VisionCare™
OPHTHALMIC TECHNOLOGIES

VISIONCARE'S IMPLANTABLE MINIATURE TELESCOPE (BY DR. ISAAC LIPSHITZ)

AN INTRAOCULAR TELESCOPE FOR TREATING SEVERE TO PROFOUND VISION IMPAIRMENT DUE TO BILATERAL END-STAGE AGE-RELATED MACULAR DEGENERATION

PATIENT INFORMATION BOOKLET

MAY 5, 2010

IMPORTANT INFORMATION

This booklet will help you decide whether or not to have surgery to implant the Implantable Miniature Telescope (by Dr. Isaac Lipshitz) (intraocular telescope) in your eye to reduce the effects of your vision impairment from age-related macular degeneration. Please read the whole booklet. Discuss it thoroughly with your eye doctor, your surgeon, your family and your friends until you get answers to all your questions. You need to understand the risks and benefits of implanting the intraocular telescope before you decide to have the surgery. You and your doctor must both complete the Acceptance of Risk and Informed Decision Agreement before you can have the surgery.

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PATIENT INFORMATION BOOKLET
VISIONCARE'S IMPLANTABLE MINIATURE TELESCOPE (BY DR. ISAAC LIPSHITZ)

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GLOSSARY

Age-Related Macular Degeneration (AMD): an eye disease in older individuals that destroys sharp, central vision by damaging the retina. AMD makes it hard to read and recognize faces.

Bilateral AMD: AMD in both eyes.

Cataract: the natural lens of the eye becomes cloudy, causing hazy vision.

Central vision: ability to see "straight ahead" for reading, recognizing faces, or seeing details.

Contrast sensitivity: how well your eyes function in low light and how well you can distinguish one object from another or from the background.

Cornea: the clear front portion of the eye.

Corneal edema: swelling of the cornea that can make it cloudy and cause blurred vision.

Corneal endothelial cells: layer of cells on the inside of the cornea that keeps the cornea healthy and transparent by controlling the amount of fluid in it; if you lose too many corneal endothelial cells due to eye surgery or disease, your cornea can become cloudy and cause blurred vision.

Corneal transplant: replacement of your cornea with a new cornea from an organ donor.

Depth perception: the ability to see in three dimensions and to identify how far away an object is.

End-stage AMD: advanced AMD causing severe central vision loss that is not treatable by medication or laser surgery.

External telescope: a hand-held or externally worn telescope used to magnify objects.

Field of view: the angle of view from the center to the sides when looking forward, for example, 180 degrees of vision.

Implantable Miniature Telescope ("intraocular telescope"): a very small telescope that is surgically implanted in the eye after removing the natural lens. An intraocular telescope magnifies images and is intended to improve central vision in patients with end-stage AMD.

Intraocular: inside the eye.

Intraocular lens (IOL): a very small lens implanted in the eye to replace a cloudy natural lens during cataract surgery.

GLOSSARY (CONTINUED)

Lens or Natural Lens: transparent structure inside the eye behind the iris that focuses light onto the retina to create an image.

Macula: the central part of the retina at the back of the eye that is responsible for central vision.

Peripheral vision: vision outside the center of gaze, on the sides.

Profound vision impairment: vision 20/400 or worse.

Retina: the light sensitive inner layer of the eye that is responsible for sight.

Severe vision impairment: vision 20/160 to less than 20/400.

Visual acuity: a measure of how well someone can see, for example, 20/20 or 20/200.

Wet AMD: abnormal blood vessels under the retina that leak blood and fluid that cause damage to the retina.

INTRODUCTION

If you are thinking about having surgery to have the **Implantable Miniature Telescope** (by Dr. Isaac Lipshitz), also called the **intraocular telescope,** placed in your eye, please read this Patient Information Booklet carefully. You may want a friend or family member to read it to you. You may want to discuss it with your family and friends. You should ask questions of your eye doctor, your surgeon and the eye care professionals who work with your eye doctor and surgeon. Take all the time you need to thoroughly consider and understand the information and get all your questions answered.

The intraocular telescope has potential benefits and potential risks. Only you can decide whether intraocular telescope surgery is a good option for improving your vision.

