three-month: IntraLase vs. Hansatome: **73** vs. **55** percent
- Six-month: IntraLase vs. Hansatome: **66** vs. **57** percent

Standard Treatment Study (N=37):

- Day-one: IntraLase vs. Hansatome: **32** vs. **16** percent
- One week: IntraLase vs. Hansatome: **41** vs. **27** percent
- One month: IntraLase vs. Hansatome: **62** vs. **35** percent
- Three-month: IntraLase vs. Hansatome: **69** vs. **33** percent
- Six-month: IntraLase vs. Hansatome: **67** vs. **36** percent

Status: Presented:

- Congress of the American Society of Cataract & Refractive Surgery, May 4, 2004, San Diego, CA; April 18, 2005, Washington, DC
- Joint Meeting of the American Academy of Ophthalmology & the International Society of Refractive Surgery, November 14, 2003, Anaheim, CA; October 23, 2004, New Orleans, LA
- European Society of Cataract and Refractive Surgeons, September 20, 2004, Paris, France
- 5th International Congress of Wavefront Sensing and Optimized Refractive Corrections, February 22, 2004, Whistler, British Columbia

Published:

- Durrie DS: "Laser vs. Manual Keratectomy." *Cataract & Refractive Surgery Today*, March 2004 Supplement.
- Durrie DS: "IntraLase vs. Hansatome: Which is better?" *Ophthalmology Management*, January 2004.
- Peer-Reviewed: Durrie DS, Kezirian, GM: " Femtosecond Laser versus Mechanical Keratome Flaps in Wavefront-guided Laser in situ Keratomileusis: A Prospective Contralateral Eye Study" *Journal of Cataract and Refractive Surgery,V31, Jan. 2005*.

"Comparison of Visual Outcomes with Femtosecond and Mechanical Microkeratomes for Wavefront-guided LASIK," 2005

Authors: Steven C. Schallhorn M.D. and David J. Tanzer, M.D.

Methodology: Randomized, prospective, study of 300 patients (600 eyes) undergoing bilateral wavefront-guided LASIK with VISX Star S4 Custom-Vue technology. Bilateral flap creation was performed with IntraLase FS Laser, Amadeus microkeratome or Hansatome microkeratome. Half of the patients had traditional LASIK (same day as flap creation) and half of the patients had the excimer treatment delayed for one month after flap creation ("staged").

Key Findings: Clinically and statistically significant visual acuity improvements were seen in the IntraLase-treated eyes. IntraLase-treated eyes resulted in a quicker visual acuity recovery as well as better visual acuity than the microkeratome-treated eyes. Additionally, eyes receiving LASIK with IntraLase showed improved mesopic contrast acuity. There was no difference in traditional vs. staged treatments.

Post-operative Uncorrected Visual Acuity (UCVA) 20/16 or better *(n=100 each keratome)*:

- Day-one: IntraLase vs. Amadeus/Hansatome: **68** vs. **49/42** percent
- One month: IntraLase vs. Amadeus/Hansatome: **85** vs. **73/71** percent
- Three-month: IntraLase vs. Amadeus/Hansatome: **88** vs. **79/78** percent

Status: Presented:

- Joint Meeting of the American Academy of Ophthalmology & the International Society of Refractive Surgery, October 23, 2004, New Orleans, LA; October 14, 2005,Chicago, IL
- European Society of Cataract & Refractive Surgeons, September 21, 2004, Paris, France; September 13, 2005, Lisbon, Portugal
- Congress of the American Society of Cataract & Refractive Surgery, May 4, 2004, San Diego, CA; April 18, 2005, Washington, DC
- 6th International Congress of Wavefront Sensing and Optimized Refractive Corrections, February 11-13, 2005, Athens, Greece

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"A Prospective, Randomized Eye to Eye Comparison between IntraLase and the Hansatome in Myopic LASIK Using the VISX CustomVue," 2005

Author: Edward E. Manche, M.D.

Methodology: Randomized, prospective, contralateral, study of 47 patients (94 eyes) undergoing bilateral wavefront-guided LASIK with VISX Custom-Vue technology. Each eye was randomized for flap creation with IntraLase or the Hansatome.

