- Calibration activity that discloses the potential for discrepant material results in the initiation of a nonconforming product report for the purpose of determining whether or not the potential was realized.

Validation of Test Software

- All test hardware and software used for inspection activities are subject to the same requirements as listed above for inspection, measuring, and test equipment.

Control of a Nonconforming Product / Services

Policy

- When the device is not operational it is identified to prevent it from unintended use.
- All nonconformances are evaluated and the responsibility for disposition is defined and documented
- Dr. Nevyas and the Director of IR are made aware of all nonconformities.

Identification and Control of Nonconforming Product

- All employees at Nevyas Eye Associates are responsible for identifying nonconformances concerning the device
- Nonconformance can be applied to any raw material, component, assembly or the device that fails to conform to specified requirements.
- Nonconformances are segregated and labeled until the nonconformity is evaluated and the disposition approved. Only Dr. Nevyas or the Director of IR can release the device for use.
- All nonconformances are documented no matter how insignificant they may seem or how easily they can be reworked. Each non-conformity is given a unique number and all activities are tracked.
- Dr. Nevyas and the Director of IR are made aware of all nonconformities.

Review and Disposition of Nonconformances

- Nevyas Eye Associates are responsible for all nonconformities and the preliminary investigation and identification of the root cause. In cases where the root cause is not easily identifiable, a formal investigation is initiated by the Director of IR.
- All dispositions are reviewed and approved by Dr. Nevyas. A justification of the disposition is recorded.
- Nonconformity reports are not closed until the investigations and corrective actions associated with it are completed.

Control of the Device when Repair is Required

- When the device is approved for repair, the repair procedure will be documented as such.
- All repairs will be reinspected, documented and approved to insure that device meets current approved specifications.
- Repair activities are documented in the device master record.

CORRECTIVE AND PREVENTIVE ACTION

Policy

Corrective and Preventive actions are initiated to fix and eliminate the causes of nonconformances and potential nonconformances. Corrective actions are also initiated to correct internal audit findings. All employees are encouraged to initiate preventive action requests when a potential nonconformity is observed. All customer complaints are documented and given a unique tracking number. Product performance related complaints are tracked and resolved through the customer complaint system.

Corrective Action

- Corrective action is taken when a nonconformance is identified. Corrective actions are initiated to fix the root cause or causes that contributed to a non-conformity or in response to internal audit observations. All corrective action requests receive a unique number and are documented.
- Proposed corrective actions are reviewed before they are implemented.
- Corrective actions are assigned a due date to ensure timely implementation.
- Corrective action that results in a process or design change is validated before implementation. All corrective actions are verified by the Director of IR. Nevyas keeps files on corrective action issues in order to ensure that actions are implemented and verified in a timely manner.
- Corrective actions are analyzed, trended and submitted for management review.

Preventive Action

- Preventive action is taken when the potential for a nonconformance is identified. The need for preventive action is determined by reviewing internal audit reports, customer complaints, nonconformity reports, and other sources of quality data.
- Trends are analyzed and action is taken. All employees are responsible for bringing potential nonconformity's to the attention of the Director of IR.

- Preventive actions are tracked and documented using the same system as corrective actions. Proposed preventive actions are reviewed and approved prior to implementation.
- Preventive action that results in a process or design change is validated before implementation.
- All preventive actions are verified by the Director of IR. The effectiveness of preventive action is verified during internal audits and is submitted for management review.

Customer Complaints

- Customer Complaints are initiated in response to all complaints related to product performance. Customer Complaints are assigned a unique tracking number by Nevyas.
- All Customer Complaints are documented and contains at least the following information: Date the complaint was received, customer name, address and phone number, product, catalog number, lot number, description of the complaint, determination of serious injury or death, complaint activity investigation, and review and approval signature of the Director of IR.
- Complaints involving the possible failure of the Nevyas device are investigated, unless an investigation has already been performed for a similar complaint. When an investigation is not determined to be necessary, a justification and the name of the person responsible are recorded on the form.
- Any complaints that may be reportable to the FDA are promptly reviewed, evaluated, and investigated. A Medical Device Report (MDR) is filed. The Director of IR is responsible for all communications and follow up with the FDA.
- Customer complaints are analyzed and trended. Corrective action is initiated as appropriate. All complaint information is submitted for management review.