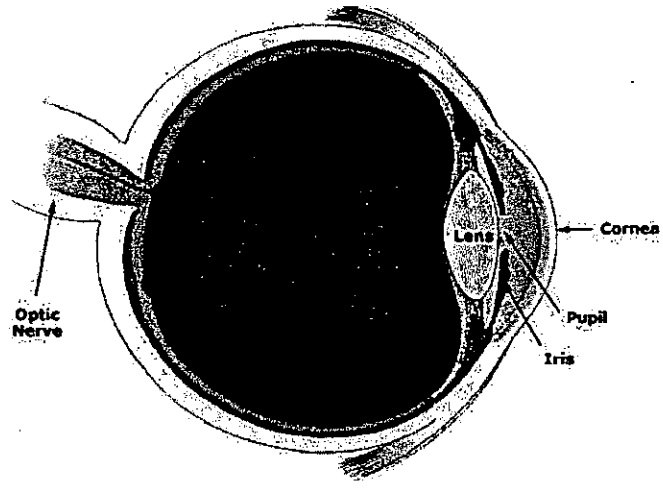
Information about the Eye and Age-Related Macular Degeneration (AMD)

The eye acts like a camera to focus light from outside the eye to form images or pictures on the surface of the **retina**. Light enters the eye through the **cornea** and **lens** which focus the light onto the retina.

The **macula** is located in the center of the retina. The macula provides **central vision**. Central vision allows you to see objects clearly and to do common daily tasks such as reading and recognizing faces.

AMD is a disease related to aging that gradually destroys the macula and therefore central vision. Figure 1 shows a picture of the inside of the eye.

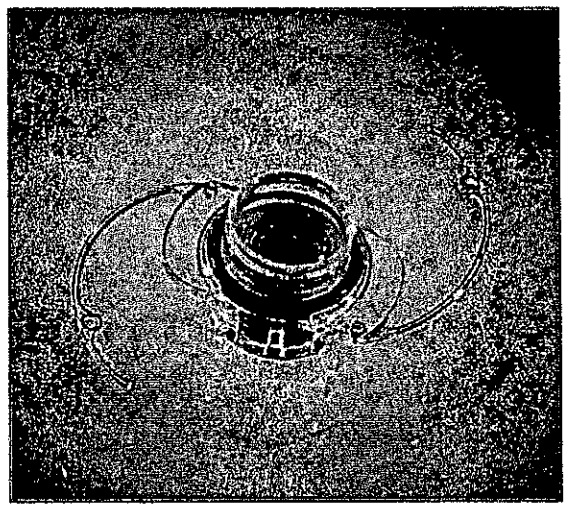
FIGURE 1
CROSS SECTION OF THE EYE



What Does the Intraocular Telescope Do?

The intraocular telescope is intended to improve distance and near vision in people who have lost central vision in both eyes because of **end-stage AMD**. The intraocular telescope is about the size of a pea and is surgically placed inside one eye. The implanted eye provides central vision. The other eye provides **peripheral vision**. A picture of the intraocular telescope is shown in Figure 2.

FIGURE 2: IMPLANTABLE MINIATURE TELESCOPE (BY DR. ISAAC LIPSHITZ)



How Does the Intraocular Telescope Work?

When implanted in your eye, the intraocular telescope magnifies images and projects them onto a part of your retina that is healthy and can still see images.

ARE YOU A CANDIDATE FOR THE INTRAOCULAR TELESCOPE?

You are a candidate if you meet these criteria:

- You have end-stage AMD in both eyes.
- You are at least 75 years old.
- Your distance vision is no better than 20/160 but no worse than 20/800.
- You have cataract.
- You show improvement on an eye test chart using an **external telescope**.
- You agree to pre-surgery training with external telescopes with a **low vision specialist** long enough to make an informed decision.
- You agree to training with a low vision specialist after intraocular telescope surgery.
- You are informed of the intraocular telescope's risks and benefits.
- You understand and sign the Acceptance of Risk and Informed Decision Agreement for the intraocular telescope surgery.

ARE YOU SOMEONE WHO SHOULD NOT HAVE AN INTRAOCULAR TELESCOPE?

You should not have intraocular telescope surgery if:

- You have already had surgery in the same eye.
- You have poor peripheral vision in the other eye.
- You have uncontrolled glaucoma.
- You rub your eyes. Rubbing your eye after surgery could damage both the cornea and the intraocular telescope.
- Your eye doctor says you have a disease or condition that would make you a poor candidate.

You should discuss your medical and vision history completely with your eye doctor.