Key Findings: Clinically and statistically significant visual acuity improvements were seen in the IntraLase-treated eyes. IntraLase-treated eyes also showed a clinically and statistically significant improvement of postoperative UCVA and BCVA as compared to preoperative BCVA. Contrast acuity results were better with IntraLase-treated eyes.

Post-operative Uncorrected Visual Acuity (UCVA) 20/12.5 or better:

- Day-one: IntraLase vs. Hansatome: **54** vs. **59** percent
- One week: IntraLase vs. Hansatome: **79** vs. **50** percent
- One month: IntraLase vs. Hansatome: **94** vs. **74** percent
- Three-month: IntraLase vs. Hansatome: **89** vs. **70** percent
- Six-month: IntraLase vs. Hansatome: **90** vs. **86** percent

Post-operative Improvement in Uncorrected Visual Acuity (% showing gain):

- 1M Postop UCVA vs. PreoOP BCVA IntraLase vs. Hansatome: **37** vs. **17** percent
- 3M Postop UCVA vs. PreoOP BCVA IntraLase vs. Hansatome: **30** vs. **7** percent
- 6M Postop UCVA vs. PreoOP BCVA IntraLase vs. Hansatome: **38** vs. **19** percent

Post-operative Improvement in Best Corrected Visual Acuity (% showing gain):

- 1M Postop BCVA vs. PreoOP BCVA IntraLase vs. Hansatome: **60** vs. **31** percent
- 3M Postop BCVA vs. PreoOP BCVA IntraLase vs. Hansatome: **50** vs. **27** percent
- 6M Postop BCVA vs. PreoOP BCVA IntraLase vs. Hansatome: **52** vs. **38** percent

Status: Presented:

- The American Academy of Ophthalmology, October 17, 2005, Chicago, IL
- European Society of Cataract and Refractive Surgeons, September 12, 2005, Lisbon, Portugal
- Congress of the American Society of Cataract & Refractive Surgery, April 18, 2005, Washington, DC

"LASIK Outcomes with IntraLase FS Laser vs. Hansatome Microkeratome," 2005

Author: Ella G. Faktorovich, M.D.

Methodology: Retrospective 6 month post operative data of 111 WFG-LASIK with IntraLase and 115 WFG-LASIK with Hansatome cases were reviewed. Cases were age and refraction matched.

Key Findings: WFG-LASIK with IntraLase resulted in more eyes achieving 20/15 or better UCVA at one, three and six months and fewer eyes losing BSCVA at 3 months post operatively.

Status: Presented:

- Congress of the American Society of Cataract & Refractive Surgery, April 18, 2005, Washington, DC
- Joint Meeting of the American Academy of Ophthalmology & the International Society of Refractive Surgery, October 14, 2005, Chicago, IL

"Early Experience with the 30 kHz IntraLase," 2005

Authors: Elizabeth A. Davis, M.D., Richard L. Lindstrom, M.D

Methodology: Retrospective analysis of initial 24 eyes having IntraLase FS30-initiated LASIK procedures with 60 keratome (Hansatome) cases performed during the same time period (Summer 2005).

Key Findings: Visual outcomes were improved at all time points using the IntraLase FS30.

Status: Presented:

- Ocular Surgery News, September 16-18, 2005 New York, NY

"Initial Experience Integrating IntraLase and CustomVue in Myopic LASIK," 2004

Authors: Richard M. Launer, M.D., John C. Foley, M.D., Jonathan J. Schorn, O.D.

Methodology: Retrospective two-arm trial comparing 159 IntraLase-initiated LASIK procedures with 89 keratome cases performed the prior year.

Key Findings: Statistically significant visual outcome improvements were realized using IntraLase for flap creation as compared to the keratome-initiated LASIK group. Authors concluded that the use of IntraLase seemed to be more significant than the addition of custom treatment.

Status: Presented:
- Congress of the American Society of Cataract & Refractive Surgery, May 2, 2004, San Diego, CA

"The IntraLase Advantage," 2003

Author: Charles C. Manger III, M.D.

Methodology: Retrospective study comparing 510 cases of IntraLase-initiated LASIK performed in March and April 2003 with 500 cases of microkeratome-initiated LASIK from March and April of the previous year.