CONTROL OF QUALITY RECORDS

Policy

Quality records demonstrate that procedures were performed correctly and that the specified level of product / service quality was achieved.

Device Master Record (DMR)

- The device master record was established and maintained for the device produced at Nevyas Eye Associates. The device master record contains or references the device specifications, production methods and specifications, Quality Control procedures, installation, maintenance, and servicing procedures where appropriate.

Device History Record (DHR)

- Multiple devices will not be built. Multiple DHRs are not applicable in this case.

Design History File (DHF)

- Design history files are established for each new/improved product as it is designed. It contains or references the records necessary to demonstrate that the design was developed in accordance with the approved design plan and appropriate regulations.

Quality System Record

- The quality system record refers to the location of procedures and the documentation of activities that are not specific to a particular type of device. The quality system record will be stored under document control in the Director of Nursing office.

Establishment of Records

- Quality Records are established to demonstrate conformance with specified requirements and the effective operation of the quality system. Records are usually established by the person who performs the activity that is being documented. When appropriate, quality records from subcontractors are part of the quality records.
- Records are stored in a manner to facilitate their retrieval. This includes appropriate labeling of containers and storage cabinets.
- Where required by contract, quality records will be made available for evaluation by the customer, the customer's representative and the FDA .

Storage and Retention Periods

- Records are stored in a manner to minimize deterioration and allow for timely retrieval. Electronic records are backed up on a regular basis.
- Device history records are maintained for the design and expected life of the product or a minimum of two years from the date of the release of the product for commercial distribution.
- Storage and retention periods of department specific documents and records has been determined to be seven years.
- Management review records, internal audit reports and other non-device specific documents are maintained for a period specified in their respective procedures.

INSTALLATION AND SERVICING

Policy

Installation and servicing procedures and instructions are documented. Service reports are reviewed and service information is passed on to the affected areas.

Installation

- Installation is performed according to documented procedures to ensure that the device functions properly. Inspection and test results are documented to demonstrate proper installation.

Servicing

- When servicing is specified by procedures and instructions are maintained to ensure that servicing activities meet specified requirements.
- Service reports are reviewed to assure that: servicing meets specified requirements, trends are noted and communicated to Dr. Nevyas.
- Service reports are documented and maintained by the Manager of Quality Assurance. Note: Service data is submitted for Dr. Nevyas for review in all cases.

STATISTICAL TECHNIQUES

Policy

The responsibility to establish methods and instructions for the application of trending and statistical analysis is assumed at Nevyas. All incoming materials, components, parts, etc. are 100% inspected prior to use.

Identification of Need

- Nevyas employees are responsible for identifying and determining where trending and statistical techniques are needed as related to customer complaints and MDR issues.
- They are also responsible for procedures to implement and control the application of trending and statistical techniques in this area.

Sampling Plans

- Sampling plans are based on 100% inspection of parts and components used to service, repair or preventatively maintain the device.

Clinical Research Consultants, Inc.
3928 North Cliff Lane • Cincinnati, Ohio 45220
Telephone: (513) 751-3637 • FAX: (513)-751-3773

MEMORANDUM

To: Richard Sterling -- Dr. Nevyas

From: Barbara Fant, Pharm.D.

Date: July 30, 1997

Subject: IRB Documents

Recent changes at FDA make it imperative that we get the IRB approval for your myopia protocol as soon as possible. If you already have conditional approval, you need this to start your study. If your IDE is under review, obtaining the IRB approval now will get you up and running with your study quicker.

Your myopia protocol and consent form are being sent to Schulman Associates IRB for review and approval. Enclosed is the investigator's guide for the IRB. Please complete the following documents that are contained in the investigator's guide and send them to me as soon as possible and I will forward them to Schulman's IRB:

1. Site questionnaire (Appendix II)
2. Sample Submission Letter (Appendix III)
3. Indemnity Agreement (Appendix V)

Please return by August 14.

a professional association of 350 eye doctors in the Delaware Valley who have chosen us as their refractive surgeons of choice. We conduct many educational seminars for Delaware Valley eye doctors on the subject of refractive surgery, and we routinely comanage refractive surgical patients with them to provide better care and more convenience for our patients. We have constructed, with the help of laser engineers, an extremely fine excimer laser surgical system which utilizes the highest quality components and which can be controlled by the surgeon to provide the best and most individualized surgical results. We have invented a very special fixation system which improves the centration of the excimer laser ablation. Our results have been excellent.

