STATE BOARD OF OPTOMETRY
2450 DEL PASO ROAD, SUITE 105, SACRAMENTO, CA 95834
P (916) 575-7170 F (916) 575-7292 www.optometry .ca.gov

Continuing Education Course Approval Checklist

Title: Smile Incision Lenticle Extraction

Provider Name: NVISION Eye Centers c/o Ms. Leslie Kuhlman

☑Completed Application
Open to all Optometrists? ☑Yes ☐No
Maintain Record Agreement? ☑Yes ☐No

☑Correct Application Fee

☐Detailed Course Summary

☑Detailed Course Outline

☑PowerPoint and/or other Presentation Materials

☑Advertising (optional)

☑CV for EACH Course Instructor

☑License Verification for Each Course Instructor
Disciplinary History? ☑Yes ☐No

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CONTINUING EDUCATION COURSE APPROVAL APPLICATION

$50 Mandatory Fee

Pursuant to California Code of Regulations (CCR) § 1536, the Board will approve continuing education (CE) courses after receiving the applicable fee, the requested information below and it has been determined that the course meets criteria specified in CCR § 1536(g).

In addition to the information requested below, please attach a copy of the course schedule, a detailed course outline and presentation materials (e.g., PowerPoint presentation). Applications must be submitted 45 days prior to the course presentation date.

Please type or print clearly.

Course Title	**Course Presentation Date**
Smile Incision Lenticle Extraction	03/05/2017

Course Provider Contact Information

Provider Name

Leslie (First) Kuhlman (Last) Ann (Middle)

Provider Mailing Address

Street 75 Enterprise **City** Aliso Viejo **State** CA **Zip** 92673

Provider Email Address Leslie.Kuhlman@nvisioncenters.com

Will the proposed course be open to all California licensed optometrists?	☑ YES ☐ NO
Do you agree to maintain and furnish to the Board and/or attending licensee such records of course content and attendance as the Board requires, for a period of at least three years from the date of course presentation?	☑ YES ☐ NO

Course Instructor Information

Please provide the information below and attach the curriculum vitae for each instructor or lecturer involved in the course. If there are more instructors in the course, please provide the requested information on a separate sheet of paper.

Instructor Name

Tom (First) Tooma (Last) (Middle)

License Number	**License Type** MD
Phone Number (949) 836-6614	**Email Address** Tom.Tooma@nvisioncenters.com

I declare under penalty of perjury under the laws of the State of California that all the information submitted on this form and on any accompanying attachments submitted is true and correct.

Signature of Course Provider ***Date*** 3/1/17

OPTOMETRY

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For Office Use Only

Receipt No. _____

ATS No. _____

Date Rec'd _

Request for Approval of Continuing Education Course(s)

Leslie Kuhlman
NVISION Eye Centers
75 Enterprise, Suite 200
Aliso Viejo, CA 92656

Requests for approval of continuing optometric education (CE) courses should be submitted on this form. The California State Board of Optometry requires the following information in order to process a course approval request:

- **$50** processing fee
- Name of provider
- Course title(s)
- Date(s) the course is scheduled to be offered
- Topical outline of the course subject matter
- Any announcements, notices or advertisements of the course
- Curriculum vitae (CV) of all instructors and lecturers involved (NOTE: CVs should include every term of employment, academic credential, publication, contribution or significant achievement)

Requests for approval and the supplemental information should be submitted to the Board office at least 45 days prior to the first date that the course will be offered. Requests will be reviewed by staff and forwarded to the CE Committee for final review. If necessary, Board staff will contact the requestor for additional information. Course approvals are valid for 12 months or until the course is modified.

The CE Committee's decision(s) will be noted and a copy of this form will be returned to the provider to serve as official notification of approval and/or disapproval of the course(s). Please remember to include the contact person's name and mailing address in the space provided above.

_____

CE Committee Member

YOU'RE INVITED

ORANGE COUNTY REGIONAL 5-HOUR CE EVENT

Sunday, March 5, 2017 / 7:00 am - 1:30 pm
Improv Comedy, Irvine, CA

Join NVISION for an exciting continuing education event including networking, breakfast, lunch and raffles.

FEATURED EVENTS

Exciting Presentations, Fantastic Raffle Prizes,
Vendor Booths, Delicious Food & Drinks,
and Breakfast & Lunch

SPEAKERS

Tom Tooma, MD • Franklin Lusby, MD
Sheri Rowen, MD • John Nolan, MD
Jonathan Pirnazar, MD

TOPICS

LRS, Ocular Nutrition, Crosslinking, Corneal Inlay

Limited availability. Registration ends 3/3/17.
For more information and to RSVP, visit:
https://ocregional5hrce.eventbrite.com

CA State Board of Optometry - Pending Approval

NVISION EYE CENTERS

NVISION
EYE CENTERS

STATE BOARD OF OPTOMETRY
2450 Del Paso Road, Suite 105
Sacramento, CA 95834

On behalf of NVISION Eye Centers, we are writing to request approval of Continuing Education to California doctors of optometry. The education will be delivered by Board Certified Ophthalmologists, clinical investigators and experts in technology and patient consultation.

We are writing in response to your letter for information pursuant to CCR 1536 (g), to address why our application was submitted earlier than 45 days for course accreditation. As well as additional content requested.

The reason why our application was submitted earlier than 45 days for the course named "Smile Incision Lenticle Extraction" given March 5, 2017 access to the final presentation of the material not being accessible due completion on training on behalf of the surgeon and certification on new procedure. Once information required, we moved quickly to process accreditation requests. Please accept our apologies and deepest regrets. Going forward, we will make every effort to process these applications in a timely manner.

Course Description: This course will introduce Smile Incision Lenticle Extraction procedure, patient selection, and outcomes.

Course Objective: Knowledge transferred to Help our ODs explain options to the patient as well as to help them guide through the post operative phase.

Conditions of Availability: This course will be open to all licensed ODs. They will be notified through flyers, Eventbrite, and fax by request.

Records: NVISION Eye Centers to maintain and furnish to the Board and/or attending licensee such records of course content and attendance as required for a minimum of three years.

Professional Advancement: NVISION Eye Centers seeks to offer professional education to local and regional optometrist. As a leading practice in the ophthalmology field, NVISION doctors are engaged in research and latest developments on procedures, technology, and clinical therapies. The field of optometry is constantly evolving at a rapid pace and optometrists need to keep up. All Things Refractive in an interactive presentation. This CE activity will help attending ODs learn a full understanding of refractive surgery technology, clinical treatments and procedures, candidates, post-op & pre-op care, cost, co-management, how it is performed, and benefits.

The contact person for this program is myself, and I can be reached at 949.234.8129 or Leslie.Kuhlman@nvisioncenters.com.

