

(2)

Although the literature states the more myopia (nearsightedness) exists pre surgery the less the predicted result we have found that those patients having LASIK, including those up to 10 diopters of power, have all attained at least 20/40 or better unaided visual acuity in at least 92% of the cases. When selecting out one specific limited parameter (4-6 diopters) we found 100% of those patients saw 20/40 or better!

The LASIK procedure seems to be a wonderful procedure for a very large percentage of the cases. This does not mean it is a perfect procedure but you may rest assured that when you choose to have either Dr. Anita Nevyas-Wallace or Dr. Herbert Nevyas perform LASIK on your eyes you will be in very experienced and reliable "hands".

If you should have any questions regarding the procedures that we offer at Nevyas Eye Associates, remaining concerns, or additional statistics please don't hesitate to call us at the Delaware Valley Refractive Surgery Partnership at 1-800-9-LASER-6.

Below is the latest "Visibility Report" for your web site <http://www.lasercosmeticsurgery.net>.

It shows your rankings on the major search engines for the term construction. If you need a new report you may request one at our site: www.top-10.com. If you or your company need better visibility in the search engines you may contact us directly at: +1-252-537-9222 option 1.

Date: 9/20/2000

construction

- 0 -- Snap!
- NR -- PC Beacon
- 0 -- MSN Search
- 0 -- Open Directory Project
- 0 -- Excite
- 0 -- AltaVista
- 0 -- Netscape NetFind
- 0 -- AOL Search
- 0 -- HotBot
- 0 -- Web Crawler
- 0 -- DirectHit
- 0 -- Yahoo!
- 0 -- Northern Light
- 0 -- AllTheWeb
- 0 -- Magellan Net Guide
- 0 -- iWon
- 0 -- Lycos
- 0 -- LookSmart
- 0 -- InfoSeek

NR = This engine did not return in time to be included in the report.

Top-10 Promotions, Inc.
1433 Georgia Ave.
Roanoke Rapids, NC 27870 USA
phone: +1-252-537-9222, option 1
fax: +1-252-537-3125

M. della at Boscin

Jeff Braker

[A Message From The CEO]

To Our Stockholders:

I've looked forward to this opportunity to report on the activities of our company and the steps we took in 1999 to build our business and the underlying share-holder value. I have the pleasure of being joined this year by John Galantic, our new President and Chief Operating Officer. John came to us in August from SmithKline Beecham and has been hard at work preparing the consumer programs that are beginning to be launched as I write this letter.

The theme for this year's annual report is the personal stories behind Intacs. We chose the look of a well known human-interest magazine because Intacs are such a human-interest story. Our product can change millions of lives for the better. It was in recognition of this that Intacs were recently named by CNN and Health magazine to their joint list of "The Year's Top 10 Medical Advances." (More about that later.)

Now, let me tell you about the major projects and achievements that made 1999 a pivotal year in the transition from a research and development organization to a consumer-driven company.

1999: The end of the "beginning"

The research phase of the company, which is the foundation on which KeraVision was built, achieved its primary objective in April 1999 when we received Food and Drug Administration approval to sell Intacs prescription Inserts for correcting mild myopia, or nearsightedness. This followed eight years of clinical studies proving that Intacs are a safe, effective treatment for a condition that affects an estimated 20 million American consumers. Along the way, we acquired 29 U.S. patents, 59 foreign patents and another 168 pending.

Throughout the rest of 1999, the company's total focus was on commercial development. Phase 1 was medical market development - that is, preparing surgeons and their staffs to receive Intacs consumers. We started by training

surgeons to achieve excellent clinical results for their Intacs clients. Where we originally set 200 doctors as the training goal for 1999, surgeon demand pushed the actual number past 600.

In the months following FDA approval, over 2,300 Intacs procedures were performed. The effectiveness of the surgeon training program can be demonstrated by the fact that, in these initial cases, results appear in line with the excellent results achieved during the Intacs clinical trials. That means 20/20 vision or better, minimal discomfort and rapid visual recovery in most cases.

