

Journal of Refractive Surgery®

JULY 2009
Volume 25 (Suppl) • Number 7
journalofrefrativesurgery.com



Clinical Outcomes and Quality of Care in Refractive Surgery

Sponsored as an educational
service by Optical Express

Published for the Society by **SLACK**
INCORPORATED
SUPPLEMENT TO THE JULY 2009 ISSUE OF THE
JOURNAL OF REFRACTIVE SURGERY



International Society of
Refractive Surgery of the
American Academy of
Ophthalmology

Europe's No.1 provider of laser eye surgery.

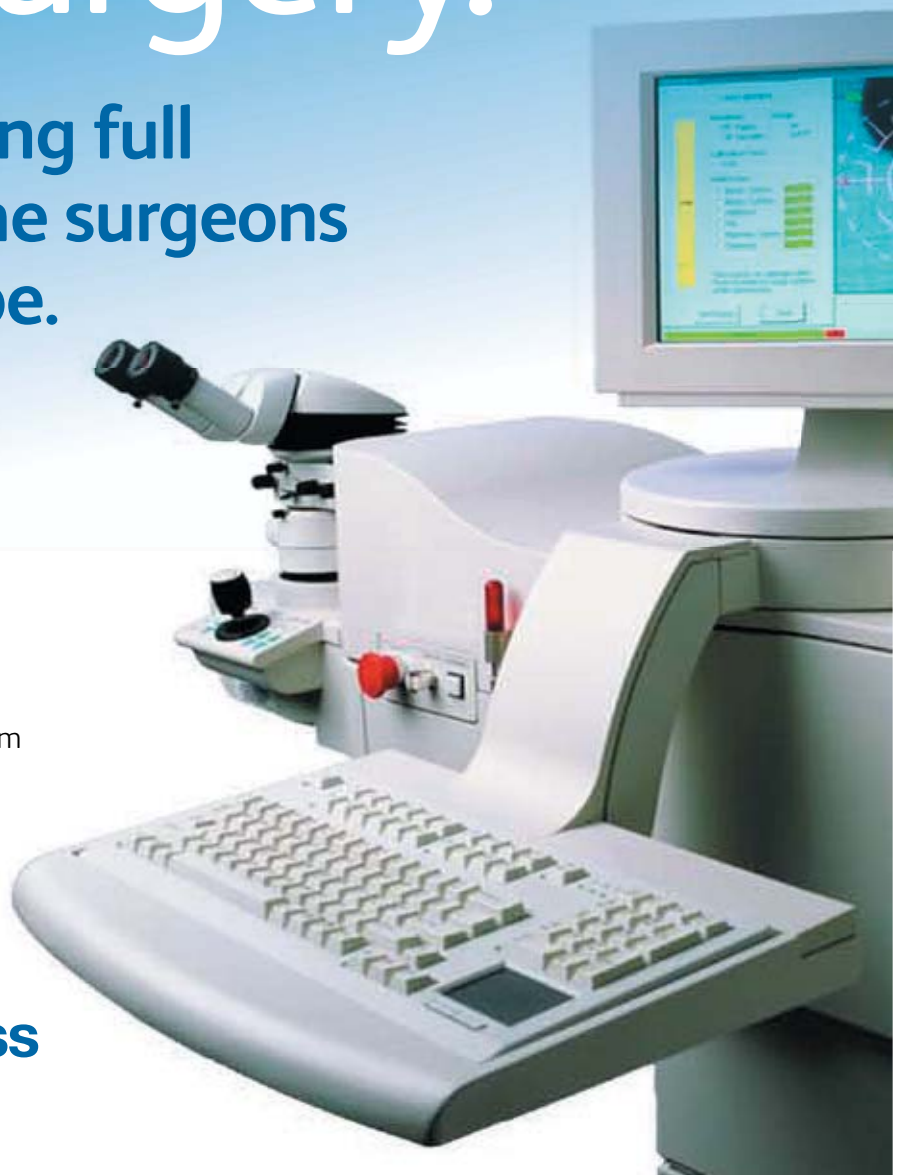
Now recruiting full
and part-time surgeons
across Europe.

To apply, call David Carson
on +44 (0)1236 723300
or +44 (0)7771 930423.
Alternatively e-mail:
davidcarson@opticalexpress.com
or write to Optical Express,
5 Deerdykes Road, Westfield,
Cumbernauld, G68 9HF,
United Kingdom.

Optical Express

Vision For A Better Life

www.opticalexpress.com



JULY 2009

Volume 25 (Suppl) • Number 7



Official Journal of the ISRS/AAO

Journal of Refractive Surgery®



ISRS | AAO

International Society of
Refractive Surgery of the
American Academy of
Ophthalmology

Clinical Outcomes and Quality of Care in Refractive Surgery

Steven C. Schallhorn, MD, Guest Editor

INTRODUCTION

S632 Optical Express: Its Growth and Role in the Future of Refractive Surgery

David Mouldsdale

ARTICLES

S634 One-month Outcomes of Wavefront-guided LASIK for Low to Moderate Myopia With the VISX STAR S4 Laser in 32,569 Eyes

Steven C. Schallhorn, MD; Jan A. Venter, MD

S642 Satisfaction of 13,655 Patients With Laser Vision Correction at 1 Month After Surgery

Mitchell C. Brown, OD; Steven C. Schallhorn, MD; Keith A. Hettinger, MS, MBA; Stephanie E. Malady, BS

S647 Using an International Medical Advisory Board to Guide Clinical Governance in a Corporate Refractive Surgery Model

John A. Vukich, MD

S651 The Role of Biostatistics in the Quality Improvement of Refractive Surgery

Keith A. Hettinger, MS, MBA

S655 A Complex Case Management System Provides Optimal Care for All Patients

Jan A. Venter, MD; Stephen J. Hannan, MCOptom

S661 An Evidence-based Approach to Patient Selection for Laser Vision Correction

Mitchell C. Brown, OD

S668 Femtosecond Laser Versus Mechanical Microkeratome: A Retrospective Comparison of Visual Outcomes at 3 Months

Mesha Tanna, BSc(Hons), MCOptom; Steven C. Schallhorn, MD; Keith A. Hettinger, MS, MBA

S672 Effect of Keratometry on Visual Outcomes 1 Month After Hyperopic LASIK

Jill J. Young, BSc(Hons), MCOptom; Steven C. Schallhorn, MD; Mitchell C. Brown, OD; Keith A. Hettinger, MS, MBA



“Miradas del Alma”
(“Gazes from the Soul”)

150×100 cm, watercolor
 Lola Catalá Sanz

Lola Catalá Sanz is a senior artist with a long-standing, professional career. Following an extensive artistic education, she has experimented with different techniques, specifically watercolors and etching. Most of her artwork has been produced using watercolors. She has received a number of national awards, and her work is included in several private collections and museums in Spain.

In this symbolic painting, children are looking at a landscape full of wonders. They use devices, such as magnifying glasses and telescopes, to change their perception of the fantastic surroundings. The light enhances the environment and creates the enjoyment of sight. The naive souls of the children play with the light. In these magical surroundings, one child hides from the light, not seeing the wonders it provides, symbolizing blindness. The sight of the soul varies, as perspectives and understanding differ among human beings.

Description by Jorge L. Alió

The “Miradas” competition was created by Jorge Alió, Journal of Refractive Surgery Editorial Board Member, and his wife, María Lopez, in 1998 with the intention of using artistic sensibility to bring society’s attention to the phenomenon of sight, vision, and blindness. “Miradas,” which means sight, is a contest in which artists from Spain and several Latin American countries submit paintings dealing with the topic of sight and the prevention of blindness. Each cover of the Journal of Refractive Surgery features paintings that were submitted to this competition. “Miradas” is partially supported by AMO.

Journal of Refractive Surgery®

SLACK Incorporated

EDITORIAL

Editorial Director Jennifer A. Kilpatrick, ELS
Executive Editor Aileen M. Wiegand, ELS
Associate Editor Betti Bandura

SALES

National Account Manager Kara Datz
Sales Administrator Ann Marie Randolph-Ferguson
Sales Director, Classified/Recruitment Division Kristy Irwin
Classified/Recruitment Sales Representative Michael Rusch
Director of Reprint Sales John Kain

PUBLISHING

Chief Operating Officer John C. Carter
Vice President John Bond
Marketing Communications Director Michelle Gatt
Production Manager Mike Kearney
Circulation Director Lester J. Robeson, CCCP

The Wyanoke Group

President Peter N. Slack
Executive Vice President Richard N. Roash
Chief Financial Officer Darrell Blood
Senior Vice President Denise Mealey

Mindworks Communications

Publication Design Linda Baker

JOURNAL OF REFRACTIVE SURGERY (ISSN1081-597X; Canadian BN #129780466RT) is published monthly by SLACK Incorporated, 6900 Grove Road, Thorofare, NJ 08086. Telephone 856-848-1000. Fax 856-848-6091.

Copyright 2009 by SLACK Incorporated. All rights reserved. No part of this publication may be reproduced without prior written consent of the publisher. Printed in USA. Permission requests to copy or reuse material published herein should be addressed to publishingpermissions@slackinc.com. For reprint orders and prices, contact John Kain at 856-848-1000. Authorization to photocopy items for internal or personal use, or the internal or personal use of specific clients, is granted by SLACK Incorporated, provided the fee of \$.25 per page per copy is paid directly to Copyright Clearance, 222 Rosewood Drive, Danvers, MA 01923. This consent does not extend to other kinds of copying, such as for general distribution, resale, advertising and promotional purposes, or for creating new collective works.

Subscription rates in the US and possessions: One year-\$229.00; Two years-\$458.00; Three years-\$687.00. Institutional: One year-\$349.00; Two years \$698.00; Three years-\$1,047.00; **Canada:** add 6% GST tax to total subscription price; **Outside US** add \$53.00 each year, delivered by air service. Resident and Fellow rate in the US: \$114.00 (a letter of certification from the institution indicating residency/fellowship of the subscriber is required). Single copies of current issues may be obtained for \$48.00. Subscriptions to the Journal of Refractive Surgery are included in the membership dues for the ISRS. Subscription requests should be addressed to the publisher.

Change of address. Notice should be sent to the publisher six weeks in advance of effective date. Include old and new addresses with zip codes. The publisher cannot accept responsibility for undelivered copies. **Postmaster:** Send change of address to the Journal of Refractive Surgery, 6900 Grove Road, Thorofare, NJ 08086. Periodicals Class Postage paid at Deptford, NJ 08096 and at additional mailing offices.

Responsibility for statements. The publication of advertising in the Journal does not constitute any guarantee or endorsement by the ISRS/AAO, editors, publishers, or editorial boards of SLACK Incorporated of the advertised product or service or of claims made by the advertiser. The publication of articles and other editorial material in the Journal does not represent the policy or recommendations of, or endorsement by, the ISRS/AAO, editors, publishers, or editorial boards of SLACK Incorporated.

SLACK
 INCORPORATED
 6900 GROVE ROAD
 THOROFARE, NJ 08086-9447
 www.slackinc.com



Journal of
**Refractive
Surgery®**



ISRS | AAO

International Society of
Refractive Surgery of the
American Academy of
Ophthalmology

EDITOR-IN-CHIEF

George O. Waring III, MD, FACS, FRCOphth
InView
301 Perimeter Center North
Suite 600
Atlanta, GA 30346
Tel: 678.222.5102
E-mail: drgeorge@georgewaring.com

SENIOR ASSOCIATE EDITOR

Michael C. Knorz, MD
Mannheim, Germany

ASSOCIATE EDITORS

Francesco Carones, MD
Milan, Italy

Maria Regina Chalita, MD
Sao Paulo, Brazil

Daniel Epstein, MD, PhD
Zurich, Switzerland

David Hardten, MD
Minneapolis, Minnesota

J. Bradley Randleman, MD
Atlanta, Georgia

James T. Schwiegerling, PhD
Tucson, Arizona

Jason Stahl, MD
Overland Park, Kansas

Kazuo Tsubota, MD
Tokyo, Japan

SECTION EDITORS

Biomechanics

Dan Z. Reinstein, MD, MA(Cantab), FRCSC
London, United Kingdom

Cynthia Roberts, PhD
Columbus, Ohio

Supplements and Special Sections

Ronald R. Krueger, MD, MSE
Cleveland, Ohio

MANAGING EDITOR

Aileen M. Wiegand, ELs
6900 Grove Road
Thorofare, NJ 08086
Tel: 856.848.1000
Fax: 856.848.6091
E-mail: awiegand@slackinc.com

JRS OSN PAGE EDITOR

Edward E. Manche, MD
Stanford, California

FOUNDING EDITOR

James J. Salz, MD
Los Angeles, California

The Journal of Refractive Surgery
is the official journal of the International Society
of Refractive Surgery of the American Academy
of Ophthalmology (ISRS/AAO)
655 Beach Street
San Francisco, CA 94109
Tel: 415.561.8500; Fax: 415.561.8533;
www.isrs.org

EDITORIAL BOARD

Jorge Alió, MD, PhD
Alicante, Spain

Raymond Applegate, OD, PhD
Houston, Texas

Gordon Balazsi, MD, FRCSC
Quebec, Canada

Edmondo Borasio, MD
Dubai, United Arab Emirates

Wallace Chamon, MD
Sao Paulo, Brazil

Roy S. Chuck, MD, PhD
Baltimore, Maryland

Joseph Colin, MD
Bordeaux Cedex, France

Deepinder Dhaliwal, MD
Pittsburgh, Pennsylvania

Paul J. Dougherty, MD
Camarillo, California

Beatrice Frueh, MD
Bern, Switzerland

Günther Grabner, MD
Salzburg, Austria

Michael Grimmert, MD
Palm Beach Gardens, Florida

Farhad Hafezi, MD, PhD
Zurich, Switzerland

D. Rex Hamilton, MD
Los Angeles, California

Jesper Hjortdal, MD, PhD
Aarhus, Denmark

Jack Holladay, MD
Houston, Texas

W. Bruce Jackson, MD, FRCSC
Ottawa, Ontario, Canada

Stephen C. Kaufman, MD, PhD
Detroit, Michigan

Stephen Klyce, PhD
New Orleans, Louisiana

George D. Kymionis, MD, PhD
Crete, Greece

Keith Liang, MD, FACS
Sacramento, California

Richard L. Lindstrom, MD
Minneapolis, Minnesota

Scott MacRae, MD
Rochester, New York

Parag A. Majmudar, MD
Chicago, Illinois

Robert K. Maloney, MD, MA (Oxon)
Los Angeles, California

Marguerite B. McDonald, MD
Lynbrook, New York

Stephen D. McLeod, MD
San Francisco, California

Erik L. Mertens, MD, FEBO
Antwerp, Belgium

Rajiv R. Mohan, PhD
Columbia, Missouri

Robert Montés-Micó, OD, PhD
Valencia, Spain

Michael Mrochen, PhD
Zurich, Switzerland

Jay Pepose, MD, PhD
Chesterfield, Missouri

Konrad Pesudovs, PhD
Bedford Park, Australia

Roberto Pinelli, MD
Brescia, Italy

Francis Price, MD
Indianapolis, Indiana

Sherman W. Reeves, MD, MPH
Minneapolis, Minnesota

Kimiya Shimizu, MD
Kanagawa, Japan

Raymond F. Stein, MD
Ontario, Canada

R. Doyle Stulting, MD, PhD
Atlanta, Georgia

Ikuko Toda, MD
Tokyo, Japan

Steven E. Wilson, MD
Cleveland, Ohio

ISRS/AAO EXECUTIVE COMMITTEE

Marguerite B. McDonald, MD
Chair
United States

Francesco Carones, MD
Ex-officio
Italy

Joseph Colin, MD
France

Alaa M. El-Danasoury, MD
Saudi Arabia

Michael C. Knorz, MD
Germany

Ronald Krueger, MD
United States

Richard L. Lindstrom, MD
Ex-officio
United States

Roberto Pinelli, MD
Italy

Steven C. Schallhorn, MD
Ex-officio
United States

Stephen G. Slade, MD
Ex-officio
United States

Gustavo E. Tamayo, MD
Ex-officio
Colombia

George O. Waring III, MD
Ex-officio
United States

(Potential conflicts of interest for members of the editorial board are available upon request from the office of the Managing Editor of the *Journal of Refractive Surgery*.)

Optical Express: Its Growth and Role in the Future of Refractive Surgery

David Mouldsdale

It is my pleasure to open the Optical Express 2008 Annual Refractive Surgery Scientific Meeting. My goal in this introduction is to help those who are new to Optical Express understand what drives the company and what we plan to accomplish in the years ahead.

As the highest volume provider of refractive surgery in Europe, Optical Express is dedicated to improving patients' vision and their quality of life. Toward this end, we pay meticulous attention to clinical detail, and we strive for excellence in both the visual outcomes and the service we provide our customers. We also continually analyze our clinical results and the feedback we receive from our patients to find new ways of improving our performance.

In addition to spurring improvements within Optical Express, these analyses also allow us to contribute to the field of refractive surgery. Our large volume of computerized patient records—we now have data on hundreds of thousands of procedures—provides an information resource that can be mined to provide data on a wide range of issues that challenge the industry.

In the spirit of improving the quality of care for all patients, Optical Express made a commitment to share some of our recent findings from this scientific meeting in this supplement to the *Journal of Refractive Surgery*.

ABOUT THE OPTICAL EXPRESS GROUP

For those not familiar with Optical Express, let me provide some background about the company. Founded

From Optical Express, Glasgow, United Kingdom.

Mr Mouldsdale is an employee and stockholder of Optical Express.

The following address was given by David Mouldsdale, CEO of Optical Express, at the opening of the company's annual scientific meeting, held December 7, 2008, in Birmingham, United Kingdom. Some aspects were revised during the editing process for inclusion in the supplement.

Correspondence: David Mouldsdale, Optical Express, 5 Deerdykes Rd, Westfield Industrial Estate, Cumbernauld, Glasgow G68 9 HF, United Kingdom.

doi:10.3928/1081597X-20090611-01

in 1991, Optical Express started as a provider of spectacles and contact lenses; we have since expanded into refractive surgery, dentistry, healthcare services, and cosmetic surgical and non-surgical treatments. Our entry into refractive surgery occurred in 2002 when we acquired seven laser centers in the United Kingdom, and we have continued to expand this aspect of our business over the ensuing years. The Table provides details about this growth and other milestones.

Currently, we utilize 28 ophthalmologists, 248 optometrists, and over 3000 support personnel at 213 locations throughout the United Kingdom, Ireland, Croatia, France, Germany, the Netherlands, and the United States.

CORPORATE MISSION

At Optical Express, our mission is to grow and develop our network of clinics globally and to provide science-based products and services that enhance people's lives. To achieve this goal, Optical Express embraces eight core values: performance, integrity, transparency, consistency, diligence, adaptability, innovation, and respect.

In addition to these values, we place an emphasis on evidence-based medicine. By developing an electronic records system, we have created an infrastructure that allows us to collect massive amounts of data. To ensure accuracy, the data have been successfully audited by an independent clinical research organization (Registrar Inc, Lexington, Ky). With careful analysis, we can then turn this data into useful, actionable information that can guide future clinical practice.

EUROPE'S LARGEST REFRACTIVE SURGERY PROVIDER

Optical Express has, in 6 years, grown to be the largest refractive surgery provider in Europe. When Optical Express entered the refractive surgery business, we committed ourselves to long-term success. Supporting this commitment, we hire staff and physicians with extreme care, adhere to meticulously crafted protocols, and utilize robust information technology resources and state-of-the-art diagnostic and surgical technology.

TABLE
**Key Milestones in the Growth of
 Optical Express**

| Year | Milestone |
|------|---|
| 1991 | First Optical Express store opened in Edinburgh, Scotland |
| 1995 | Acquisition of 11 optical stores in Scotland |
| 1997 | Entry into English market with acquisition of 63 stores |
| 2002 | Entry into refractive surgery with acquisition of 7 laser vision correction (LVC) clinics in the United Kingdom |
| 2004 | Entry into the Dutch market with the acquisition of 2 LVC clinics |
| 2006 | International Medical Advisory Board (IMAB) formed |
| 2007 | Entry into German and Croatian markets with acquisition of 10 LVC clinics |
| 2008 | Entry into the French market with acquisition of 5 LVC clinics |
| 2008 | Entry into the US market with acquisition of 2 LVC clinics |
| 2008 | Formation of a Research and Development Center in California |

Specifically, Optical Express has invested over £250 million (\$368 million) in our clinics and technology, allowing us to treat our patients with the VISX S4 IR excimer laser (Abbot Medical Optics [AMO], Santa Ana, Calif) and the IntraLase femtosecond laser (AMO) platforms. In 2008 alone, Optical Express invested over £40 million (\$58 million) to open new clinics, acquire new diagnostic and treatment equipment, and upgrade our information technology and data transfer systems. We also invested over £2 million (\$3 million) in educational initiatives such as training and development events.

In addition to this financial investment, Optical Express has also invested in clinical leadership by establishing an International Medical Advisory Board (IMAB)—a group of internationally known refractive surgeons who bring a wealth of expertise to Optical Express. Headed by Steven C. Schallhorn, MD, former Director of Refractive Surgery for the US Navy, the IMAB reviews and monitors clinical outcomes, provides insight into new opportunities and technology, and offers their experience to our clinicians at educational forums.

THRIVING IN A CHALLENGING ENVIRONMENT

Given the economic tumult of 2008, which will likely extend through 2009 and perhaps beyond, there is no

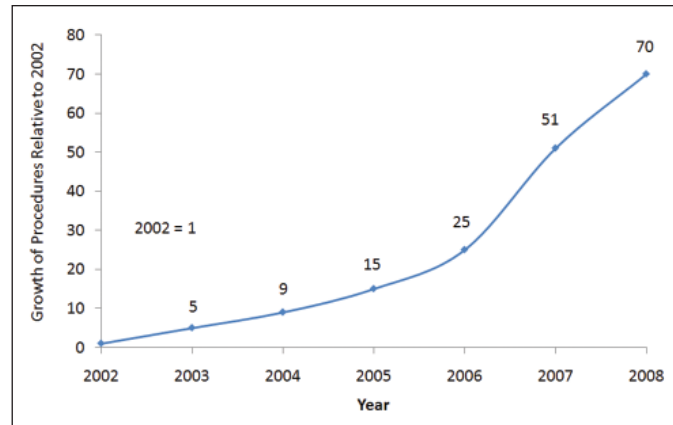


Figure. Optical Express laser vision correction procedure volume growth relative to year 2002 (in multiples of 1).

question that the current market is challenging. Indeed, I believe that 2008 will be remembered as one of the most significant years in modern history—unfortunately, like 1929, for reasons that are almost all negative.

In this economic climate, virtually no industry has escaped unscathed, and refractive surgery is no exception. In the United States, the largest laser vision correction market in the world, surgical volume is declining at an unprecedented rate. The three largest corporate providers in the United States were down more than 30% in 2008. Many independent ophthalmologists and regional groups in the United States are also reporting volume drops—in some cases up to 70% (Dave Harmon, personal communication, May 2009).

At Optical Express, however, the picture is different. In 2008, our refractive surgery business had solid, double-digit growth (Fig). Same-clinic growth has consistently been better than 20% year over year, and we have seen additional growth from new clinics and acquisitions.

THE FUTURE OF OPTICAL EXPRESS

Although the world faces unprecedented uncertainty due to continuing changes in the economy, environment, and global political landscape, I believe this is a time of tremendous opportunity. Our company has historically grown by capitalizing on unexpected possibilities—by swimming against the tide and making acquisitions when the market was weak.

Optical Express stands well positioned to experience major growth during the next 2 years. By remaining focused on our goals and striving to become better, more efficient, and more productive, Optical Express remains dedicated to improving both the quality of our clinical outcomes and the quality of our patients' experiences.

One-month Outcomes of Wavefront-guided LASIK for Low to Moderate Myopia With the VISX STAR S4 Laser in 32,569 Eyes

Steven C. Schallhorn, MD; Jan A. Venter, MD

ABSTRACT

PURPOSE: To determine the safety and efficacy of wavefront-guided LASIK for the correction of low to moderate myopia, as performed by surgeons employed by Optical Express, a large corporate provider.

METHODS: Data were extracted from the Optical Express central database on 22,900 patients (42,143 eyes) who underwent primary LASIK to treat low to moderate myopia and/or astigmatism. All treatments used a wavefront-guided ablation profile and had a refractive target of emmetropia. Outcomes were evaluated using 1-month follow-up data, which were available for 32,569 eyes of 17,713 patients (77% follow-up). Complications were tabulated using all available data.