Key Findings: Monocular and binocular UCVA were significantly better in IntraLase-initiated eyes at 1 day.
- 60 percent of IntraLase-initiated eyes achieved binocular UCVA 20/15 or better on day 1 vs. 29 percent of microkeratome-initiated eyes.

Four of the 500 microkeratome-treated eyes (0.8 percent) developed diffuse lamellar keratitis (DLK) while none of the IntraLase eyes encountered this complication. Author noted that not once in 7,000 IntraLase procedures that he performed had DLK occurred.

Status: Published:
- Manger CC: "The IntraLase Advantage." *Ophthalmology Management*, February 2004.

"Clinical Outcomes of 933 LASIK Cases Using the IntraLase FS Laser Keratome," 2003

Author: Jonathan D. Christenbury, M.D.

Methodology: Retrospective analysis of 933 cases from one practice: 475 myopic correction subjects received LASIK using the IntraLase laser for flap creation during May through August 2002.

Key Findings: Post-operative results were equivalent or better than the practice standard LASIK results. Corneal flap creation with IntraLase is an excellent alternative to traditional microkeratomes.
- 97 percent of eyes reported a UCVA of 20/40 or better at one-month post-op
- 67 percent of eyes demonstrated a UCVA of 20/20 or better at one-month post-op

Status: Presented:
- Congress of the American Society of Cataract & Refractive Surgery, April 12 - 16, 2003, San Francisco, CA

"Clinical Outcomes: Mechanical versus IntraLase FS Laser Keratectomy," 2003

Author: Herman D. Sloane, M.D.

Methodology: Retrospective study of last 85 LASIK cases performed with the Moria microkeratome keratome and first 89 eyes that underwent LASIK with IntraLase.

Key Findings: IntraLase group reported better results, indicating that a new user can quickly achieve safe and effective clinical results, equivalent to or better than standard LASIK results, with the IntraLase FS laser.

- 87 percent of IntraLase-treated eyes reported a one-month post-op UCVA of 20/20 or better versus 66 percent of keratome subjects.
- 55 percent of IntraLase subjects demonstrated a one-month UCVA of 20/16 or better versus 28 percent of keratome cases.

Status: Presented:

- Congress of the American Society of Cataract & Refractive Surgery, April 12 - 16, 2003, San Francisco, CA

IntraLase Reduces Retreatment Rates

"Enhancement Rates of IntraLase Laser and Microkeratome-Assisted LASIK," 2004

Author: Charles C. Manger III, M.D.

Methodology: Retrospective review of 510 IntraLase-created LASIK flaps and 500 microkeratome cases with low to high myopia. The enhancement criterion was a decrease in visual acuity of at least two lines or a residual manifest refraction of at least -0.75D.

Key Findings: The IntraLase laser group had a 0 percent enhancement rate after six months of follow-up versus a 5.8 percent enhancement rate for the microkeratome group.

Status: Presented:

- Congress of the American Society of Cataract & Refractive Surgery, May 2, 2004, San Diego, CA

"IntraLase and the Incidence of LASIK Retreatment in Myopic Eyes," 2004

Author: Howard S. Kornstein, M.D.

Methodology: Retrospective study of 250 consecutive myopic eyes treated with LASIK using IntraLase compared with 250 consecutive myopic eyes treated with LASIK using a mechanical microkeratome.

Key Findings: After at least six months of follow-up, 1.2 percent (3) of IntraLase eyes versus 4.8 percent (12) of microkeratome eyes underwent re-treatment.

Status: Presented:

- Congress of the American Society of Cataract & Refractive Surgery, May 3, 2004, San Diego, CA

"Does IntraLase Make Sense?" 2004

Author: Michael Gordon, M.D.

Methodology: Retrospective data review.

Key Findings: IntraLase group reported lower enhancement rates of 6% vs. historical microkeratome enhancement rates of 10 to 15%.

Status: Published:

- Gordon, MG: "Does IntraLase Make Sense?" *Ophthalmology Management*, April 2004

IntraLase Reduces Post-op Dry Eye

"Randomized Prospective Clinical Study of LASIK: IntraLase Laser versus Mechanical Keratome," 2004

Author: Daniel S. Durrie, M.D.