How should I choose my eye surgeon?

It would be best to choose a surgeon who is highly skilled, highly experienced and well recommended. He or she should have recommendations from patients and particularly from doctors who are familiar with his/her work. He or she should not have a large malpractice experience. He or she should utilize an excimer laser in a true surgical operating room rather than a commercial office suite. You should meet with him or her and feel comfortable with his or her degree of expertise.

What is the advantage of having my refractive surgery in a fully licensed ambulatory surgical center such as The Delaware Valley Laser Surgery Institute?

Our ambulatory surgical center has fully equipped ophthalmic operating rooms which are available should any emergency surgery be required. The operating rooms are equipped with special air cleaners with finely filtering HEPA filters that reduce particulate matter in the air and thereby make it less likely that particulate matter will be trapped in the flap-corneal interface. Such particles can be irritating and can carry infection. The operating rooms have special flooring which does not allow dust to collect at the corners and is easily cleaned. We use powder-free gloves and our personnel wear scrub suits to reduce the possibility of contamination.

Some refractive surgery centers place their lasers in regular carpeted office suites in an office building. Such environments are conducive to high levels of particulate matter and fibers in the air and do not protect adequately against infection. Our operating rooms are carefully controlled as to particulate matter, temperature and humidity, making LASIK surgery safer and more precise.

What refractive errors can you correct?

With refractive surgery of one variety or another, we can correct almost any refractive error in existence. We are experienced in a number of procedures, not just one, and we utilize the procedure which is best for each patient. The majority of our refractive surgical patients do best with LASIK surgery which is performed in our own

surgical center. We correct myopia from -0.5 to -15 diopters and astigmatism from 0.5 to 7 diopters. We correct hyperopia from 0.5 to 5 diopters with hyperopic LASIK, and we can correct any degree of high myopia or high hyperopia with refractive lensectomy and intraocular lens implantation. We have corrected as much as 42 diopters of nearsightedness with refractive lensectomy and as much as 12 diopters of farsightedness. With astigmatic keratotomy we have corrected as much as 14 diopters of astigmatism.

Will I have any pain?

There is essentially no pain reported by most of our LASIK surgery patients. Some stretching of the eyelid is felt as the eyelid holder is put into position, and a transient feeling of pressure usually for less than a minute, is felt while the suction ring is placed for creating the corneal cap with microkeratome. Most people have just slight operative discomfort and no postoperative pain at all. We usually give a small amount of oral Valium prior to surgery to relax you.

Do you do both eyes at one time?

We usually perform LASIK on both eyes together, however in some cases, especially those of very high nearsightedness, we may perform the two procedures at two separate times. This also depends on the patient's preference. We always perform refractive lensectomy with the two eyes done at separate times, usually a week or two apart. Radial and astigmatic keratotomy are usually performed bilaterally.

What are the risks of refractive surgery?

The primary annoyance with LASIK is seeing halos around lights at night. This is more prominent in people with large pupils and less pronounced in people with relatively small pupils. We measure everyone's pupil with a "night vision" measuring device so that we can know the size of the pupil in the dark to enable us to warn patients with unusually large pupils that they may be subject to glare at night.

The extremely rare case of infection or retinal detachment has been reported at times around the world. We have never had either of these problems occur after refractive surgery in our center.

There is a relatively rare situation known as diffuse lamellar keratitis or "Sands of the Sahara" syndrome characterized by a sterile inflammation of the interface between the corneal cap and the deeper part of the cornea. We have seen a very mild case of this on only one occasion and have never seen another case or a more severe case. The one case which we saw responded very well to a short course of steroid eyedrops. We take great pains to clean all blades with acetone prior to using them in order to remove any machine oil residues which are thought to be one factor responsible for this condition.

A few cases of postoperative retinal hemorrhage have been reported, primarily in Korea where very large ablations for extremely high refractive errors, much larger than we will do, were performed. We have never seen such a case.

Refractive lensectomy entails all of the risks of cataract surgery including infection, inflammation and dislocation of the intraocular lens. However, we have never seen any of these problems with refractive lensectomy, and they're quite rare with modern cataract surgery in general, especially cataract surgery performed on a relatively clear lens. We use the latest technique of clear corneal, self-sealing, no suture surgery with "no needle" eyedrop anesthesia for most cases of refractive lensectomy.