Sincerely,

Leslie Kuhlman
NVISION Laser Eye Centers
Continuing Education and Special Projects Coordinator

75 Enterprise, Suite 200, Aliso Viejo, CA 92656
p: 949.274.4652 • *f:* 949.509.4858 • *e:* info@nvisioncenters.com • *w:* www.nvisioncenters.com

NVISION
EYE CENTERS

Presenter – Tom Tooma, M.D.

Course Title – Smile Incision Lenticule Extraction

Course Outline –

U.S. LVC Market
Procedural Volumes Down from Historical Highs & Never Recovered
LASIK IS THE SAFEST ELECTIVE PROCEDURE WITH THE HIGHEST PATIENT SATISFACTION IN THE WORLD TODAY
U.S. LVC Market
Key Market Drivers
REFRACTIVE SURGEONS HAVING LASIK
5X MORE LIKELY – 65%
95% OPERATED ON A FAMILY MEMBER
3 Month Uncorrected Visual Acuity Outcomes
No enhancements performed
Overall Satisfaction With Present Vision WAS 99%
Cosmetic Procedures and Patient Satisfaction Rates
LASIK FACTS
DRY EYE TYPICALLY RESOLVES
LASIK FACTS
NO DRY EYE PRE OP = NONE POST-OP
LASIK FACTS
ONLY PATIENTS WITH DRY EYES PRE-OP, MAY DEVELOP DRY EYES POST-OP
Tear Lab
InflammaDry
MMP-9
LipiView
Gland Imaging
LipiView
Gland Imaging
CTL
SINGLE LARGEST RISK FACTOR FOR MICROBIAL KERATITIS
CTL RELATED INFECTIONS
1,000,000 VISITS ANNULALLY
4% OF ER VISITS
Proportion that strongly recommended their current vision correction (%)
Former CL wearers who had LASIK were asked:
"Does LASIK work better for you than contacts?"
LASIK improved ease of night driving

LASIK did not increase dry eyes relative to baseline CL use
LASIK – MY OUTCOMES
UCVA 20/20 = 95.1%
BINOCULAR UCVA 20/20 = 99%
POST OP MEAN SPHERE
-0.08 +/- 0.24D
68.2% +/- 0.24D
95.4% +/- 0.48D
POST OP MEAN CYLINDER
0.17D +/- 0.21D
POST-OP MEAN UCVA
20/17.4 +/- 0.6
U.S. LVC Market
Impact of ReLEx SMILE
ReLEx SMILE
Procedure Step-by-Step
Series of lamellar resections
1st lamellar cut defines posterior surface of lenticule
1st side cut defines lenticule diameter
2nd lamellar cut defines anterior surface of lenticule/posterior surface of attached cap
2nd side cut creates incision for removal of lenticule
Understanding SMILE
Docking
Centration on Visual Axis
Low Suction Pressure
Extremely Comfortable
Dissection of Lamellar Planes
And at the end...a smile
Day 1 SMILE
Day 1 SMILE Fellow eye
ReLEx SMILE – POTENTIAL BENEFITS
80% SMALLER SIDE CUT
30% SMALLER CAP CUT
UPPER CORNEAL LAYERS REMAIN INTACT
SMALL INCISION – FEWER TRANSECTED NERVES = LESS DRY EYES
SMILE – POTENTIAL BENEFITS
80% smaller side cut – less transected nerves, less dry eyes
Anterior lamellae of cornea preserved, including bowman's layer - better structural integrity
No flap to dislodge
Minimally invasive – flapless surgery
SMILE – PATIENT PERCEPTION
LESS INVASIVE
FOR PATIENTS WHO ARE AFRAID OF LASIK
FOR PATIENTS WITH DRY EYES

CTL FAILURES – IDEAL
BRAND NEW LASER VISION CORRECTION PROCEDURE
SMILE IS NOT FLAPLESS LASIK, IT IS A BRAND NEW PROCEDURE
SMILE Limitations

1. Vision recovery is a bit slower than LASIK
2. Final visual outcomes on par with LASIK
3. No eye tracking technology – NOT NEEDED
4. No centration technology – NOT NEEDED
5. Tissue removal on par with LASIK
6. No custom ablation, but aspheric lenticule, so risk of glare on par with LASIK – NOT FOR ABERRATED CORNEAS

SMILE Limitations

8. No hyperopia capabilities as yet – EARLY STUDIES
9. No presbyopia capabilities as yet
10. Retreatment may be performed using LASIK

SMILE Superiority

1. Less dry eyes than LASIK
2. Less risk with eye injury, eye rubbing or sports
3. Same laser energy and treatment time for -10.00D and -2.00D
4. Same predictability with SMILE for -2.0D and -10.00D
5. Greater biomechanical stability/corneal structural integrity

SMILE expands Refractive Options
SMILE expands but does not replace patient options for refractive surgery
SMILE complements PRK and LASIK, with lots of benefits and some limitations
LASIK requires Femtosecond Laser and Excimer Laser, PRK only an Excimer Laser and SMILE only a Femtosecond Laser
SMILE expands Refractive Options
SMILE like LASIK, preserves the epithelium for excellent post-operative comfort
SMILE like PRK, preserves the biomechanical stability of the anterior stroma
SMILE expands Refractive Options
Visual recovery is faster than PRK but slower than LASIK
Intra-operative comfort is greater with SMILE
Post-operative comfort greater with LASIK and SMILE, perhaps better with SMILE
Study Design & Objective
FDA Study
Study Design & Objectives
VisuMax Study Investigators
Key Inclusion Criteria

- 22+ years of age
- MYOPIA from ≥ -1.00 D to ≤ -10.00 D; with ≤ -0.50 D cylinder and MRSE ≤ -10.25 D
- STABLE REFRACTION FOR THE PAST 12 MONTHS
- UCVA < 20/40
- BSCVA at least 20/20
- CENTRAL THICKNESS > 500 microns

Key Exclusion Criteria

- MESOPIC PUPIL DIAMETER > 8.0 mm
- Cylinder > -0.50 D
- STROMAL BED UNDER CAP OF <250 MICRONS
- UNRESOLVED DRY EYES
- PREVIOUS INTRAOCULAR SURGERY OR CORNEAL SURGERY