RESULTS: The mean manifest spherical equivalent (MSE) was reduced from -2.97 ± 1.33 diopters (D) (range: -0.37 to -6.00 D) to -0.03 ± 0.29 D (range: -3.50 to $+4.50$ D) 1 month after surgery. Ninety-four percent of eyes were within 0.50 D of the intended correction, and the correlation coefficient of the attempted versus achieved MSE was 0.96. Uncorrected visual acuity (UCVA) of 20/20 or better was achieved in 92% of eyes; 99% of eyes achieved UCVA of 20/40 or better. Among patients who had bilateral laser vision correction, 98% achieved 20/20 uncorrected binocular vision. Average best spectacle-corrected visual acuity (BSCVA) improved slightly 1 month after surgery (mean change: $+0.01$ logMAR). There were 210 (0.67%) eyes that lost 2 or more lines of BSCVA; however, all eyes were 20/40 or better. Intraoperative complications occurred in 25 eyes (0.06%; 1:1686), and postoperative complications occurred in 210 eyes (0.64%; 1:155). The most common complications were dry eye ($n=58$; 0.18%; 1:562) and mild diffuse lamellar keratitis (grade 1 or 2) ($n=58$; 0.18%; 1:562).

CONCLUSIONS: Wavefront-guided LASIK can safely and effectively correct low to moderate myopia, as demonstrated by 1-month postoperative visual outcomes from a large number of patients. [*J Refract Surg.* 2009;25:S634-S641.] doi:10.3928/1081597X-20090611-02

The quality of laser vision correction provided in corporate settings has been questioned by some, particularly with respect to the quality of outcomes and the safety of the procedures. However, the depth of resources provided by a large corporation and the potential advantages of a standardized patient care model may actually enhance the quality of care. To assess the safety and effectiveness of surgical outcomes in a large corporate practice, Optical Express conducted a retrospective review of early postoperative results following wavefront-guided LASIK treatment for low to moderate myopia.

Optical Express is Europe's largest provider of laser vision correction, employing over 3000 optometrists, surgeons, and support staff in the United Kingdom, Ireland, the Netherlands, Germany, France, Croatia, and the United States. Like many refractive surgery providers in the United States and elsewhere, Optical Express takes advantage of a coordinated, multidisciplinary model in which both optometrists and surgeons deliver patient care. In this model, optometrists and surgeons share responsibility for patient care, with additional support provided by nurses, surgical technicians, counselors, administrative personnel, and head office staff.

To ensure a positive patient experience with seamless provision of care, each patient follows a specific pathway through the refractive surgery process. For most patients, the clinical journey begins with a preoperative examination conducted by an optometrist, often with the assistance of a technician or counselor. During this evaluation, the optometrist collects all necessary clinical data and continues the informed consent process (which starts when the patient receives a surgical

From Optical Express, San Diego, Calif (Schallhorn) and London, United Kingdom (Venter).

Dr Schallhorn is the Chief Medical Director for Optical Express and a consultant to Abbott Medical Optics and AcuFocus. Dr Venter is the UK Medical Director for Optical Express.

Assistance in preparing this manuscript was provided by medical writer Kay Downer.

Correspondence: Steven C. Schallhorn, MD, Optical Express, 4520 Executive Dr, Ste 230, San Diego, CA 92121. Tel: 858.695.3849; Fax: 858.235.2101; E-mail: SteveSchallhorn@OpticalExpress.com

information package via mail and/or e-mail) by discussing lifestyle, motivation, risks, benefits, and alternatives to surgery.

After a complete review of clinical data, the surgeon meets with the patient. During this meeting, the surgeon examines the patient, performs any additional tests that may be needed, and completes the informed consent process. The surgery and perioperative care are then delivered by the surgeon.

Finally, postoperative examinations are conducted by the optometrist in close consultation with the surgeon. At the conclusion of the final postoperative follow-up examination, the patient exits the surgical care cycle, after which he or she receives routine annual vision care at an Optical Express clinic.

For patients who require an enhancement or secondary procedure following surgery, the optometrist works closely with the surgeon to provide the necessary care. If an enhancement is needed, the patient re-enters the surgical care cycle and a second preoperative examination is conducted. In the instances when a patient experiences a complication, a complex case management program provides immediate, definitive clinical and surgical care.¹ This program also offers a communications and support structure for both clinicians and patients.

To facilitate efficient patient care across multiple locations, Optical Express uses an electronic medical records system to capture and store all relevant clinical information. Because information can be extracted from this database, the Optical Express biostatistics department has the data resources necessary to perform a range of large-scale patient outcomes analyses.² The data presented in this article represent one such endeavor.

PATIENTS AND METHODS

Patient records for wavefront-guided LASIK procedures were extracted from the Optical Express electronic medical records system if they met the following criteria: 1) preoperative low to moderate myopia (manifest spherical equivalent [MSE] ≤ 6.00 diopters [D]), 2) refractive target was emmetropia, 3) no prior refractive procedures, and 4) treated in 2008. This search yielded 42,143 eyes of 22,900 patients treated by 30 surgeons at 41 Optical Express centers. The size of the overall dataset and the extraction techniques are described in another article in this supplement.²

Indications for surgery were similar to the VISX Professional Use manual for CustomVue (Abbott Medical Optics [AMO], Santa Ana, Calif) treatments.³ However, three exceptions were allowed: 1) the minimum age for treatment was 18 years, 2) the maximum preoperative

cylinder was 6.00 D, and 3) patients with inactive or well-controlled and stable collagen vascular diseases could be treated if they had no ocular involvement and had received clearance from their primary care provider. There was no restriction on patients with large low-light pupil diameters as measured with an infrared pupillometer.

All treatments were performed using the STAR S4 IR excimer laser system (AMO) using a wavefront-guided ablation profile (Advanced CustomVue, AMO). First, an aberrometer (WaveScan, AMO) measured the wavefront of the eye under low-light conditions. Each capture was then assessed to determine the quality of the lenslet pattern as well as the disparity between the derived sphere and the manifest sphere; poor quality captures were repeated. If necessary, a physician adjustment was made to match the treatment sphere to within 0.50 D of the manifest sphere. The wavefront treatment profile was then transferred from the aberrometer to the excimer laser via a USB stick. All treatments were performed with a 6.0-mm optical zone and 8.0-mm transition zone.

Corneal flaps were created using either the IntraLase FS-60 (AMO) or the Moria Evo3 One Use-Plus microkeratome (Moria SA, Antony, France). The diameter of the femtosecond flaps ranged from 8.2 to 9.2 mm, and the programmed depth ranged from 100 to 120 μm . The 130- μm head was used for the mechanical keratome. Patient preference determined the method of flap creation.

Postoperative medications consisted of a commercially available third-generation fluoroquinolone and 1% prednisolone acetate, both of which were prescribed four times a day for 1 week after surgery. Patients were also instructed to use an artificial tear solution at least four times a day for 1 month after surgery.

Patients returned for follow-up at 1 day, 1 week, 1 month, 3 months, and 6 months postoperatively. At each examination, the manifest refraction was measured using a "push plus" technique, and uncorrected (UCVA) and best spectacle-corrected visual acuity (BSCVA) were measured with either a projected eye chart or an LCD wall-mounted display using logarithmically sized letters. All patients had both monocular and binocular UCVA documented. Beginning in the summer of 2008, patients also completed a postoperative patient experience questionnaire at select follow-up examinations; results of this survey are discussed in a separate article in this supplement.⁴

Data tabulation and statistical operations were performed with SAS 9.1 (SAS Institute Inc, Cary, NC) and Microsoft Office Excel 7.0 (Microsoft, Redmond, Wash).

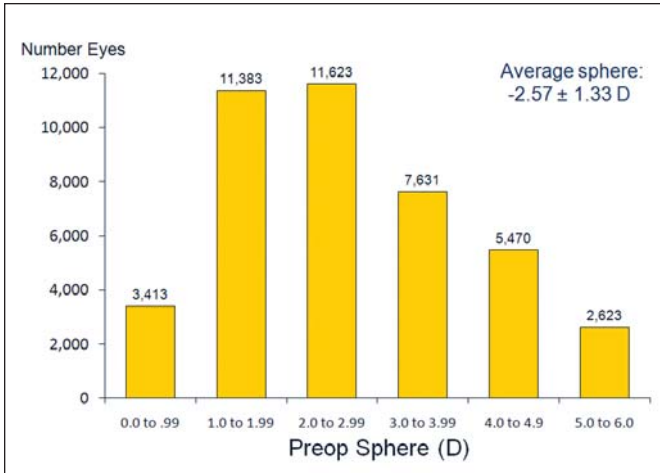


Figure 1. Preoperative sphere ranged from 0.0 to 6.00 D in 42,143 eyes that underwent LASIK.

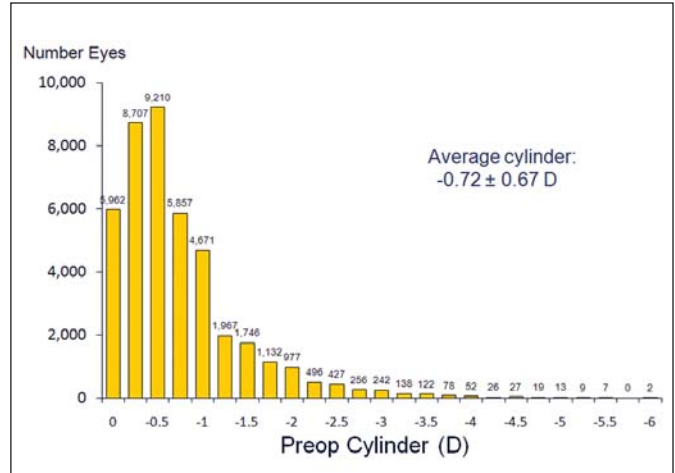


Figure 2. Preoperative cylinder ranged from 0.0 to -6.00 D in 42,143 eyes that underwent LASIK.

TABLE 1

Preoperative Comparison of Patients Who Did and Did Not Attend 1-month Follow-up

| | 1-month Follow-up | |
|------------------------|-------------------|-----------------|
| | Attended | Did Not Attend |
| No. of eyes (patients) | 32,569 (17,250) | 9574 (5650) |
| Mean age (range) (y) | 36.2 (18 to 69) | 35.1 (18 to 68) |
| Male/female (%) | 47.4/52.6 | 52.0/48.0 |
| MSE (D) | -2.97±1.34 | -2.93±1.35 |
| FS laser/keratome (%) | 76.6/23.4 | 73.5/26.5 |

MSE = manifest spherical equivalent

RESULTS

PATIENT DEMOGRAPHICS

Of the 22,900 patients included in this study, 51.2% were female and 48.8% were male. Patients ranged in age from 18 to 69 years, with an average age of 35.6 years. The mean preoperative sphere was -2.57 ± 1.33 D (range: -0.25 to -6.00 D) (Fig 1). The mean preoperative cylinder was -0.72 ± 0.67 D (range: 0.00 to -6.00 D) (Fig 2). Preoperative cylinder >2.00 D was present in 1894 eyes. The average preoperative MSE was -2.93 ± 1.34 D (range: -0.38 to -6.00 D). Most eyes (99.5%) had a BSCVA of 20/20 or better; all other eyes (329; 0.8%) had BSCVA between 20/20 and 20/32.

The majority of corneal flaps (75.7%) were created with the femtosecond laser, with the remainder created by the mechanical microkeratome.

One-month postoperative examination data were

available for 32,569 eyes of 17,713 patients, representing a follow-up rate of 77.3%. A manifest refraction was recorded in 98% of these eyes (31,755 eyes of 17,348 patients), and BSCVA was documented in 97% (31,390 eyes of 17,187 patients). Almost all eyes (98.6%) that did not have a refraction and BSCVA had UCVA of 20/20 or better at their 1-month examination; the remaining 12 eyes had UCVA of 20/25.

A comparison of patients who completed 1-month examination and those who did not showed that the preoperative mean MSE was similar for both groups (-2.97 D and -2.93 D, respectively) (Table 1). However, patients who did not attend 1-month follow-up were slightly younger (35.1 vs 36.2 years), more likely to be male (52.0% vs 47.4%), and more likely to have had a corneal flap created using a mechanical keratome (26.5% vs 23.4%).

REFRACTIVE AND VISUAL ACUITY OUTCOMES

Mean MSE at 1-month follow-up was -0.03 ± 0.29 D (range: -3.50 to $+4.50$ D). A linear regression of attempted versus achieved MSE yielded a slope of 0.96, an intercept of $+0.08$, and a correlation coefficient of 0.95 (Fig 3). Manifest spherical equivalent was within 0.50 D of target for 93.7% of eyes and within 1.00 D for 99.3% of eyes. Two hundred twenty-five eyes were >1.00 D from target; 49 (0.15%) eyes were overcorrected by >1.00 D MSE, and 176 (0.54%) eyes were undercorrected by >1.00 D.

The mean defocus equivalent at 1 month was 0.27 ± 0.31 D (range: 0.00 to $+5.25$ D). Defocus equivalent was within 0.50 D of target in 88.6% of eyes and within 1.00 D in 98.2% of eyes.

The average manifest cylinder at 1 month was -0.17 ± 0.26 D (range: 0.00 to -4.00 D), representing

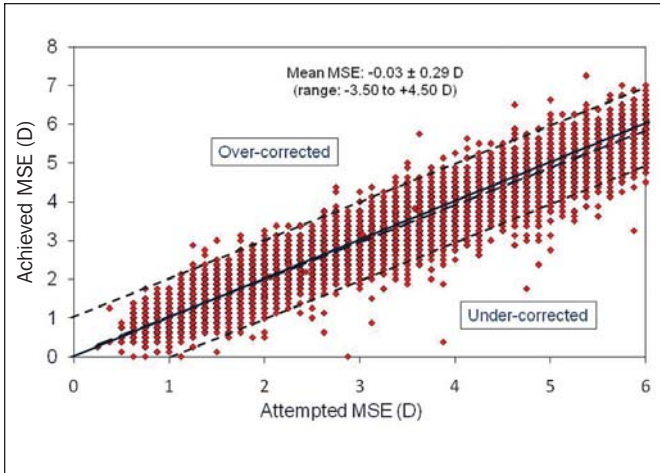


Figure 3. The linear regression of attempted versus achieved manifest spherical equivalent (MSE) 1 month after surgery in 31,755 eyes is displayed as a long-dashed line (slope 0.96 and intercept of +0.08) with a correlation coefficient of 0.95.

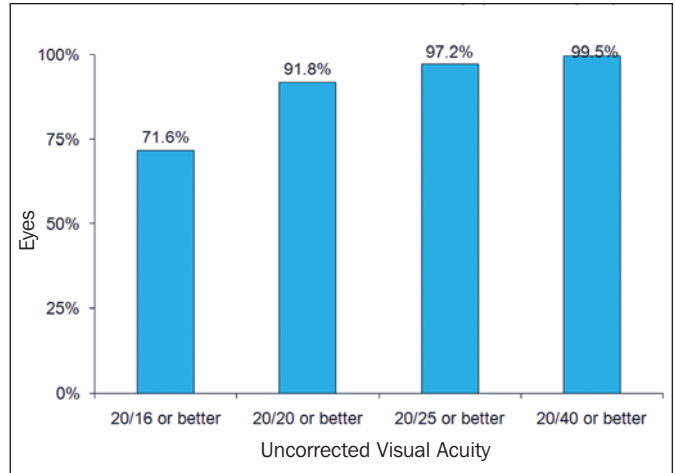


Figure 4. One month after surgery, the majority of eyes (97.2%, 31,657/32,569) had achieved at least 20/25 uncorrected visual acuity (UCVA).

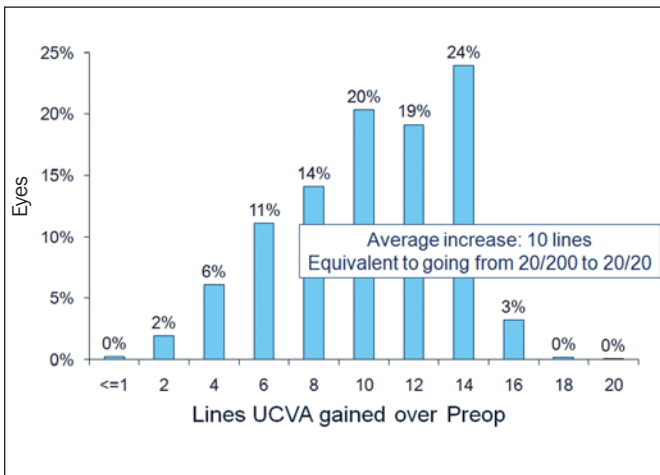


Figure 5. Compared to preoperative values, uncorrected visual acuity (UCVA) at 1 month in 32,569 eyes showed an average improvement of 10 lines.

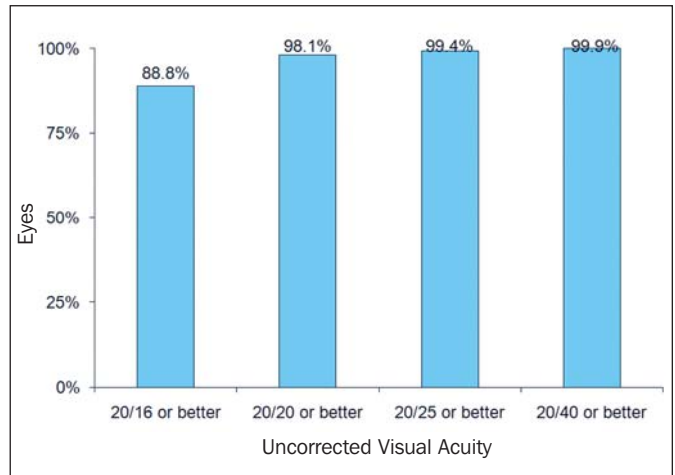


Figure 6. Of the 15,035 patients who underwent bilateral LASIK, the majority (98.1%) achieved binocular uncorrected visual acuity of 20/20.

a 76% mean reduction in absolute cylinder. In those eyes that had preoperative cylinder >2.00 D and a 1-month refractive examination (1504 eyes; mean preoperative cylinder: -2.87 ± 0.68 D), an 81% reduction was noted in the absolute manifest cylinder at 1 month (mean: -0.51 ± 0.46 D). Seven (0.02%) eyes had a postoperative manifest cylinder >2.00 D.

The majority of eyes (91.8%) achieved UCVA of at least 20/20 at 1 month, and 71.6% of eyes achieved 20/16 UCVA (Fig 4). Almost all eyes (99.5%) achieved 20/40 UCVA. The efficacy index for the procedure (mean postoperative UCVA/mean preoperative BSCVA) was 0.96. Compared to preoperative UCVA, treated eyes gained an average of 10 lines following surgery—equivalent to the change from 20/200 to 20/20 (Fig 5).

Among patients who had bilateral LASIK (30,070

eyes of 15,035 patients), 98.1% achieved 20/20 or better uncorrected binocular vision at 1 month (Fig 6).

Average BSCVA was slightly improved 1 month after surgery compared to preoperatively (mean change in BSCVA: 0.014 logMAR, 95% confidence interval [CI]: 0.013-0.014). The safety index for the procedure (mean postoperative BSCVA/mean preoperative BSCVA) was 1.02, and most eyes (98.3%) remained within 1 line of their preoperative BSCVA (Fig 7). There were 210 eyes (0.67%) that lost 2 or more lines of BSCVA. No eye had a BSCVA worse than 20/40, and 98.8% of eyes had BSCVA of 20/20 or better.

COMPLICATIONS

Both intra- and postoperative complications were assessed (Tables 2 and 3). Of the 42,143 eyes treated,

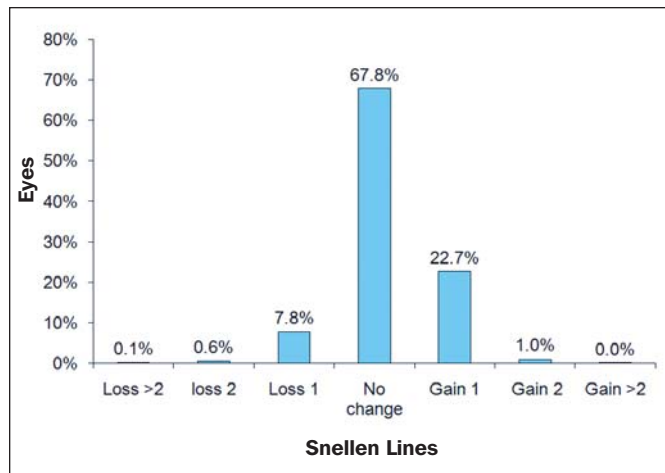


Figure 7. Most eyes (98.3%) were within one line of their preoperative best spectacle-corrected visual acuity.

25 (0.06%; 1:1686) experienced an intraoperative complication. The most common intraoperative complications were related to flap creation (n=22, 0.05%; 1:1916) and included epithelial abrasion as well as incomplete, buttonhole, and free flaps.

For postoperative complications, all available follow-up data were included in the analysis, and the incidence was computed based on the number of eyes evaluated at 1 month (32,569). There were 210 eyes that experienced a postoperative complication (0.64%; 1:155) between 1 day and 7 months after surgery.

Most of the common LASIK complications were observed, but many of these were transient and eventually resolved. The most common postoperative complications were dry eye (n=58; 0.18%; 1:562), mild diffuse lamellar keratitis (DLK, grade 1 or 2) (n=58; 0.18%; 1:562), and night vision symptoms (n=19, 0.06%; 1:1714). Thirteen eyes (0.04%; 1:2505) had flap striae that required flap lift and repositioning. Eight of these eyes had striae due to frank flap displacement caused by trauma; 7 (88%) of these 8 flaps were created with the mechanical keratome. When flaps required repositioning, this procedure was performed an average of 16 days (range: 1 to 127 days) following surgery.

In addition to these common complications, a few eyes experienced rare but serious complications. Six cases of microbial keratitis or presumed microbial keratitis were observed in the perioperative time period (0.018%; 1:5428). All cases were successfully treated with intense antibiotics, and 4 of these 6 eyes had a resultant BSCVA of 20/20 or better; the remaining 2 eyes had a BSCVA of 20/25 and 20/25⁻². Other serious complications included grade 3 or 4 DLK (8 eyes; 0.025%; 1:4071), crystalline lens changes noted 2 and 7 months following surgery (2 eyes; 0.006%; 1:16,285),

TABLE 2
Summary of Intraoperative Complications (N=42,143 Eyes)

| Complication | n | Incidence (%) | 1: __ |
|----------------------------|----|---------------|--------|
| Flap creation complication | 22 | 0.052 | 1916 |
| Incorrect treatment | 2 | 0.005 | 21,072 |
| Decentered ablation | 1 | 0.002 | 42,143 |
| Total | 25 | 0.06 | 1686 |

TABLE 3
Summary of Postoperative Complications (n=32,569 eyes)

| Complication | n | Incidence (%) | 1: __ |
|-----------------------------|-----|---------------|--------|
| Dry eye | 58 | 0.18 | 562 |
| Mild DLK | 58 | 0.18 | 562 |
| Glare/halos | 19 | 0.058 | 1714 |
| Flap striae | 13 | 0.040 | 2505 |
| Delayed healing | 9 | 0.028 | 3619 |
| Grade 3/4 DLK | 8 | 0.025 | 4071 |
| Sterile infiltrates | 8 | 0.025 | 4071 |
| Postop cylinder >2.00 D | 7 | 0.022 | 4653 |
| Transient light sensitivity | 6 | 0.018 | 5428 |
| Microbial keratitis | 6 | 0.018 | 5428 |
| Significant haze | 5 | 0.015 | 6514 |
| Elevated IOP | 4 | 0.012 | 8142 |
| Recurrent erosions | 3 | 0.009 | 10,856 |
| Epithelial ingrowth | 2 | 0.006 | 16,285 |
| Crystalline lens changes | 2 | 0.006 | 16,285 |
| Ectasia | 1 | 0.003 | 32,569 |
| Retinal detachment | 1 | 0.003 | 32,569 |
| Total | 210 | 0.64 | 155 |

DLK = diffuse lamellar keratitis, IOP = intraocular pressure

ectasia diagnosed 3 months after surgery (1 eye; 0.003%; 1:32,569), retinal detachment (1 eye; 0.003%; 1:32,569), and a decentered ablation (1 eye; 0.003%; 1:32,569).

DISCUSSION

The purpose of this study was to evaluate the early postoperative outcomes of wavefront-guided LASIK offered by a corporate provider for the treatment of low

to moderate myopia. The large study population was gender and age diverse (range: 18 to 69 years). A high percentage of patients achieved the refractive target (emmetropia) 1 month after surgery; 94% of eyes had a postoperative MSE within 0.50 D and 99% of eyes were within 1.00 D. Excellent refractive predictability was also demonstrated by the tight distribution of the postoperative MSE (standard deviation of 0.29 D) and the high correlation coefficient of the attempted versus achieved MSE (0.96).

Another measure of refractive accuracy is the defocus equivalent. Unlike MSE, this measure considers the defocus effect of both residual sphere and residual cylinder without allowing opposite signs of sphere and cylinder to cancel each other. As a result, defocus equivalent has only positive values. In this study, 89% of eyes were within 0.50 D of the defocus equivalent target (0.0 D).