What is RK?

Radial Keratotomy (RK) is one of a group of procedures that can be used to correct nearsightedness. There are many such procedures that as a group are called refractive surgery. RK gets its name from the fact that it involves making radial incisions on the edge of the cornea to cause it to bulge outward, flattening the center of the cornea. Which of the refractive surgery procedures is right for you is a decision that your surgeon will make in consultation with you after he or she has evaluated your needs.

Note: Since the introduction of the first refractive surgery technique in the 1970's, over two million people have had refractive surgery performed. The success record is impressive. The vast majority of these people have experienced correction to at least 20/40 without the need for glasses.

Will I have 20/20 vision after the procedure?

Having a successful experience with your refractive surgery begins with realistic expectations of what it can do. The purpose of the surgery is to enable you to perform many activities without glasses, not to give you 20/20 vision. While the vast majority of patients achieve at least 20/40 unaided vision, not everyone gains complete freedom from glasses. The goal of refractive surgery is to obtain <u>uncorrected</u> vision close to the same <u>corrected</u> vision as you have now using your glasses or contacts.

What is the procedure that uses a laser?

When people talk about using a laser for refractive surgery, they are referring most often to the excimer laser. This laser vaporizes corneal tissue instantaneously. There are two main ways of using the laser to correct nearsightedness. One is to flatten the cornea by removing tissue from the front of the cornea (Photorefractive Keratectomy (PRK). The second is to raise a very thin flap of the front of the cornea and to use the excimer laser to remove tissue from within the cornea rather than the surface (Laser in-situ keratomileusis or LASIK).

Do you think I need refractive surgery?

Nobody <u>needs</u> refractive surgery. It is an elective procedure. Many people can benefit from it, however. Refractive surgery can make a person less dependent on contact lenses or glasses. This can be valuable from a quality of life standpoint and even in certain circumstances from a safety perspective, particularly in occupations where unimpaired eyesight is critical.

Will I be able to see without glasses after the procedure?

The majority of refractive surgery patients are able to perform most activities without glasses, but some may still need help for especially demanding vision situations (such as driving at night or reading stock market quotations). Also, you may still need reading glasses as you grow older. Your surgeon will give you more information on what results you can realistically expect.

How long will it take?

The procedure itself takes about ten minutes. There is some equipment setup and patient preparation time, but once everything is set up, it doesn't take very long at all.

How much does it cost?

Refractive surgery, depending on the procedure recommended for you can cost between $1500 to $2500 per eye. The fee covers all pre-operative services, the surgery itself and any enhancements needed in the first year of post-operative care. (It is rare to require further surgery after six months.) If needed, payment plans are available. The full details will be explained to you when you go for your evaluation by the surgeon.

Who will do the procedure and are they experienced?

The surgeons at Nevyas Eye Associates: Dr. Herbert Nevyas, Dr. Anita Nevyas-Wallace, or both. The surgeons are very experienced and prominent in their fields, with many years of experience in anterior segment surgery and refractive surgery. Their refractive surgery experience extends to all aspects of refractive surgery and not just one or two modalities.

Where will the procedure by done?

It will be performed next to Nevyas Eye Associates offices in Bala Cynwyd in the Delaware Valley Laser Surgery Institute. The DVLSI is the most modern and well-equipped private ophthalmological surgical facility in the Delaware Valley. It is fully accredited by the Accreditation Association for Ambulatory Health Care (AAAHC) and licensed by the State of Pennsylvania.

Can I change my mind after I go for this evaluation?

Yes, This is an elective procedure. You may change your mind at any time. Before you decide whether to have the procedure, we will explain the procedure to you, as well as possible complications and previous results. We want you to be fully informed so that you will have all the information you need to make an informed decision.

Why do I have to make out two checks before surgery?

Your surgeon and the comanaging doctor (Optometrist and Ophthalmologist)if you choose to be comanaged are independent professionals working together to manage the care of your eyes. We each bill separately for our portion of your services.

Will my insurance cover this procedure?

Most health insurance does not cover refractive surgeon. The procedure is considered elective and almost cosmetic in as much as anyone can continue to wear glasses. Enhancement of lifestyle does not count as medical necessity for most insurance companies. Medicare and some insurances will cover astigmatic keratotomy for astigmatism generated during surgery.