Preoperative Refraction Parameters
FDA Study
Effectiveness: Post-Operative UCVA
FDA Study
Refractive Stability: Mean Change in MRSE
Refractive Predictability
High MRSE Predictability at 6 Months
FDA Study
Refractive Stability: Predicted MRSE at 6 mo.
High MRSE Predictability at 12 Months
FDA Study
Refractive Stability: Predicted MRSE at 12 mo.
FDA Study
Patients with Post-op UCVA ≥ Pre-op BSCVA
My two cents on SMILE
I still give a slight edge to Custom All Laser LASIK, but there are definitely patients that are better served with SMILE
I think it is an amazing procedure, superior to PRK and it is rapidly evolving and improving
Many patients standing on the sidelines will choose SMILE – No cut, no flap, less dry eyes, structurally intact eye
My two cents on SMILE
I have no hesitation to treat anyone with SMILE rather than LASIK today, not a year ago, but today
In the past decade 1 million SMILE procedures have been performed, that is, the worldwide volume has doubled in the past year
This growth rate is faster than any other refractive procedure including LASIK
ReLEx SMILE
FDA Approved Indications
Indications for Use:
Reduction or elimination of myopia -1.00 D to -8.00D (-8.01 D to -10.0 D will trigger a flagged warning), with ≤ -0.50D cylinder and MRSE -8.25D in the eye to be treated in patients who are 22 years of age or older with documentation of stable manifest refraction over the past year.
ReLEx SMILE
Difference Between U.S. and O.U.S.
U.S. Indications
Sphere: -1.00 to -8.00 D (-8.01 D to
-10.0 D will trigger a flagged warning)
Cylinder: Not FDA approved. Must have ≤ 0.5 D of residual cylinder
MRSE: -8.25 D

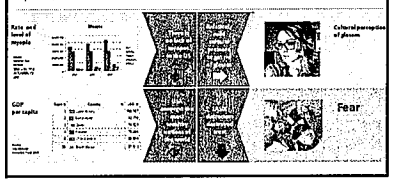
ReLEx SMILE
Difference Between U.S. and O.U.S.
U.S. Parameters
ReLEx SMILE
Difference Between U.S. and O.U.S.
U.S. Parameters
Incision size = 90 degrees (~6mm)
Incision orientation = superior
Optical Zone = 6.0 – 6.5mm
Spot separation = 3.0um
ReLEx SMILE
Efforts to Expand U.S. Treatment Ranges / Parameters
ZEISS VisuMax® Spherocylindrical SMILE Study
ReLEx SMILE
Efforts to Expand U.S. Treatment Ranges / Parameters
Military Study
ReLEx SMILE
Quickly Gaining Popularity OUS
ReLEx SMILE
China a predictor of US market with VisuMax and SMILE?
ZEISS ReLEx SMILE grew refractive procedures by more than 200% on average per ZEISS VisuMax laser over a 5-year period in China.
ReLEx SMILE
By the Numbers
VisuMax Femtosecond System
Designed for Corneal Laser Surgery
Technical Benefits
High-precision flaps and corneal incision due to high performance femtosecond (500,000 Hz) technology
Widely adjustable flap diameter, thickness, hinge position, side cut angle
Easy repositioning of the flap (dock, re-dock)
Only femtosecond laser that can perform ReLEx® SMILE
Thank You!
WHAT ABOUT PATIENTS WITH DISTORTED CORENAS
CONTOURA
TOPOGRAPHY GUIDED LASIK
Zernike Pyramid - Low Order Aberrations Sphere and Cylinder
High Order Aberrations to 6th Order are Measured and Treated with Contoura Vision (see slide 12)
Image Validation – Registration Data
Image Validation – Reproducibility Check
Maps 1 and 2 compare well (0.75 Diopters difference or less)
Treatment Planning – Step 2
Analyzed Area
Treatment Planning – Step 4
Higher Order Aberrations *(HOA'S)*

NVISION
EYE CENTERS

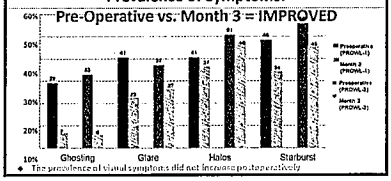
Additional Treatment Planning
Comparing Treatments
43 Y/O FEMALE
CONTACT LENS RELATED CORNEAL ULCER – PARACENTRAL SCAR
PRE OP BCVA 20/30
OD -2.50-1.50X20
35 Y/O female
Pre Op – OD -6.75-1.25X180 20/20
OS -6.50-2.00X170 20/20
Post Op UCVA – 20/15 OU
Ghosting of images
PRE ENHANCEMENT
13 MONTHS LATER
UCVA 20/15 OU
GHOSTING OF IMAGES

ZEISS ReLEx SMILE (SMALL INCISION LENTICULE EXTRACTION)
Minimally Invasive LVC for Myopia Correction

U.S. LVC Market
Key Market Drivers

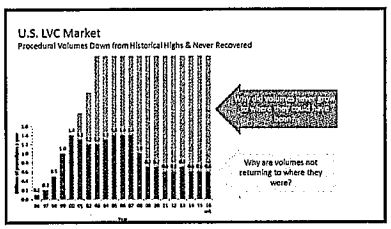


Prevalence of Symptoms:
Pre-Operative vs. Month 3 = IMPROVED



- The prevalence of visual symptoms did not increase postoperatively

U.S. LVC Market
Procedural Volumes Down from Historical Highs & Never Recovered

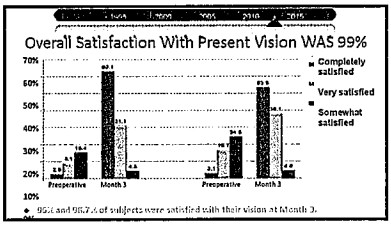


REFRACTIVE SURGEONS HAVING LASIK

5X MORE LIKELY – 65%

95% OPERATED ON A FAMILY MEMBER

Overall Satisfaction With Present Vision WAS 99%



- 99.6 and 99.7 % of subjects were satisfied with their vision at Month 3.

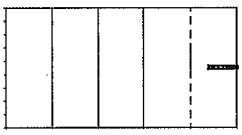
LASIK IS THE SAFEST ELECTIVE PROCEDURE WITH THE HIGHEST PATIENT SATISFACTION IN THE WORLD TODAY

3 Month Uncorrected Visual Acuity Outcomes

	PROWL-1 N=225	PROWL-2 N=270
UCVA 20/20 or better		
OU	99%	96%

- No enhancements performed

Cosmetic Procedures and Patient Satisfaction Rates

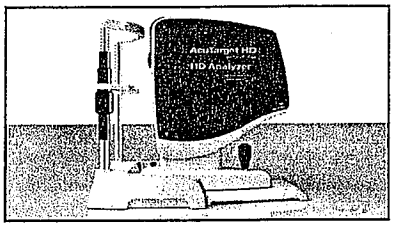


Percentage of Patients Satisfied with the Procedure

LASIK FACTS

DRY EYE TYPICALLY RESOLVES

Tear Lab



LASIK FACTS

NO DRY EYE PRE OP = NONE POST-OP

InflammaDry

MMP-9

LipiView

Gland Imaging

LASIK FACTS

ONLY PATIENTS WITH DRY EYES PRE-OP, MAY DEVELOP DRY EYES POST-OP

LipiView

Gland Imaging

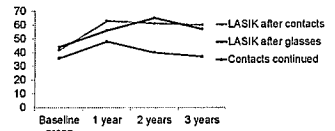
CTL

SINGLE LARGEST RISK FACTOR FOR MICROBIAL KERATITIS

CTL RELATED INFECTIONS

1,000,000 VISITS ANNUALLY
4% OF ER VISITS

LASIK improved ease of night driving

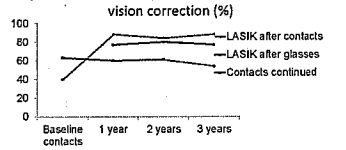


Price et al. Ophthalmology 2016;123:1659 - 66

POST OP MEAN SPHERE

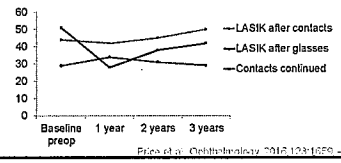
-0.08 +/- 0.24D
68.2% +/- 0.24D
95.4% +/- 0.48D