Only you, with the help of your eye doctor, surgeon, friends, and family, can decide whether to have the intraocular telescope implanted. If the potential benefits are more important to you than the risks, then you should ask your doctor if you are a good candidate for the intraocular telescope. If the risks seem greater to you than the potential benefits, you should let your doctor know that you do not want to have an intraocular telescope.

CLINICAL STUDIES

The following sections (What are the Risks of The Intraocular Telescope and What are the Benefits of the Intraocular Telescope) give the results of clinical studies of the intraocular telescope. 217 patients with vision impairment due to end-stage AMD in both eyes were studied at 28 U.S. centers to evaluate the safety and effectiveness of the intraocular telescope. Patients averaged 76 years of age, about half were female and half were male, and most were Caucasian.

WHAT ARE THE RISKS OF THE INTRAOCULAR TELESCOPE?

This section talks about the risks of having intraocular telescope surgery and about the risks of having the intraocular telescope during the 5 years after surgery. There may be other risks that were not detected in the studies, and the long-term risks of having the intraocular telescope more than 5 years are unknown.

Surgery. After surgery has started, your surgeon may not be able to implant the intraocular telescope. If this happens, an **intraocular lens (IOL)** will be implanted instead. You will have all the risks of the surgery but without any of the benefits of the intraocular telescope. About 5% (1 out of 20) of patients had this problem.

Corneal Edema. You may develop corneal edema, which is swelling of the cornea. Intraocular telescope surgery will cause you to lose some **corneal endothelial cells** immediately, and afterward you will continue to lose more cells over time than normally happens with aging. Once you lose corneal endothelial cells, they do not grow back.

During the 5-year period after intraocular telescope surgery, about 12% of patients had very low corneal endothelial cell density, which can cause corneal edema to develop. Corneal edema is usually not painful except in very severe cases. If corneal edema is persistent (does not go away) and becomes bad enough to impair your vision, you may need a **corneal transplant**. It may also be necessary to remove the intraocular telescope during the corneal transplant surgery.

Persistent corneal edema and persistent vision-impairing corneal edema are serious conditions that do not get better over time. Implanting the intraocular telescope in your eye will increase your risk of getting persistent corneal edema, which can progress to persistent vision-impairing corneal edema or the need for a corneal transplant. The risks of these events reported over a 5-year period of time are shown in Table 1.

TABLE 1
RISK OVER 5 YEARS

Persistent Corneal Edema	Persistent Vision-Impairing Corneal Edema	Corneal Transplant
9%	7%	4%

Vision Loss. Your vision may get worse. The risk of losing more than 2 lines of vision on the eye chart was about 12% over the 5 years following intraocular telescope surgery. Also, 48% of patients in the study reported that their vision-related quality of life either stayed the same or got worse after intraocular telescope surgery.

Removing the Intraocular Telescope. If you are unhappy with your vision after intraocular telescope surgery, you may want to have your eye surgeon remove the intraocular telescope. This requires another surgery with risks that are at least as high as the risks of the surgery to implant the intraocular telescope. The surgery to remove the intraocular telescope may cause additional loss of corneal endothelial cells, which may lead to corneal edema. During the 5-year period after intraocular telescope surgery, about 4% of patients had their intraocular telescope removed and replaced with an intraocular lens.

Some Other Risks of Intraocular Telescope Surgery:

- double vision
- inability or difficulty controlling when to switch from using one eye to the other
- decreased **peripheral vision** in the eye with the intraocular telescope
- bleeding in the eye due to surgery
- infection inside the eye
- decrease in **contrast sensitivity**
- the need to surgically remove the intraocular telescope if it breaks inside your eye
- medical or visual complications
- dizziness or a queasy feeling

- changes in **depth perception**
- difficulty seeing in dim light
- difficulty seeing in bright light
- cloudy or blurred vision that makes it hard to see
- difference in speed of motion of the images in the two eyes, when the eyes are moved together.

If you have intraocular telescope surgery, you should have a complete annual eye examination that includes checking your corneal endothelial cells. The annual examination will help you know whether any of the risks discussed in this section are happening to you.

WHAT ARE THE BENEFITS OF THE INTRAOCULAR TELESCOPE?

This section talks about the potential benefits of having intraocular telescope surgery.

The intraocular telescope may improve your vision (the ability to see) and may improve your vision-related quality of life.