Am I a candidate for LASIK?

Anyone dependent on glasses and/or contact lenses, who is at least 18 years old can be considered a candidate. We are able to correct nearsightedness, farsightedness and/or astigmatism with LASIK. The best way for you to find out if you are a candidate for LASIK is to schedule an evaluation with Nevyas Eye Associates.

Why is LASIK the preferred procedure at this time?

The LASIK procedure is extremely accurate and treats a broader range of patients with a more rapid and more comfortable recovery time than other refractive procedures.

Am I awake during the procedure and will I feel any pain?

You are fully awake during the procedure. Your eyes will be numbed with topical eye drops so you should not feel any pain. Most patients report minimal discomfort, and report only a feeling of slight pressure during the procedure.

You may be given a mild sedative, but the majority of our patients do not need any medication.

How long is the recovery time and what should I expect during that time?

Recovery from LASIK is very rapid and is one of the reasons it is the preferred procedure. Immediately following the procedure, most

patients show marked improvement and within 12-24 hours have a return to normal function and can return to work the next day.

During the first week, you may notice some fluctuations in your vision which is normal and is part of the healing process. Night glare and halos may persist for the first few weeks but usually cease by the end of the two to three month healing process.

Is LASIK considered permanent or does it need to be repeated?

LASIK has undergone numerous clinical trials and has been done for years in Canada and Europe. Patients that have had this procedure several years ago are still enjoying remarkable vision. NEA feels so strongly that LASIK is permanent and we offer to do any additional laser treatments at no cost to you. Some patients do not require full correction with the initial procedure and may have a need for an enhancement. An enhancement is a secondary procedure where additional laser must be added to achieve the full correction. This is more common in patients who are moderately to extremely nearsighted or have a lot of astigmatism.

What are Intacs?

KeraVision Intacs corneal ring segments are two small, transparent crescents or arcs. Thay are composed of the same material that has been safely used for nearly 50 years in hard contact lenses and intraocular lenses used to treat patients with cataracts (clouding of the eye's natural lens of the eye). Since Intacs are placed in the outer edge of the cornea, the center of the cornea remains untouched. Intacs are meant to remain permanently within the cornea; however, they can be removed or replaced.

Who is a candidate for Intacs?

Intacs are currently available for people with mild myopia (nearsightedness) who have no more than .75 diopters of astigmatism. The best way to find out if you are a candidate for the procedure is to schedule an appointment with the surgeons of NEA so that he/she can evaluate your vision.

You may qualify for Intacs, if:

Your prescription for eyeglasses or contacts is between -1.00 and -3.00 diopters, with no more than .75 diopters of astigmatism. If you don't know your current prescription, we can schedule you for a (complimentary) examination and consultation;

You have healthy eyes, free from disease or injuries;

You have had stable vision for at least one year; and

You are at least 21 years of age.

Who it NOT a candidate for Intacs?

You should NOT have Intacs placed if:

You have autoimmune or immunodeficiency diseases (lupus, rheumatoid arthritis or AIDS, for example);

You are pregnant or nursing (6 months after delivery);

You have conditions of the eye that may increase the possibility of future problems; or

You are taking prescription medications that may affect corneal healing or your vision.

The surgeons of NEA will review your general medical history with you and will evaluate your eyes for any conditions that might suggest you should not have Intacs. It is important to advise NEA if you have had a herpes infection in your eyes or if you have insulin-dependent diabetes or other conditions that might affect wound healing. You should also bring a list of any prescription and over-the-counter medicines that you take.

What are Intacs made of?

Intacs are made of a special biocompatible plastic that has been safely used for nearly 50 years in contact lenses and in the intraocular lenses used to treat patients with cataracts. Intacs are designed for permanent placement in the eye, but they are also removable.

What is the difference between Intacs and other refractive procedures:

Intacs are designed to be placed in the outer edge of the cornea away from the "central optical zone." Because nearly all the light that reaches the retina must pass through the central optical zone, it is the part of your cornea most important for clear vision. Therefore, it is essential not to damage the central optical zone. The procedure for Intacs does not cut or remove tissue from the central optical zone. This makes the procedure quite different from refractive surgical procedures that permanently alter the central cornea. Intacs are also removable and replaceable.

How do Intacs work?