Proportion that strongly recommended their current vision correction (%)



Price et al. Ophthalmology 2016;123:1659 - 66

LASIK did not increase dry eyes relative to baseline CL use

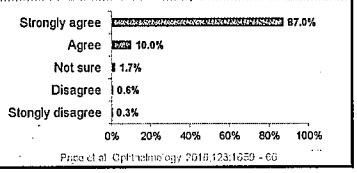


Price et al. Ophthalmology 2016;123:1659 - 66

POST OP MEAN CYLINDER

0.17D +/- 0.21D

Former CL wearers who had LASIK were asked: "Does LASIK work better for you than contacts?"



Price et al. Ophthalmology 2016;123:1659 - 66

LASIK – MY OUTCOMES

UCVA 20/20 = 95.1%
BINOCULAR UCVA 20/20 = 99%

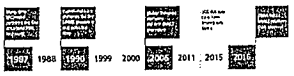
POST-OP MEAN UCVA

20/17.4 +/- 0.6

U.S. LVC Market
Impact of ReLEx SMILE

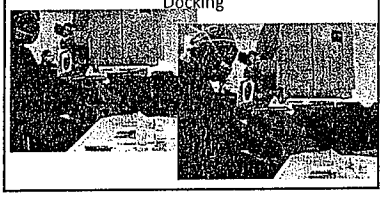
ZEISS ReLEx SMILE will (hopefully!) grow LVC market

- First major innovation in U.S. LVC market in 16-years (Femto-LASIK in 2000)
- New LVC option for refractive surgeon to offer patients fearful of LASIK and those waiting for the "next thing"
- Unlike PRK and LASIK, SMILE developed in Europe and so arrives in U.S. as proven technology; 600,000+ procedures performed internationally, to bolster physician and patient confidence as proven technology

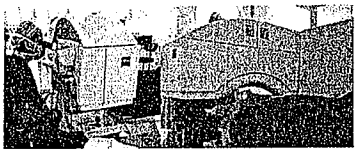


1988 1999 2000 2011 2015

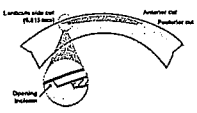
Docking



Extremely Comfortable



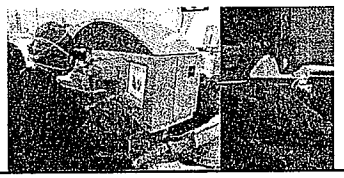
ReLEx SMILE
Procedure Step-by-Step



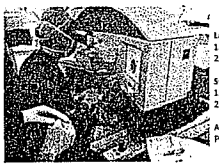
Series of lamellar resections

- 1st lamellar cut defines posterior surface of lenticule
- 1st side cut defines lenticule diameter
- 2nd lamellar cut defines anterior surface of lenticule/posterior surface of attached cap
- 2nd side cut creates incision for removal of lenticule

Centration on Visual Axis



Dissection of Lamellar Planes



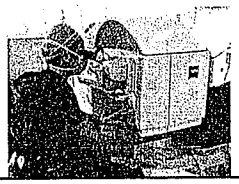
Laser Cuts:
1. Posterior Refractive Plane first
2. Anterior Lamellar Plane last

Surgeon Dissection:
1. Anterior Lamellar Plane first
2. Posterior Refractive Plane last

Anterior Plane 7.5mm
Posterior Plane 6.5mm

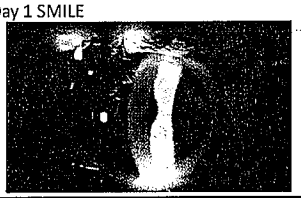
Understanding SMILE

Low Suction Pressure

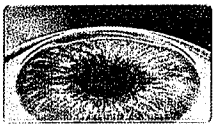


And at the end...a smile

Day 1 SMILE

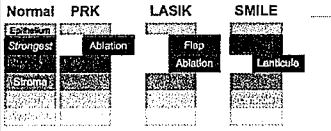


ReLEx SMILE – POTENTIAL BENEFITS



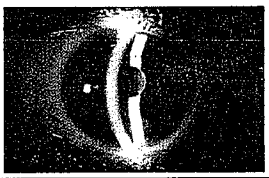
- 80% SMALLER SIDE CUT
- 30% SMALLER CAP CUT
- UPPER CORNEAL LAYERS REMAIN INTACT
- SMALL INCISION – FEWER TRANSECTED NERVES = LESS DRY EYES

Biomechanical Advantages of SMILE



Conclusion 2: Even if SMILE needs more tissue, it ***still*** leaves the cornea stronger than LASIK

Day 1 SMILE Fellow eye



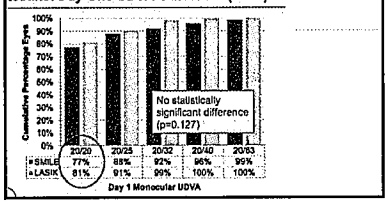
SMILE – POTENTIAL BENEFITS

- 80% smaller side cut – less transected nerves, less dry eyes
- Anterior lamellae of cornea preserved, including bowman's layer - better structural integrity
- No flap to dislodge
- Minimally invasive – flapless surgery

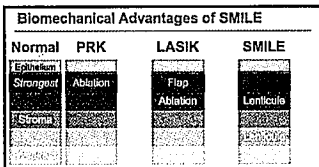
SMILE – PATIENT PERCEPTION

- LESS INVASIVE
- FOR PATIENTS WHO ARE AFRAID OF LASIK
- FOR PATIENTS WITH DRY EYES
- CTL FAILURES – IDEAL
- BRAND NEW LASER VISION CORRECTION PROCEDURE
- SMILE IS NOT FLAPLESS LASIK, IT IS A BRAND NEW PROCEDURE

Results: Day One UDVA Outcomes (n=75)