Once surgeons were trained, we switched gears in the fourth quarter and focused on training surgeon staffs. We want every employee in each surgeon's practice to be able to fully communicate the unique attributes of Intacs to their clients and to fully manage the client's experience. Each step of the transaction is covered in this training, from answering clients' basic questions about Intacs, to conducting formal clinical consultations, to supporting the surgeon in the Intacs procedure, to providing postoperative care. The goal is to leave nothing to chance when it comes to meeting the expectations of the Intacs consumer.

A foundation of "Fast Track" practices

As I write to you, we are conducting practice-development training with about 40 surgeons' practices, and additional practices are scheduled to undergo training every quarter. We refer to this group as "Fast Track" practices because of their commitment to making Intacs the procedure of choice for mildly near-sighted clients. (By "mildly" nearsighted, we mean people with vision of between 20/40 and 20/400 who need glasses or contacts for tasks like driving, watching a movie, or seeing an alarm clock in the morning.)

We, in turn, make a commitment to the Fast Track practices that we will help insure their clinical and commercial success by supporting them with marketing programs ranging from cooperative advertising, to special promotions, to strategies designed to help expand referral channels between Fast Track surgeons and referring optometrists. Mid-year, expect to see us roll out a new direct-to-consumer, interactive Internet site. When you consider our consumer profile—high education, high income, high Internet use—the Internet seems to make a great deal of sense.

The Fast Track practices form the foundation for receiving Intacs consumers.

Using what we've learned about the consumer. People have asked me why we didn't initiate these direct-to-

consumer programs earlier. The fact is, until the surgeon and total practice infrastructure was in place and ready to receive consumers, it would have been irresponsible to spend money on consumer marketing. Moving through the year 2000, we intend to link consumers with Fast Track practices through marketing programs that we believe will build KeraVision's business by building the Fast Track practices' business.

In developing these marketing programs, the company made a significant investment in 1999 in learning more about our consumers and the decision process for giving up eyeglasses and contact lenses in exchange for Intacs. We applied these learnings in developing Fast Track marketing models aimed at creating consumer demand. During the first half of 2000, one of our jobs will be to test and fine-tune these models. Because of the research work, we feel confident in our grasp of Intacs consumers - who they are, where to find them, and what needs to happen to make them satisfied Intacs wearers who will want to help convert family and friends to becoming Intacs consumers.

Intacs: One of "The Year's Top 10 Medical Advances"

We finished 1999 with Intacs being chosen one of "The Year's Top 10 Medical Advances" by CNN and its partner, Health magazine. In their joint report, Intacs were recognized for attributes that we believe make Intacs unique and appealing to many people with mild nearsightedness. In their words, Intacs belong to the year's list of "best discoveries" because Intacs are:

- "relatively painless"
- "take only a few minutes"
- "leave the eyes unaltered"
- "if the results aren't up to par or a recipient's vision changes later, the implants can be removed or replaced",
- "less frightening treatment for the myopic millions",

The real honor of this recognition goes to the R&D and clinical group, including those from the earliest days such as Darlene Crockett-Billig, Tom Silvestrini, John Scholl, Val Defiesta-Ng and Diana Lopez. Thanks to all who have labored more than a decade to make Intacs a life-improving product worldwide.

Expanding our vision with potential new applications and products

There were a number of initiatives in 1999 that have the potential to lead to new applications for Intacs, including as a complimentary procedure to LASIK. Some surgeons independently began using Intacs prescription inserts in combination with LASIK to treat presbyopia (i.e., the need

for reading glasses) and people who are in the pre-presbyopia stage. With Intacs in at least one eye, consumers enjoy the flexibility for prescription changes that can be necessary as part of the normal aging process.

In Europe, the Company initiated a multi-center clinical study of Intacs in the treatment of keratoconus, a thinning-of-the-cornea disorder that has eluded effective treatments. Also outside the U.S., several surgeons are conducting independent studies of Intacs to treat LASIK induced ectasia that has been observed in some LASIK patients who experience corneal thinning, according to medical literature.