Simply, Intacs gently change the shape of your cornea to correct your vision. In the nearsighted eye, the curve of the cornea is too steep. Light rays entering the eye are bent too much and are focused in front of the retina instead of on it. As a result, things far away appear blurry. Intacs change the shape of the cornea, allowing the light rays to focus on the retina. But unlike laser surgery, which reshapes the cornea by removing tissue from the center, Intacs are placed in the outer edge leaving the central optical zone intact.

What is the central optical zone and why is it so important?

The central optical zone refers to the center area of your cornea. Virtually all light that enters your eye passes through the central optical zone in order to be focused. For this reason, the central optical zone is crucial to clear vision. Intacs corneal ring segments are specially designed to be placed in the outer edge of the cornea away from the central optical zone.

What's involved in the procedure?

Typically, patients are given a mild oral sedative and eyedrops to numb the eye before the procedure. A tiny opening, less than 2 mm is made near the upper edge of the cornea beneath the eyelid. Intacs are inserted through this opening so that they rest between the layers of tissue in the cornea, outside the central optical zone. This procedure usually takes about 15 minutes and is performed on an outpatient basis.

What are the risks?

As with any refractive surgical procedure, there are certain risks and complications. Clinical studies in the U.S. showed that infection, which is a risk with any surgical procedure, occurred 0.2% of the time with Intacs. Other adverse events included: shallow Intacs placement (0.2%); temporary loss of 2 lines of best corrected vision (0.2%); and anterior chamber perforation during surgery (0.4%). None of these events resulted in a permanent loss of vision. Other complications included: overcorrection, reduction in central corneal sensation, difficulty with night vision, undercorrection, induced astigmatism, blurry vision, double vision, corneal blood vessels, halos, glare, fluctuating distance vision and a reduction of 2 or more lines of best corrected vision. If the results of the procedure are not satisfactory, you may need to have your Intacs removed or replaced. The surgeons of NEA will be happy to discuss the potential risks and benefits in detail with you.

Is the procedure reversible?

Intacs are <u>removable</u>. While the Intacs are in your eye, it gently reshapes the corneal tissue, which causes the light rays to focus properly. But it doesn't touch the part of your cornea most critical for clear vision. Clinical data has shown that patients' refractions returned to their preoperative levels by 3 months following removal, in most cases. The patient's correctable vision was 20/20 or better in all cases following removal of Intacs.

Is the procedure painful?

Usually there is no pain associated with this procedure. You may experience some discomfort (typically a pressure sensation) that only

lasts for a couple of minutes. Topical anesthetic will be used to help alleviate any discomfort during the procedure.

Will I have a lot of pain following surgery?

You may experience some discomfort or pain in your eye following the procedure. You will be mildly sensitive to light and will have the feeling that something is in your eye for the first few days. Most patients describe their discomfort as moderate and it typically diminishes within 48 hours. Your doctor may recommend a medication to help ease your discomfort. Give your eyes plenty of rest. Taking a nap after the procedure may help to alleviate any discomfort you may have.

Will I be able to drive myself the day of surgery?

You should arrange for transportation the day of the procedure and to your next examination, since you should not drive immediately after the procedure. Your doctor will advise you when it is safe to resume driving.

After the procedure will I have to wear a shield?

Your doctor may recommend that you may wear an eye shield at night. The shield should be worn to protect your eye from irritation and injury, such as rubbing or scratching, while you sleep.

When will I be able to return to work/resume normal activities?

While some people return to work the day after surgery, we recommend you take the day after surgery off. Generally, you can expect to return to your normal daily routines within a few days.

How long does the procedure take?

The procedure takes approximately 15 minutes for one eye, and you go home the same day. The total procedure, including the pre-surgical preparation, is usually completed in less than one hour.

What can I expect my vision to be?

In U.S. clinical studies, 97% of patients saw 20/40 or better with Intacs; 74% saw 20/20 or better--the standard for good vision, and 53% saw 20/16 or better, a level that exceeds the standard for good vision. To better understand what your potential results might be, we can schedule a complimentary exam for you.

	DAY 1	MONTH 3	MONTH 12
UNCORRECTED VISION			53%
20/16	13%	49%	74%
20/20	34%	71%	87%
20/25	55%	86%	

NYA 00675

20/40 81% 97% 97%

In the first couple of months, you may experience some glare, starbursts, halos and fluctuating vision. This is normal and improves slowly throughout the postoperative period. In most patients, these symptoms improve when Intacs are placed in the second eye.