Biomechanical Advantages of SMILE



Conclusion: Can use larger optical zones and ***still*** leave the cornea stronger than LASIK

SMILE Limitations

1. Vision recovery is a bit slower than LASIK
2. Final visual outcomes on par with LASIK
3. No eye tracking technology – NOT NEEDED
4. No centration technology – NOT NEEDED
5. Tissue removal on par with LASIK
6. No custom ablation, but aspheric lenticule, so risk of glare on par with LASIK – NOT FOR ABERRATED CORNEAS

SMILE Limitations

8. No hyperopia capabilities as yet – EARLY STUDIES
9. No presbyopia capabilities as yet
10. Retreatment may be performed using LASIK

SMILE expands Refractive Options

- SMILE like LASIK, preserves the epithelium for excellent post-operative comfort
- SMILE like PRK, preserves the biomechanical stability of the anterior stroma

FDA Study

Study Design & Objectives

Design & Objectives

- Prospective, multi-center, open label, single-arm study
- Proposed sample size: 360 subjects
- Unilateral treatment with 12-month follow-up period
- Fellow eye treatment with approved laser procedure (clinical data not part of pivotal study)
- Objective: to evaluate the safety and effectiveness of the VisuMax Femtosecond Laser lenticule removal procedure for the reduction or elimination of myopia from ≥ -1.00 D to ≤ -10.00 D with ≤ -0.50 D cylinder and MRSE ≤ -10.25 D (subjects with ≤ -0.50 D cylinder were enrolled, but the cylinder was not treated as part of the clinical trial)

SMILE Superiority

1. Less dry eyes than LASIK
2. Less risk with eye injury, eye rubbing or sports
3. Same laser energy and treatment time for -10.00D and -2.00D
4. Same predictability with SMILE for -2.0D and -10.00D
5. Greater biomechanical stability/corneal structural integrity

SMILE expands Refractive Options

- Visual recovery is faster than PRK but slower than LASIK
- Intra-operative comfort is greater with SMILE
- Post-operative comfort greater with LASIK and SMILE, perhaps better with SMILE

VisuMax Study Investigators

Jon Dishler, M.D.	Dishler Laser Institute	Dishler Laser Institute
John Doane, M.D.	Discover Vision Centers	Leawood, KS
Vance Thompson, M.D.	Vance Thompson Vision	Sioux Falls, SD
William Culbertson, M.D. Sonia You, M.D.	Bascom Palmer Eye Institute	Miami, FL
John Vukich, M.D.	Davis Duehr Dean	Madison, WI

SMILE expands Refractive Options

- SMILE expands but does not replace patient options for refractive surgery
- SMILE complements PRK and LASIK, with lots of benefits and some limitations
- LASIK requires Femtosecond Laser and Excimer Laser, PRK only an Excimer Laser and SMILE only a Femtosecond Laser

Study Design & Objective

- Prospective, multi-center, open-label, single arm study
- 336 eyes treated
- 5 U.S. sites
- Unilateral treatment with 12-month follow-up
- Fellow eye had Lasik
- Up to -10D of myopia and less than 0.50D Cylinder

Key Inclusion Criteria

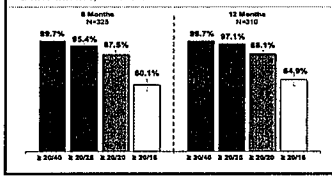
- 22+ years of age
- MYOPIA from ≥ -1.00 D to ≤ -10.00 D, with ≤ -0.50 D cylinder and MRSE ≤ -10.25 D
- STABLE REFRACTION FOR THE PAST 12 MONTHS
- UCVA < 20/40
- BSCVA at least 20/20
- CENTRAL THICKNESS > 500 microns

Key Exclusion Criteria

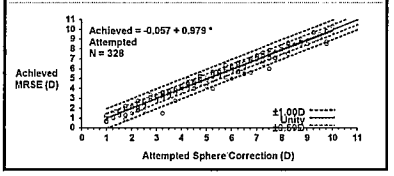
- MESOPIC PUPIL DIAMETER > 8.0 mm
- Cylinder > -0.50 D
- STROMAL BED UNDER CAP OF <250 MICRONS
- UNRESOLVED DRY EYES
- PREVIOUS INTRAOCULAR SURGERY OR CORNEAL SURGERY

FDA Study

Effectiveness: Post-Operative UCVA



High MRSE Predictability at 6 Months



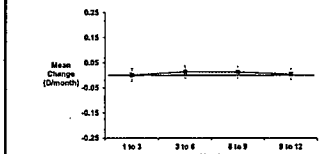
Preoperative Characteristics

Baseline Demographics	N=336	Percent
Female	196	58.3%
Race		
White	309	92.0%
Black	10	3.0%
Other	17	5.1%

Other Characteristics	Mean	Range
Age (years)	33.3	22 to 58
Baseline MRSE (D)	-4.86	-1.00 to -10.25
Baseline MRSPH (D)	-4.76	-1.00 to -10.00
Baseline Cylinder (D)*	-0.19	0 to -0.50

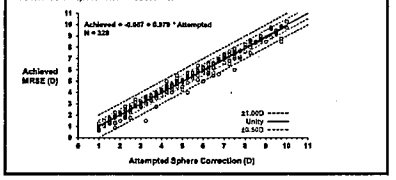
FDA Study

Refractive Stability: Mean Change in MRSE



FDA Study

Refractive Stability: Predicted MRSE at 6 mo.



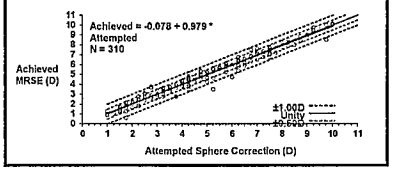
Preoperative Refraction Parameters

	All Treated Eyes	
Manifest Refraction Sphere (D)	n	%
-1.00 to -2.00	39	11.6%
-2.01 to -3.00	54	16.1%
-3.01 to -4.00	50	14.9%
-4.01 to -5.00	50	14.9%
-5.01 to -6.00	43	12.8%
-6.01 to -7.00	44	13.1%
-7.01 to -8.00	29	8.6%
-8.01 to -9.00	15	4.5%
-9.01 to -10.0	12	3.6%
Mean	-4.76	

Refractive Predictability

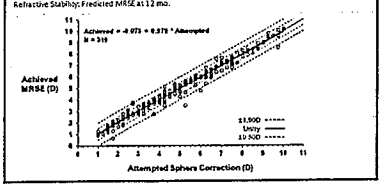
	Month 6 N=325		Month 12 N=310	
MRSE Attempted vs. Achieved	n	%	n	%
±0.50D	305	93.8%	291	93.9%
±1.00D	323	98.5%	306	99.6%

High MRSE Predictability at 12 Months



FDA Study

Refractive Stability: Predicted MRSE at 12 mo.