In terms of UCVA, most eyes achieved 20/16 or 20/20 vision (71.6% and 91.8%, respectively). The efficacy score was 0.96—the ratio of mean postoperative UCVA to the mean preoperative BSCVA. Although not commonly reported, binocular acuity may also be a useful metric of functional vision, and almost all patients (98.1%) who underwent bilateral LASIK (15,035 patients) achieved 20/20 bilateral UCVA.

The safety of the procedure was assessed by the postoperative and pre- to postoperative change in BSCVA. All eyes had a BSCVA of 20/40 or better 1 month after surgery, and almost all eyes (98.8%) were 20/20 or better. A slight improvement in the mean BSCVA occurred in this study, which is commonly observed when treating myopia. A small number of eyes lost 2 or more lines of BSCVA (210 eyes, 0.67%) at 1 month postoperative. However, visual improvement can occur for several months after LASIK.^{5,6} Visual results may improve in the later postoperative period.

Large, multicenter studies that are not part of a US Food and Drug Administration (FDA) clinical trial are uncommon in the literature. To the authors' knowledge, this study represents the largest study to report on the safety and effectiveness of LASIK.

The largest series previously published reported 34,099 eyes of 17,388 patients who underwent LASIK performed by 48 surgeons in 15 centers.⁷ However, these authors only evaluated intraoperative complications, not postoperative outcomes.

Another large series reported 1-month data on 10,052 eyes of 5081 patients treated at a hospital in China.⁸ However, the study did not discuss refractive outcomes, change in BSCVA, or the percentage of eyes that achieved specific levels of UCVA.

Other studies that have evaluated the outcomes of

wavefront-guided LASIK performed to treat low to moderate myopia have had much smaller sample sizes (range: 25 to 187 eyes) and varying lengths of follow-up (range: 1 to 6 months). Overall, these studies have reported mixed refractive and acuity results, with the percentage of eyes being within 0.50 D MSE ranging from 72% to 98%, and the percentage of eyes achieving UCVA of 20/20 ranging from 56% to 98%.⁹⁻¹⁶

The results of the current study are similar to the regulated and controlled premarket approval (PMA) FDA clinical trial reported in 2003, which was conducted by the manufacturer using the same laser platform and wavefront-guided treatment profile.³ The same optical and transition zones were used in this trial and in the current study, and the refractive indications for both studies were similar, with the exception that the PMA study limited preoperative cylinder to 3.00 D, whereas this study included eyes with up to 6.00 D of cylinder. In fact, our study included 1504 eyes with >2.00 D of preoperative cylinder. Higher levels of cylinder can result in less predictable refractive and acuity outcomes.⁹

The PMA study reported 331 eyes with 1-month follow-up data, whereas our study had approximately 100 times that number of eyes (32,569). Despite the difference in sample size, the percentage of eyes with an MSE within 0.50 D at 1 month was similar for both studies (92.7% and 93.7% for the PMA and this study, respectively), and the percentage of patients who attained 20/20 UCVA was the same (91.8% for both). In the PMA study, no eye lost more than 2 lines of BSCVA; the 95% CI for this measure was 0 to 0.9%. The percent of eyes in this study that lost more than 2 lines of BSCVA (0.12%) was within this range.

In addition to visual outcomes, this study also provides data on LASIK complications. Many of the complications previously reported for LASIK were observed in this study, including dry eye, DLK, and loss of BSCVA.¹⁷ Most of the observed complications—such as dry eye, DLK, flap striae, and transient light sensitivity—were treated successfully without sequelae or long-term visual effects. Rare but potentially vision-threatening complications were also observed, such as microbial keratitis and ectasia. Despite these complications, the worst BSCVA at 1 month after surgery was 20/40. The low overall rate of complications in this study (intraoperative: 0.06% and postoperative: 0.64%) also reflects the high level of safety that modern LASIK has achieved.

This complication rate is lower than the rate of intraoperative complications described in another large LASIK study. In a study of 34,099 eyes that were treated using a mechanical keratome (Moria LSK One man-

ual), Albelda-Vallés et al⁷ observed that 1338 (3.92%) eyes experienced intraoperative complications, with the most common being a free cap (571 eyes, 1.67%) and epithelial abrasion (282 eyes, 0.82%). Part of the reason for the disparity in complication rates may be due to the fact that the majority of procedures in our study were created with the femtosecond laser (76%). A free cap from a femtosecond-created flap has not been reported. Also, because there is no movement of the keratome head over the cornea, the rate of epithelial abrasion with the femtosecond laser is believed to be lower than with a mechanical keratome.¹⁸

The most important limitation of the current study was the number of patients lost to follow-up. Of the original cohort of 22,900 patients, 5187 patients (22.7%) did not attend the 1-month examination. These patients tended to be younger (35.1 vs 36.2 years), more often male (52.0% vs 47.4%), and had a higher percentage of mechanical keratome flaps (26.5% vs 23.4%).

A literature review shows that the possible influence of these factors on refractive and acuity outcomes is mixed. Gender does not appear to be a predictor of LASIK outcomes. Some reports have found that age is a factor, with younger patients having better outcomes, but other studies have not found an association.^{9,19,20} In addition, studies of the possible benefit of femtosecond-created LASIK flaps have shown both similar and improved outcomes compared to mechanical keratome-created flaps.^{4,21-24} Given these mixed results, it is not known whether patients who did not attend the 1-month examination would have collectively done better, worse, or the same as the cohort who attended the 1-month examination.

In addition to some patients being lost to follow-up, another limitation of this study is that several factors could have resulted in an overestimation or underestimation of the complication rates reported. With only 77% follow-up at 1 month, some complications may have been missed; however, the ready access to care and the network of Optical Express clinics throughout the countries where the treatments were performed should help minimize such losses. It is also possible that patients who missed their 1-month examination may have been less likely to have a complication, resulting in an overestimation of the actual complication rate.

Also, while most complications after laser vision correction occur during the perioperative period, some complications can occur much later; ectasia has been reported to occur years after surgery.²⁵ Although one ectasia case was reported in this study (diagnosed 3 months after surgery), additional long-term follow-up could reveal other late complications.

Although the factors affecting complications were

not analyzed in depth, flap-related complications appeared to be significantly more common in eyes treated with a mechanical keratome. Of eight traumatic flap dislocations, seven occurred with the mechanical keratome. Reflecting a growing public awareness of such advantages, most patients (76%) elected to have flaps created with the femtosecond laser, despite the significantly higher procedure fee (~\$1200) associated with this option.

This study demonstrates that a large corporate provider employing a surgeon/optometrist comanagement model and using wavefront-guided and femtosecond/mechanical keratome technology can achieve excellent 1-month refractive surgery outcomes with a low complication rate, even when treating a large and diverse population. Because of this study's large sample size, these results also help further validate laser vision correction as a safe and effective method of correcting refractive errors in the general population.

AUTHOR CONTRIBUTIONS

Study concept and design (S.C.S., J.A.V.); data collection (S.C.S.); interpretation and analysis of data (S.C.S.); drafting of the manuscript (S.C.S.); critical revision of the manuscript (S.C.S., J.A.V.); statistical expertise (S.C.S.); administrative, technical, or material support (S.C.S.); supervision (S.C.S., J.A.V.)

REFERENCES

1. Venter JA, Hannan SJ. A complex case management system provides optimal care for all patients. *J Refract Surg.* 2009;25:S655-S660.
2. Hettinger KA. The role of biostatistics in the quality improvement of refractive surgery. *J Refract Surg.* 2009;25:S651-S654.
3. Professional use information. VISX STAR S4 IR™ Excimer Laser System and WaveScan WaveFront® System. CustomVue™ Treatment. Available at: www.accessdata.fda.gov/cdrh_docs/pdf/P930016S020c.pdf. Accessed May 2009.
4. Brown MC. Satisfaction of 13,655 patients with laser vision correction at 1 month after surgery. *J Refract Surg.* 2009;25:S642-S646.
5. Durrie DS, Kezirian GM. Femtosecond laser versus mechanical keratome flaps in wavefront-guided laser in situ keratomileusis: prospective contralateral eye study. *J Cataract Refract Surg.* 2005;31:120-126.
6. Durrie DS, Slade SG, Marshall J. Wavefront-guided excimer laser ablation using photorefractive keratectomy and sub-Bowman's keratomileusis: a contralateral eye study. *J Refract Surg.* 2008;24:S77-S84.
7. Albelda-Vallés JC, Martin-Reyes C, Ramos F, Beltran J, Llovet F, Baviera J. Effect of preoperative keratometric power on intraoperative complications in LASIK in 34,099 eyes. *J Refract Surg.* 2007;23:592-597.
8. Sun L, Liu G, Ren Y, Li J, Hao J, Liu X, Zhang Y. Efficacy and safety of LASIK in 10,052 eyes of 5081 myopic Chinese patients. *J Refract Surg.* 2005;21:S633-S635.
9. Randleman JB, White AJ Jr, Lynn MJ, Hu MH, Stulting RD. Incidence, outcomes, and risk factors for retreatment after wave-

- front-optimized ablations with PRK and LASIK. *J Refract Surg.* 2009;25:273-276.
10. Schallhorn SC, Tanzer DJ, Kaupp SE, Brown M, Malady SE. Comparison of night driving performance after wavefront-guided and conventional LASIK for moderate myopia. *Ophthalmology.* 2009;116:702-709.
 11. Bahar I, Levinger S, Kremer I. Wavefront-guided LASIK for myopia with the Technolas 217z: results at 3 years. *J Refract Surg.* 2007;23:586-590.
 12. Stonecipher KG, Kezirian GM. Wavefront-optimized versus wavefront-guided LASIK for myopic astigmatism with the ALLEGRETTO WAVE: three-month results of a prospective FDA trial. *J Refract Surg.* 2008;24:S424-S430.
 13. Awwad ST, El-Kateb M, Bowman RW, Cavanagh HD, McCulley JP. Wavefront-guided laser in situ keratomileusis with the Alcon CustomCornea and the VISX CustomVue: three-month results. *J Refract Surg.* 2004;20:S606-S613.
 14. Slade S. Contralateral comparison of Alcon CustomCornea and VISX CustomVue wavefront-guided laser in situ keratomileusis: one-month results. *J Refract Surg.* 2004;20:S601-S605.
 15. Durrie DS, Stahl J. Randomized comparison of custom laser in situ keratomileusis with the Alcon CustomCornea and the Bausch & Lomb Zyoptix systems: one-month results. *J Refract Surg.* 2004;20:S614-S618.
 16. Venter J. Wavefront-guided LASIK with the NIDEK NAVEX platform for the correction of myopia and myopic astigmatism with 6-month follow-up. *J Refract Surg.* 2005;21:S640-S645.
 17. Schallhorn SC, Amesbury EC, Tanzer DJ. Avoidance, recognition, and management of LASIK complications. *Am J Ophthalmol.* 2006;141:733-739.
 18. Binder PS. One thousand consecutive IntraLase laser in situ keratomileusis flaps. *J Cataract Refract Surg.* 2006;32:962-969.
 19. Perlman EM, Reinert SE. Factors influencing the need for enhancement after laser in situ keratomileusis. *J Refract Surg.* 2004;20:783-789.
 20. Feltham MH, Wong R, Wolfe R, Stapleton F. Variables affecting refractive outcome following LASIK for myopia. *Eye.* 2008;22:1117-1123.
 21. Tanna M, Schallhorn SC, Hettinger KA. Femtosecond laser vs mechanical microkeratome: a retrospective comparison of visual outcomes. *J Refract Surg.* 2009;25:S668-S671.
 22. Montés-Micó R, Rodríguez-Galietero A, Alió JL. Femtosecond laser versus mechanical keratome LASIK for myopia. *Ophthalmology.* 2007;114:62-68.
 23. Chan A, Ou J, Manche EE. Comparison of the femtosecond laser and mechanical keratome for laser in situ keratomileusis. *Arch Ophthalmol.* 2008;126:1484-1490.
 24. Lim T, Yang S, Kim M, Tchah H. Comparison of the IntraLase femtosecond laser and mechanical microkeratome for laser in situ keratomileusis. *Am J Ophthalmol.* 2006;141:833-839.
 25. Randleman JB, Woodward M, Lynn MJ, Stulting RD. Risk assessment for ectasia after corneal refractive surgery. *Ophthalmology.* 2008;115:37-50.

Satisfaction of 13,655 Patients With Laser Vision Correction at 1 Month After Surgery

Mitchell C. Brown, OD; Steven C. Schallhorn, MD; Keith A. Hettinger, MS, MBA; Stephanie E. Malady, BS

ABSTRACT

PURPOSE: To assess the level of laser vision correction patient satisfaction achieved by a large corporate provider of refractive surgery.

METHODS: A computer-based, interactive survey was used to query patients regarding their satisfaction with the services, experience, and results of their laser vision correction procedure.

RESULTS: Responses from 13,655 consecutive patients who completed their 1-month postoperative examination were analyzed in this study. A very high level of satisfaction was observed both for the quality of postoperative care provided (98.6%) and for the visual results obtained (95.0%). Most patients (94.2%) indicated that the surgery improved their life, and most would recommend both laser vision correction (96.5%) and the corporate provider (97.5%) to friends and family.

CONCLUSIONS: Patients report a high level of satisfaction with laser vision correction performed by a large corporate provider. [*J Refract Surg.* 2009;25:S642-S646.] doi:10.3928/1081597X-20090611-03

A

lthough excellent clinical outcomes are essential to the success of every refractive surgery practice, the best providers do more than simply improve unaided visual acuity—they also provide a positive patient experience. To achieve this goal, leading refractive surgery practices evaluate the care they provide from their patients' perspective and use this feedback to continuously improve care.

Influenced by more than just the visual results of surgery, patient satisfaction hinges on a number of factors, including the demeanor and attentiveness of staff, how well the practice manages patients' expectations, and whether the surgery team effectively addresses patient anxiety before and during the procedure. Patient satisfaction can also be influenced by factors such as the physical appearance of the laser center and whether patients must wait a significant length of time before being examined or treated.

Optical Express, the largest corporate provider of laser vision correction in Europe, aims to continually measure its success in a variety of ways. An electronic patient satisfaction questionnaire was instituted in 2008 to evaluate the quality of care provided, how well patient expectations were met, and the level of patient satisfaction.

MATERIALS AND METHODS

The Optical Express questionnaire is an online, real-time, interactive survey that is accessible on computer stations located in isolated areas of every Optical Express clinic. All laser vision correction patients are asked to complete this questionnaire immediately after 1-day, 1-week, 1-month, and 3-month postoperative follow-up. A unique patient identification number created by the Optical Express central office

From Optical Express, San Diego, Calif.

Dr Brown, Mr Hettinger, and Ms Malady are employees of the Optical Express Group. Dr Schallhorn is the Chief Medical Director for Optical Express and a consultant to Abbott Medical Optics and AcuFocus.

Assistance in preparing this manuscript was provided by medical writer Kay Downer.

Correspondence: Mitchell C. Brown, OD, 4520 Executive Dr, Ste 230, San Diego, CA 92121. Tel: 858.597.0897; Fax: 858.597.0896; E-mail: mitchbrown@opticalexpress.com

TABLE

One-month Questionnaire

1. How satisfied are you with the post-operative care that we have provided for you since your treatment? (Very satisfied; Satisfied; Neither satisfied nor dissatisfied; Dissatisfied; Very dissatisfied)
2. Overall how would you rate your Optical Express experience so far? (Excellent; Good; Average; Poor; Very Poor)
3. How long did you wait in the clinic before your post-operative appointment commenced? (Less than 10 minutes; 10-20 minutes; More than 20 minutes)
4. How is your vision now compared with your expectations pre-treatment? (Better; Same; Worse)
5. How satisfied are you with your vision today? (Very satisfied; Satisfied; Neither satisfied nor dissatisfied; Dissatisfied; Very dissatisfied)
6. Is your vision better than it was with spectacles/contact lenses? (Yes; No)
7. Has Laser Vision Correction changed your life for the better? (Yes; No)
8. Would you recommend Laser Vision Correction to your friends and family? (Yes; No)
9. Would you recommend Optical Express to your friends and family? (Yes; No)

is used to identify patient responses, but individual survey responses are not available to clinicians or other clinic personnel. The Table shows the questions included in the 1-month postoperative survey. The responses have 2-, 3-, or 5-distractor scales, specific to each question.

All refractive surgery patients were treated with either LASIK or laser epithelial keratomileusis (LASEK) depending on medical indications and patient preference. Ablations were performed using a STAR S4 IR excimer laser system (Abbott Medical Optics [AMO], Santa Ana, Calif). For LASIK patients, corneal flaps were created using either the IntraLase FS-60 (AMO) or the Moria Evo3 One Use-Plus microkeratome (Moria SA, Antony, France). For LASEK procedures, the epithelium was removed with an alcohol solution.

Questionnaire data were then extracted from the central clinical database for this analysis. Tabulations and statistics were performed using SAS 9.1 (SAS Institute Inc, Cary, NC) and Microsoft Office Excel 7.0 (Microsoft, Redmond, Wash).

RESULTS

A total of 34,760 consecutive patients underwent laser vision correction at Optical Express clinics after the questionnaire was implemented. The clinical model employed and details of clinical outcomes for these patients are described in another article

“Overall, how would you rate your Optical Express experience so far?”

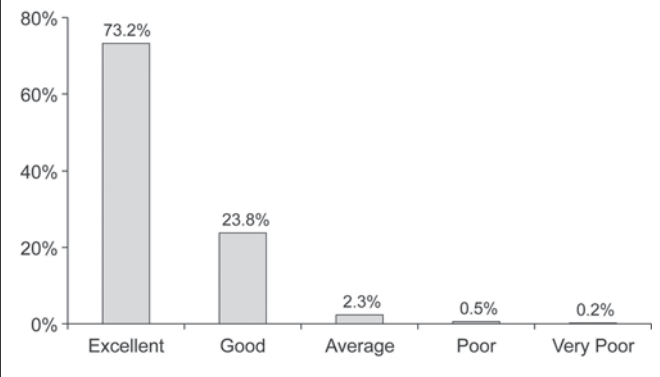


Figure 1. Of 13,655 patients who completed the 1-month questionnaire, 73% rated their overall experience with Optical Express as “excellent” at 1-month follow-up.

in this supplement.¹ Ninety-two percent of patients (n=31,979) attended their 1-month postoperative examination. Of this subset, the 13,655 patients (43%) who completed the 1-month questionnaire were included in this analysis.

The 13,655 patients who completed the 1-month questionnaire were diverse in age (mean: 39.4 years; range: 18 to 71 years) and gender (45% male, 55% female). Treatments included both myopic and hyperopic corrections (mean manifest spherical equivalent: -2.27 ± 2.66 diopters [D]; range: -11.63 to $+6.00$ D) performed using both procedure types (91% LASIK, 9% LASEK).

Most demographic and preoperative factors were equivalent between patients who completed the 1-month questionnaire and those who did not. No significant differences were observed for pre- and postoperative sphere, cylinder, best spectacle-corrected visual acuity (BSCVA), and uncorrected visual acuity (UCVA). However, statistically significant differences were observed for age (difference 0.3 years; *t* test, $P=.0159$), gender (male/female difference 3%; chi-square, $P=.0076$), and type of procedure (LASIK/LASEK difference 2%; chi-square, $P \leq .0001$).

Overall, survey results indicated a high level of patient satisfaction, with the majority of patients (97.0%) rating their overall experience with Optical Express as “good” or “excellent” (Fig 1). Most patients also gave positive feedback when asked about specific aspects of their care. For example, 98.6% of patients reported being satisfied with their postoperative care, and most patients said they did not have to wait long before the start of their postoperative appointment (Figs 2 and 3).

The majority of patients (95.0%) also reported being satisfied with their visual results after surgery (Fig 4).

“How satisfied are you with the postoperative care that we have provided for you since your treatment?”

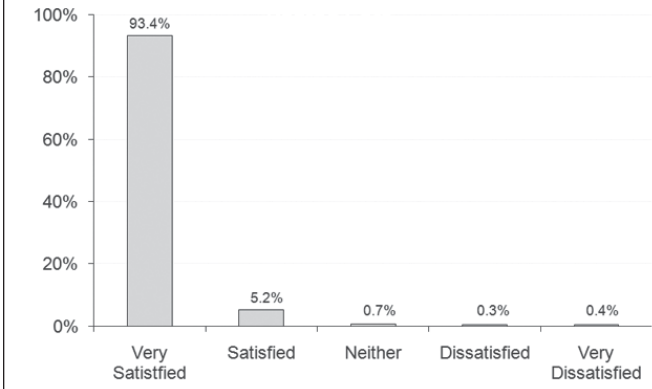


Figure 2. Of 13,655 patients who completed the 1-month questionnaire, 93.4% of patients reported being “very satisfied” with their postoperative care.

“How long did you wait in the clinic before your postoperative appointment commenced?”

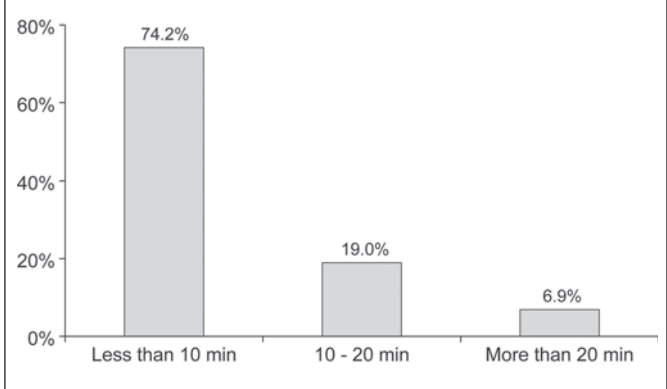


Figure 3. Of 13,655 patients who completed the 1-month questionnaire, the majority (74.2%) reported that they had to wait less than 10 minutes prior to their appointment.

“How satisfied are you with your vision today?”

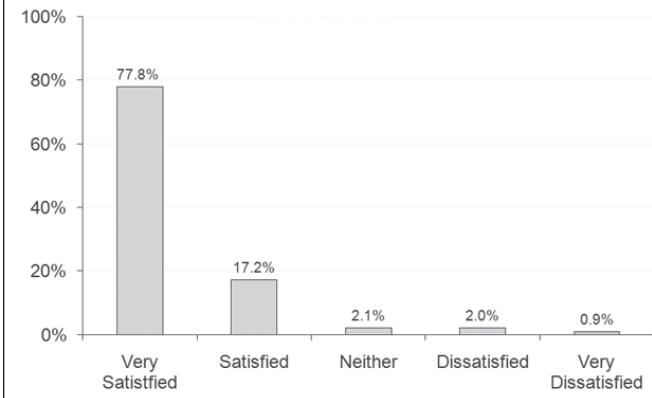


Figure 4. Of 13,655 patients who completed the 1-month questionnaire, when asked “How satisfied are you with your vision today?” 77.8% of patients reported being very satisfied.

“How is your vision now compared with your expectations pre-treatment?”

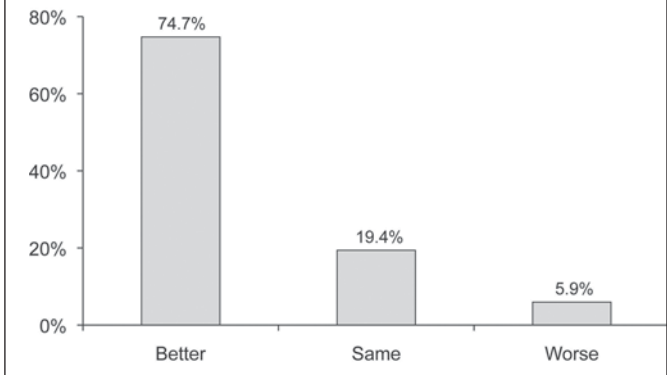


Figure 5. Of 13,655 patients who completed the 1-month questionnaire, 75% reported that their vision after surgery was better than expected.

When asked to compare these results to their preoperative expectations, 94.1% of patients indicated that their visual results met or exceeded their expectations (Fig 5).

Finally, a high level of satisfaction was reported on a series of “yes/no” questions. A majority of patients (94.2%) stated that laser vision correction had changed their life for the better, and most patients (82.8%) indicated that their vision was better after surgery than it had been with spectacles or contact lenses (Fig 6). Almost all patients also indicated that they would recommend both laser vision correction (96.5%) and Optical Express (97.5%) to friends and family (Fig 7).

DISCUSSION

This study represents a real-world, large-scale evaluation of patient satisfaction with laser vision correction

delivered by a corporate provider. Including patients with a broad range of preoperative ametropia who received treatment using current technology, this study found a high level of satisfaction in terms of both the quality of care provided and patients’ visual results. Most patients also indicated that the surgery improved their life and that they would recommend both the procedure and the corporate provider to friends and family. These findings validate the perceived value of this elective procedure, and they confirm that a corporate provider can deliver laser vision correction in such a way that patients develop a high opinion of both the quality of care and their visual outcomes.