Will I still need glasses or contact lenses after the procedure?

Typically, patients no longer depend on glasses for correction of their distance vision. Some patients may still wear glasses for reasons specific to their situation. For example, Intacs does not correct presbyopia, so you may still need reading glasses. It is not recommended that a contact lens be worn on an eye that has Intacs.

How long do Intacs stay in the eye?

Intacs are intended to remain permanently in place without maintenance, yet a trained ophthalmic surgeon can easily remove them.

Can Intacs be felt once they are in place?

No. Intacs are not felt because they are placed in the cornea beneath the nerve endings.

Can Intacs be seen by the naked eye?

Intacs are barely noticeable to other people and their appearance in the eye is similar to a contact lens.

Can they dry out or get dirty like a contact lens?

No. Intacs are designed to remain permanently in placed within the cornea and don't require maintenance.

Could I have an allergic reaction to Intacs?

The material used for Intacs has a long history of being safely used in the eye. It has not been known to interact with eye tissue to produce an allergic reaction or other side effects, such as swelling or irritation.

What if my vision changes?

As you get older, your eyesight will change. If the Intacs you were given no longer provide the amount of correction you need, they may be removed or replaced. Your doctor will help you determine the best means to accommodate any changes in your vision.

What will my vision be like if I later want Intacs removed?

Intacs can be easily removed in a brief outpatient procedure. When Intacs were removed in U.S. Clinical studies, patients' vision returned to their preoperative levels, in most cases. This process

typically took three months. All patients' corrected vision was 20/20 or better following the removal of Intacs.

typically took three months. All patients' corrected vision was 20/20 or better following the removal of Intacs.

TESTIMONIALS

Andrew Kessler-

Why did you decide to have the LASIK procedure:

I lead a relatively active lifestyle. In addition to being a father, I'm a skier and a tennis player and I like to spend (obviously skiing) a lot of time outdoors. Coming indoors from outdoors in the winter, anyone who wears glasses has had the experience of having the condensation on their glasses, and just being able to be in the ocean, doing the things I want to do, glasses were an inconvenience.

With any surgery we know there's some risk involved, when you approached this, how did you weigh benefits against the risks?

Well, obviously what I was looking at was the opportunity to not have to wear glasses anymore but primarily I looked at all the potential operations that were available and I've been looking for a lot of years. I have the benefit of being the son of an optometrist, so for about the last fifteen years I've been looking for some way to avoid wearing my glasses and at some point it was made known to me that there was this LASIK procedure which has a very high level of success, for which I was a very good candidate.

After being through this procedure, what do you think?

I'm ecstatic. I'm also grateful to Dr. Nevyas-Wallace. Since I had the procedure, I am corrected glasses free. I am thrilled.

Dr. Tammy Schuler-

As an optometrist and someone who has had LASIK performed, what kind of legwork do you recommend to people when researching and deciding whether they should get this done and by whom.

Usually when patients are interested in refractive procedures, I recommend that they look for a surgeon that they feel comfortable with and also one that has experience. You should be comfortable with the person who performs the surgery because you will have concerns both from a vision standpoint and from an anxiety standpoint.

How do you feel about your results?

I am very very pleased. From the moment that I had the procedure I was 20/20 and I experienced very very little discomfort. I was told that I could anticipate a little bit of glare night because I have a large pupil size. I did experience glare at night however it was never hindering because my vision was clear. After about three months it totally dissipated and is now gone.

Glenn Macnow-

I'm one of those people who couldn't see the hand in front of their face when it's two feet in front. I wore glasses up until my 30's; I wore contacts after that. I hated it. I hated breaking the glasses. I hate cleaning the lenses. I hated not being able to see in the morning until I put the glasses on, I couldn't even read the clock.