Summary: Excellent Outcomes

UCVA at Point of Stability (6 months)

- 99.7% ≥ 20/40
- 95% ≥ 20/25
- 88% ≥ 20/20
- 70% had UCVA better than or equal to pre-op BSCVA

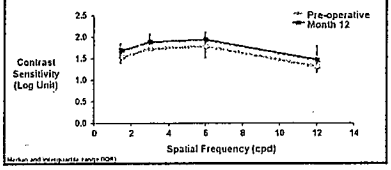
MRSE Predictability

- 98.5% had MRSE within ± 1.00D
- 93% had MRSE within ± 0.50D

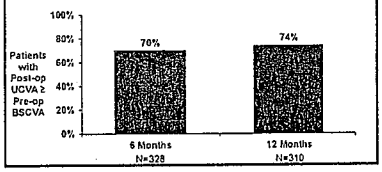
MRSE Stability

- Achieved at 3 to 6 month interval

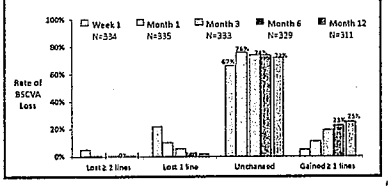
Mesopic Contrast Sensitivity Remains Unchanged at All Study Visits



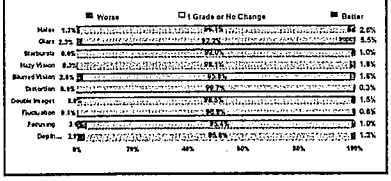
Patients with Postoperative UCVA ≥ Preoperative BSCVA



BSCVA Loss

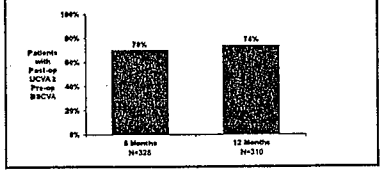


Change in Visual Symptoms at 12 Months



FDA Study

Patients with Post-op UCVA ≥ Pre-op BSCVA



No Incidence of Induced Manifest Refractive Astigmatism

- Percentage of eyes with induced manifest refractive cylinder > 2.00D at point of stability
  - No eye presented with increase in cylinder > 2.00D at any postoperative visit

OSDI: Ocular Symptoms and Discomfort at 12 Months

	Worse (↑ ≥ 2 Grades)		No Change or ± 1 Grade		Better (↓ ≥ 2 Grades)	
	n	%	n	%	n	%
Ocular Symptoms (N=309)						
Experienced symptoms during last week	8	3%	286	93%	14	5%
Environmental triggers (N=288)						
Felt uncomfortable in environmental situations during last week[1]	9	3%	263	90%	17	6%

Have Refractive Surgery Again?

Response	Month 12* N=309	
	n	%
Yes	295	96%
No	2	<1%
Maybe	12	4%

Summary: Excellent Safety Outcomes

- No study eye with BSCVA worse than 20/40 beyond Week 1
- No study eye with increased astigmatism > 2.0D
- No unanticipated adverse device effects (UADE)
- 8 eyes with BSCVA loss ≥ 2 lines at Month 1 or later
  - All resolved by subsequent visit
- 14 patients with reported AEs
  - 13 patients completed study with UCVA ≥ 20/20
  - 1 patient with UCVA of 20/25 at study completion

ReLEx SMILE

FDA Approved Indications

Indications for Use:

Reduction or elimination of myopia -1.00 D to -8.00D (-8.01 D to -10.0 D will trigger a flagged warning), with ≤ -0.50D cylinder and MRSE -8.25D in the eye to be treated in patients who are 22 years of age or older with documentation of stable manifest refraction over the past year.

Satisfied with Refractive Surgery?

	Month 6 N=329		Month 12* N=309	
	n	%	n	%
Very Satisfied	292	89%	286	93%
Moderately Satisfied	30	9%	18	6%
Neutral	4	1%	2	<1%
Dissatisfied	2	<1%	3	1%
Very Dissatisfied	1	<1%	0	0%

My two cents on SMILE

- I still give a slight edge to Custom All Laser LASIK, but there are definitely patients that are better served with SMILE
- I think it is an amazing procedure, superior to PRK and it is rapidly evolving and improving
- Many patients standing on the sidelines will choose SMILE – No cut, no flap, less dry eyes, structurally intact eye

ReLEx SMILE

Difference Between U.S. and O.U.S.

U.S. Indications

- Sphere: -1.00 to -8.00 D (-8.01 D to -10.0 D will trigger a flagged warning)
- Cylinder: Not FDA approved. Must have ≤ 0.5 D of residual cylinder
- MRSE: -8.25 D

O.U.S. Indications

- Sphere: -0.50 to -10.00 D
- Cylinder: 0 to 5.00 D
- Spherical equivalent: -0.50 to -12.50 D

Intraoperative Ocular AE

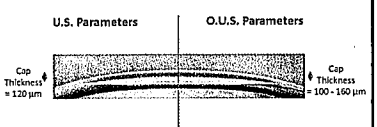
- 5 events (n=5 patients)
  - Cap perforation (n=1)
  - Difficult lenticule removal with tissue damage (n=2)
  - Retained tissue following lenticule removal (n=2)
- Only 1 persisted beyond 1-week visit
- All patients completed study with UCVA 20/16 or better

My two cents on SMILE

- I have no hesitation to treat anyone with SMILE rather than LASIK today, not a year ago, but today
- In the past decade 1 million SMILE procedures have been performed, that is, the worldwide volume has doubled in the past year
- This growth rate is faster than any other refractive procedure including LASIK

ReLEx SMILE

Difference Between U.S. and O.U.S.

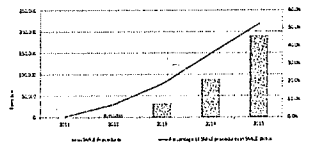


ReLEx SMILE
Difference Between U.S. and O.U.S.

U.S. Parameters
- Incision size = 90 degrees (~6mm)
- Incision orientation = superior
- Optical Zone = 6.0 – 6.5mm
- Spot separation = 3.0um

O.U.S. Parameters
- Incision size = 2+ mm
- Incision orientation = arbitrary
- Optical Zone = 5.5 – 7.5mm
- Spot separation = 3.0 – 4.5um

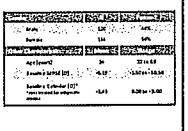
ReLEx SMILE
Quickly Gaining Popularity OUS



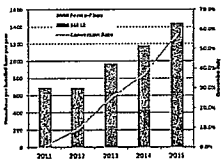
VisuMax Femtosecond System
Designed for Corneal Laser Surgery

Technical Benefits
- High-precision flaps and corneal incision due to high performance femtosecond (500,000Hz) technology
- Widely adjustable flap diameter, thickness, hinge position, side cut angle
- Easy repositioning of the flap (dock, re-dock)
- Only femtosecond laser that can perform ReLEx® SMILE

ReLEx SMILE
Efforts to Expand U.S. Treatment Ranges / Parameters



ReLEx SMILE
China a predictor of US market with VisuMax and SMILE?