Vision Improvement. Most patients implanted with the intraocular telescope had significant improvement in vision. At 1 and 2 years after surgery, about 75% of patients had an improvement in their distance visual acuity of 2-lines or more on the eye chart. A 2-line improvement would be from 20/200 to 20/125 or from 20/400 to 20/250.

About 60% of patients improved their distance vision by 3-lines or more on the eye chart. About 40% of patients improved their vision by 4-lines or more. Improvements in distance and near vision were similar.

There was a slight decline in visual acuity at 3 and 4 years after surgery. However, improvements in vision after intraocular telescope surgery are generally retained over time. Results beyond 5 years are unknown.

Vision-Related Quality of Life Improvement. The majority (52%) of patients implanted with the intraocular telescope reported improvement in their vision-related quality of life. This means that they were more able to carry out activities that required distance or near vision. It also means they were more able to take part in social activities, and to independently carry out the activities of daily life.

Other benefits include: Eye movements are normal with the intraocular telescope. Because the intraocular telescope is implanted inside your eye, whatever you are looking at can be followed with natural eye movements rather than by turning your head.

WHAT OTHER QUESTIONS SHOULD YOU CONSIDER BEFORE INTRAOCULAR TELESCOPE SURGERY?

Is There a Way to See What Your Vision Will Be Like With the Intraocular Telescope Before the Surgery to Help You to Decide if the Intraocular Telescope May Work for You?

Yes. Before you decide whether to have intraocular telescope surgery, you will meet with low vision specialists to use an external telescope to see if your vision improves when using the external telescope. Using the external telescope will help you understand what it could be like to have an intraocular telescope in your eye. You will be asked to use the external telescope for as long as you need to see what the intraocular telescope will be like in your activities of daily living. You need to do this even if you have used external telescopes before. If you do not like your vision with the external telescope or your vision does not improve, you should not have the intraocular telescope implanted in your eye.

Your eye doctor will recommend low vision specialists to you. The low vision specialists will check your vision. They will show you how to use the external telescope and help you understand what your vision will be like with the intraocular telescope implanted in your eye. The specialists will work with you to see whether or not you are able to adjust to the magnification to improve your vision. They will discuss your functional goals (what you want to be able to do) and evaluate them with you. Most people will need 2 to 4 meetings with the low vision specialists. The meetings will be about thirty minutes to an hour long.

The external telescope will only determine if you will respond to magnification. Your ability to use the external telescope does not guarantee that you will be able to successfully use the intraocular telescope.

Will You Need Training to Learn How to Use Your Intraocular Telescope?

Yes. After you have surgery to implant your intraocular telescope, you will need to attend several training sessions with low vision specialists. The specialists will create a plan of care for you based on your individual situation and functional goals. The low vision specialists will work with you to teach you how to do your daily activities with your new intraocular telescope. Visits with the low vision specialists are important to getting the most benefit from your intraocular telescope. Each session will be thirty minutes to one hour long.

Are There Other Options You Could Use Instead of the Intraocular Telescope?

Yes. You can use handheld external telescopes, spectacle-mounted telescopes, or special magnifying eyeglasses instead of the intraocular telescope. You should discuss these options with your doctor.

What About Lucentis® and Other Drugs? Can You Use Them Instead?

No. Lucentis® is a medication used for earlier stages of AMD, called **wet AMD**. It is not used for your stage of AMD, which is called "end-stage" AMD. The intraocular telescope is intended to be used when Lucentis® is no longer effective.

WHAT TO EXPECT WITH THE SURGICAL PROCEDURE?

Before the Surgery

Before the surgery, your surgeon will get your medical history and check the health of both of your eyes.

Tell your surgeon if you take any medication or have any allergies. Be sure to discuss all your questions with your surgeon before scheduling your surgery. Ask your surgeon if you should eat or drink right before the surgery. You should arrange for transportation to and from where you live.

The Day of Surgery

Surgery will be performed in an outpatient surgical setting. You should plan on 2 to 3 hours for surgical preparation, the surgery, and recovery period. You will remain awake during surgery. Your eye will be numbed at the beginning of the surgery so you will not feel any pain. You will get special eye drops to enlarge the pupil. Your eye will be held open with a special instrument, and an operating microscope will be placed in front of your eye. Your eye's **natural lens** will be removed. The intraocular telescope will then be implanted inside your eye in the same position where the natural lens was. The numbness will wear off after surgery.