Other surgeons, also acting independently, are using Intacs in combination with LASIK to treat high myopes. In these cases, LASIK is used to bring clients within the Intacs range, at which point Intacs are inserted for final correction. Some surgeons feel this combination procedure gives clients who are normally outside the Intacs range an added margin of safety against LASIK-induced corneal thinning.

Meanwhile, we launched a multi-center hyperopia (farsightedness) study in Europe in 1999. In the U.S., the FDA approved expanding our U.S. Phase III clinical trials of Intacs for wider ranges of myopia than are currently approved for sale. Both the hyperopia and myopia studies are progressing on schedule.

As our technology continues to evolve, KeraVision is providing surgeons with unique new practice-building opportunities and consumers with safe and convenient new vision correction options. Increasingly, Intacs are a solution that's hard to ignore. I look forward to keeping you informed as we achieve results with our marketing programs and expand our market with potential new applications for Intacs.

Best personal regards,

Thomas M. Loarle
Chairman and Chief Executive Officer

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Crystalens Intraocular Lens

Nevyas Eye Associates is proud to be the first in the Delaware Valley to be certified to perform the Crystalens IOL surgery.

Why Crystalens?

The answer is simple. Crystalens offers patients the chance to see the way they want to see, without the help of glasses or contact lenses.... near, far and all distances in between, effortlessly. Everyday tasks, such as reading the morning paper, watching your children play baseball, or just driving to work are once again a possibility, usually without depending on glasses or contacts. Why Crystalens? Why not?

What is Crystalens?

Crystalens is a revolutionary breakthrough in refractive and cataract surgeries. It is the first and only intraocular lens that allows patients to focus at all distances, much like their own natural lens once did. This lens works with the muscles of the eye to restore vision at near, far and everywhere in between. It is designed to move when the patient attempts to see at different distances. This movement is what gives the Crystalens its unique focusing ability. Crystalens can be used to replace a natural lens that has developed a cataract, as well as a natural lens that does not have a cataract. When there is not a cataract present, the surgery would be considered elective, and be done in order to eliminate the need for glasses and contacts.

How does Crystalens work?

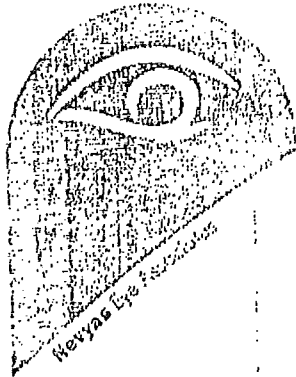
The Crystalens is designed with two hinges that allow the lens to move back and forth as the muscles in the eye contract and relax. This movement is what gives patients the ability to see at all distances seamlessly. Most patients are able to see without depending on glasses for near or far soon after surgery.

The Crystalens is implanted in the same, safe manner that traditional intraocular lenses have been for over 30 years. Our surgeons use a small incision to first remove the patient's current lens, and then implant the Crystalens in its place. Follow up and post-operative care is very similar to that of traditional cataract or refractive lensectomy patients.

Who are the best Crystalens candidates?

Crystalens is well suited for men and women who are between the ages of 40-65, who are either bothered by cataracts or just bothered by nearsightedness, farsightedness or presbyopia. It is ideal for patients who not only want to restore vision lost due to cataracts or aging, but who also want to greatly reduce their dependency on glasses and contacts. We are proud to have Crystalens as an alternative for those patients who are not candidates for LASIK.

A complete eye exam by one of our surgeons is necessary to determine if Crystalens is truly the best option. To schedule an exam, please call 800-952-7376, or fill out the information under [contact us](#).(LINK)



Nevyas Eye Associates

▶ Anita Nevyas-Wallace, M.D. ▶ Herbert J. Nevyas, M.D. ▶ Joann Yaskin Nevyas, M.D. ▶ Ira B. Wallace, M.D. ▶ Edward A. Deglin, M.D. ▶ Mitchell E. Stein, M.D. ▶ Joseph M. Ortiz, M.D. ▶ Richard Sterling, O.D.

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Herbert J. Nevyas, M.D.