Because patient satisfaction is a valuable indicator of a practice’s performance, other studies have analyzed satisfaction with laser vision correction.²⁻⁷ In fact, a re-

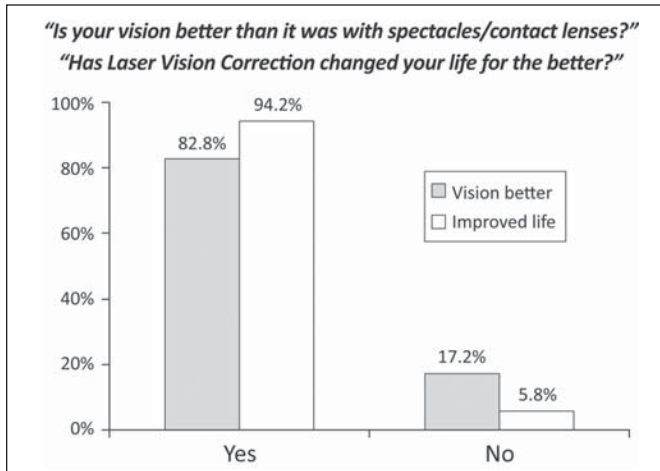


Figure 6. Of 13,655 patients who completed the 1-month questionnaire, 83% reported that their vision was better than it was with spectacles or contact lenses, and 94.2% said that laser vision correction had changed their life for the better.

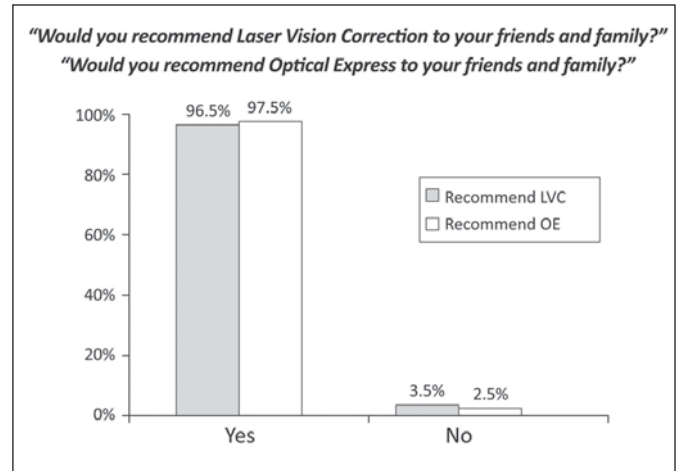


Figure 7. Of 13,655 patients who completed the 1-month questionnaire, the majority (96.5%) would recommend laser vision correction (LVC) to friends and family, and a similarly high percentage (97.5%) would recommend Optical Express (OE).

cent meta-analysis of the laser vision correction literature was conducted in response to concerns about patient dissatisfaction after LASIK.⁸ This meta-analysis included 309 pertinent articles with a combined total of 2199 patients, and overall satisfaction with LASIK was found to be 95.4%. Although this meta-analysis only evaluated LASIK patients and included assessments over a wide postoperative time period (range: 1 month to 10 years), the overall result was similar to the result of the current study.

One possible limitation of the current study is that it included LASEK patients who may not have achieved their final visual outcome by the time the 1-month questionnaire was administered. It is well known that visual recovery after a surface procedure, such as LASEK, can take longer than after LASIK.⁹⁻¹¹ If patients had not yet achieved their optimal visual outcome when the 1-month survey was taken, this could negatively impact the results obtained by the questionnaire. In addition, satisfaction after surgery can continue to improve beyond the 1-month postoperative follow-up regardless of the procedure. Together, these factors suggest that patient satisfaction could be higher if assessed at later time periods.

Another possible limitation of the current study is that only 43% of patients who attended the 1-month postoperative examination completed the patient satisfaction questionnaire. To evaluate a possible selection bias, patients who completed the questionnaire were compared to those who did not. Although this comparison found no differences in most preoperative parameters, small differences in age, gender, and type of procedure were statistically significant due to the large sample size. Although these differences are un-

likely to have true clinical relevance and the groups were well-matched for all other parameters, it is still possible that the patients who chose to fill out the survey were selectively satisfied or dissatisfied.

Finally, this study did not analyze all of the factors that may have contributed to patient satisfaction. Patients can be dissatisfied even when a procedure achieves a normal clinical outcome, so further work is ongoing to elucidate clinical factors that can influence patient satisfaction after surgery.

Clinical outcomes can determine the safety and efficacy of a procedure, however, these metrics cannot fully assess how patients value a procedure. By providing an essential complement to clinical outcome analyses, a computerized questionnaire such as that developed by Optical Express represents a valuable tool for assessing how patients perceive the quality of care they receive.

The most obvious use of such data is to direct changes that will enhance future patients' satisfaction. For instance, data from different clinical centers can be compared and analyzed, and centers that produce consistently high marks can be identified and studied. By applying the lessons learned from these centers to other centers, a large corporate provider can duplicate its successes over many locations.

AUTHOR CONTRIBUTIONS

Study concept and design (M.C.B., S.C.S.); data collection (M.C.B., S.C.S., K.A.H., S.E.M.); interpretation and analysis of data (M.C.B., S.C.S., K.A.H., S.E.M.); drafting of the manuscript (M.C.B., S.C.S.); critical revision of the manuscript (M.C.B., S.C.S., K.A.H., S.E.M.); statistical expertise (S.C.S., K.A.H.); administrative, technical, or material support (S.C.S., S.E.M.); supervision (M.C.B., S.C.S.)

REFERENCES

1. Schallhorn SC, Venter JA. One-month outcomes of wavefront-guided LASIK for low to moderate myopia with the VISX STAR S4 laser in 32,569 eyes. *J Refract Surg.* 2009;25:S634-S641.
2. Morse JS, Schallhorn SC, Hettinger K, Tanzer D. Role of depressive symptoms in patient satisfaction with visual quality after laser in situ keratomileusis. *J Cataract Refract Surg.* 2009;35:341-346.
3. Schallhorn SC, Farjo AA, Huang D, Boxer Wachler BS, Trattler WB, Tanzer DJ, Majmudar PA, Sugar A; American Academy of Ophthalmology. Wavefront-guided LASIK for the correction of primary myopia and astigmatism a report by the American Academy of Ophthalmology. *Ophthalmology.* 2008;115:1249-1261.
4. Tuan KM. Visual experience and patient satisfaction with wavefront-guided laser in situ keratomileusis. *J Cataract Refract Surg.* 2006;32:577-583.
5. Tahzib NG, Bootsma SJ, Eggink FA, Nabar VA, Nuijts RM. Functional outcomes and patient satisfaction after laser in situ keratomileusis for correction of myopia. *J Cataract Refract Surg.* 2005;31:1943-1951.
6. Lee J, Lee J, Park K, Cho W, Kim JY, Kang HY. Assessing the value of laser in situ keratomileusis by patient-reported outcomes using quality of life assessment. *J Refract Surg.* 2005;21:59-71.
7. Bailey MD, Mitchell GL, Dhaliwal DK, Boxer Wachler BS, Zadnik K. Patient satisfaction and visual symptoms after laser in situ keratomileusis. *Ophthalmology.* 2003;110:1371-1378.
8. Solomon KD, Fernández de Castro LE, Sandoval HP, Biber JM, Groat B, Neff KD, Ying MS, French JW, Donnenfeld ED, Lindstrom RL; Joint LASIK Study Task Force. LASIK world literature review: quality of life and patient satisfaction. *Ophthalmology.* 2009;116:691-701.
9. Durrie DS, Slade SG, Marshall J. Wavefront-guided excimer laser ablation using photorefractive keratectomy and sub-Bowman's keratomileusis: a contralateral eye study. *J Refract Surg.* 2008;24:S77-S84.
10. Walker MB, Wilson SE. Recovery of uncorrected visual acuity after laser in situ keratomileusis or photorefractive keratectomy for low myopia. *Cornea.* 2001;20:153-155.
11. El-Maghraby A, Salah T, Waring GO III, Klyce S, Ibrahim O. Randomized bilateral comparison of excimer laser in situ keratomileusis and photorefractive keratectomy for 2.50 to 8.00 diopters of myopia. *Ophthalmology.* 1999;106:447-457.

Using an International Medical Advisory Board to Guide Clinical Governance in a Corporate Refractive Surgery Model

John A. Vukich, MD

ABSTRACT

PURPOSE: To describe the role played by the International Medical Advisory Board (IMAB) in clinical and corporate governance at Optical Express, a corporate provider of refractive surgery.

METHODS: A review of goals, objectives, and actions of the IMAB.

RESULTS: The IMAB has contributed to study design, data analysis, and selection of instruments and procedures. Through interactions with Optical Express corporate and clinical staff, the IMAB has supported management's effort to craft a corporate culture focused on continuous improvement in the safety and visual outcomes of refractive surgery.

CONCLUSIONS: The IMAB has fashioned significant changes in corporate policies and procedures and has had an impact on corporate culture at Optical Express. [*J Refract Surg.* 2009;25:S647-S650.]
doi:10.3928/1081597X-20090611-04

To remain competitive, every medical enterprise must continuously ask itself: How can we deliver better patient care? An effectively run medical business will also ask itself: How do we organize ourselves to maximize efficiency and profitability without diminishing the quality of care?

All medical enterprises seek answers to these questions, and although it would be nice if the answers always came from within the practice or the corporation, every group recognizes the occasional need for outside assistance. Outsiders can bring a fresh perspective and a broad base of knowledge, and commonly it is their guidance that provides the solutions—or a way to find the solutions—that those within the company seek.

Like other similar enterprises, Optical Express has created an International Medical Advisory Board (IMAB) (Table 1). What distinguishes the Optical Express IMAB from most similar advisory groups is the role it plays within the Optical Express organization (Table 2). The IMAB's function is not to put a seal of approval on what others decide nor is it to simply offer suggestions on how to do things incrementally better. Rather, the IMAB is an integral part of determining the future of Optical Express. Not only does the IMAB participate in decision making, but it is intended to shape the process by which corporate decisions are made.

SETTING STANDARDS

For members of the IMAB, this is an extraordinary opportunity. Optical Express is possessed of resources—particularly data—that give it the ability to critically self-assess the

From Davis Duehr Dean, Madison, Wisc.

The author receives research support from STAAR Surgical, Abbot Medical Optics, Alcon Laboratories Inc, and Carl Zeiss Meditec. He is a member of the Optical Express International Medical Advisory Board.

Assistance in preparing this manuscript was provided by medical writer Kay Downer.

This paper was presented at the Optical Express Annual Refractive Meeting; December 6-8, 2008; Birmingham, England.

Correspondence: John A. Vukich, MD, 1025 Regent St, Madison, WI 53715. Tel: 608.282.2000; Fax: 608.282.2048; E-mail: javukich@gmail.com

TABLE 1

Optical Express International Medical Advisory Board (IMAB)

- Steven C. Schallhorn, MD, IMAB Chairman
- Jan Venter, MD, IMAB Clinical Director
- Mitchell C. Brown, OD, IMAB Deputy Medical Director
- Stephen C. Coleman, MD
- Joseph Colin, MD
- Steven J. Dell, MD
- Colman R. Kraff, MD
- Marguerite B. McDonald, MD
- Stephen Slade, MD
- John A. Vukich, MD

safety and efficacy of refractive surgery delivered in a corporate setting. The ultimate aim of the IMAB is to meld Optical Express’ rich data resources with the IMAB’s expertise in a process that continuously raises the quality of care for patients. The remainder of the article describes how the IMAB will contribute to this process.

First, what does the IMAB bring to the table that can help the company achieve its goals? The members of the IMAB are well known as teachers and innovators. By exposing Optical Express to thinking from outside the corporation, they serve as a source of fresh ideas. The IMAB members’ experience qualifies them to provide the guidance needed for Optical Express to adopt those practices that are likely to enhance visual outcomes and patient satisfaction.

DATA DRIVEN

As an enterprise, Optical Express places an emphasis on data: collecting data, analyzing data, and utilizing data. This supplement has a presentation with data from over 40,000 eyes. A database of that size is unprecedented in ophthalmology.

The value of such data is great, for it is the marriage of large quantities of reliable data with skilled analysis that drives sound medical decisions. To ensure data quality and sound study design, Optical Express maintains a corporate biostatistics department, a major function of which is to support the IMAB.¹

The combination of Optical Express’ data and a cadre of experienced scientists and clinicians who can work with it put Optical Express in a position to drive positive change in the refractive surgery industry.

Even with a large quantity of data and significant expertise, this endeavor will not be easy. I have a favorite

TABLE 2

Purpose and Role of the Optical Express International Medical Advisory Board (IMAB)

The IMAB offers

- A global view of trends
- Broad base of experience
- Diversity of views
- Proven track record of leadership

The IMAB’s role

- Introduce new techniques and technologies
- Help Optical Express utilize its wealth of data
- Provide continuing education within the organization
- Review and guide medical management decisions
 - Use evidence-based medicine to aid decision making
 - Continuous quality improvement
- Establish Optical Express leadership in creating a global standard of care
- Share Optical Express’ experience
- Publication of studies
 - Major presence at meetings around the world
- Improve the overall standard of care for all providers of refractive surgery
 - Benefit Optical Express patients and those of other providers
 - Enhance the reputation of the refractive surgery industry
 - Maintain public confidence in the safety and efficacy of refractive surgery
- Shape Optical Express corporate culture

saying that goes: “Most people do not recognize opportunity, because it comes dressed in jeans and looks like work.” And, in fact, collecting, collating, analyzing, and finding useful applications for this massive amount of data is an enormous task, so it’s fair to ask: What good can come from this effort?

Let us take an example. In this supplement, there are papers that use Optical Express data to analyze outcomes. Outcome measurements are a key element to driving success, and Optical Express’ data resources give it the ability to track results over very large numbers of patients and many physicians. From those results we can make decisions; we can establish practice guidelines. And we can use the same data facility to test those guidelines after implementation. Please note that although the data presented herein are limited to 1- to 3-months, patient follow-up is ongoing and longer-term data will be available.

ROLE OF THE IMAB

Clearly, the Optical Express store of data will be used internally to create better patient outcomes, but Optical Express also intends to share much of this data with the rest of the world to advance the field of refractive surgery.

First, the IMAB members will review and guide medical management decisions. Working with Optical Express biostatisticians, IMAB expertise can be used to structure studies to produce the most useful information. When studies are complete, the IMAB will assist in the analysis and application of their results to medical decisions. This evidence-based, decision-making process is a key aspect of the continuous quality improvement to which Optical Express is dedicated.

I would like to underscore that point. With its organization, expertise, access to data, and dedication to continuous improvement, Optical Express can set standards that others may look to for guidance. Indeed, that is a corporate goal, and an additional function of the IMAB is to make Optical Express an active institutional presence in the global refractive surgery community. We can do this by writing and publishing papers and posters, speaking at meetings (including those held electronically), and entering into dialogue with colleagues around the world. While the future is always uncertain, I believe that, if Optical Express lives up to its promise, if it continues to study issues and make evidence-based decisions in a credible, transparent manner, it can be a force in guiding decision-making around the world.

A secondary benefit is that through careful analysis and public reporting of outcomes, the IMAB can help maintain public confidence in the safety and efficacy of refractive surgery—not just of refractive surgery at Optical Express but of refractive surgery in general. The simple fact is that all of us in the field rise or sink based on the public perception of what we do. If patients believe in refractive surgery, there is a place for all of us. If they don't believe, neither Optical Express nor anyone else in the field will succeed.

A STRONG PRESENCE

The IMAB aims to help establish Optical Express as an institution dedicated to teaching others the art and science of refractive surgery. This process has begun with invitational symposia (such as the one for which this paper is written) where information is shared within the company to raise our own standards.

Moving outside the corporation, IMAB members will participate in national and international programs. The IMAB gives Optical Express the ability to offer a continuing stream of lectures and courses at meetings around the world.

The IMAB can lead in taking the Optical Express story to our colleagues globally. We can publish in professional journals. We can establish ongoing relationships with the media to explain and reinforce what we do. We can interact with Optical Express personnel to develop articles and symposium presentations at congresses.

It is a stated goal of the IMAB to establish a regular flow of information to ensure that the world is aware of Optical Express and its commitment, experience, and professional standing. Indeed, although relatively new to the field of refractive surgery, Optical Express is transforming itself from a consumer of medical education that in the past has learned and applied what others have taught to an active contributor to the knowledge base of peer-reviewed information in refractive surgery. It is becoming a net exporter of experience and expertise. This is a fundamental milestone in corporate development and a sign of the company's determination to hold a leadership position within the industry.

BUILDING THE BUSINESS OF REFRACTIVE SURGERY

How does this impact Optical Express' business? Where is the return on the investment made in the IMAB? For one thing, the IMAB can direct the use of Optical Express data in ways that are useful to the company. For example, Optical Express can not deliver what patients want if we do not know what that is. We need our patients to tell us how we are doing, but we can't just talk about patient satisfaction—we need to measure it. There are standardized metrics for evaluating patient satisfaction, and the IMAB can ensure that these additional data are gathered and used.

The patient satisfaction data presented by Brown et al² establish that Optical Express is already doing a good job of giving patients what they want. But patient satisfaction data can do more than simply tell us how we are doing. Increasingly, patient satisfaction is being taken into account by insurance and governmental organizations seeking criteria by which to evaluate providers.

For example, in the United States, the Consumer Assessment of Healthcare Providers and Systems (CAHPS) program is a public-private initiative to develop standardized surveys of patients' experiences with ambulatory and facility-level care. The majority of large US clinics report their results to this database. By using the same standardized metrics, Optical Express can measure itself against the other providers in the database, allowing the company to see how it compares to prestigious clinics in the United States and elsewhere. These are the exciting things we can do with Optical Express data, and ideas such as this

are the kinds of opportunities that the IMAB brings to Optical Express.

THE FUTURE

Going forward, the IMAB will help Optical Express continue to develop a holistic approach to refractive surgery. We know that the technology is not the only key driver for patient outcomes and satisfaction. Outcomes are influenced by such things as dry eye management, and patient satisfaction is heavily influenced by the individual's experience before, during, and after the procedure. The role of the IMAB is to help Optical Express stay focused on all of these areas.

But the role of the IMAB goes beyond advice and education. It includes the development of a corporate culture. Our role is to ensure that Optical Express not only does things well today, but that in all its operations, the company continuously lays the groundwork to do them better tomorrow.

REFERENCES

1. Hettinger KA. The role of biostatistics in the quality improvement of refractive surgery. *J Refract Surg.* 2009;25:S651-S654.
2. Brown MC, Schallhorn SC, Hettinger KA. Satisfaction of 13,655 patients with laser vision correction at 1 month after surgery. *J Refract Surg.* 2009;25:S642-S646.

The Role of Biostatistics in the Quality Improvement of Refractive Surgery

Keith A. Hettinger, MS, MBA

ABSTRACT

PURPOSE: To demonstrate how the large quantity of uniformly collected data available to a corporate refractive surgery provider, Optical Express, is applied to drive improvements in patient outcomes.

METHODS: Optical Express employs a skilled team of biostatisticians to analyze the information in its electronic medical records database of over 5,500,000 patient records. The techniques used to ensure high data quality and the selection of statistical methods used in making data-driven clinical decisions are described. The importance of appropriate statistical methods is demonstrated in an example in which the effect of age on refractive outcomes in low myopes is studied. The use of a corporate database in prospective and retrospective analyses is detailed.

RESULTS: By providing the resources necessary to interpret the information in Optical Express' medical records database, the biostatistics department has helped Optical Express refine its procedures and improve surgical protocols and patient outcomes.

CONCLUSIONS: Biostatistical analyses help transform the large quantities of uniformly collected clinical data available to a corporate surgery provider into information that can be applied to improve clinical practice. Such data-driven process improvements play a key role in improving patient outcomes. [*J Refract Surg.* 2009;25:S651-S654.] doi:10.3928/1081597X-20090611-05

W

ith data on over 5,500,000 patients, the Optical Express clinical outcomes database has the potential to shed light on a wide range of medical and surgical questions. In addition to evaluating the performance of individual surgeons, this database is used to answer broad questions about the safety and efficacy of various refractive surgery procedures and the factors influencing patient outcomes.

Optical Express employs a biostatistics department that ensures the appropriateness of statistical methodology and the quality of data. By ensuring that the conclusions drawn from this data are statistically valid, the biostatistics department is essential to the company's effort to answer a range of questions about both the science and business of refractive surgery.

ENHANCING OUTCOMES WITH DATA-DRIVEN DECISIONS

The primary function of data analysis is to promote evidence-based decisions that improve patient care. By analyzing data from tens of thousands of patients, statistical models can be developed that identify the key factors that impact surgical outcomes. Surgeons can then use these models to modify treatment variables and improve patient outcomes.

In addition to helping with the large-scale analyses reported in this supplement, the biostatistics department performs a variety of other assessments. For example, surgeon reviews are performed biannually to provide quality control information about each surgeon's performance. As part of these reviews, surgeons' performance is compared in a way that takes into account the patient population that each surgeon treats and the types of procedures he or she performs. Thus, the scoring system developed by the biostatistics department gives a valid "apples to apples" comparison.

Finally, the biostatistics department responds to queries regarding the merits of anecdotal information. For example,

From the Biostatistics Department, Optical Express, San Diego, Calif.

The author is an employee of the Optical Express Group.

Assistance in preparing this manuscript was provided by medical writer Kay Downer.

Correspondence: Keith A. Hettinger, MS, MBA, 4520 Executive Dr, Ste 230, San Diego, CA 92121. Tel: 858.597.0897; Fax: 858.597.0896; E-mail: keith.hettinger@opticalexpress.com

if a clinician notices increased induction of cylinder in a small series of patients, the biostatistics department can perform a retrospective analysis to determine whether the findings represent a significant trend or are just a statistical anomaly. If the former, the biostatistics department can perform additional analyses, including prospective studies, to determine the cause of this trend.

IMPORTANCE OF DATA SAFETY AND QUALITY

The Optical Express database is a highly systematized collection of electronic medical records, which uses a scalable private Multi Protocol Label Switching (MPLS) network. The data center where the information is hosted has multiple features such as redundant air supply, redundant power capabilities, and security measures. This system (Tier 4) is considered the highest level by the Telecommunications Industry Association. Security provisions include redundant communication links, fire suppression, intruder detection, private power substation, diesel generators, and 24-hour security. All databases are held in Microsoft SQL 2005 (Microsoft Corp, Redmond, Wash) using Windows authentication and role-based security. There are separate servers in three locations across two continents.

As with any such collection, data accuracy must be maintained to ensure the validity of conclusions drawn from analyses of the data. Optical Express' electronic medical records system includes features that help enhance data quality, including range validations, range restrictions, controls on applicable data types, and comment boxes to verify unexpected values. In addition to these features, everyone who enters data into the Optical Express system is continually reminded to be vigilant about data accuracy.

The Optical Express system is independently audited by Registrat Incorporated (Lexington, Ky), a third-party clinical research organization that specializes in data management. The intention of these independent audits is to provide an unbiased assessment of the data accuracy.

In an effort to further promote accuracy, the biostatistics department also routinely performs a thorough internal audit on all data to identify and query extreme values and other aberrations. For example, by comparing the distribution of preoperative visual acuity measurements, statistical analyses can identify optometrists who may require more training to obtain a precise and accurate refraction for each patient.

IMPORTANCE OF STATISTICAL METHODS

Although data quality is essential for accurate results, using appropriate methods for all analyses is

also crucial. The complexity of statistical questions can vary, but all analyses require proper methods to achieve valid results.^{1,2} To select the correct type of statistical test for a given application, statisticians consider a multitude of issues, including the inherent distribution of the data, the data type available, and whether an assumption of normality is met.

As an example of how different methods can affect the outcome of a statistical analysis, consider the question of patients versus eyes. If a procedure is performed binocularly on 50 patients, should the data be analyzed as 50 patients or 100 eyes? Because the treatments were binocular, one theorized approach is to average both eyes for a single patient and perform the analysis for 50 patients. Another approach is to disregard the fact that data on two particular eyes come from the same patient and perform the analysis on 100 eyes as though each eye was from a different patient.

Intuitively, clinicians know that neither of these extremes is accurate. Because two eyes from a single person are more similar than two eyes from two different people, the statistical analysis should not disregard the fact that eyes come in pairs. But because some patients may have eyes that are different, averaging results from a patient's two eyes will result in a loss of information. Appropriate statistical methodology will therefore account for the similarity between a patient's two eyes while still maintaining each eye as an independent data point. Rather than being an analysis of 50 patients or 100 eyes, a better approach may be an analysis performed on 50 pairs of eyes.