Methodology: Randomized, prospective, contralateral, two-arm study of 88 patients (176 eyes) undergoing bilateral LASIK, each eye randomized to flap creation with IntraLase or the leading microkeratome (Hansatome). Patients in first arm underwent Custom treatment, while those in the second arm received Standard treatment.

Key Findings: Clinically and statistically significant improvement in Schirmer's test and/or lissamine green corneal stain results in Intralase-treated eyes versus Hansatome-treated eyes at one week, one month and three month post-op, indicating better tear production.

Status: Presented:

- Congress of the American Society of Cataract & Refractive Surgery, May 4, 2004, San Diego, CA; April 18, 2005, Washington, DC
- Joint Meeting of the American Academy of Ophthalmology & the International Society of Refractive Surgery, November 14, 2003, Anaheim, CA; October 23, 2004, New Orleans, LA
- European Society of Cataract and Refractive Surgeons, September 20, 2004, Paris, France
- 5th International Congress of Wavefront Sensing and Optimized Refractive Corrections, February 22, 2004, Whistler, British Columbia

Published:

- Durrie DS: "Laser vs. Manual Keratectomy." *Cataract & Refractive Surgery Today*, March 2004 Supplement.
- Durrie DS: "IntraLase vs. Hansatome: Which is better?" *Ophthalmology Management*, January 2004.

"Post-LASIK Corneal Hypoesthesia and Dry Eye," 2003

Author: Neda Shamie, M.D.

Methodology: Prospective, randomized, contralateral study comparing corneal sensation and dry eye following IntraLase-vs. Microkeratome-initiated LASIK in fourteen eyes of seven patients.

Key Findings: Dry eye following LASIK is associated with decreased corneal sensation. Corneal sensation in IntraLase-initiated eyes was clinically and statistically better than in microkeratome-initiated eyes. Author attributed this phenomenon to reduced variability in flap thickness, reduced hinge angle, and the construction of the flap edge that is achieved with the IntraLase laser.

Status: Presented:

- Congress of the American Society of Cataract & Refractive Surgery, April 12-16, 2003, San Francisco, CA (under Dr. Dan Tran)
- Jules Stein Eye Institute, Los Angeles, CA, 2003

"Outcomes for LASIK Performed with a Femtosecond Laser Keratome," 2002

Author: Johathan D. Christenbury, M.D.

Methodology: Retrospective study of the author's first 300 eyes of 156 patients who underwent IntraLase-initiated myopic LASIK, with comparison to the last 300 microkeratome-initiated LASIK cases.

Key Findings: IntraLase-initiated eyes had a lower incidence of dry eye complaints (16 percent) and a reduced need for punctual plugs as compared to the author's experience with traditional microkeratome-initiated LASIK. Fifty-five percent of microkeratome-initiated eyes had complaints of dry eyes.

Status: Presented:

- Annual Meeting of the American Academy of Ophthalmology, October 22, 2002, Orlando, FL., and data on file, IntraLase Corp.

IntraLase Provides Clinically Proven Predictability and Precision

"Comparison of Visual Outcomes with Femtosecond and Mechanical Microkeratomes for Wavefront-guided LASIK," 2005

Authors: David Tanzer, M.D., Steven Schallhorn, M.D.

Methodology: Wavefront-guided LASIK was performed with the VISX Star S4 CustomVue using one of three keratomes: Amadeus (100 eyes), Hansatome (76 eyes) and IntraLase (98 eyes).

Key Findings: The achieved depth accuracy was greater in IntraLase created flaps than in either microkeratome.

- ***IntraLase*** 97 µm +/- 16 (range: 55-126 µm)
- ***Amadeus*** 143 µm +/- 18 (range: 94-195 µm)
- ***Hansatome*** 113 µm +/- 18 (range: 72-161 µm)

Status: Presented:

- European Society of Cataract & Refractive Surgeons, September 13, 2005, Lisbon, Portugal
- Joint Meeting of the American Academy of Ophthalmology & the International Society of Refractive Surgery, October 14, 2005,Chicago, IL

"Reproducibility of Flap Thickness with Femtosecond Laser and Mechanical Microkeratomes," 2005

Authors: Jonathan Talamo, M.D., Jeremy Meltzer, M.D., John Gardner, C.O.A.