Dr. Herbert J. Nevyas is a recognized leader in ophthalmic surgery, particularly cataract and refractive surgery. He is a Clinical Professor of Surgery in Ophthalmology at the Allegheny University Hospitals-MCP Division. He received his undergraduate and medical degrees from the University of Pennsylvania, where he was awarded the Oliver Memorial Prize in Ophthalmology. He completed his postgraduate training at Thomas Jefferson University, the Institute of Ophthalmology of the University of London and the Hospital of the University of Pennsylvania.



Dr. Nevyas has operated a practice in medical and surgical ophthalmology since 1964. Nevyas Eye Associates currently has four locations: Bala Cynwyd, Center City Philadelphia, Northeast Philadelphia and Marlton, New Jersey. He founded the practice's ambulatory surgical center, the Delaware Valley Laser Surgery Institute in 1989.

An innovator in surgical equipment and procedures, Dr. Nevyas holds a number of ophthalmic patents. Techniques and instruments bearing his name are used worldwide. He also has invented two varieties of intraocular lens implants. In addition to cataract and a full range of refractive surgery procedures including LASIK excimer laser surgery, Dr. Nevyas performs other procedures including corneal transplant and YAG laser surgery. He has lectured widely and has authored more than 40 ophthalmic publications.

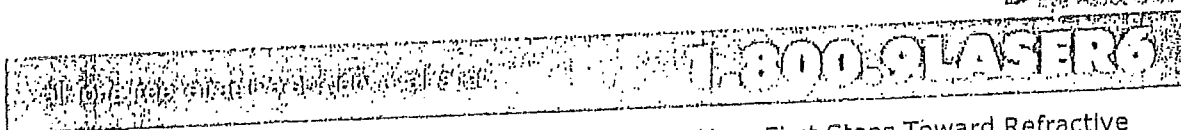
NYA 00785

Dr. Nevyas is a Diplomate of the American Board of Ophthalmology, a Fellow of the American Academy of

Ophthalmology, a founding member of the American Society for Cataract and Refractive Surgery, and a member of numerous other professional organizations.

▶ [Next](#)

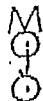
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Joann Yaskin Nevyas, M.D.

Dr. Joann Yaskin Nevyas has practiced ophthalmology since 1973, with a special interest in laser and medical treatment of glaucoma. She is a Clinical Associate Professor of Surgery at the Allegheny University Hospitals-MCP Division, and practices at Nevyas Eye Associates.



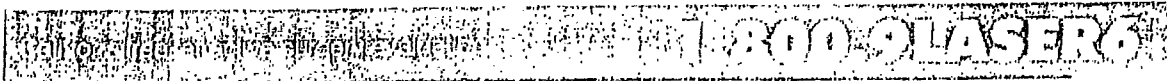
Dr. Nevyas earned her undergraduate degree from the University of Pennsylvania and her medical degree from the Medical College of Pennsylvania. She completed a preceptorship in ophthalmology under Dr. Herbert J. Nevyas. This program, approved by the American Board of Ophthalmology, also included training at the Schele Eye Institute, Wills Eye Hospital and Children's Hospital of Philadelphia.

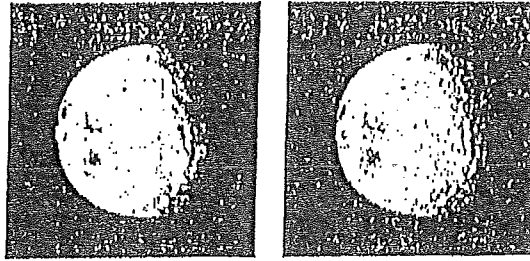
A Diplomate of the American Board of Ophthalmology and a Fellow of the American Academy of Ophthalmology, Dr. Nevyas is an active member of many ophthalmic societies. She has had extensive experience in combined cataract-glaucoma surgery, a topic on which she has lectured and written. Dr. Nevyas received the "Best Paper of Session" award at the 1995 American Society of Cataract and Refractive Surgeons meeting for her work on combined cataract and glaucoma surgery.