ZEISS ReLEx SMILE grew refractive procedures by more than 200% on average per ZEISS VisuMax laser over a 5-year period in China.

Thank You!

Image (Head Shot or Institution Image)

<SPEAKER>
<Title>
<Institution>
<City, State>

<website>

ReLEx SMILE
Efforts to Expand U.S. Treatment Ranges / Parameters

Military Study

University Study

ReLEx SMILE
By the Numbers

More than	More than	More than	More than
600	1,000	62	700,000+
clinics worldwide	practicing surgeons	countries	ReLEx SMILE procedures

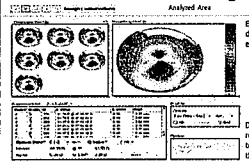
WHAT ABOUT PATIENTS WITH DISTORTED CORENAS

CONTOURA

TOPOGRAPHY GUIDED LASIK

Zernike Pyramid - Low Order Aberrations Sphere and Cylinder High Order Aberrations to 6th Order are Measured and Treated with Contoura Vision (see slide 12)

Treatment Planning – Step 2



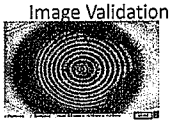
Exams supplying less then 80% data (at the OZ chosen), are excluded by the algorithm.

Decreasing the optical zone, might result in passing the 90% criteria to include more examinations to the calculation

43 Y/O FEMALE
CONTACT LENS RELATED CORNEAL ULCER – PARACENTRAL SCAR

PRE OP BCVA 20/30
OD -2.50-1.50X20

Image Validation – Registration Data

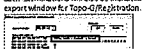


An examination is marked with ■ in the lower right corner of the camera image if validation criteria for registration are met.

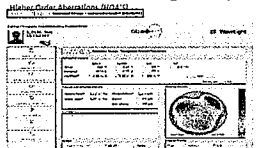
Minimum criteria for registration data are:
- Limbus information
- Pupil data within a certain range
- Iris landmark detection (iris image quality)

An examination is marked with ■ the lower right corner of the camera image if validation criteria for registration are not met.
Such examinations will also be indicated in the export window for Topo-G/Registration.

Click on ... display the Optical Zone Analysis Screen for additional information.



Treatment Planning – Step 4



Tilt off and sphere/cylinder set to "0" will show the ablation profile correcting the higher order aberration only (hot spot test).

"Reset" sets "Modified" back to clinical refraction

Removing the Modified Sphere and Cylinder will demonstrate Max= HOA Maximum Ablation Depth / Cen= HOA Central Ablation Depth of HOA

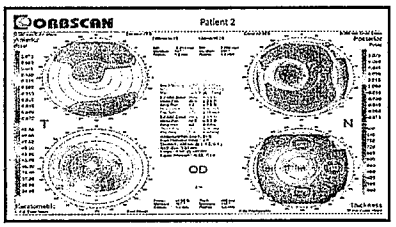
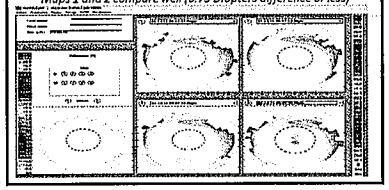
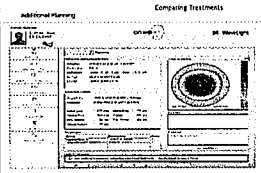


Image Validation – Reproducibility Check
Maps 1 and 2 compare well (0.75 Diopters difference or less)



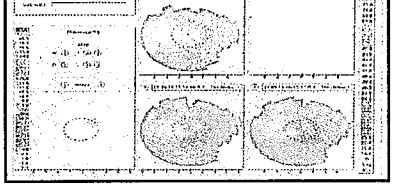
Additional Treatment Planning

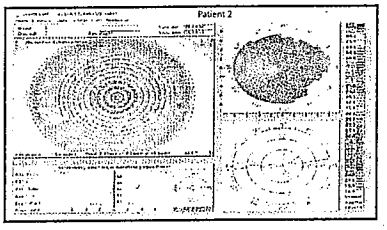


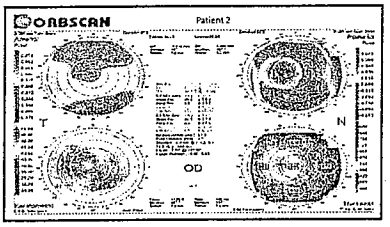
Ablation profiles can be compared

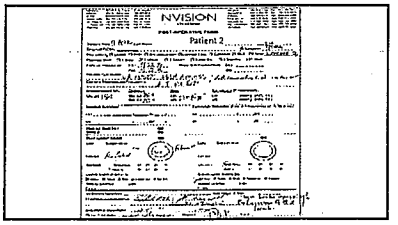
Individually enlarged

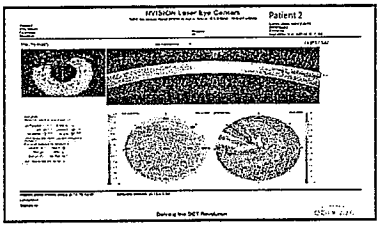
Treatment plans at ablation profile preview can be toggled

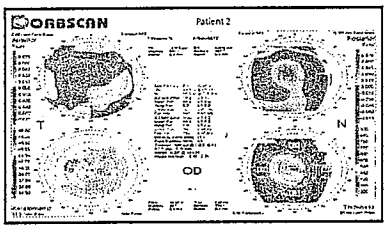






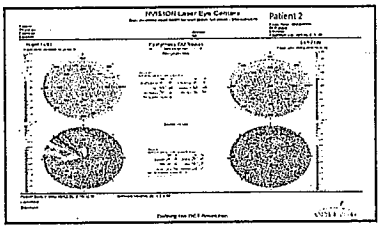


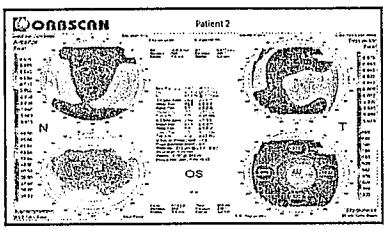




35 Y/O female

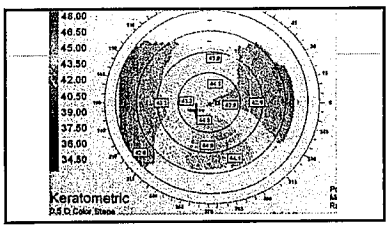
Pre Op – OD -6.75-1.25X180 20/20
OS -6.50-2.00X170 20/20
Post Op UCVA – 20/15 OU
Ghosting of images