If your surgeon is unable to implant the intraocular telescope during surgery, your surgeon will implant an intraocular lens (IOL).

After the Surgery

After the intraocular telescope is implanted you will be provided with several types of eye drops to use at home. These eye drops will prevent infection and reduce redness, burning and swelling. You will be provided instructions on when to use the medications and how long to use them. Your surgeon may also give you a protective eye patch to use over the first few days (2 to 5 days) after your surgery. Your surgeon may tell you to limit certain activities for several weeks after the surgery.

You will be asked to return for an eye exam one day after surgery, to make sure that you are recovering as expected.

You should follow all of your surgeon's instructions. They are important. This includes using the eye medications and eye patch as your doctor directs. If you have a sudden worsening of your vision you should contact your doctor as soon as possible.

You should expect improvement in central vision in the intraocular telescope implanted eye to occur over a period of time, from weeks to months.

DO NOT RUB YOUR EYE after the intraocular telescope has been implanted inside your eye. You should not rub your eye for the rest of your life, not just in the immediate postoperative period. Rubbing your eye can damage the corneal endothelial cells. Damaging the corneal endothelial cells can lead to corneal edema and the need for a corneal transplant.

Will You Need Glasses after Implantation of the Intraocular Telescope?
Yes, you will probably need glasses to adjust both your distance and near vision.

Will You Be Able to Drive after Implantation of the Intraocular Telescope?
No. Even with both an intraocular telescope and glasses, you will not be able to drive a car. Your vision will not be good enough (20/40 in most states).

WHO SHOULD YOU TALK TO ABOUT YOUR QUESTIONS?

You should talk to your eye doctor, the surgeon to whom your eye doctor has referred you, the eye care professionals in their offices and your family and friends.

This Patient Information Booklet provides you with information by asking and answering many questions about the intraocular telescope. In addition, here are a few questions you may want to ask your eye doctor, surgeon or other professionals:

- What are the benefits of the intraocular telescope for my end-stage AMD?
- What are the risks of the intraocular telescope?
- Are there other options for treating my end-stage AMD?
- What is the possibility that the intraocular telescope will not improve my central vision?
- What vision problems may happen with the intraocular telescope implanted in one eye?
- Do I have any conditions that would increase my risk of problems for intraocular telescope surgery?
- Will I be able to drive after getting the intraocular telescope?
- If I am not satisfied with the results after intraocular telescope surgery, will it be necessary for me to have another surgery to remove the intraocular telescope?
- Based on my age and the condition of my cornea, what is my risk of needing a corneal transplant in the future if I have intraocular telescope surgery?
- What could happen if I rub my eye after intraocular telescope surgery?
- Is the intraocular telescope fragile? Can it break in my eye? What would happen if the intraocular telescope breaks?
- How much will the surgery and follow-up cost? Will my health insurance cover this surgery?

ACCEPTANCE OF RISK AND INFORMED DECISION AGREEMENT INFORMATION

You will be given an Acceptance of Risk and Informed Decision Agreement for review and discussion with your eye surgeon. If you accept each risk and sign the Agreement, it means you have decided to have intraocular telescope surgery. You must complete the form by accepting each risk and sign the Agreement before you can have intraocular telescope surgery.

PATIENT ASSISTANCE INFORMATION

Your eye doctor will fill this in so you will know whom to contact if you have any questions about or problems with the intraocular telescope.

EYE DOCTOR

Name: _____

Address: _____

Telephone No: _____

E-mail: _____

SURGEON IMPLANTING THE INTRAOCULAR TELESCOPE

Name: _____

Address: _____

Telephone No: _____

E-Mail: _____

SURGERY LOCATION:

Name: _____

Address: _____

Telephone No: _____

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ACCEPTANCE OF RISK AND INFORMED DECISION AGREEMENT

To the patient: This is the last step in deciding whether you want to have intraocular telescope surgery. This Agreement lists important risks of intraocular telescope surgery. Please review this Agreement carefully with your eye surgeon. You should sign this Agreement only if you are satisfied that each risk has been explained to you and you understand and accept each risk. If you accept each risk and sign the Agreement, it means you have decided to have intraocular telescope surgery. You must accept each risk and sign the Agreement before you can have intraocular telescope surgery.

To the eye surgeon: Please review this Agreement carefully with your patient. For each item, initial if you are satisfied that the patient understands the item and has accepted it. Your signature confirms that the patient has completed and signed the Agreement.