REAL-WORLD APPLICATIONS

To demonstrate this approach, consider a nomogram adjustment designed to account for the possible influence of patient age in the treatment of low myopia (≤ -3.00 diopters [D] with ≤ -1.50 D of astigmatism). For this analysis, the statistician will first set the null hypothesis: age does not affect outcomes for low myopia treatment. Whether this hypothesis is confirmed or rejected depends on the method used to address the "patients versus eyes" question.

As the first step in this analysis, a generalized linear model is created to determine whether patient age significantly affects the postoperative mean spherical equivalent refraction. Using a Simple Random Sample Without Replacement, 1000 randomly selected eyes (507 patients) with low myopia were included in this analysis; patient age ranged from 18 to 65 years. The follow-up time used for the analysis was 1 month for all patients.

Next, the analysis must address the "patients versus eyes" question. The simplest approach is to make no

adjustment to the model and assume that a patient's two eyes behave completely independent of one another. In this approach, 100 eyes from 50 patients would be treated the same as 100 eyes from 100 patients. Using this method, an analysis performed using actual data from the Optical Express database yields $P=.0013$, and the null hypothesis is rejected.

Because of common factors such as identical genes and measurement conditions, however, some correlation between a patient's two eyes is expected. Therefore, a second analytical method takes a "patient centered" approach, assuming a correlation exists between a patient's eyes and accounting for it by using an average of both eyes for the analysis. This approach yields $P=.2178$, which confirms the null hypothesis.

Finally, a third method—which I believe yields the most accurate result—accounts for the possible correlation between a patient's eyes by adjusting the model for intraclass correlation.³ With the use of repeated measures, this method treats each patient as a cluster of data points, and an adjustment is made within that cluster. The result of this method is $P=.0895$, which confirms the hypothesis that age does not significantly affect the treatment of low myopia.

As this example shows, different methods of statistical analysis can yield different conclusions. Compared to the most accurate statistical method (presented last), the first option overestimates the P value and incorrectly rejects the null hypothesis. Likewise, whereas the second method correctly confirms the hypothesis, it nonetheless underestimates the relationship that age may play in the treatment of myopia. In-house biostatisticians ensure the application of appropriate methods for each type of analysis.

DEMONSTRATING IMPROVEMENTS IN CLINICAL OUTCOMES

The clinical benefit that can be achieved through statistical analyses is demonstrated by the following example. Following a comprehensive analysis of the sphere adjustment applied to wavefront-guided treatments, Optical Express surgeons implemented several changes to this adjustment. Specifically, the protocol was changed to specify that the treatment sphere (using a 4-mm wavefront sphere calculation on the aberrometer) should be adjusted to be equivalent to the manifest sphere if both the preoperative wavefront and manifest refraction were of high quality. Previously, the protocol was to either select a wavefront capture that was within the VISX PMA guidelines or to adjust the treatment sphere to be within 0.50 D of the manifest sphere.⁴ The analysis supporting the implementation of this change predicted that this modification would increase refrac-

TABLE
Preoperative and Demographic Characteristics of Patients Treated Before and After a Change in the Sphere Adjustment Applied to Wavefront-guided Treatments

| | Before | After |
|----------------------|----------------------------------|----------------------------------|
| No. of eyes | 5799 | 5885 |
| Gender (M/F, %) | 33/67 | 33/67 |
| Mean age (range) (y) | 38.1±10.8 (18 to 69) | 37.5±10.6 (18 to 70) |
| Mean SEQ (range) (D) | -3.77±2.13 (-0.25 to -12.125) | -3.75±2.02 (-0.38 to -12.125) |

SEQ = spherical equivalent refraction

tive accuracy and allow a higher percentage of patients to achieve their target refraction.

Following the implementation of this change, the biostatistics team analyzed patient outcomes to evaluate its effect. The sample size for this analysis was extracted from the central Optical Express database using the following selection criteria: 1) all primary wavefront-guided LASIK procedures performed in the 3 months immediately before and 3 months after the change, 2) emmetropia was the refractive goal, 3) treatment of myopia, 4) preoperative cylinder ≤ 2.00 D, and 5) 1-month follow-up. This yielded a total of 11,684 patients; patients treated before the surgical change comprised one cohort ($n=5799$) and those treated following the implementation of the change comprised a second cohort ($n=5885$). This number included all patients in the database at the time period that met the requirements for analysis and had 1-month follow-up. The 1-month follow-up rate for this group was 89%. Preoperative and demographic characteristics were statistically similar for both groups (Table).

The results of this analysis revealed a statistically significant increase (3%) in the percentage of patients achieving 20/20 postoperative uncorrected visual acuity (UCVA) after the surgical protocol was updated ($P<.0001$, Fig). A statistically significant increase (4%) was also noted in the percentage of patients achieving 20/25 postoperative UCVA ($P<.0001$). This result shows that statistical analyses can be used both to drive improvements in treatment technique and to analyze the impact of these improvements.

CHALLENGES

Given the large size of the datasets being analyzed and the nature of the data collection in a real clinical

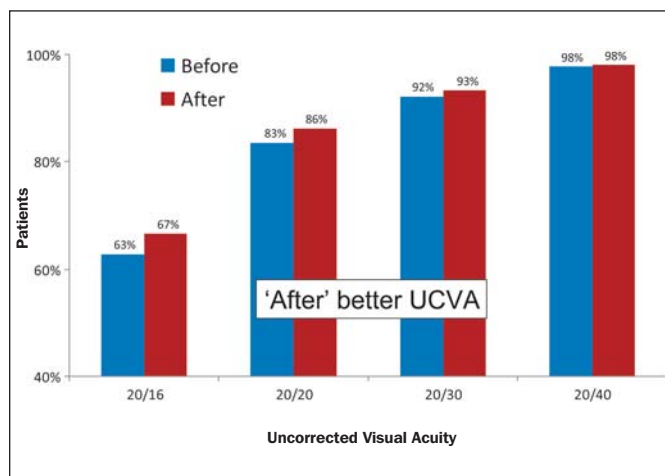


Figure. Patients treated after implementation of a change in treatment technique had better postoperative uncorrected visual acuity (UCVA) compared to patients treated prior to the implementation of this change.

setting, there are challenges that must be addressed. For instance, follow-up times can become a particularly important factor to consider. In a typical clinical setting not all patients will return for a 1-, 3-, 6-, or 12-month postoperative follow-up. Thus, when selecting a follow-up time point for an analysis it is important to examine the characteristics for the group of patients who did not make that clinic visit. Any clinical or statistically significant difference in preoperative or treatment characteristics of the “lost to follow-up” patients must be addressed for selection bias. In many cases, the initial analysis is completed with 1-month data, given the higher rate of follow-up. Additional analysis is then completed at later time points (3, 6, and 12 months) to ensure consistency of conclusions.

Another challenge is that with such a great amount of data comes a great amount of inherent variability. This may be due to a host of issues, such as variability in patient healing responses, differences in examination room chart illumination, or variations in surgeon technique. When analyzing multiple effects for hypothesis testing, building an appropriate model can become complicated. It is imperative to address all identifiable potential independent variables for effect as well as covariance and interaction.^{1,3} A lengthy and stepwise approach is warranted to ensure no lurking variables exist or incomplete conclusions are made.

A unique challenge arises in hypothesis testing when analyzing such large datasets. Historically, hypothesis testing was developed as a tool to infer significant relationships in smaller sample sizes. When these traditional tests are used in the presence of large amounts of data, statistical significance can become prevalent. To address this tendency, it is essential to always include an evaluation of clinical significance. If an explanatory variable is found to be statistically significant in one cohort, it is important to assess whether the mean difference between the two cohorts is clinically meaningful. Another practical way of addressing this tendency is to more regularly employ the use of random sampling. By sampling from these large datasets, more reliable *P* values can be created for inferential purposes. This random sampling testing can be done in a repeated manner.³ This will yield multiple *P* values from multiple random samples that can be analyzed for variability, thus providing a reliability estimate for our hypothesis testing conclusions.

The quantity of data that a large corporate provider such as Optical Express collects is a valuable resource. The company’s biostatistics department plays a key role in interpreting the data. In addition to selecting appropriate statistical methods for each type of analysis, the biostatistics department works to ensure the accuracy and consistency of all data entered into the Optical Express system.

As a result of these efforts, Optical Express can apply its data resources in areas ranging from internal quality control checks to large clinical studies, such as those presented in this supplement. The result is that the quantity of uniformly collected data available in the corporate environment can be used to improve the quality of patient outcomes.

REFERENCES

1. Fleiss JL, Levin B, Cho Paik M. *Statistical Methods for Rates and Proportions*. 3rd ed. Hoboken, NJ: Wiley John & Sons Inc; 2003.
2. Fleiss JL. *The Design and Analysis of Clinical Experiments*. Hoboken, NJ: Wiley-Interscience Publications; 1999.
3. Hansen PL. Large sample properties of generalized method of moments estimators. *Econometrica*. 1982;50:1029-1054.
4. Professional use information. VISX STAR S4 IR™ Excimer Laser System and WaveScan WaveFront® System. CustomVue™ Treatment. Available at: www.accessdata.fda.gov/cdrh_docs/pdf/P930016S020c.pdf. Accessed May 2009.

A Complex Case Management System Provides Optimal Care for All Patients

Jan A. Venter, MD; Stephen J. Hannan, MCOptom

ABSTRACT

PURPOSE: To describe the complex case management system developed by Optical Express, a large corporate provider of laser vision correction, and to detail the benefits this system offers for managing the surgical complications of laser vision correction.

METHODS: The classification scheme Optical Express uses to categorize surgical complications is described, and the various pathways patients can take through the complex case system are detailed. This process is illustrated with a case study describing the treatment of a patient with postoperative LASIK ectasia. The benefits of the complex case system are also discussed.

RESULTS: A total of 1363 eyes were treated in the complex case management system during the 5-year period between January 1, 2004 and December 31, 2008. These 1363 eyes represent a small fraction (0.45%) of the approximately 300,000 eyes treated during this period. The Optical Express complex case management system organizes complications based on severity and urgency. Grade A complications (40 eyes, 2.9% of all complications) are the most serious and urgent, followed by grade B (327 eyes, 24.0%), and grade C (996 eyes, 73.1%). For each complication, the patient's journey through the complex case system starts with an evaluation by an optometrist. Depending on the severity of the complication, the patient may then be referred to the treating surgeon, a regional complex case surgeon, or an external consultant. A complex case manager coordinates care and logistics throughout this process.

CONCLUSIONS: The complex case management system used by Optical Express provides clinical care and support for patients who experience a surgical complication. [*J Refract Surg.* 2009;25:S655-S660.] doi:10.3928/1081597X-20090611-06

Significant complications following laser vision correction occur in <1% of patients, but the quality of care provided in these cases can define the way surgeons and their practices are perceived. With proper management and excellent communication, most complications can be resolved with minimal or no loss of vision or patient dissatisfaction. When a complication is managed poorly, however, a single unhappy patient can significantly damage a practice's reputation. On a larger scale, a small cadre of dissatisfied refractive surgery patients can negatively influence public perception of the entire industry.

Because effective complication management is essential for quality patient care, Optical Express has developed a complex case management system dedicated to treating patients who experience a complication. Staffed by highly trained clinicians and support personnel, equipped with state-of-the-art of technology, and supported by the expertise of the company's International Medical Advisory Board (IMAB), this system provides the resources necessary to ensure appropriate and timely treatment for any potential complication.

CATEGORIZING COMPLEX CASES

Complications after laser vision correction can range from minor ocular surface irritation to potentially blinding conditions that require immediate treatment. Because long-term outcomes often hinge on the appropriateness and timeliness of initial treatment, the complex case management system provides resources to help optometrists and surgeons assess the urgency of each patient's condition. Central to this effort is a standardized classification scheme that categorizes com-

From Optical Express, London, United Kingdom (Venter) and Scotland (Hannan).

Dr Venter is the UK Medical Director for Optical Express. Mr Hannan is an employee of the Optical Express Group.

Assistance in preparing this manuscript was provided by medical writer Kay Downer.

Correspondence: Jan A. Venter, MD, Optical Express, 5 Deerdynes Rd, Westfield, Cumbernauld G68 9HF, United Kingdom. Tel: 44 1236 795104; Fax: 44 1236 795062; E-mail: janventer@opticalexpress.com

TABLE
Classification Scheme of the Complex Case Management System

| Grade | Complication | Examples |
|----------------------|--|--|
| Grade A - Emergency | Visually disabling conditions that require immediate management. The risk of disability increases rapidly with time. | <ul style="list-style-type: none"> • Microbial keratitis • Severe DLK • Displaced flap • Retinal detachment • Flat anterior chamber/wound leak • Pupillary block glaucoma (IOP >30 mmHg) |
| Grade B - Urgent | Visually disabling conditions that require urgent management (within 2 to 3 days). | <ul style="list-style-type: none"> • Visually significant flap striae • Progressive epithelial ingrowth (visually significant or with flap melt) • Wound leak with formed anterior chamber • Displaced IOL • Visually significant cystoid macular edema • Loss of ≥ 2 lines BSCVA at 3 months or later due to a progressive condition |
| Grade C - Not Urgent | Other non-emergency and nonprogressive visually disabling conditions, or symptoms that cannot be managed by local optometrist and are not due to conditions listed in categories A or B. | <ul style="list-style-type: none"> • Quality or clarity of vision symptoms, such as glare, halos, and/or difficulty driving, at 3 months or later • Decrease in BSCVA of ≥ 2 lines at 3 months or later • Unsatisfactory refractive or visual outcome • Severe dry eye complaints and/or persistent punctuate epithelial erosions not responsive to conventional treatment • Other nonprogressive ocular or visual conditions or symptoms |

DLK = diffuse lamellar keratitis, IOP = intraocular pressure, IOL = intraocular lens, BSCVA = best spectacle-corrected visual acuity

plications by their severity and the timeframe in which they should be treated (Table).

By helping to ensure that complications are addressed with the appropriate urgency, this classification scheme can be a useful tool for guiding clinical management. Because the complex case management system deals with any complication experienced by an Optical Express patient, not just refractive surgery complications, this scheme includes a wide range of postoperative complications.

Although all complications require careful treatment, the majority of complications are not vision threatening. Of the complications treated in the Optical Express complex case management system, 2.9% (0.01% of all eyes [N=300,000]) were categorized as grade A conditions. Twenty-four percent of complex cases (0.11% of all eyes [N=300,000]) were categorized as grade B and 73.1% of complex cases (0.33% of all eyes [N=300,000]) were grade C. The most common reasons for referral to the complex case management system are dry eyes that affect vision, residual myopia following laser vision correction, and overall patient dissatisfaction (Fig 1).

TREATMENT OF COMPLEX CASES

In addition to providing guidance that helps clinicians evaluate the severity of various complications, the complex case management system also offers a range of resources to treat these cases. Not only does

this system ensure that patients receive care from expert clinicians, it also makes available complex case managers who communicate with the patient and the responsible clinicians on a regular basis, facilitate referrals, make appointments, and arrange transportation and accommodation as needed. These individuals provide a communication and logistics link that is important to the system and the patient.

Because each case is unique, the complex case management system offers multiple treatment pathways (Fig 2). Although the patient’s initial contact is generally an optometrist, the patient may subsequently be referred to either the treating surgeon, a surgeon who specializes in complication management, or an expert consultant outside of the Optical Express system.

When a patient presents with a problem, the optometrist first performs an evaluation and makes an initial assessment. If the problem is straightforward and falls within the scope of optometric practice, the optometrist provides appropriate treatment. For example, a patient who has postoperative dry eye complaints after LASIK (with an otherwise normal examination) can often be managed successfully with standard dry eye therapies.

For more complex problems that may require advanced medical or even surgical management, the optometrist refers the patient to the treating surgeon and notifies a complex case manager about the case.

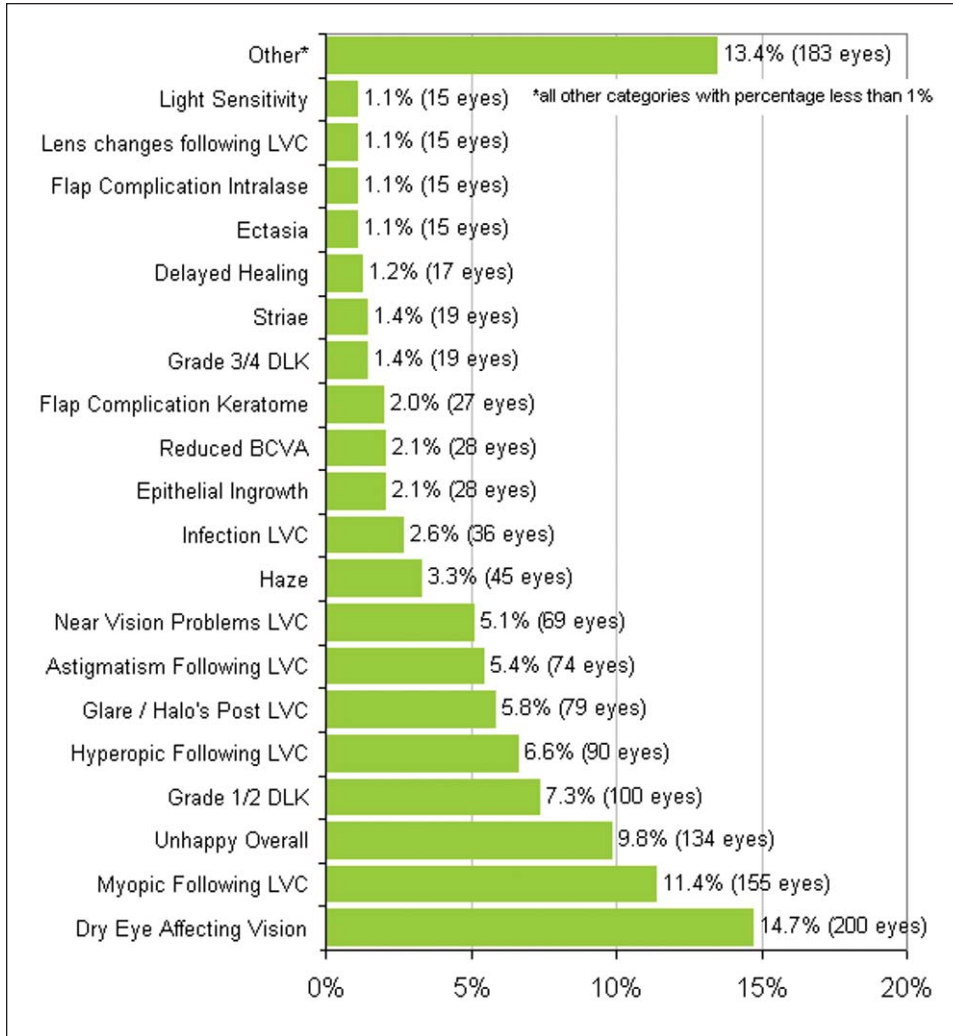


Figure 1. Patients are referred to the complex case management system for a variety of reasons, including postoperative dry eye, residual myopia, and overall patient dissatisfaction (N=1363 eyes). LVC = laser vision correction, DLK = diffuse lamellar keratitis, BCVA = best spectacle-corrected visual acuity

Because multiple clinicians may become involved in providing care for complex cases, the complex case manager serves as a communication link between the patient and the clinicians involved in the case. The complex case manager tracks and records the relevant details of every case and oversees all of the logistics related to the patient's care.

The treating surgeon then evaluates the patient and either treats the patient personally or refers the patient to an appropriate sub-specialist. In most cases, the treating surgeon provides the necessary treatment. For example, a patient with visually significant flap striae could be treated by relieving and repositioning the flap.

In some circumstances, the surgeon may need to refer the patient to a regional complex case surgeon. These individuals specialize in managing rare complications, such as ectasia after laser vision correction, and they have access to equipment and resources that are not available at every laser center. For example, these individuals can use specialized diagnostic in-

struments such as anterior segment optical coherence tomography to perform a more in-depth examination of a patient, and they also have the resources to perform advanced surgical procedures such as collagen cross-linking, premium intraocular lens implantation, or topography-guided laser retreatment.

Alternatively, if the treating surgeon believes that the case is particularly serious or falls outside his or her areas of expertise, he or she may immediately refer the patient to an external consultant. For example, a patient with a macula-off retinal detachment may need immediate care by a retina specialist. The complex case management system has consulting arrangements in place to facilitate such outside referrals.

Once the complication has been stabilized or resolved, the patient is referred back to the normal Optical Express system for any remaining follow-up care. Although the patient is now back in the regular patient care system, the optometrist and surgeon remain in regular contact with each other and with the complex case manager.

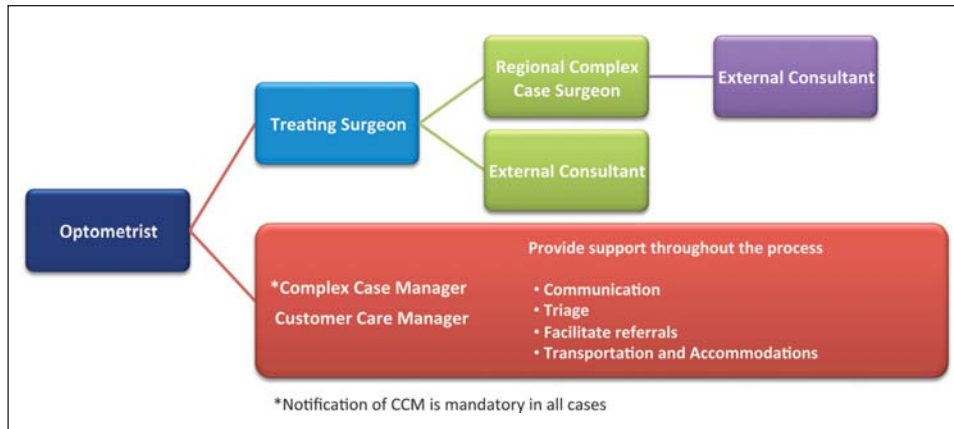


Figure 2. Depending on the severity of the complication, patients referred to the complex case system may receive care from an optometrist, the treating surgeon, a regional complex case surgeon, or an external consultant.

Throughout this process, communication takes place in many ways. The complex case manager is available through a direct telephone link as well as an internal e-mail system that can be accessed by all optometrists and surgeons. The medical director and the complex case manager also discuss new and existing cases in detail during telephone conference calls that take place on a weekly basis. A summary report is composed by the complex case manager ahead of this weekly conference call.

CASE STUDY: A PATIENT WITH ECTASIA AFTER LASIK

To see how the complex case management system works in practice, the following case study is presented. Note that the care provided by the complex case management system allowed the patient to ultimately achieve a good outcome, even after experiencing a serious complication.

A 34-year-old man underwent uneventful bilateral LASIK in May 2006. The patient’s medical, ocular, and family history was unremarkable. The preoperative manifest refraction was $-3.00 -1.75 \times 095$ with a best spectacle-corrected visual acuity (BSCVA) of 20/15 in the right eye and $-4.75 -2.00 \times 095$ with a BSCVA of 20/15 in the left eye. Over 2 years of documentation confirmed refractive stability.

Keratometry was 43.50/45.50 diopters [D] @ 010 in the right eye and 45.00/46.50 D @ 176 in the left eye. The preoperative corneal shape (Orbscan; Bausch & Lomb, Rochester, NY) was assessed to be normal in both eyes. Ultrasound pachymetry measured corneal thickness as 563 μm in the right eye and 560 μm in the left eye.

The IntraLase FS-60 (Abbott Medical Optics [AMO]; Santa Ana, Calif) was used to create a 9.0-mm diameter flap with a planned flap thickness of 120 μm in both eyes. A standard ablation treatment was performed with a VISX S4 IR excimer laser (AMO); the maximum ablation depth was 57 μm in the right eye and 81 μm

in the left eye. Based on this ablation depth and the preoperative corneal thickness measurements, the estimated residual stromal bed thickness was 383 μm in the right eye and 362 μm in the left eye.

The patient had a normal postoperative recovery with follow-up care provided at standard intervals by the patient’s local Optical Express optometrist. At 12-month postoperative follow-up, an increase in astigmatism was noted in both eyes. A reduction in uncorrected visual acuity (UCVA) and a slight reduction in BSCVA were also observed in the left eye. At this examination, the UCVA was 20/20 in the right eye and 20/60 in the left eye. The manifest refraction was $+0.75 -2.00 \times 050$ with a BSCVA of 20/12⁻² in the right eye and $+0.25 -2.50 \times 130$ with a BSCVA of 20/20⁺¹ in the left eye.

Suspecting ectasia, the optometrist referred the patient back to the treating surgeon and notified the complex case manager. The surgeon confirmed the diagnosis of postoperative LASIK ectasia, worse in the left eye than the right eye (Fig 3). The patient was referred into the complex case system for further management.

As the first step in managing this complication, the complex case manager discussed the case with both the referring surgeon and complex case surgeon. The complex case manager assigned to this patient was an optometrist with many years of experience managing complex refractive surgery patients, and the complex case surgeon was an experienced refractive and intraocular surgeon with expertise in the tertiary management of corneal diseases, including ectasia after laser vision correction.