Methodology: Retrospective study of flap thickness values of three different keratome systems; IntraLase FS laser, Moria LSK-1 and Moria M2.

Key Findings: The IntraLase FS laser had a statistically significant ($p<0.0001$) and more reproducible mean achieved flap thickness than either microkeratome, reducing the comparative risk of overly thick flaps.

- ***IntraLase (n=99):*** 119 ± 12 µm (range: 82-149 µm)
- ***Moria LSK-1 (n=100):*** 130 ± 19 µm (range: 71-186 µm)
- ***Moria M2 (n=135):*** 142 ± 24 µm (range: 84-203 µm)

Status: In press: Peer-Reviewed: Talamo JH: "Reproducibility of Flap Thickness with Femtosecond Laser and Mechanical Microkeratomes," accepted by *Journal of Refractive Surgery,* October 2005.

"1000 Consecutive IntraLase LASIK Flaps," 2004

Author: Perry S. Binder, M.D.

Methodology: Consecutive flaps created with the Intralase were measured with subtraction ultrasound with the Storz Cornea Scan II 50 MHz.

Key Findings: The IntraLase laser reduces flap thickness variability by about 50% while reducing the achieved range. It eliminates complications associated with mechanical flap creation as well

as the effect of preoperative pachymetry and corneal power. The IntraLase laser permits greater amounts of myopia to be safely operated on without risking deep ablations.

Status: Presented:

Poster Presentation #PO342, Annual Meeting of the American Academy of Ophthalmology, October 23-26, 2004, New Orleans, LA

"Comparison of the IntraLase Femtosecond Laser and Mechanical Keratomes for LASIK," 2004

Authors: Guy M. Kezirian, M.D., Karl G. Stonecipher, M.D.

Methodology: Retrospective analysis of LASIK outcomes with the IntraLase laser (106 eyes), CB microkeratome (126 eyes) and the Hansatome (143 eyes).

Key Findings: IntraLase demonstrated more predictable flap thickness, better astigmatic neutrality and decreased epithelial injury than two popular mechanical keratomes.

Status: Presented:

- Congress of the American Society of Cataract & Refractive Surgery, May 3, 2004, San Diego, CA

Published:

- Peer-Reviewed: Kezirian GM, Stonecipher KG: "Comparison of the IntraLase Femtosecond Laser and Mechanical Keratomes for Laser In Situ Keratomileusis," *Journal of Cataract Refractive Surgery,* 2004; 30:804-811.

"Wavefront Characteristics After IntraLase Laser Flap Formation," 2004

Author: Dan B. Tran, M.D.

Methodology: Randomized, prospective, contralateral study of 18 eyes of 9 patients undergoing myopic correction (range: -1.38 to -4.00 D). Flaps were created with either IntraLase FS laser or Hansatome microkeratome, lifted and repositioned without the excimer treatment. Post-flap wavefront aberration measurements were compared to pre-operative statistics.

Key Findings: IntraLase laser flap creation did not cause significant change in the eye's existing higher-order aberrations, while Hansatome-treated eyes showed a statistically significant worsening of such aberrations.

- Author concludes that the IntraLase–created flap may be the ideal procedure for wavefront-guided custom LASIK treatments.

Status: Presented:

- Congress of the American Society of Cataract & Refractive Surgery, May 1, 2004, San Diego, CA
- Joint Meeting of the American Academy of Ophthalmology & the International Society of Refractive Surgery, November 14, 2003, Anaheim, CA

Published:

- Guttman C: "Femtosecond Laser Minimizes Wavefront Distortions," *Ophthalmology Times*, January 2004.
- Peer-Reviewed: Tran, DB, et al: "Randomized Prospective Clinical Study Comparing Induced Aberrations with IntraLase and Hansatome Flap Creation in Fellow Eyes," *Journal of Cataract and Refractive Surgery, 2005;31:97-105*.

"Flap Dimensions Created with the IntraLase Pulsion Laser," 2004

Author : Perry S. Binder, M.D.