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Nevyas

Eye Associates





Before Enhancement

After Enhancement

Taking the eye chart as an example, just being able to see the 20/20 line doesn't always mean that your vision is ideal. The eye chart can only measure how small an image you can see, not how clearly you see those images. Higher-level distortions can cause even the 20/20 line to become shadowed or to have a "double image". Just being able to identify the letters on the chart doesn't always mean that you have excellent vision. By treating these higher-level distortions, the quality of your vision can be significantly improved.



Before Enhancement

20/20

The goal of LADARwave Custom Cornea treatments is to address the remaining 10-15% of higher-level distortions in the eye. By doing this, your surgeon can decrease the risk of undesirable side effects and improve both the quality of your vision and of your way of life. Custom Cornea is able to achieve this goal by mapping each patient's individual optical distortions and then translate those distortions to the LADARvision system to help guide the laser as it reshapes your cornea.

To find out if LADARwave Custom Cornea is right for you, please call the office to schedule your cost free examinations with one of our surgeons. You can reach us by calling 800-9LASER6 or by [clicking here](#).

NYA 00308

CK (Conductive Keratoplasty)

CK is a relatively new procedure used to treat mildly farsighted



Clinical Research Consultants, Inc.
3307 Clifton Avenue • Cincinnati, Ohio 45220
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E-Mail: BSFANT@aol.com

January 5, 2002

Everett Beers, Ph.D.
IDE Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

RE: IDE #G970088 Supplement #24 (Nevyas Excimer Laser)

Dear Dr. Beers:

Enclosed in triplicate is IDE Supplement #24 for the above referenced IDE, which I am submitting on behalf of Dr. Herbert Nevyas. This supplement provides the 2001 annual report for this IDE. An interim clinical summary is provided in the report, including an analysis from the contrast sensitivity substudy.

If you have any questions in this regard, please do not hesitate to contact me at (513)-961-8200 or Dr. Nevyas.

Yours Truly,

BARBARA FANT

Barbara S. Fant, Pharm.D.

(Consultant to Dr. Herbert Nevyas)

NYA 00872

IDE Supplement No. 24

ANNUAL REPORT

IDE NUMBER: G970088

DEVICE: Nevyas Excimer Laser

**INVESTIGATOR/
SPONSER:** Herbert J. Nevyas, M.D. *
Anita Nevyas-Wallace, M.D.
Delaware Valley Laser Surgery Institute
333 City Line Avenue
Bala Cynwyd, Pennsylvania 19004

Telephone: (610) 668-2777
FAX: (610) 668-1509

INDICATIONS: LASIK for Myopia with or without Astigmatism
(-0.5 to -22 Diopters Sphere with up to -7 Diopters
Astigmatism)

DATE SUBMITTED: December 30, 2001

PURPOSE: Supplement #24 is being filed as the annual report.

* Address correspondence to Herbert J. Nevyas, M.D.

ANNUAL REPORT

1.0 STUDY PROGRESS

Since the last annual report (submitted 14 March 2001), monitoring visits have been completed to completely review the data in the database for all subjects through August 1, 2001. The data review showed a very low rate of data entry errors and data in the database were in agreement with the source documents. Data from visits after this date have been reviewed for obvious errors and omissions. The last date of surgery included in this report is December 19, 2001. Dr. Nevyas recently acquired a commercially approved excimer laser and is evaluating whether to continue use of the Nevyas Excimer Laser. Individual summaries of the study progress for NEV-97-001 and Substudy NEV-98-002 are provided below. An interim clinical summary for NEV-97-001 and NEV-98-002 (contrast sensitivity) is attached to the end of this submission.

1.1 PROTOCOL NEV-97-001 -- LASIK for Myopia with or without Astigmatism
(-0.5 D to -22.00 D sphere; 0 to -7.0 D cylinder)

A. STATUS: Ongoing

B. NUMBER OF INVESTIGATORS: Two

This remains a single site study which is being conducted by the joint sponsor-investigators:

Herbert J. Nevyas, M.D.