After a full discussion of the patient’s condition and the proposed treatment plan, the complex case manager contacted the patient. In addition to arranging an initial appointment with a specialist surgeon, the complex case manager used this opportunity to reassure the patient, answer any questions the patient might have had, and provide e-mail and mobile phone contact information in case the patient had any questions between clinical

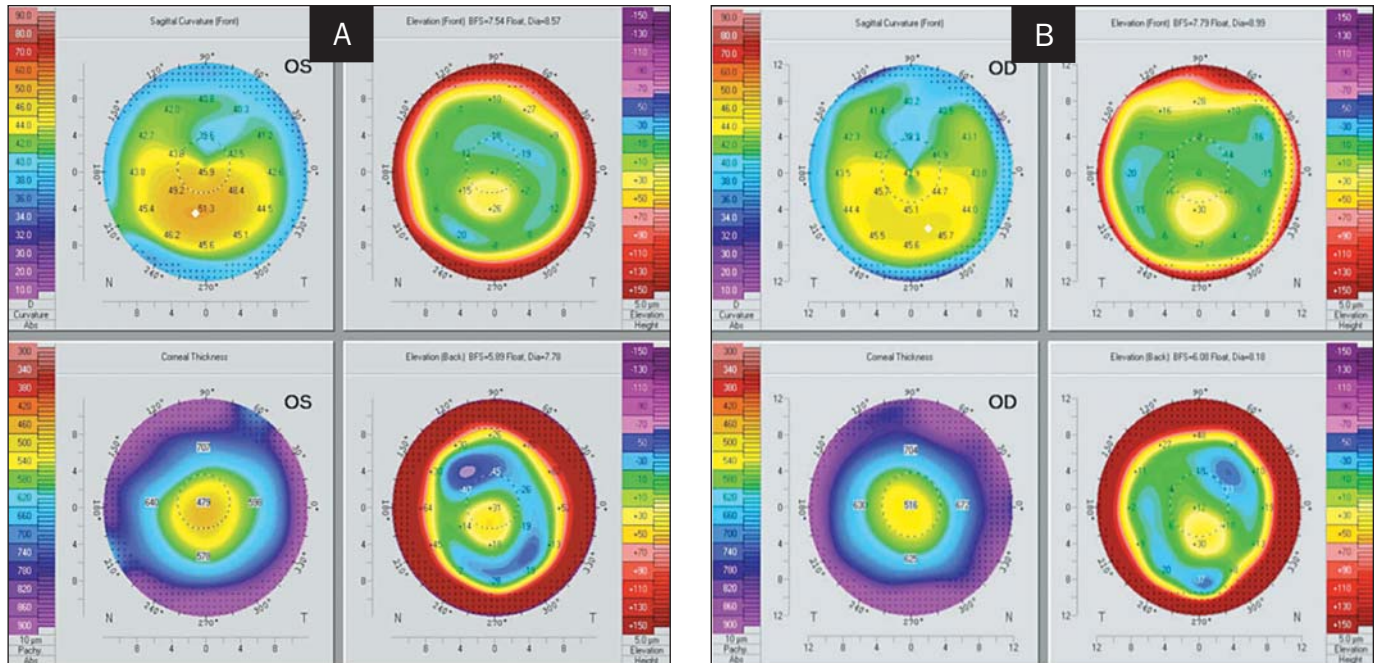


Figure 3. In this case, Pentacam (Oculus Optikgeräte, Wetzlar, Germany) images taken 1 year after LASIK revealed ectasia that was worse in the **A)** left eye than the **B)** right eye. In the left eye, the sagittal curvature map shows an 11.00-D difference in superior-inferior K readings, as well as an abnormal K reading (51.30 D). The abnormal anterior elevation map (apex +32 μm) corresponds with the abnormal posterior elevation map (apex +49 μm). The thinnest point on the pachymetry map is 466 μm . In the right eye, the superior-inferior difference in K readings is 6.00 D, with the anterior elevation map showing an apex +31 μm and the posterior elevation map showing an apex +36 μm . The thinnest point on the pachymetry map is 512 μm .

appointments. For patients with a complicated postoperative course who are likely to be apprehensive, this immediate attention, support, and reassurance may be as important as the clinical care rendered.

After entering the complex case management system, the patient was followed closely by the complex case manager and the patient management team for a period of 3 months, during which time the inferior steepening and astigmatism in the left eye progressed. In October 2007, the refraction in the left eye was plano -4.00×103 with UCVA of 20/80 and BSCVA of 20/25. To halt further progression, a collagen cross-linking procedure was performed in the left eye 17 months after the primary LASIK procedure.¹⁻³

Over the ensuing year, close follow-up care was provided by the complex case team and the patient's local optometrist. Residual refractive error in both eyes was managed with spectacles and contact lenses. No further progression of ectasia was noted in the left eye, and BSCVA improved to 20/20.

In December 2008, 14 months after the collagen cross-linking procedure, the complex case surgeon corrected the residual refractive error of plano -4.25×085 by implanting an Artisan toric lens (Ophtec BV, Groningen, Netherlands).⁴⁻⁷ The patient noticed immediate visual improvement, and UCVA was 20/32 on the first postop-

erative examination following lens implantation. Two months after phakic IOL implantation, the left eye had achieved UCVA of 20/20, with a manifest refraction of $+0.25 -1.25 \times 140$ and BSCVA of 20/15.

As of this writing, this patient is continuing to receive follow-up care by his local optometrist. The optometrist regularly reports the patient's progress to the complex case team, and the complex case manager maintains regular communication with the patient. Because the right eye is also showing signs of progressive postoperative LASIK ectasia, a second collagen cross-linking procedure is planned.

BENEFITS OF THE COMPLEX CASE SYSTEM

As this example shows, the complex case management system quickly and effectively provides the appropriate level of care for each patient and ensures that the patient is tracked and followed until the complication has been resolved. Although the effective and rapid provision of clinical care is the most obvious element of this system—and arguably, the most important—this system also provides other important benefits.

By offering a detailed and well-coordinated protocol for continuous communication between the patient, clinical providers, and complex case manager, this system ensures that patients believe they are receiving ap-

appropriate attention and the best possible care for their condition. Given that these patients are likely to be anxious, this dedicated communication is a key element in maintaining patient satisfaction. In fact, many of these patients become ambassadors for the practice following completion of their care, regardless of their complication, because of the care and attention they received.

AUTHOR CONTRIBUTIONS

Study concept and design (J.A.V., S.J.H.); data collection (S.J.H.); interpretation and analysis of data (J.A.V.); drafting of the manuscript (S.J.H.); critical revision of the manuscript (J.A.V.); administrative, technical, or material support (S.J.H.); supervision (J.A.V.)

REFERENCES

1. Hafezi F, Kanellopoulos J, Wiltfang R, Seiler T. Corneal collagen crosslinking with riboflavin and ultraviolet A to treat induced keratectasia after laser in situ keratomileusis. *J Cataract Refract Surg.* 2007;33:2035-2040.
2. Wittig-Silva C, Whiting M, Lamoureux E, Lindsay RG, Sullivan LJ, Snibson GR. A randomized controlled trial of corneal collagen cross-linking in progressive keratoconus: preliminary results. *J Refract Surg.* 2008;24:S720-S725.
3. Coskunseven E, Jankov M, Hafezi F. Contralateral eye study of corneal collagen cross-linking with riboflavin and UVA irradiation in patients with keratoconus. *J Refract Surg.* 2009;25:371-376.
4. Budo C, Bartels MC, van Rij G. Implantation of Artisan toric phakic intraocular lenses for the correction of astigmatism and spherical errors in patients with keratoconus. *J Refract Surg.* 2005;21:218-222.
5. Moshirfar M, Grégoire FJ, Mirzaian G, Whitehead GF, Kang PC. Use of Verisyse iris-supported phakic intraocular lens for myopia in keratoconic patients. *J Cataract Refract Surg.* 2006;32:1227-1232.
6. Kamiya K, Shimizu K, Ando W, Asato Y, Fujisawa T. Phakic toric Implantable Collamer Lens implantation for the correction of high myopic astigmatism in eyes with keratoconus. *J Refract Surg.* 2008;24:840-842.
7. Alfonso JF, Palacios A, Montés-Micó R. Myopic phakic STAAR collamer posterior chamber intraocular lenses for keratoconus. *J Refract Surg.* 2008;24:867-874.

An Evidence-based Approach to Patient Selection for Laser Vision Correction

Mitchell C. Brown, OD

ABSTRACT

PURPOSE: To describe the process used by Optical Express, a large corporate refractive surgery provider, to develop evidence-based patient selection guidelines for laser vision correction.

METHODS: The evaluation of patient selection criteria for laser vision correction is part of a larger corporate process of continuous quality improvement and clinical due diligence. The procedures used to evaluate patient selection criteria are described in detail and the benefits of this process are explained. The criterion review process involves the company's International Medical Advisory Board (IMAB) and includes an evaluation of the published literature and analyses generated from the large Optical Express clinical outcomes database. This article offers a case study in which the IMAB used the criterion review process to examine the upper limit for estimated postoperative keratometry in hyperopic laser vision correction.

RESULTS: The patient selection criteria undergo continuous scrutiny and are modified whenever medical evidence indicates that change is appropriate.

CONCLUSIONS: Using an established protocol for reviewing patient selection criteria, Optical Express continuously measures its patient selection criteria against both external (published) and internal data sources. This process ensures that decisions about patients' suitability for surgery are based on the best-available current medical evidence. [*J Refract Surg.* 2009;25:S661-S667.] doi:10.3928/1081597X-20090611-07

A

lthough most people with refractive error can safely undergo laser vision correction, a subset of individuals who present for the procedure are not suitable candidates. To achieve consistently good outcomes while minimizing the risk of complications, refractive surgery providers must decide which patients to approve for surgery and which to guide towards alternative treatments. The ultimate determination of suitability for surgery is made by the operating surgeon. A multifaceted process, this decision includes a consideration of data generated in the patient's ocular examination, an assessment of the patient's medical health, and a determination that the patient can make an informed decision based on realistic expectations.

THE EVOLUTION OF PATIENT SELECTION CRITERIA

Typically, eye care providers base patient selection decisions on community standards that have evolved over time. These standards represent a set of informal selection criteria to which most clinicians in the field adhere. Although some of these standards are based on rigorous clinical studies, many are derived from less methodically scrutinized sources, including case reports, studies with small sample sizes, or medical reasoning.

In the absence of strong evidentiary support, many surgeons apply these community standards conservatively. Although it may seem reasonable to exclude from surgery every patient who is outside of today's community standards, these standards may unnecessarily disqualify individuals who could be treated safely and would benefit from the life-changing experience of laser vision correction. Conversely, there may be community standards that unnecessarily expose patients to risk.

From Optical Express, San Diego, Calif.

The author is an employee of the Optical Express Group.

Assistance in preparing this manuscript was provided by medical writer Kay Downer.

Correspondence: Mitchell C. Brown, OD, 4520 Executive Dr, Ste 230, San Diego, CA 92121. Tel: 858.597.0897; Fax: 858.597.0896; E-mail mitchbrown@opticalexpress.com

TABLE 1

Process for Evaluating Patient Selection Guidelines

| |
|--|
| Current Optical Express standard |
| Basis of the current Optical Express standard |
| Number of patients deemed unsuitable each year based on the standard |
| Potential concerns/risks |
| Literature search |
| Regulatory/organizational guidance |
| Optical Express experience/data |
| IMAB discussion (risk vs benefit) |
| IMAB consensus |

IMAB = International Medical Advisory Board

Optical Express, Europe's largest provider of laser vision correction, recently established a systematic process for reviewing patient selection guidelines (Table 1). Applied on an ongoing basis, this process engages Optical Express' International Medical Advisory Board (IMAB) to perform a comprehensive review of patient selection guidelines based on a thorough review of the available literature (including regulatory and organizational guidance) and analysis of the Optical Express database.

DEVELOPING A STRUCTURED REVIEW PROCESS

In determining whether a patient is a suitable candidate for laser vision correction, eye care providers must consider a number of factors: the nature, degree, and stability of the refractive error; corneal shape, thickness, and topography; the health of the ocular surface; and the presence of any systemic medical conditions or ocular pathology. Because clinical findings related to any one of these factors may make a patient unsuitable for surgery, patient selection guidelines must address a wide range of criteria.

For each selection criterion, the Optical Express review process begins by evaluating the current guideline in the context of its scientific basis or origin. In many cases, the IMAB will judge the current criterion to be well supported, in which case the standard can be accepted without further review. In other cases, the current standard simply reflects a previously established medical consensus, and further review is needed.

After identifying the guidelines that are well supported, an assessment of the remaining guidelines is then conducted. The relative risk and benefit of performing laser vision correction in patients with vari-

ous preoperative conditions is carefully considered, as is the community incidence of the condition or clinical issue under review.

In the most recent IMAB review session, this initial screening process revealed a total of 17 guidelines that required in-depth review (Table 2).

REVIEWING AVAILABLE DATA

For each criterion, the next step of the process involves a comprehensive review of laser vision correction literature published in the English language. For the latest review, the PubMed literature search engine was employed using the following search terms: laser in situ keratomileusis, LASIK, photorefractive keratectomy, PRK, LASEK, and epi-LASIK, in combination with other search terms related to each particular issue being studied (eg, autoimmune, rheumatoid, collagen vascular, Crohns, Lupus, etc).

This initial search yielded a total of 1486 citations related to the 17 guidelines being considered. Encompassing the vast spectrum of published literature, these citations included human clinical trials, case reports, letters, and editorials.

The citation titles were then reviewed and abstracts were obtained for those titles that appeared to have relevance to surgical suitability. After 139 abstracts were reviewed, 63 full text articles were obtained and deemed sentinel for this evaluation. These 63 articles were then subdivided based on the criterion to which each article applied (see Appendix).

The IMAB next examined other evidence related to each suitability criterion. This evidence included device labeling and the summary of safety and effectiveness reports from the US Food and Drug Administration (FDA), as well as position statements from the European and American Societies of Cataract and Refractive Surgery, the American Academy of Ophthalmology, the Royal College of Ophthalmologists, and the American Optometric Association.

For certain patient selection criteria, an analysis of the Optical Express clinical outcomes database was also performed to provide additional information. The large sample size available in this database provided a high degree of statistical power even for low-incidence conditions.

To illustrate the strength of the Optical Express data, consider the amount of information available regarding clinical outcomes for hyperopic LASIK. The literature review for this topic included 16 sentinel reports with a combined total of 3504 eyes; the average sample size in these studies was 219 eyes. The FDA clinical trial of wavefront-guided LASIK with the VISX laser (Abbott Medical Optics, Santa Ana, Calif) consisted of 131 eyes.

TABLE 2

**Guidelines Recently Reviewed by the Optical Express
International Medical Advisory Board**

| Guidelines | Previous Criteria | Revised Criteria |
|--|---|---|
| Maximum sphere for hyperopic LASIK | +5.00 D | +4.50 D |
| Maximum estimated postoperative keratometry for hyperopic correction | 48.00 D | 50.00 D |
| Minimum preoperative pachymetry for LASIK | 500 μ m | 480 μ m |
| Low refractive error | Treatment provides demonstrated benefit | No change |
| Use reading glasses only | Treatment provides demonstrated benefit | No change |
| Refractive stability definition | Sphere and cylinder change is <0.50 D over the past 12 months, regardless of type of refractive error | Use algorithm that accounts for type of refractive error, magnitude and direction of change, time interval of change and effects of accommodation |
| Amblyopia | No treatment of "good" eye if best spectacle-corrected visual acuity of amblyopic eye is 20/40 or worse | No change |
| Autoimmune conditions | No treatment | Treatable if stable, well-controlled with letter from patient's general practitioner; no ocular involvement or dry eye |
| Glaucoma | No treatment | No change |
| Ocular hypertension/glaucoma suspect | Treatable if condition is stable and well controlled | No change |
| Nystagmus | Surgeon discretion | No change |
| Diabetes | No treatment of type 1 diabetics | Treatable with stable type 1 or type 2 diabetics |
| Tamoxifen | No treatment | Treatable if stable, well-controlled medical condition with letter from patient's general practitioner; no ocular involvement or dry eye |
| Methotrexate | No treatment | Treatable if stable, well-controlled medical condition with letter from patient's general practitioner; no ocular involvement or dry eye |
| Epilepsy | No treatment if there has been a seizure within 12 months | Treatable if well controlled and seizure-free for the past 3 months |
| Cancer | No treatment for patients with terminal or metastatic cancer | Case-by-case basis; weigh patient's general health against potential quality of life benefit of surgery |
| Pacemaker | No treatment | Surgeon discretion |

In contrast, the Optical Express database included outcomes on 5099 treated eyes, a sample size that allowed for analyses of high statistical power (Table 3).

After careful consideration of all of this information, proposed changes (if any) to the existing patient selection criteria are drafted, thoroughly discussed, and voted on by the IMAB. A unanimous vote is required to change a guideline.

AN EXAMPLE OF THE REVIEW PROCESS

During the latest review meeting, one of the patient selection criteria the IMAB evaluated was the maximum safe value for estimated postoperative keratom-

etry following hyperopic LASIK. The previous Optical Express guideline for this criterion, which was based on the current medical consensus, limited estimated postoperative keratometry to a maximum value of 48.00 diopters (D) in the steepest meridian.

The initial literature search for relevant articles yielded 137 citations. A review of abstracts produced 6 full articles with direct clinical relevance to this topic, with sample sizes in these articles ranging from 43 to 376 eyes. The conclusions of the articles were mixed, with some studies showing a correlation between outcomes and pre- or postoperative keratometry and others showing no association.

TABLE 3

Available Data on Hyperopic Corrections

| Studies | Average No. Eyes | Total No. Eyes |
|--|------------------|----------------|
| VISX CustomVue FDA clinical trial of hyperopic LASIK | | 131 |
| Published hyperopia studies | 219 | 3504 |
| Optical Express hyperopia analysis | | 5099 |

One article of particular interest to the IMAB was a study by Williams et al,¹ which found that preoperative keratometry >44.00 D following hyperopic LASIK was associated with an increased incidence of loss of best spectacle-corrected visual acuity and decreased patient satisfaction. The sample size of this study was 49 eyes.

In addition to the literature search, other sources of data also informed the IMAB's deliberation. Food and Drug Administration guidance related to hyperopic LASIK states that safety and effectiveness of hyperopic corrections have not been established if the anticipated postoperative keratometry is >50.00 D in any meridian. Guidance provided by the American Academy of Ophthalmology likewise states that postoperative keratometry steeper than 49.00 to 50.00 D may be associated with quality of vision problems.

To further evaluate the association between postoperative keratometry and visual outcomes, an analysis of Optical Express clinical outcomes data (n=1695 eyes) was performed.² The large sample size available for this analysis allowed sub-analyses of single variables while controlling for other variables (specifically, preoperative keratometry and the degree of spherical correction, both of which are related to postoperative keratometry). The conclusion of this analysis was that

preoperative sphere is the dominant determinant of visual outcomes after hyperopic LASIK, and that postoperative keratometry was not associated with adverse outcomes.

Based on a review of all the clinical data and other information available, the IMAB voted unanimously to increase the selection criterion for estimated postoperative keratometry to 50.00 D in the steepest meridian.

SETTING EVIDENCE-BASED PATIENT SELECTION CRITERIA

Using this system for each patient selection criterion under review, the IMAB recently modified 11 of the 17 guidelines they considered. Some criteria were replaced with more restrictive guidelines, whereas others were replaced with guidelines that expanded the indications for laser vision correction. Whatever the outcome, all of these changes were supported by a rigorous, evidence-based, scientific review process performed by a panel of refractive surgery experts.

CONCLUSION

By using evidence-based selection criteria to evaluate each patient's suitability for laser vision correction, eye care professionals can have greater confidence in the scientific foundation supporting their recommendations. A systematic process such as the one described herein represents a valuable tool to help surgeons improve patient selection—that is, more confidently offer a life-enhancing treatment to patients who can safely undergo laser vision correction while steering others toward alternative treatment options.

REFERENCES

1. Williams LB, Dave SB, Moshirfar M. Correlation of visual outcome and patient satisfaction with pre-operative keratometry after hyperopic laser in situ keratomileusis. *J Cataract Refract Surg.* 2008;34:1083-1088.
2. Young JJ, Schallhorn SC, Brown MC, Hettinger KA. Effect of keratometry on visual outcomes 1 month after hyperopic LASIK. *J Refract Surg.* 2009;25:S672-S676.

APPENDIX

List of articles considered by the Optical Express International Medical Advisory Board during a recent review of patient selection criteria

AMBLYOPIA

Barequet IS, Wynanski-Jaffe T, Hirsh A. Laser in situ keratomileusis improves visual acuity in some adult eyes with amblyopia. *J Refract Surg.* 2004;20:25-28.

Levenger S, Nemet P, Hirsh A, Kremer I, Nemet A. Refractive eye surgery in treating functional amblyopia in children. *Binocul Vis Strabismus Q.* 2006;21:231-234.

Sakatani K, Jabbur NS, O'Brien TP. Improvement in best corrected visual acuity in amblyopic adult eyes after laser in situ keratomileusis. *J Cataract Refract Surg.* 2004;30:2517-2521.

AUTOIMMUNE CONDITIONS

Alió JL, Artola A, Belda JL, Perez-Santonja JJ, Muñoz G, Javaloy J, Rodríguez-Prats JL, Galal A. LASIK in patients with rheumatic diseases: a pilot study. *Ophthalmology.* 2005;112:1948-1954.

Cobo-Soriano R, Beltrán J, Baviera J. LASIK outcomes in patients with underlying systemic contraindications: a preliminary study. *Ophthalmology.* 2006;113:1118-1124.

Smith RJ, Maloney RK. Laser in situ keratomileusis in patients with autoimmune diseases. *J Cataract Refract Surg.* 2006;32:1292-1295.

DIABETES

Costin JA. Is laser vision correction safe in patients with diabetes? *Cleve Clin J Med.* 2001;68:385.

Ersanli D, Akin T, Karadayi K. Aggravation of proliferative diabetic retinopathy after laser in situ keratomileusis. *J Cataract Refract Surg.* 2005;31:868.

Fraunfelder FW, Rich LF. Laser-assisted in situ keratomileusis complications in diabetes mellitus. *Cornea.* 2002;21:246-248.

Ghanbari H, Ahmadieh H. Aggravation of proliferative diabetic retinopathy after LASIK. *J Cataract Refract Surg.* 2003;29:2232-2233.

Halkiadakis I, Belfair N, Gimbel HV. Laser in situ keratomileusis in patients with diabetes. *J Cataract Refract Surg.* 2005;31:1895-1898.

Jabbur NS, Chicani CF, Kuo IC, O'Brien TP. Risk factors in interface epithelialization after laser in situ keratomileusis. *J Refract Surg.* 2004;20:343-348.

GLAUCOMA

Bashford KP, Shafranov G, Tauber S, Shields MB. Considerations of glaucoma in patients undergoing corneal refractive surgery. *Surv Ophthalmol.* 2005;50:245-251.

Bushley DM, Parmley VC, Paglen P. Visual field defect associated with laser in situ keratomileusis. *Am J Ophthalmol.* 2000;129:668-671.

Chan KC, Poostchi A, Wong T, Insull EA, Sachdev N, Wells AP. Visual field changes after transient elevation of intraocular pressure in eyes with and without glaucoma. *Ophthalmology.* 2008;115:667-672.

Jabbur NS, Tuli S, Barequet IS, O'Brien TP. Outcomes of laser in situ keratomileusis in patients with pigment dispersion syndrome. *J Cataract Refract Surg.* 2004;30:110-114.

Katsanos A, Kóthy P, Nagy ZZ, Holló G. Scanning laser polarimetry of retinal nerve fibre layer thickness after laser assisted in situ keratomileusis (LASIK): stability of the values after the third post-LASIK month. *Acta Physiol Hung.* 2004;91:119-130.

Kook MS, Lee S, Tchah H, Sung K, Park R, Kim K. Effect of laser in situ keratomileusis on retinal nerve fiber layer thickness measurements by scanning laser polarimetry. *J Cataract Refract Surg.* 2002;28:670-675.

Lleó-Pérez A, Sanchis Gimeno J. Changes in the visual field following laser in situ keratomileusis for myopia. *Ophthalmic Physiol Opt.* 2007;27:201-209.

Najman-Vainer J, Smith RJ, Maloney RK. Interface fluid after LASIK: misleading tonometry can lead to end-stage glaucoma. *J Cataract Refract Surg.* 2000;26:471-472.

Samuelson TW. Refractive surgery in glaucoma. *Curr Opin Ophthalmol.* 2004;15:112-118.