	Patient Initials	Physician Initials
I understand that the intraocular telescope is implanted in only one eye. The eye with the intraocular telescope provides central vision. I will need to use my other eye for peripheral vision when I want to walk around.	_____	_____
I used an external telescope to see if my vision would improve with magnification and it did. I find the vision acceptable.	_____	_____
I had training in the use of an external telescope to see whether I can adjust to using one eye for central vision and the other eye for peripheral vision. I was able to do this with practice.	_____	_____
I understand that my ability to use the external telescope does not guarantee that I will be able to successfully use the intraocular telescope.	_____	_____
The field of view in the eye implanted with the intraocular telescope is restricted. I understand that I will lose peripheral vision in the eye implanted with the intraocular telescope and that I will need to rely on my other eye for peripheral vision.	_____	_____
I understand that I may experience double vision after intraocular telescope surgery.	_____	_____

ACCEPTANCE OF RISK AND INFORMED DECISION AGREEMENT (continued)

	Patient Initials	Physician Initials
I understand that if I have intraocular telescope surgery, I will need training to learn to use the intraocular telescope. I agree to attend such training.	_____	_____
I understand that after intraocular telescope surgery, I will probably need glasses to adjust my near and distance vision.	_____	_____
I understand there may be problems during surgery that may prevent my surgeon from implanting the intraocular telescope. If this happens, I understand that I may receive an intraocular lens (IOL) instead of the intraocular telescope. This means that I will have all the surgical risks, but I will not get the benefits of the intraocular telescope.	_____	_____
I understand that instead of the intraocular telescope improving my vision, my vision could get worse.	_____	_____
I understand that with the intraocular telescope implanted in my eye, my eye doctor may not be able to see parts of my eye or perform some procedures I may need in the future.	_____	_____
I understand that having the intraocular telescope could cause corneal edema. This could happen at any time, even 5 or more years after my surgery, and require me to have corneal transplant surgery.	_____	_____
If I have to have a corneal transplant, I understand that I may not be able to keep the intraocular telescope in my eye.	_____	_____
My eye surgeon gave me the Patient Information Booklet on the intraocular telescope. I have had the chance to discuss the information in the Patient Information Booklet with my eye doctor, my eye surgeon, my family and my friends.	_____	_____

ACCEPTANCE OF RISK AND INFORMED DECISION AGREEMENT (CONTINUED)

I have had enough time to read and understand the information in the Patient Information Booklet. My eye doctor and eye surgeon have answered my questions. I have considered alternatives to the intraocular telescope such as external telescopes, spectacle mounted telescopes, and special magnifying eyeglasses.

I choose to proceed with surgery to implant the intraocular telescope.

Patient Name (Printed): _____

Patient Signature: _____

Date: _____

Surgeon Name (Printed): _____

Surgeon Signature: _____

Date: _____

Witness Name (Printed): _____

Witness Signature: _____

Date: _____

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AN INTRAOCULAR TELESCOPE FOR TREATING SEVERE TO PROFOUND VISION IMPAIRMENT DUE TO BILATERAL END-STAGE AGE-RELATED MACULAR DEGENERATION

MAY 5, 2010

PROFESSIONAL USE INFORMATION

IMPORTANT INFORMATION

Please read this entire booklet. A thorough understanding of the principles, clinical application, risks, and benefits associated with VisionCare's Implantable Miniature Telescope (by: Dr. Isaac Lipshitz) is necessary before using this product. Provide the Patient Information Booklet to candidate patients and advise them to read or have it read to them by a friend or family member. Give the patient ample time to consider whether to have the procedure. Please encourage and provide candidate patients the opportunity to ask you questions and to ask questions to their referring ophthalmologist or other eye care professionals. The patient and the implanting physician must complete an Acceptance of Risk and Informed Decision Agreement before intraocular telescope implantation surgery.

RESTRICTED DEVICE: U.S. Federal Law restricts this device to sale, distribution, and use by or on the order of a physician or other licensed practitioner.