Anita Nevyas-Wallace, M.D.

Delaware Valley Laser Surgery Institute

333 City Line Avenue

Bala Cynwyd, Pennsylvania 19004

Telephone: (610) 668-2777

Fax: (610) 668-1509

C. NUMBER OF SUBJECTS ENROLLED:

NYA 00874

CONFIDENTIAL

1. Number of Subjects Enrolled: 779 IDE Subjects Total
Number of Eyes Treated: 779 Primary eye treatments
714 Fellow eye treatments
1,493 Total eyes treated
2. First Date of Enrollment: August 28, 1997
Last Date of Enrollment: December 19, 2001

D. NUMBER OF DEVICES SHIPPED:

Not Applicable. The device was assembled on-site at Nevyas Eye Center. No additional devices have been shipped or assembled.

E. SUMMARY OF CLINICAL RESULTS

An interim clinical summary is provided in Attachment 1.1.E-1. The clinical summary includes the following tables:

- Accountability
- Preoperative Refractive Parameters (*eyes treated for sphere only*)
- Summary of Key Safety and Efficacy Variables
- Comparison with FDA Safety and Effectiveness Criteria
- Stability of Manifest Refraction
- Number of Eyes within the Preop Sphere and Cylinder Range (*myopic astigmatism eyes only*)
- Accuracy of Sphere (to target) and Cylinder to Zero Component (*myopic astigmatism eyes only*)
- Residual Astigmatic Error at Stability Time Point (*myopic astigmatism eyes only*)
- Vector Analysis Summary Tables
- Safety Summary Tables (adverse events, complications, subjective complaints)
- Contrast Sensitivity Analysis

G. SUMMARY OF COMPLICATIONS AND ADVERSE EVENTS:

The complications and adverse events that occurred intraoperatively and postoperatively for the 1,493 eyes treated under the IDE are summarized in the clinical summary in Attachment 1.1.E-1.

1.2 Substudy NEV-97-002: Changes in Contrast Sensitivity in Patients Undergoing LASIK Treatment with the Nevyas Excimer Laser

A. Substudy to Protocol: NEV-97-001 (Myopia/Myopic Astigmatism)

B. STATUS: Complete

C. NUMBER OF INVESTIGATORS: Two

This remains a single site study which is being conducted by the joint sponsor-investigators:

Herbert J. Nevyas, M.D.

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333 City Line Avenue

Bala Cynwyd, Pennsylvania 19004

Telephone: (610) 668-2777

Fax: (610) 668-1509

D. NUMBER OF SUBJECTS ENROLLED:

1. Number of Subjects Enrolled:	92 Low myopia subjects
	21 High myopia subjects
	Total of 184 eyes tested

E. SUMMARY OF RESULTS

A summary of the contrast sensitivity testing results is included in the interim clinical summary provided in Attachment 1.1.E-1.

2.0 RISK ANALYSIS

The risk analysis remains unchanged from that submitted with the original IDE. There are no emerging complications or adverse events that alter the risk analysis. The adverse event and complication rates remain low.

3.0 DEVICE CHANGES

No device changes have occurred since the last annual report.

4.0 CHANGES IN INVESTIGATIONAL PLAN

All reportable changes to the investigational plan have been previously submitted to the FDA for review and approval via amendments, revised versions of the protocol(s), or substudies.

5.0 PROGRESS TOWARDS PMA APPROVAL

All preoperative and postoperative data obtained through August 1, 2001 have been monitored and compared to the source documents. Any reportable adverse events, complications, or subjective complaints noted in the source documents were added to the study database. Preparation of this interim report has generated some additional data entry queries that are outstanding. A comprehensive software validation was completed and a quality system for maintenance and replacement of device components is in process.

Dr. Nevyas has obtained a commercially available excimer laser for use in his practice and is currently evaluating the results compared to the Nevyas Excimer Laser to determine whether to pursue filing the PMA for Nevyas Excimer Laser. If he decides to pursue the PMA approval, work on preparation of the PMA will begin the end of January 2002 with filing expected by the end of February 2002.