Weiss HS, Rubinfeld RS, Anderschat JF. Case reports and small case series: LASIK-associated visual field loss in a glaucoma suspect. *Arch Ophthalmol.* 2001;119:774-775.

Zangwill LM, Abunto T, Bowd C, Angeles R, Schanzlin DJ, Weinreb RN. Scanning laser polarimetry retinal nerve fiber layer thickness measurements after LASIK. *Ophthalmology.* 2005;112:200-207.

HYPEROPIA

- Albarrán-Diego C, Muñoz G, Montés-Micó R, Rodríguez A, Alió JL. Corneal aberration changes after hyperopic LASIK: a comparison between the VISX Star S2 and the Asclepion-Meditec MEL 70 G Scan excimer lasers. *J Refract Surg.* 2006;22:34-42.
- Albelda-Vallés JC, Martín-Reyes C, Ramos F, Beltran J, Llovet F, Baviera J. Effect of preoperative keratometric power on intraoperative complications in LASIK in 34,099 eyes. *J Refract Surg.* 2007;23:592-597.
- Alió J, Galal A, Ayala MJ, Artola A. Hyperopic LASIK with Esiris/Schwind technology. *J Refract Surg.* 2006;22:772-781.
- Alió JL, Piñero DP, Espinosa MJ, Corral MJ. Corneal aberrations and objective visual quality after hyperopic laser in situ keratomileusis using the Esiris excimer laser. *J Cataract Refract Surg.* 2008;34:398-406.
- de Ortueta D, Arba-Mosquera S, Baatz H. Topographic changes after hyperopic LASIK with the SCHWIND ESIRIS laser platform. *J Refract Surg.* 2008;24:137-144.
- Desai RU, Jain A, Manche EE. Long-term follow-up of hyperopic laser in situ keratomileusis correction using the Star S2 excimer laser. *J Cataract Refract Surg.* 2008;34:232-237.
- Jaycock PD, O'Brart DP, Rajan MS, Marshall J. 5-year follow-up of LASIK for hyperopia. *Ophthalmology.* 2005;112:191-199.
- Kanellopoulos AJ, Conway J, Pe LH. LASIK for hyperopia with the WaveLight excimer laser. *J Refract Surg.* 2006;22:43-47.
- Kermani O, Schmeidt K, Oberheide U, Gerten G. Hyperopic laser in situ keratomileusis with 5.5-, 6.5-, and 7.0-mm optical zones. *J Refract Surg.* 2005;21:52-58.
- Kezirian GM, Moore CR, Stonecipher KG; SurgiVision Consultants Inc WaveLight Investigator Group. Four-year postoperative results of the US ALLEGRETTO WAVE clinical trial for the treatment of hyperopia. *J Refract Surg.* 2008;24:S431-S438.
- Kohnen T, Mahmoud K, Bühren J. Comparison of corneal higher-order aberrations induced by myopic and hyperopic LASIK. *Ophthalmology.* 2005;112:1692.
- O'Brart DP, Mellington F, Jones S, Marshall J. Laser epithelial keratomileusis for the correction of hyperopia using a 7.0-mm optical zone with the Schwind ESIRIS laser. *J Refract Surg.* 2007;23:343-354.
- Pesudovs K. Wavefront aberration outcomes of LASIK for high myopia and high hyperopia. *J Refract Surg.* 2005;21:S508-S512.
- Spadea L, Sabetti L, D'Alessandri L, Balestrazzi E. Photorefractive keratectomy and LASIK for the correction of hyperopia: 2-year follow-up. *J Refract Surg.* 2006;22:131-136.
- Waring GO III, Fant B, Stevens G, Phillips S, Fischer J, Tanchel N, Schanzer C, Narvaez J, Chayet A. Laser in situ keratomileusis for spherical hyperopia and hyperopic astigmatism using the NIDEK EC-5000 excimer laser. *J Refract Surg.* 2008;24:123-136.
- Zaldivar R, Oscherow S, Bains HS. Five techniques for improving outcomes of hyperopic LASIK. *J Refract Surg.* 2005;21:S628-S632.

NYSTAGMUS

- Barbara A, Shehadeh-Masha'our R, Garzozzi HJ. Laser ablation in eyes with congenital nystagmus. *J Refract Surg.* 2007;23:623-625.
- Konuk O, Bilgihan K, Hasanreisoglu B. Laser in situ keratomileusis in an eye with congenital nystagmus. *J Cataract Refract Surg.* 2001;27:636-638.
- Mahler O, Hirsh A, Kremer I, Barequet IS, Marcovich AL, Nemet P, Levinger S. Laser in situ keratomileusis in myopic patients with congenital nystagmus. *J Cataract Refract Surg.* 2006;32:464-467.
- Soloway BD, Roth RE. Laser in situ keratomileusis in a patient with congenital nystagmus. *J Cataract Refract Surg.* 2002;28:544-546.

POSTOPERATIVE KERATOMETRY

- Cobo-Soriano R, Llovet F, González-López F, Domingo B, Gómez-Sanz F, Baviera J. Factors that influence outcomes of hyperopic laser in situ keratomileusis. *J Cataract Refract Surg.* 2002;28:1530-1538.
- Ditzen K, Huschka H, Pieger S. Laser in situ keratomileusis for hyperopia. *J Cataract Refract Surg.* 1998;24:42-47.
- Esquenazi S, Mendoza A. Two-year follow-up of laser in situ keratomileusis for hyperopia. *J Refract Surg.* 1999;15:648-652.
- Jin GJ, Lyle WA, Merkley KH. Laser in situ keratomileusis for primary hyperopia. *J Cataract Refract Surg.* 2005;31:776-784.
- Tabbara KF, El-Sheikh HF, Islam SM. Laser in situ keratomileusis for the correction of hyperopia from +0.5 to +11.50 diopters with the Keracor 117C laser. *J Refract Surg.* 2001;17:123-128.
- Williams LB, Dave SB, Moshirfar M. Correlation of visual outcome and patient satisfaction with pre-operative keratometry after hyperopic laser in situ keratomileusis. *J Cataract Refract Surg.* 2008;34:1083-1088.

THIN CORNEA/PACHYMETRY

- Binder PS. Analysis of ectasia after laser in situ keratomileusis: risk factors. *J Cataract Refract Surg.* 2007;33:1530-1538.
- Caster AI, Friess DW, Potvin RJ. Absence of keratectasia after LASIK in eyes with pre-operative central corneal thickness of 450 to 500 microns. *J Refract Surg.* 2007;23:782-788.
- Condon PI, O'Keefe M, Binder PS. Long-term results of laser in situ keratomileusis for high myopia: risk for ectasia. *J Cataract Refract Surg.* 2007;33:583-590.

- Hashemi H, Fotouhi A, Sadeghi N, Payvar S, Foudazi H. Laser epithelial keratomileusis (LASEK) for myopia in patients with a thin cornea. *J Refract Surg.* 2004;20:90-91.
- Klein SR, Epstein RJ, Randleman JB, Stulting RD. Corneal ectasia after laser in situ keratomileusis in patients without apparent pre-operative risk factors. *Cornea.* 2006;25:388-403.
- Kremer I, Bahar I, Hirsh A, Levinger S. Clinical outcome of wavefront-guided laser in situ keratomileusis in eyes with moderate to high myopia with thin corneas. *J Cataract Refract Surg.* 2005;31:1366-1371.
- Kymionis GD, Bouzoukis D, Diakonis V, Tsiklis N, Gkenos E, Pallikaris AI, Giaconi JA, Yoo SH. Long-term results of thin corneas after refractive laser surgery. *Am J Ophthalmol.* 2007;144:181-185.
- Miyata K, Tokunaga T, Nakahara M, Ohtani S, Nejima R, Kiuchi T, Kaji Y, Oshika T. Residual bed thickness and corneal forward shift after laser in situ keratomileusis. *J Cataract Refract Surg.* 2004;30:1067-1072.
- Ou RJ, Shaw EL, Glasgow BJ. Keratectasia after laser in situ keratomileusis (LASIK): evaluation of the calculated residual stromal bed thickness. *Am J Ophthalmol.* 2002;134:771-773.
- Randleman JB. Post-laser in-situ keratomileusis ectasia: current understanding and future directions. *Curr Opin Ophthalmol.* 2006;17:406-412.
- Randleman JB, Woodward M, Lynn MJ, Stulting RD. Risk assessment for ectasia after corneal refractive surgery. *Ophthalmology.* 2008;115:37-50.
- Reinstein DZ, Srivannaboon S, Archer TJ, Silverman RH, Sutton H, Coleman DJ. Probability model of the inaccuracy of residual stromal thickness prediction to reduce the risk of ectasia after LASIK part I: quantifying individual risk. *J Refract Surg.* 2006;22:851-860.
- Reinstein DZ, Srivannaboon S, Archer TJ, Silverman RH, Sutton H, Coleman DJ. Probability model of the inaccuracy of residual stromal thickness prediction to reduce the risk of ectasia after LASIK part II: quantifying population risk. *J Refract Surg.* 2006;22:861-870.
- Tabbara KF, Kotb AA. Risk factors for corneal ectasia after LASIK. *Ophthalmology.* 2006;113:1618-1622.

Femtosecond Laser Versus Mechanical Microkeratome: A Retrospective Comparison of Visual Outcomes at 3 Months

Mesha Tanna, BSc(Hons), MCOptom; Steven C. Schallhorn, MD; Keith A. Hettinger, MS, MBA

ABSTRACT

PURPOSE: To compare the visual outcomes of LASIK procedures in which flaps were created with a femtosecond laser (IntraLase FS 60Hz, Abbott Medical Optics [AMO]) to procedures in which flaps were created with a mechanical microkeratome (Moria Evo3 One Use-Plus, Moria SA).

METHODS: A retrospective analysis was performed on 2000 eyes treated in 2008 for low myopia and astigmatism (sphere < -3.00 diopters [D]; cylinder ≤ -0.75 D). The first 1000 consecutive eyes that had LASIK flaps created with a femtosecond laser were compared with the first 1000 consecutive eyes that had flaps created with a mechanical microkeratome. All eyes received wavefront-guided LASIK treatments performed with a VISX S4 IR Advanced CustomVue excimer laser (AMO). Refractive predictability, change in mean spherical equivalent refraction, postoperative uncorrected visual acuity (UCVA), and loss of best spectacle-corrected visual acuity (BSCVA) were compared at 1 day, 1 week, 1 month, and 3 months following surgery.

RESULTS: The refractive accuracy was the same for both groups. At all time points measured, the percentage of eyes that achieved a postoperative UCVA of 20/20 or better was significantly higher in the femtosecond laser group than in the mechanical keratome group. Also, a higher percentage of eyes in the femtosecond laser group achieved a postoperative UCVA of 20/16 at 3 months. Finally, a lower percentage of eyes in the femtosecond laser group lost two or more lines of BSCVA at 1 week and 1 month postoperative.

CONCLUSIONS: Creating LASIK flaps with the femtosecond laser resulted in faster visual recovery and better UCVA. [*J Refract Surg.* 2009;25:S668-S671.] doi:10.3928/1081597X-20090611-08

Compared to a flap created with a mechanical microkeratome, a femtosecond laser flap offers several potential advantages: more uniform flap thicknesses, customizable flap diameter and hinge position, smoother stromal beds, and lower rates of flap creation complications. However, mechanical keratomes have a long track record of safety, and they cost significantly less than a femtosecond laser.

A few published reports have compared these two competing techniques, but the results of these studies have been mixed.¹⁻⁴ Some studies have shown equivalency between the femtosecond laser and the mechanical keratome whereas other studies have reported improved visual results with the femtosecond laser.¹⁻⁴ The current study was designed to determine whether use of different flap creation techniques yields differences in visual outcomes and visual recovery.

PATIENTS AND METHODS

Data for this study were taken from patient records extracted from the Optical Express 2008 clinical database. For both the mechanical microkeratome and femtosecond laser groups, the first 1000 consecutive eyes that met the following conditions were included in the study: 1) preoperative myopia < -3.00 diopters (D), 2) preoperative cylinder ≤ -0.75 D, 3) target refraction of emmetropia, 4) primary wavefront-guided ablation, and 5) 3-month examination data available.

The femtosecond laser flaps were created using an IntraLase FS-60 femtosecond laser (Abbott Medical Optics, Santa Ana, Calif), and the mechanical microkeratome flaps were created using the disposable Moria Evo3 One Use-Plus (Moria SA, Antony, France). The femtosecond laser flap diameter varied

From Optical Express, London, United Kingdom (Tanna) and San Diego, Calif (Schallhorn, Hettinger).

Ms Tanna and Mr Hettinger are employees of the Optical Express Group. Dr Schallhorn is the Chief Medical Director for Optical Express and a consultant to Abbott Medical Optics and AcuFocus.

Assistance in preparing this manuscript was provided by medical writer Kay Downer.

Correspondence: Mesha Tanna, BSc(Hons), MCOptom, Optical Express, 5 Deerdykes Rd, Westfield, Cumbernauld G68 9HF United Kingdom. Tel: 44 1236 723300; Fax: 44 1236 730300; E-mail: meshatanna@opticalexpress.com

TABLE 1

Demographic and Preoperative Parameters in Eyes That Underwent LASIK Flap Creation With a Femtosecond Laser or Mechanical Microkeratome

| Parameter | Mean±Standard Deviation (Range) | | P Value* |
|-----------------|------------------------------------|---|----------|
| | Femtosecond Laser (n=1000 eyes) | Mechanical Microkeratome (n=1000 eyes) | |
| Male/female (%) | 31/69 | 28/72 | .3796 |
| Age (y) | 37.3±10.8 (18 to 69) | 35.6±10.0 (18 to 65) | .0019 |
| Sphere (D) | -1.92±0.69 (-0.25 to -3.00) | -1.88±0.69 (-0.25 to -3.00) | .1748 |
| Cylinder (D) | -0.38±0.25 (-0.75 to 0.00) | -0.37±0.26 (-0.75 to 0.00) | .4142 |
| MSE (D) | -2.11±0.69 (-0.50 to -3.38) | -2.07±0.69 (-0.50 to -3.38) | .1332 |
| Pupil size (mm) | 6.3±1.1 (3.0 to 9.0) | 6.3±1.0 (3.0 to 9.0) | .2095 |

MSE = mean spherical equivalent refraction

*For continuous variables, a two-sample t test was used to measure significance. For categorical variables, a chi-square test was used. All assumptions were met for these respective tests.

from 8.4 to 9.2 mm, with a programmed ablation depth between 100 and 120 μm (median=110 μm). The 130- μm head was used for the mechanical microkeratome. Patients were educated about both methods of flap creation and selected the one they preferred for their procedure. The wavefront-guided treatments were performed using a VISX STAR S4 IR Advanced CustomVue excimer laser (AMO) with an optical zone of 6.0 mm and transition zone of 8.0 mm. Postoperative examinations were conducted by Optical Express optometrists who were unaware of the method of flap creation.

Demographic and other preoperative parameters were analyzed to ensure that the groups were well matched. Refractive predictability, change in mean spherical equivalent refraction, postoperative uncorrected visual acuity (UCVA), and loss of best spectacle-corrected visual acuity (BSCVA) were compared at 1-day, 1-week, 1-month, and 3-month follow-up. Visual acuity was measured at each visit using a projected eye chart.

Tabulations of data and statistics were performed with SAS 9.1 (SAS Institute Inc, Cary, NC) and Microsoft Office Excel 7.0 (Microsoft, Redmond, Wash).

RESULTS

The two groups were well matched in terms of gender, sphere, cylinder, mean spherical equivalent refraction, and pupil size (Table 1). The mean preoperative sphere was -1.92 D for the femtosecond laser group and -1.88 D for the mechanical microkeratome group; the mean cylinder was -0.38 D for the femtosecond laser group and -0.37 D for the mechanical microkeratome group. A small difference in mean age was noted between groups (femtosecond laser: 37.2 years; mechanical keratome: 35.6 years),

but this difference was not deemed clinically relevant.

Both groups achieved similar refractive predictability results. The percentage of eyes with a postoperative mean spherical equivalent refraction within 0.50 D of the target was high in both groups and similar at all follow-up examinations (Fig 1). Both groups also achieved similar levels of refractive stability, with eyes in both groups remaining close to plano from the 1-day follow-up through the 3-month follow-up (Fig 2).

Although refractive results were similar, a significant difference was observed in the percentage of eyes that achieved a postoperative UCVA of 20/20 or better (Table 2). At 1-day follow-up, 88.6% of eyes in the femtosecond laser group achieved UCVA of 20/20, compared to 83.2% of eyes in the mechanical microkeratome group ($P=.0005$). Both groups showed improvement with continued follow-up, but a higher percentage of eyes in the femtosecond laser group achieved 20/20 UCVA at each time point (Fig 3).

In addition to achieving faster visual recovery immediately after surgery, eyes in the femtosecond laser group also achieved significantly better 3-month UCVA (one-way analysis of variance, $P=.0058$). At 3-month follow-up, 78% of eyes in the femtosecond laser group achieved UCVA of 20/16 or better, compared to 70% of eyes in the mechanical microkeratome group (Fig 4).

Fewer eyes in the femtosecond laser group experienced a loss of two or more lines of BSCVA in the early postoperative period. At 1-week postoperative, only 0.9% of eyes in the femtosecond laser group had lost two or more lines of BSCVA, compared to 2.8% in the mechanical microkeratome group (Fig 5). By 3 months postoperatively, however, both groups showed similar results.

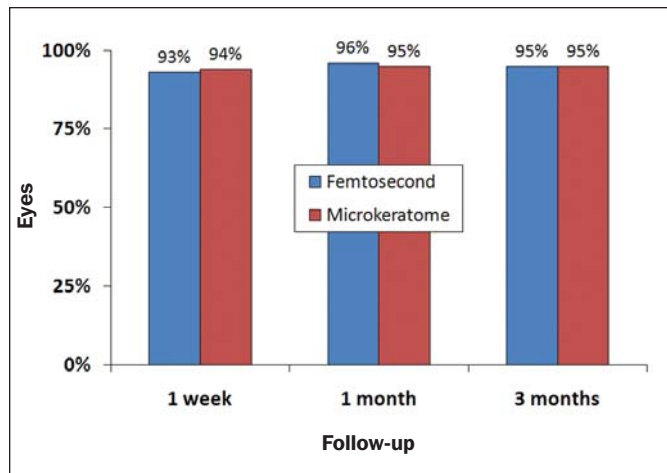


Figure 1. Efficacy. A high percentage of eyes achieved a mean spherical equivalent refraction within 0.50 D of the intended refraction at all time points following surgery.

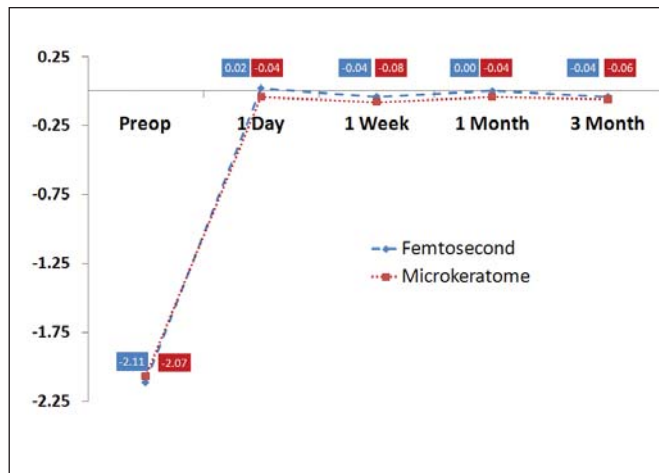


Figure 2. Refractive stability. Eyes in both the femtosecond laser group and mechanical microkeratome group achieved high levels of refractive stability from 1-day follow-up through 3-month follow-up.

TABLE 2

Percent of Eyes Achieving 20/20 Uncorrected Visual Acuity After LASIK With the Femtosecond Laser or Mechanical Microkeratome

| Time point | Percentage of Eyes | | Difference | P Value* |
|------------|--------------------|--------------------------|------------|----------|
| | Femtosecond Laser | Mechanical Microkeratome | | |
| 1 day | 88.6 | 83.2 | 5.4 | .0005 |
| 1 week | 92.6 | 85.9 | 6.7 | <.0001 |
| 1 month | 95.5 | 93.0 | 2.5 | .0166 |
| 3 months | 96.0 | 93.5 | 2.5 | .0098 |

*Chi-square test.

DISCUSSION

As this study shows, the femtosecond laser significantly improves both the speed of visual recovery as well as UCVA through 3 months postoperative. This improvement occurred despite similar refractive predictability in both the femtosecond laser group and mechanical microkeratome group. Thus, the improved UCVA was not due to residual refractive error in the mechanical microkeratome group.

The percentage of eyes that experienced a loss of two or more lines of BSCVA at 1 week postoperative was three times higher in the mechanical microkeratome group compared to the femtosecond laser group. Although this difference disappeared by 3 months postoperative, the initial disparity further indicates a faster visual recovery when flaps are created with the femtosecond laser.

Given that most patients prefer LASIK over surface ablation in part because LASIK offers a more rapid improvement in vision, the enhanced speed of visual re-

covery after a femtosecond laser procedure represents a significant advantage. Speed of visual recovery also has implications for when patients can return to work after surgery, particularly for patients who have jobs that require excellent vision, such as aviators.

The results of previous studies comparing the outcomes of femtosecond laser LASIK with mechanical keratome procedures have been varied. A study by Patel et al¹ examined 21 patients who had a femtosecond laser flap created in one eye and a mechanical microkeratome flap created in the other eye, and they found that the method of flap creation did not affect visual outcomes. Similarly, Lim et al² (n=55 eyes) and Kezirian and Stonecipher³ (n=375 eyes) concluded that use of a femtosecond laser failed to produce any statistically significant difference in postoperative UCVA at 3 months postoperative. In contrast, Durrie and Kezirian⁴ (n=102 eyes) reported that the femtosecond laser-created flaps produced a statistically better UCVA. Several reasons for these different results are

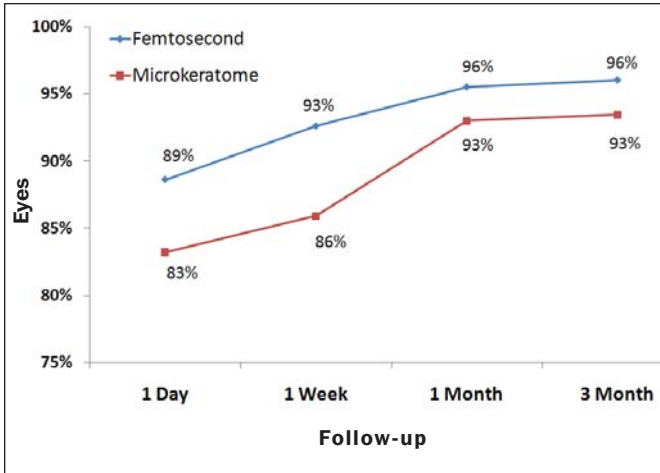


Figure 3. Percentage of eyes that achieved uncorrected visual acuity of 20/20 or better was higher for the femtosecond laser group at all time points.

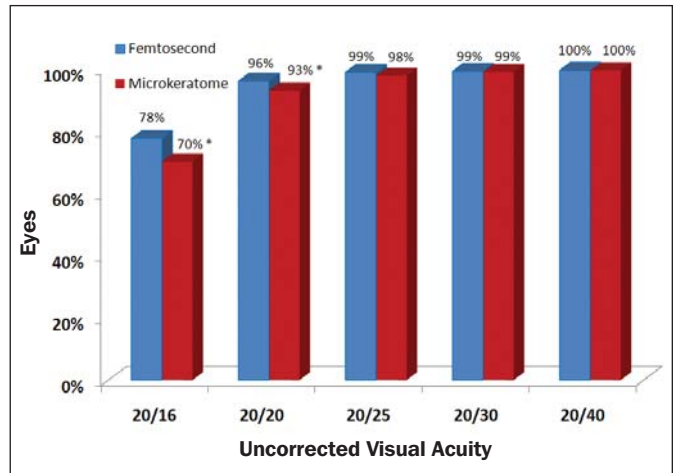


Figure 4. A higher percentage of eyes in the femtosecond laser group achieved uncorrected visual acuity of 20/16 at 3-month follow-up.

possible, including the relatively small sample sizes of these studies, which may be partially responsible for their lack of agreement.

Although the retrospective nature of the current study is a drawback, the study design also has several strengths. The large sample size (2000 well-matched eyes) allowed for statistically valid conclusions; limiting the study to consecutive treatments minimized selection bias. Also, the limits on preoperative myopia and cylinder reduced the confounding influence of unpredictable clinical results that can occur when treating higher levels of ametropia. In addition, all treatments were performed in 2008 using the latest technology and the same wavefront-guided ablation profile, therefore the study is representative of modern clinical practice.