Methodology: In the first 103 eyes in which flaps were created with the IntraLase laser, the flap thickness was measured by the ultrasonic difference between the preoperative and post-flap-creation central corneal thickness and the flap diameter was measured with calipers.

Key Findings: The IntraLase laser, while adding technical complexity to the laser in situ keratomileusis procedure, is able to predictably create flap diameters, hinge location, and flap thickness while eliminating the risk for cap perforations. The technique of flap elevation affects rapidity of visual recovery.

Status: Published:

- Peer-Reviewed: Binder PS: "Flap Dimensions Created with the IntraLase Pulsion Laser," *Journal of Cataract and Refractive Surgery,* 2004;30:26-32.

"Femtosecond Laser Pros and Cons," 2004

Author: Jonathan Talamo, M.D.

Methodology: Retrospective study of the author's first 410 consecutive IntraLase cases, including historical comparative data from two leading microkeratomes.

Key Findings: Mechanical microkeratomes were 10 times more likely to produce a seriously thin flap and 1,000 times more likely to create extremely thick flaps.

Status: Presented:

- Joint Meeting of the American Academy of Ophthalmology & the International Society of Refractive Surgery, November 14, 2003, Anaheim, CA

Published:

- Talamo JH: "Optimizing Flap Outcomes with the INTRALASE FS Laser," *Ophthalmology Management*, May 2004.

"Femtosecond Technology: Is Now the Time to Buy?" 2003

Author: Ming Wang, M.D., Ph.D.

Methodology: Mathematical analysis comparing the probability of achieving a flap that is dangerously thin or dangerously thick with IntraLase versus a microkeratome.

Key Findings: A ratio of the standard deviations of flap thickness for the microkeratome versus the IntraLase laser of a factor of two to three translates into a much more significantly improved safety profile for the laser approach when considering the percentage of flaps which may be extremely thin or extremely thick.

Status: Published:

- Wang M: "Femtosecond Technology: Is Now the Time to Buy?" *Refractive Eyecare for Ophthalmologists,* May 2003.

IntraLase vs. Microkeratome: Complications

"Early Experience with the 30 kHz IntraLase," 2005

Authors: Elizabeth A. Davis, M.D., Richard L. Lindstrom, M.D

Methodology: Retrospective analysis of initial 24 eyes having IntraLase FS30-initiated LASIK procedures with 60 keratome (Hansatome) cases performed during the same time period (Summer 2005).

Key Findings: No intraoperative complications occurred with either keratome. Typical postoperative complications were found more often in the Hansatome treated eyes.

Common postoperative complications (Rates at 1day/1 week/ 1 month):

DLK/Photophobia:	IntraLase FS30™	0% all visits vs. Hansatome 0% all visits
Slipped Flap/Microstriae:	IntraLase FS30	0% all visits vs. Hansatome 2% / 7% / 4%
Epithelial Ingrowth:	IntraLase FS30	0% all visits vs. Hansatome 2% / 3% / 4%
Epithelial Defect:	IntraLase FS30	0% all visits vs. Hansatome 3% / 2% / 0%

Status: Presented:
- Ocular Surgery News, September 16-18, 2005 New York, NY

"Complications of IntraLase Femtosecond LASIK Flap Creation by Multiple Surgeons in a Closed Access Setting," 2004

Authors: James Davison, M.D., Eric Bligard, M.D., Todd Gothard, M.D., Steven Johnson, M.D., Louis Scallon, M.D., Daniel Vos, M.D., Norman Woodlief, M.D.

Methodology: Retrospective study of 2010 consecutive LASIK procedures performed over one year by seven surgeons (case volumes of 768, 517, 273, 228, 122, 57 and 45) using the IntraLase laser for corneal flap creation.

Key Findings: The IntraLase femtosecond laser technology can be successfully adopted by surgeons of widely differing surgical volumes.
- Among these newly trained surgeons, only one free cap and one incidence of flap with significant striae were reported.

Status: Presented:
- Congress of the American Society of Cataract & Refractive Surgery, May 3, 2004, San Diego, CA

IntraLase vs. Microkeratome: Biomechanical Effect

"Flap Biomechanics with Femtosecond and Mechanical Microkeratomes," 2005

Author: Jorge Alio, M.D.