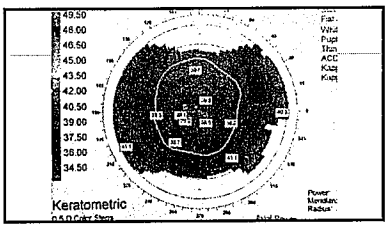


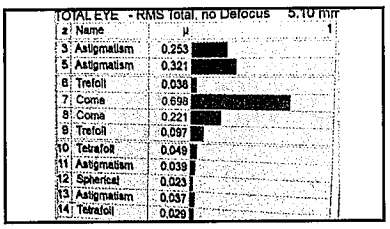


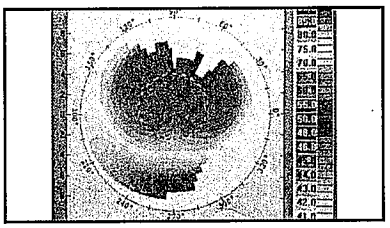
PRE ENHANCEMENT

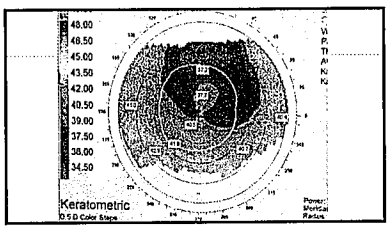
13 MONTHS LATER
UCVA 20/15 OU
GHOSTING OF IMAGES


Keratometric


Keratometric


TOTAL EYE - RMS total, no Defocus 5.10 mm
z Name μ 1
3 Astigmatism 0.253
5 Astigmatism 0.321
6 Trefoil 0.036
7 Coma 0.698
8 Coma 0.221
9 Trefoil 0.097
10 Tetrafoil 0.049
11 Astigmatism 0.039
12 Spherical 0.023
13 Astigmatism 0.037
14 Tetrafoil 0.029

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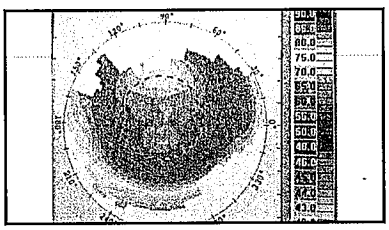
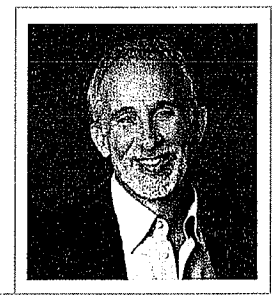


NVISION
LASER EYE CENTERS | THE EYE DOCTORS' #1 CHOICE



Dr. Tom Tooma

Medical Director NVISION Laser Eye Centers

Dr. Tooma has performed more than 100,000 LASIK procedures and believes that laser vision correction at NVISION is as safe as it can be. In fact, he has performed LASIK surgery on hundreds of doctors, including 250 eye doctors. That's why NVISION and Dr. Tooma are The Eye Doctors' #1 Choice for their eyes and their patients' eyes. Dr. Tooma believes that the combination of experience and technology gives NVISIONS's patients the highest possible likelihood of achieving 20/20 or better vision through LASIK procedures.

A pioneer in the world of LASIK surgery, Dr. Tooma has been a principal investigator in the field of laser vision correction since 1993. He helped several excimer laser manufacturers obtain FDA approvals for their lasers in the United States. He holds the record for many firsts: he was the first doctor in California to perform LASIK surgery and was the first to perform custom Wavefront-guided LASIK. He was also the first in the U.S. to use the FemtoSecond Laser (IntraLase FS30 – bladeless all laser LASIK), which is safer and more precise than a traditional blade.

In 2010, Dr. Tooma purchased TLC's interest in the 8 Southern California locations and formed NVISION Laser Eye Centers. At NVISION, Dr. Tooma provides his patients with a lifetime commitment, giving them the assurance that if they need any enhancement surgeries in the future, they can be performed at any NVISION center, for life and at no cost.

Dr. Tooma received his M.D. from Loma Linda University School of Medicine, where he also completed his internship in internal medicine and residency in ophthalmology. He completed his fellowship in Corneal and Refractive Surgery at the Emory University Department of Ophthalmology in Atlanta, Georgia. He has been board certified in ophthalmology for more than 25 years.

For Dr. Tooma, helping patients achieve their vision goals is his passion. "I feel privileged and blessed to participate in what is a life-changing experience for my patients," he said.

In his spare time, Dr. Tooma has served on medical teaching missions to Romania, Bulgaria, China and Fiji, helping teach local ophthalmology doctors new surgical techniques. In 2008, he and his wife, Marta Tooma, D.D.S., founded the Mission at Natuvu Creek in Fiji. The Mission serves the 250,000 people living on the island, with medical, dental and eye care provided by visiting physicians, including the Toomas.

1-877-91-NVISION | NVISIONCenters.com

Biography

Education

1975 B.S. in Biochemistry, Magna Cum Laude, Loma Linda University
1979 M.D., Loma Linda University School of Medicine

Professional Training

1980 Internship in internal medicine, Loma Linda University Medical Center
1983 Completed a residency in ophthalmology, Loma Linda University Department of Ophthalmology

Fellowships

1984 Fellow in Corneal Surgery & External Disease, Emory University Department of Ophthalmology, Atlanta, GA

Board Certification

1984 American Board of Ophthalmology

Professional Affiliations

- American Society of Cataract & Refractive Surgery
- International Society of Refractive Surgery
- Castroviejo Corneal Society
- American Academy of Ophthalmology
- And many others

University & Hospital Positions

- Chief, Department of Ophthalmology, Loma Linda University Community Hospital
- Director of Cornea Service, Department of Ophthalmology, Loma Linda University
- Director of Refractive Surgery, Department of Ophthalmology, Loma Linda University

MEDICAL BOARD OF CALIFORNIA

Executive Office

January 31, 2011

Tom S. Tooma, M.D.
3501 S. Jamboree Road, Suite 1100
Newport Beach, CA 92660

RE: Physician's and Surgeon's Certificate No. G 42262
Case No. 04-2008-195312

Public Letter of Reprimand

An investigation by the Medical Board of California revealed you failed to document a pre-operative examination and develop a surgical plan before meeting with a patient.

These actions constitute a violation of Business and Professions Code 2266.

Pursuant to the authority of the California Business and Professions Code section 2233, you are hereby issued this Public Letter of Reprimand by the Medical Board of California.

Linda K. Whitney
Executive Director

2005 Evergreen Street, Suite 1200, Sacramento, CA 95815-3831 • (916) 263-2520 • FAX: (916) 263-2473 • www.mbc.ca.gov