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VisionCare™
OPHTHALMIC TECHNOLOGIES

VISIONCARE'S IMPLANTABLE MINIATURE TELESCOPE (BY: DR. ISAAC LIPSHITZ)

PROFESSIONAL USE INFORMATION

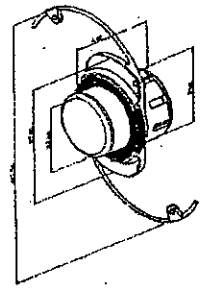
1. GENERAL

This brochure provides information about the benefits and risks of VisionCare's Implantable Miniature Telescope (by: Dr. Isaac Lipshitz), indications for use, safety information including restrictions, warnings, contraindications, and precautions, information about the training which the physician must have before implanting her or his first patient with the Implantable Miniature Telescope (by Dr. Isaac Lipshitz), information to be provided to the prospective patient before the patient decides whether to undergo surgery to implant the device, an Acceptance of Risk and Informed Decision Agreement which the patient and surgeon must sign before the intraocular telescope is implanted, a description of the device, detailed directions for use, and the results of the clinical studies.

Before a patient decides whether to have implantation of the intraocular telescope, he or she should be given a copy of the Patient Information Booklet and advised to read it or have it read to him or her by a family member or friend. The patient should be given sufficient time to consider whether he or she wishes to have the procedure. The patient should be given ample opportunity to ask questions and get answers from his/her referring ophthalmologist, the surgeon, eye care professionals at their offices, and family and friends.

2. DEVICE DESCRIPTION

VisionCare's Implantable Miniature Telescope (by Dr. Isaac Lipshitz) (intraocular telescope) is an implantable device which, when combined with the optics of the cornea, constitutes a telephoto system for improvement of visual acuity in patients with severe to profound vision impairment due to bilateral, end-stage age-related macular degeneration. The intraocular telescope is surgically implanted in the capsular bag and is held in position by haptic loops. The intraocular telescope is available in two models: Wide Angle (WA) 2.2X, and Wide Angle (WA) 2.7X. Both models are indicated for monocular implant. The implanted eye provides central vision, while the fellow eye continues to be used for peripheral vision.



The intraocular telescope is composed of three primary components: a fused silica capsule that contains optical elements, a clear polymethylmethacrylate (PMMA) carrier, and a blue PMMA light restrictor. All materials are biocompatible for long-term ocular implantation per ISO 10993. One of the internal components (not in contact with body fluids or tissue) of the intraocular telescope contains stainless steel, has been evaluated for MRI compatibility and determined to be MR-Conditional. Product specifications are described in Table 1.

Note: MRI testing was performed to evaluate the magnetic field interactions, heating, and artifacts of the intraocular telescope induced by a commercial 3-Tesla MRI system. Based on the MRI testing information, the intraocular telescope will not present any additional hazard or risk to a patient undergoing an MRI procedure using a scanner operating with a static magnetic field of 3-Tesla or less and under the MRI-related heating conditions used for the evaluation (MRI for 15 minutes at an MR system reported whole body averaged specific absorption rate, SAR, value of 3 W/Kg). The MRI image quality may be compromised if the area of interest is the same as or close to the position of the device (in this case, it may be necessary to optimize MR imaging parameters to compensate for the presence of the intraocular telescope).

TABLE 1
PRODUCT SPECIFICATIONS

FEATURE	MODEL WA 2.2X	MODEL WA 2.7X
MAGNIFICATION	2.2x ± 10%	2.7x ± 10%
DEPTH OF FIELD	1.5 to 10 m	1.5 to 10 m
OPTIMAL FOCUSING DISTANCE	3 m	3 m
FIELD OF VIEW	Full field: 24° (Nominal), 52.8° on the retina	Full field: 20° (Nominal), 54° on the retina
DIMENSIONS		
Overall Diameter	13.5 mm	13.5 mm
Clear Aperture	3.2 mm	3.2 mm
Telescope Diameter	3.6 mm	3.6 mm
Axial Length	4.4 mm	4.4 mm
Haptic Angulation	12.7°	12.7°
WEIGHT		
Air	115 mg + 10%	115 mg + 10%
Aqueous	60 mg + 10%	60 mg + 10%

3. INDICATION FOR USE

The intraocular telescope is indicated for monocular implantation to improve vision in patients greater than or equal to 75 years of age with stable severe to profound vision impairment (best corrected distance visual acuity 20/160 to 20/800) caused by bilateral central scotomas associated with end-stage age-related macular degeneration.