Methodology: Study of 82 eyes who underwent myopic or myopic with astigmatism correction with LASEK, LASIK with IntraLase and LASIK with mechanical microkeratome. The rate of change between the post-surgical and sculpted corneal radius was calculated (evolution coefficient).

Key Findings: The corneal radius evolution is lower after LASEK and INTRALASIK than after LASIK with M2 microkeratome. Moreover, with IntraLase FS the refractive results achieved are more predictable than with LASEK. These facts are relevant for the design of the surgical operation.

Status: Presented:

- Congress of the European Society of Cataract & Refractive Surgery, September 2005, Lisbon, Portugal

"Corneal Biomechanical Response Using Mechanical Microkeratomes and IntraLase with Different Flap Thickness," 2005

Authors: Ahmed Galal, M.D., Gonzalo Bernabeu Arias, M.D., Jorge Alio, M.D., Maria Dolores Ortiz, M.D., David Pinero, Bsc.

Methodology: Study of 52 eyes who underwent myopic or myopic with astigmatism correction with LASIK with Moria M2 130 um targeted flap thickness, LASIK with IntraLase 90 and 120 um targeted flap thicknesses. The rate of change between the post-surgical and sculpted corneal radius was calculated (evolution coefficient).

Key Findings: The corneal biomechanical response is better with IntraLase FS that mechanical microkeratome because IntraLase produces a lower change in corneal curvature. Comparing IntraLase groups, the response is better for patients with 90 um flap thickness.

Status: Presented:

- Joint Meeting of the American Academy of Ophthalmology & the International Society of Refractive Surgery, October 14, 2005,Chicago, IL

"Randomized Prospective Clinical Study of LASIK: IntraLase Laser versus Mechanical Keratome," 2004

Author: Daniel S. Durrie, M.D.

Methodology: Randomized, prospective, contralateral, study of 88 patients (176 eyes) undergoing bilateral LASIK, each eye randomized for flap creation with IntraLase or the leading microkeratome (Hansatome). Patients in first arm underwent Custom LASIK, while those in the second arm received Standard LASIK. 10 patients had Artemis Ultrasound imaging performed one year after LASIK was completed.

Key Findings: More uniform flap thickness was identified with IntraLase-treated eyes. The average variability in flap thickness was 27 µm (range: 20-40 µm) for IntraLase and 63 µm (range: 47-95 µm) for Hansatome treated eyes.

Status: Presented:
- Congress of the American Society of Cataract & Refractive Surgery, April 18, 2005, Washington, DC
- Joint Meeting of the American Academy of Ophthalmology & the International Society of Refractive Surgery, October 23, 2004, New Orleans, LA
- European Society of Cataract and Refractive Surgeons, September 20, 2004, Paris, France

Additional References

"Practice Styles and Preferences of ASCRS members-2003 Survey," 2004

Author: David V. Leaming, M.D.

Methodology: Twentieth annual survey of members of the American Society of Cataract and Refractive Surgery. Approximately 15.5 percent (985) of the 6,350 questionnaires were returned for analysis.

Key Findings: A majority of respondents (52%) indicated that the device they would prefer to "use/acquire" to create the corneal flap in LASIK was the IntraLase FS laser (up from 18% in 2001 and 33% in 2002); compared to 4 percent for the Bausch & Lomb Hansatome microkeratome and 21 percent for the AMO Amadeus microkeratome (down from 40% in 2001 and 36% in 2002).

Status: Published:
- Peer-Reviewed: Leaming DV: "Practice Styles and Preferences of ASCRS Members-2003 Survey," *Journal of Cataract and Refractive Surgery,* 2004;30:892-900.

"Three Year Prospective On the Business Impact of the IntraLase Technology," 2005

Author: Shareef Mahdavi

Methodology: Survey of 81 US practices currently utilizing the IntraLase laser.

Key Findings: Practices reported that 81 percent of patients chose the IntraLase laser over the microkeratome for corneal flap creation when given a choice.

Status: Data on file, SM2 Consulting, Pleasanton, CA.

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