Because this study was intentionally confined to eyes with low preoperative myopia and cylinder, it cannot predict results for hyperopia or high myopia treatment. Nonetheless, clinical reasoning suggests that similar results would be expected for a wide range of ametropia.

Although it is not readily apparent why the femtosecond laser improves visual outcomes, several possible explanations include the more predictable planar flap, more accurate repositioning of the flap at the end of the procedure, and/or improved smoothness of the stromal bed. Particularly for procedures that use complex ablation patterns, such as wavefront-guided treatments, minimizing stromal bed imperfections and maximizing the predictability of the flap dimensions may help in achieving optimal results.

AUTHOR CONTRIBUTIONS

Study concept and design (M.T., S.C.S.); data collection (S.C.S., K.A.H.); interpretation and analysis of data (S.C.S., K.A.H.); drafting

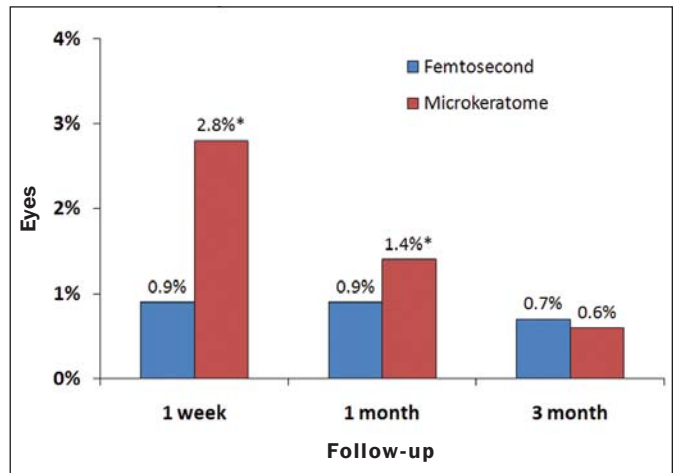


Figure 5. Loss of 2 or more lines of best spectacle-corrected visual acuity was greater in the mechanical microkeratome group at 1-week and 1-month follow-up.

of the manuscript (S.C.S.); critical revision of the manuscript (M.T., S.C.S., K.A.H.); statistical expertise (S.C.S., K.A.H.); administrative, technical, or material support (S.C.S.); supervision (S.C.S.)

REFERENCES

- Patel SV, Maguire LJ, McLaren JW, Hodge DO, Bourne WM. Femtosecond laser versus mechanical microkeratome for LASIK: a randomized controlled study. *Ophthalmology*. 2007;114:1482-1490.
- Lim T, Yang S, Kim M, Tchah H. Comparison of the IntraLase femtosecond laser and mechanical microkeratome for laser in situ keratomileusis. *Am J Ophthalmol*. 2006;141:833-839.
- Kezirian GM, Stonecipher KG. Comparison of the IntraLase femtosecond laser and mechanical keratomes for laser in situ keratomileusis. *J Cataract Refract Surg*. 2004;30:804-811.
- Durrie DS, Kezirian GM. Femtosecond laser versus mechanical keratome flaps in wavefront-guided laser in situ keratomileusis: prospective contralateral eye study. *J Cataract Refract Surg*. 2005;31:120-126.

Effect of Keratometry on Visual Outcomes 1 Month After Hyperopic LASIK

Jill J. Young, BSc(Hons), MCOptom; Steven C. Schallhorn, MD; Mitchell C. Brown, OD; Keith A. Hettinger, MS, MBA

ABSTRACT

PURPOSE: To determine whether preoperative, postoperative, or change in keratometry can be used to predict visual outcomes in hyperopic LASIK.

METHODS: A retrospective analysis was conducted on hyperopic eyes treated at Optical Express clinics. All eyes were targeted for emmetropia and treated using wavefront-guided LASIK (VISX S4, Abbott Medical Optics [AMO]), with flaps created using a femtosecond laser (IntraLase FS-60 [AMO]). A total of 1659 consecutive eyes of 895 patients met the study inclusion criteria: preoperative sphere ≥ 1.00 diopter, complete 1-month follow-up data, and availability of pre- and postoperative keratometry measurements. Factors associated with 1-month visual results were evaluated with multivariate analysis.

RESULTS: Preoperative sphere was strongly correlated with visual outcomes. Higher levels of correction were associated with a greater loss of best spectacle-corrected visual acuity (BSCVA), a lower percentage of eyes achieving 20/20 BSCVA, and a lower percentage of eyes achieving 20/20 uncorrected visual acuity. For a given level of preoperative sphere, however, no statistically significant correlation was observed between visual outcomes and either pre- or postoperative keratometry.

CONCLUSIONS: Preoperative, calculated postoperative, or 1-month postoperative keratometry values do not correlate with visual acuity outcomes following hyperopic LASIK. [*J Refract Surg.* 2009;25:S672-S676.] doi:10.3928/1081597X-20090611-09

Some refractive surgeons have expressed concern that a relatively steep postoperative cornea following hyperopic LASIK may reduce the quality of outcomes.

However, published studies examining the association between postoperative keratometry and visual outcomes yield conflicting results.¹⁻⁶ One possible reason for these conflicting findings is the covariance of postoperative keratometry with preoperative sphere. Specifically, higher levels of hyperopic correction typically result in steeper postoperative keratometry, but larger corrections (due to high preoperative sphere values) also tend to result in poorer outcomes, irrespective of keratometry.

Therefore, to accurately assess how postoperative keratometry affects visual outcomes, an analysis must differentiate the effect of a large sphere correction from the effect of a steep postoperative cornea. However, studies with limited sample sizes may lack the statistical power to discriminate between these two effects, and most of the available published reports include fewer than 150 eyes.

PATIENTS AND METHODS

A total of 2399 consecutive patients (4489 eyes) underwent hyperopic wavefront-guided LASIK with a target of emmetropia from January 4, 2008 to June 6, 2008. All procedures were performed using the VISX S4 excimer laser platform (Abbott Medical Optics [AMO], Santa Ana, Calif), with LASIK flaps created using the IntraLase FS-60 (AMO).

Of the 1533 patients who attended 1-month postoperative follow-up, 895 patients (1659 eyes, 38% of the initial cohort) met the study inclusion criteria: preoperative sphere ≥ 1.00

From Optical Express, Glasgow, United Kingdom (Young) and San Diego, Calif (Schallhorn, Brown, Hettinger).

Ms Young, Dr Brown, and Mr Hettinger are employees of the Optical Express Group. Dr Schallhorn is the Chief Medical Director for Optical Express and a consultant to Abbott Medical Optics and AcuFocus.

Assistance in preparing this manuscript was provided by medical writer Kay Downer.

Correspondence: Jill J. Young, BSc(Hons), MCOptom, Optical Express, 5 Deerdykes Rd, Westfield, Cumbernauld G68 9HF United Kingdom. Tel: 44 1236 723300; Fax: 44 1236 730300; E-mail: jillyoung@opticalexpress.com

TABLE 1

Maximum Keratometry Values at 1 Month for Eyes That Lost 2 or More Lines of Best Spectacle-corrected Visual Acuity (BSCVA)

| Preoperative Sphere (D) | Kmax (Mean±Standard Deviation [Range], D) | | P Value |
|-------------------------|---|------------------------------|---------|
| | Loss of ≥2 lines of BSCVA | No loss of ≥2 lines of BSCVA | |
| +1.00 to <+2.00 | 44.40±1.3 (41.75 to 45.50) | 43.70±1.8 (39.75 to 52.00) | .3295 |
| +2.00 to <+3.00 | 44.80±1.7 (41.00 to 48.25) | 44.60±1.5 (40.25 to 48.50) | .5097 |
| +3.00 to <+4.00 | 45.60±1.5 (43.00 to 48.25) | 45.20±1.6 (40.25 to 49.25) | .1496 |
| ≥+4.00 | 45.60±1.4 (39.50 to 48.50) | 45.80±1.5 (42.00 to 49.00) | .5585 |

diopter (D) and availability of both pre- and postoperative keratometry measurements. Keratometry was measured by a trained technician using an automated device (auto-keratometer/tonometer RK-T 7770; NIDEK Co Ltd, Gamagori, Japan). The average of three readings per eye was recorded.

Pre- and postoperative keratometry were the independent variables of interest. Other factors that could affect the visual outcome of hyperopic LASIK were also analyzed, including preoperative sphere and cylinder, temperature, humidity, laser fluence during treatment, age, and gender.

Multiple logistic regression modeling was performed with SAS 9.1 (SAS Institute Inc, Cary, NC). To further control for the effect of preoperative sphere, eyes were subdivided into four groups based on the level of correction: +1.00 to <+2.00 D; +2.00 to <+3.00 D; +3.00 to <+4.00 D; and ≥+4.00 D. The various independent effects were measured for statistical influence on the 1-month visual outcomes of interest: percent of eyes that lost two or more lines of best spectacle-corrected vision (BSCVA), percent of eyes that achieved 20/20 BSCVA, and percent of eyes that attained an uncorrected visual acuity (UCVA) of 20/20 or better.

RESULTS

Most preoperative parameters were the same for those patients who returned for the 1-month examination and for those who did not, as well as among patients who had pre- and postoperative keratometry measured and those who did not. However, a statistically significant difference was noted in age and preoperative cylinder among those patients who returned for 1-month follow-up (age 51.7 years; preoperative cylinder 1.03 D) and those who did not (age 49.5 years; preoperative cylinder 1.18 D).

Average age of the 895 patients included in the study was 51.7 years (range: 18 to 70 years); 39% of patients were men and 61% were women. The mean treatment manifest sphere was +2.28±1.03 D (range:

+1.00 to +5.50 D). The mean preoperative keratometry of the steepest axis (Kmax) was 43.50 D (range: 38.00 to 48.00 D), and the mean postoperative Kmax was 44.80 D (range: 38.00 to 52.00 D).

The most important factor influencing the postoperative visual results was preoperative sphere. It significantly affected the percentage of eyes that lost two or more lines of BSCVA, attained 20/20 or better BSCVA, and achieved UCVA of at least 20/20 ($P \leq .0001$, $P \leq .0001$, and $P \leq .0001$, respectively).

In a univariate analysis, postoperative Kmax significantly influenced visual outcomes. However, when the appropriate statistical model was used to address the interaction between preoperative sphere and keratometry, the statistical significance of keratometry was lost. When preoperative sphere was held constant, no significant correlation was observed between visual outcomes and preoperative, postoperative, or change in Kmax ($P = .1039$, $P = .1559$, and $P = .2947$, respectively).

When analyses controlled for preoperative sphere, no significant difference was noted between the postoperative Kmax of eyes that lost two or more lines of BSCVA and those that did not (Table 1). Similarly, no difference was noted in the postoperative Kmax for eyes that achieved at least 20/20 BSCVA and those that did not (Table 2); postoperative Kmax also did not differ significantly between eyes that achieved at least 20/20 UCVA and those that did not (Table 3).

As can be seen in Figures 1-3, when patients were grouped by preoperative sphere values, increases in postoperative Kmax did not affect any of the visual outcomes measured.

DISCUSSION

In agreement with the results of the current study, several reports have found that postoperative keratometry does not influence the visual outcome of hyperopic LASIK. In one study, Jin et al⁴ evaluated the safety, efficacy, and stability of hyperopia in 139 eyes with a mean preoperative spherical equivalent refraction of

TABLE 2

Maximum Keratometry Values at 1 Month for Eyes With or Without 20/20 Best Spectacle-corrected Visual Acuity (BSCVA)

| Preoperative Sphere (D) | Kmax (Mean±Standard Deviation [Range], D) | | P Value |
|-------------------------|---|----------------------------|---------|
| | BSCVA Worse Than 20/20 | BSCVA 20/20 or Better | |
| +1.00 to <+2.00 | 43.20±1.6 (40.50 to 45.00) | 43.70±1.8 (39.75 to 52.00) | .3371 |
| +2.00 to <+3.00 | 44.60±1.6 (41.00 to 48.25) | 44.60±1.5 (40.25 to 48.50) | .8249 |
| +3.00 to <+4.00 | 45.20±1.6 (41.75 to 48.25) | 45.30±1.6 (40.25 to 49.25) | .6428 |
| ≥+4.00 | 45.60±1.3 (39.50 to 48.50) | 45.90±1.5 (42.00 to 49.00) | .2914 |

TABLE 3

Maximum Keratometry Values for Eyes With or Without 20/20 Uncorrected Visual Acuity (UCVA)

| Preoperative Sphere (D) | Kmax (Mean±Standard Deviation [Range], D) | | P Value |
|-------------------------|---|----------------------------|---------|
| | UCVA Worse Than 20/20 | 20/20 UCVA | |
| +1.00 to <+2.00 | 43.60±2.1 (42.25 to 52.00) | 43.60±1.7 (39.75 to 47.50) | .8879 |
| +2.00 to <+3.00 | 44.70±1.5 (40.50 to 48.25) | 44.50±1.5 (40.25 to 48.50) | .2474 |
| +3.00 to <+4.00 | 45.30±1.7 (40.25 to 49.25) | 45.20±1.6 (41.75 to 48.75) | .7831 |
| ≥+4.00 | 45.80±1.6 (39.50 to 49.00) | 45.50±1.4 (40.75 to 48.25) | .1817 |

+2.39 D. Four eyes in this analysis had a postoperative keratometry >49.00 D, but none lost lines of BSCVA. Similarly, Tabbara et al⁶ analyzed 80 eyes with preoperative sphere treatments ranging from +0.50 to +11.50 D. Postoperative keratometry in these eyes ranged from 40.00 to 52.82 D, but none of the patients in the study reported symptoms relating to corneal steepness.

In the largest study previously reported, Cobo-Soriano et al⁵ performed a retrospective analysis of the visual outcomes of 376 eyes. Eyes with postoperative keratometry readings <48.00 D were compared to eyes with keratometry >48.00 D, and these two groups were further subdivided into lower (+1.00 to +4.00 D) and higher (+4.10 to +7.90 D) levels of hyperopia. The results showed no significant differences in visual outcomes in patients with either steep or flat postoperative keratometry.

In contrast, some studies appear to show that keratometry influences visual outcomes. Although Ditzzen et al³ (N=43 eyes) found that a flat cornea (radius <7.3 mm) led to greater regression and undercorrection, most studies that found a correlation between keratometry and visual outcomes observed worse outcomes in steeper corneas. For example, Esquenazi and Mendoza² published a retrospective study of 100 eyes and found a higher percentage of undercorrection in

eyes with hyperopia >+4.00 D when the preoperative keratometry was >45.00 D. However, this study did not separate the effects of keratometry and preoperative sphere.

Similarly, a study by Williams et al¹ found that steeper preoperative keratometry correlated with poorer outcomes, but this analysis used a limited sample size (N=26 patients). Their study found that a greater loss of BSCVA was associated with preoperative keratometry >44.00 D. Because of the small sample size, however, the analysis could be prone to sampling errors. In fact, a surprisingly large number of eyes in the steeper-K group lost two or more lines of BSCVA (10 [40%] of 25 eyes) compared to only 1 (4%) of 24 eyes in the low-K group. Such a high loss of BSCVA in the high-K group has not been previously reported.

In an effort to duplicate the results of Williams et al,¹ a sub-analysis of the Optical Express data reported above was performed. Eyes were divided into two groups based on preoperative keratometry—one group included patients with a preoperative Kmax <43.00 D (n=376) whereas the other group comprised patients with Kmax >44.00 D (n=741). (The remaining patients had Kmax between 43.00 and 44.00 D ([n=542]). Unlike the Williams et al study, however, this sub-analysis found no correlation between preoperative kera-

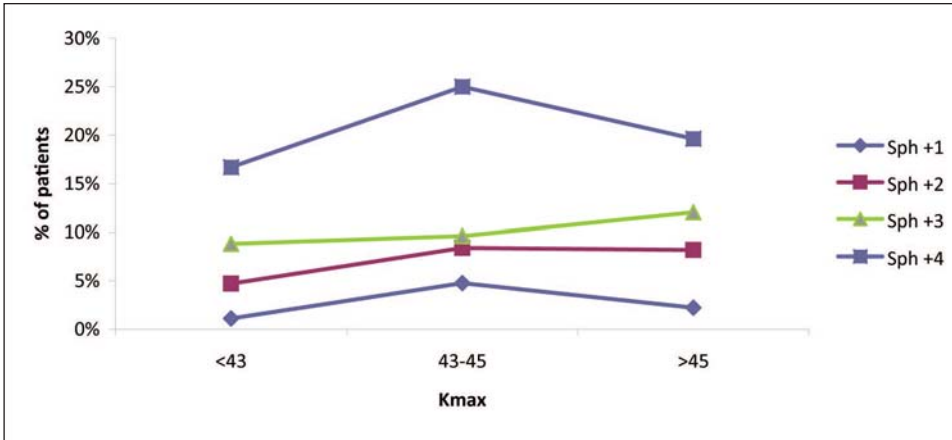


Figure 1. Proportion of patients who lost two or more lines of best spectacle-corrected visual acuity varied by preoperative sphere group but not by maximum keratometry.

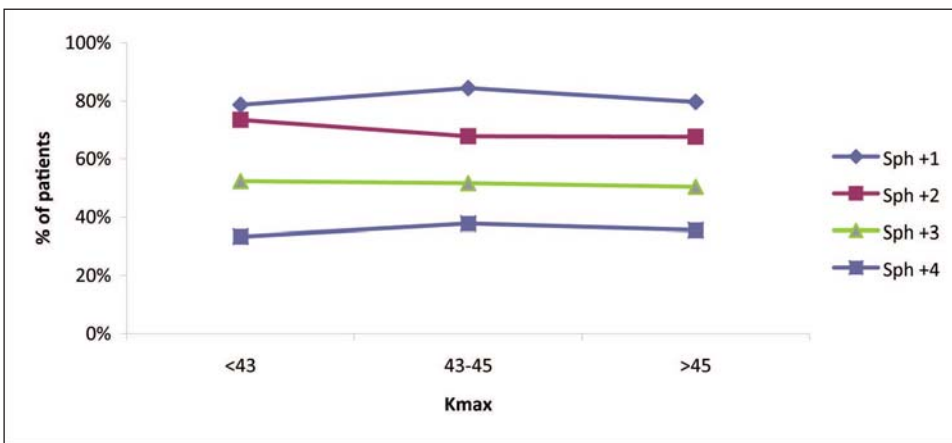


Figure 2. Proportion of patients who achieved 20/20 uncorrected visual acuity varied by preoperative sphere group but not by maximum keratometry.

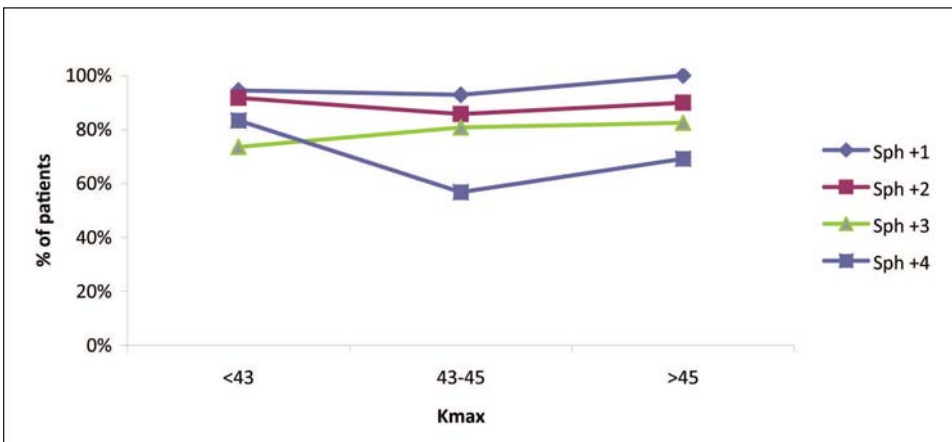


Figure 3. Proportion of patients who achieved 20/20 best spectacle-corrected visual acuity varied by preoperative sphere group but not by maximum keratometry.

tometry and loss of BSCVA. The percentage of eyes in which two or more lines of BSCVA was lost was virtually identical in both groups (<43.00 D: 2.36%; >44.00 D: 2.30%; $P>.05$).

The large sample size of the current study is a strength compared with other published reports. The combined sample size of all previously published reports that evaluated the role of keratometry after hyperopic LASIK¹⁻⁶ is 718, compared to a sample size of 1659 eyes in this study. Other strengths include the fact that data were gathered from multiple centers and

the surgeries were conducted by many surgeons, which helps reduce surgical center-specific bias. In addition, the surgical procedure (wavefront-guided LASIK with femtosecond laser flap creation) and examination techniques were identical for all eyes.

Although this study was well designed, it has certain limitations. First, like all retrospective studies, it is possible that this study included confounding variables and biases that were not accounted for.

Second, not all patients who underwent hyperopic LASIK showed up for their 1-month examination; 36%

failed to attend this appointment. The initial cohort of patients treated with hyperopic LASIK was further reduced by the requirement to have a preoperative sphere ≥ 1.00 D as well as pre- and postoperative keratometry measurements. An analysis was conducted to evaluate possible patient selection bias. Two variables were significantly different among patients who attended the 1-month follow-up and those who did not: age (51.7 vs 49.5 years) and preoperative cylinder (1.03 vs 1.18 D). However, the significance of these differences was deemed to have no clinical relevance. In addition, no significant difference was found, for any parameter, between patients who had postoperative keratometry measurements and those who did not. An important drawback of the study is that 1-month follow-up after hyperopic LASIK is a relatively short time period. Hyperopic LASIK takes longer to stabilize than treatment of myopia. Typical changes that occur after hyperopic LASIK can be a refractive shift, usually regression, and a gradual improvement in the tear film, dry eye symptoms, and BSCVA.

Third, because the preoperative Kmax was 48.00 D and the postoperative Kmax was 52.00 D, this study cannot draw any conclusions about keratometry that exceeds these values. Thus, this study cannot state whether an association exists between visual outcomes and postoperative Kmax values >52.00 D.

Fourth, keratometry is a measurement of only two points approximately 3 mm apart on the central cornea, which may not reflect the curvature of the overall cornea. Topography provides a more detailed evaluation of the shape of the cornea and would be useful to analyze. However, postoperative topography was not generally performed in the clinics.

Finally, this study did not assess visual or dry eye symptoms. Although visual acuity outcomes were not found to be related to keratometry, dry eye symptoms may still be associated with steep corneas after hy-

peropic LASIK. Williams et al¹ found an association between higher preoperative keratometry and dry eye symptoms, but because of that study's small sample size (only 14 patients had a preoperative keratometry >44.00 D), this conclusion may not be born out by larger studies. Nonetheless, the effect of keratometry on dry eyes after LASIK requires further study.

Based on an analysis of 1659 eyes, this study found that pre- or postoperative keratometry (up to 52.00 D) does not correlate with visual outcomes following hyperopic LASIK. Although patients with steeper postoperative Kmax values tend to have poorer outcomes in a univariate analysis, this association disappears when the analysis controls for preoperative sphere.

AUTHOR CONTRIBUTIONS

Study concept and design (J.J.Y., S.C.S., M.C.B.); data collection (S.C.S., M.C.B., K.A.H.); interpretation and analysis of data (J.J.Y., S.C.S., M.C.B., K.A.H.); drafting of the manuscript (S.C.S.); critical revision of the manuscript (J.J.Y., S.C.S., M.C.B., K.A.H.); statistical expertise (S.C.S., K.A.H.); administrative, technical, or material support (S.C.S., M.C.B.); supervision (S.C.S., M.C.B.)

REFERENCES

1. Williams LB, Dave SB, Moshirfar M. Correlation of visual outcome and patient satisfaction with preoperative keratometry after hyperopic laser in situ keratomileusis. *J Cataract Refract Surg.* 2008;34:1083-1088.
2. Esquenazi S, Mendoza A. Two-year follow-up of laser in situ keratomileusis for hyperopia. *J Refract Surg.* 1999;15:648-652.
3. Ditzen K, Huschka H, Pieger S. Laser in situ keratomileusis for hyperopia. *J Cataract Refract Surg.* 1998;24:42-47.
4. Jin GJ, Lyle WA, Merkle KH. Laser in situ keratomileusis for primary hyperopia. *J Cataract Refract Surg.* 2005;31:776-784.
5. Cobo-Soriano R, Llovet F, González-López F, Domingo B, Gómez-Sanz F, Baviera J. Factors that influence outcomes of hyperopic laser in situ keratomileusis. *J Cataract Refract Surg.* 2002;28:1530-1538.
6. Tabbara KF, El-Sheikh HF, Islam SM. Laser in situ keratomileusis for the correction of hyperopia from +0.50 to +11.50 diopters with the Keracor 117C laser. *J Refract Surg.* 2001;17:123-128.



Delivering the best in healthcare information and education worldwide

6900 Grove Road, Thorofare, NJ 08086 USA

phone: 856-848-1000 • fax: 856-848-6091 • www.slackinc.com • www.journalofrefractive surgery.com

Sponsored as an educational service by Optical Express