When I came to Nevyas Eye Associates what I really liked is, I didn't feel as if they were salespeople and they weren't trying to push me into it. They explained everything that was going to happen, step by step. I must have asked them six thousand questions, they never got tired of my questions. I probably had a lot of stupid questions. They never made me feel stupid about them. They figuratively held my hand through the procedure. I'm still amazed that I go to a football game, I go see the Philadelphia Eagles, and I'm up in the press box, I'm talking 200 yards away on the other side of the field is the head

coach and I can see what he's saying and I can make out who he's talking to and I can see forever and that really has amazed me. I'll tell you something else and this again may sound corny, colors are brighter than they were. I used to see the leaves on the tress, I used to see the distance as sort of a shading of colors. Now I see the leaves on the trees and it's individual leaves. Now I look off into the distance and I can see the color breaking into that color. The surprise was how much better I see. I figured I would see about the same but not have to wear the glasses or the contacts. What I learned is, how much better I could see.

MOJO INTERACTIVE

FAX

To: Dr. Sterling Fax: 609-985-1191

From: Christina Brooks Date: 6/10/99

Re: Web-site Creation Materials Pages: 13 including cover

CC:

O Urgent O For Review O Please Comment O Please Reply O Please Recycle

Comments:

Dr. Richard Sterling.

These are the contracts and forms stating the materials that we need completed before we can start developing the web-site. I did review your file and Dr. Nevyas has not sent back the signed contracts I did send them again just in case they were misplaced We have the faxed copy in the file now but we do need the originals. If you have any questions please contact me Have a great day.

Christina Brooks — they did not

Christina Brooks

Mojo Interactive Corporation

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Nevyas Eye Associates / Delaware Valley Laser Surgery Institute
Ambulatory Surgery Center

FAX COVER SHEET

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John M. DeVaro, M.D.
Pediatric Opthalmology, Ocular Motility & Neuro-Opthalmology

Richard H. Sterling, O.D.
Interprofessional Relations Refractive Surgery Coordinator

DATE: 6-29-99

TO: Christina Brooks

COMPANY: Mayo

FAX #: 407-830-9917

FROM: D. Richard Sterling

NAME: Nevyas Eye Assoc.

FAX #: (610)668-1509 BALA CYNWYD, PA

NUMBER OF PAGES INCLUDING THIS ONE: 6

I didn't remember if I had faxed this to you for use in our site. How are "we" progressing Give me an update

admin\fax

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Ambulatory Surgery Center

6-10-99

Christina Brooks
Mojo Interactive Corporation

Dear Christina:

I'm faxing you some information for you to get started on our web site design. I'll give you my input and Dr. Nevyas is working on his suggestions as we speak. I'll forward the original signed contracts as well as additional information ASAP. Please feel free to contact me at any time and I'll try and expedite answers or preferences. Thanks in advance for your assistance.

Sincerely,

Richard H. Sterling, OD

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Joann Y. Nevyas, M.D.
Cataract and Glaucoma Surgery and Therapy

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Nevyas Eye Associates- LASIK Results

The refractive surgeons of Nevyas Eye Associates, **Drs. Anita Nevyas-Wallace** and **Herbert Nevyas** pride themselves on their dedication to excellence in all surgeries they perform including laser assisted procedures such as **LASIK**. Since we began doing this technique we tried to do as much as possible to guarantee a quality result. Our dedication and hard work has paid off in the form of many very happy patients.

When excimer laser was first approved for use on the cornea in October 1995 Nevyas Eye Associates began using the excimer beam directly on the third layer of the front part of the eye, cornea (LASIK), to minimize patient postoperative discomfort and complications. Many surgeons began laser technology with PRK which is simply using the excimer to remove the first, second and part of the third layer of the cornea. Because the surgeons of Nevyas Eye Associates had experience with ALK surgery ("lifting a flap") before excimer technology was approved they were able to offer what has now been accepted as the procedure of choice for excimer laser namely LASIK.

The **patients who have had LASIK** for their distance vision (not the monovision eye) and who have at least 180 days followup have attained **20/40 or better unaided** (no glasses or contacts needed) **vision in 94% of the cases.** Of those same patients **80% have 20/25 or better** and **57% have 20/20 or better** unaided visual acuity.

The surgeons of Nevyas Eye Associates have worked very hard to improve the technique as much as possible. In February of 1998 the Drs. Nevyas invented a **fixation device** to minimize decentered laser ablations (when the laser "vaporizes" corneal tissue). The results speak for themselves **97%** of the patients we've done LASIK for are **within +/- 1.50 diopters** (smallest increment is 0.25 diopter) and **71% are within +/- 0.50 diopters.** Although there are very few **overcorrections** (removing all nearsightedness and creating farsightedness) the majority were **less than +0.50 diopters.**