Patients must:

- have retinal findings of geographic atrophy or disciform scar with foveal involvement, as determined by fluorescein angiography
- have evidence of visually significant cataract (≥ Grade 2)
- agree to undergo pre-surgery training and assessment (typically 2 to 4 sessions) with low vision specialists (optometrist or occupational therapist) in the use of an external telescope sufficient for patient assessment and for the patient to make an informed decision
- achieve at least a 5-letter improvement on the ETDRS chart with an external telescope
- have adequate peripheral vision in the eye not scheduled for surgery
- agree to participate in postoperative visual training with a low vision specialist.

4. RESTRICTIONS

RESTRICTED DEVICE: U.S. Federal Law restricts this device to sale, distribution, and use by or on the order of a physician or other licensed practitioner.

Before first implanting the intraocular telescope, physicians must participate in the required portion of the Physician Training Program provided by VisionCare.

5. CONTRAINDICATIONS

Implantation of the intraocular telescope is contraindicated in patients:

- with Stargardt's macular dystrophy
- with central anterior chamber depth (ACD) <3.0 mm; measurement of the ACD should be taken from the posterior surface of the cornea (endothelium) to the anterior surface of the crystalline lens
- with the presence of corneal guttata
- who do not meet the minimum age and endothelial cell density requirements, as shown in the grid in Table 2:

TABLE 2
BASELINE ENDOTHELIAL CELL DENSITY

Age Range	75-84	85 or Greater
Minimum Cell Density	2000	1800

The minimum baseline endothelial cell counts described in Table 2 are based on endothelial cell loss assumptions calculated from the upper 90% confidence limits observed in the PMA clinical trial, in guttata-free eyes with anterior chamber depth ≥ 3.0 mm. Additional considerations were average life expectancies and end-of-life ECD of 750 cells/mm^2 to maintain corneal clarity, although the exact ECD needed is not known and varies from patient to patient. Patients with endothelial cell counts lower than the minimum cell density shown in the grid may have a higher risk of developing low ECD levels and corneal edema before end of life. Even patients who have baseline ECD above the levels shown in Table 2 may be at risk of corneal transplant if ECD loss due to surgery is high, the chronic rate of ECD loss is high, or life span is longer than average.

The device is also contraindicated in patients:

- with cognitive impairment that would interfere with the ability to understand and complete the Acceptance of Risk and Informed Decision Agreement or prevent proper visual training/rehabilitation with the device
- who have evidence of active CNV on fluorescein angiography or treatment for CNV within the past six months
- with any ophthalmic pathology that compromises the patient's peripheral vision in the fellow eye
- with previous intraocular or cornea surgery of any kind in the operative eye, including any type of surgery for either refractive or therapeutic purposes.
- who have prior or expected ophthalmic related surgery within 30 days preceding intraocular telescope implantation
- with a history of steroid-responsive rise in intraocular pressure, uncontrolled glaucoma, or preoperative IOP >22 mm Hg, while on maximum medication
- with known sensitivity to post-operative medications
- who have a history of eye rubbing or an ocular condition that predisposes them to eye rubbing
- in whom the planned operative eye has:
  - Myopia > 6.0 D
  - Hyperopia > 4.0 D
  - Axial length < 21 mm
  - A narrow angle, i.e., < Schaffer grade 2
  - Cornea stromal or endothelial dystrophies, including guttata
  - Inflammatory ocular disease
  - Zonular weakness/instability of crystalline lens, or pseudoexfoliation

- Diabetic retinopathy
- Untreated retinal tears
- Retinal vascular disease
- Optic nerve disease
- A history of retinal detachment
- Intraocular tumor
- Retinitis pigmentosa

- In eyes in which both haptics cannot be placed within the capsular bag during surgery, the intraocular telescope should be removed and replaced with a conventional intraocular lens (IOL); sulcus fixation of either one or both haptics increases the risk of severe endothelial cell loss and corneal transplant.

6. WARNINGS

- Patients undergoing intraocular telescope implant may be at risk of developing persistent unresolved corneal edema (corneal edema that continues), persistent vision-impairing corneal edema (continuing corneal edema leading to a loss of BCDVA > 2-lines from baseline level at last available visit) and may need corneal transplantation. In up to 5 years of follow-up there were:
  - 10 reports of persistent unresolved corneal edema (cumulative probability 9.2%, 95% confidence interval 3.3%, 15.1%).
  - 8 reports of persistent vision-impairing corneal edema (cumulative probability 6.8%, 95% confidence interval 2.1%, 11.6%). Persistent vision-impairing corneal edema is a subset of persistent unresolved corneal edema.
  - 5 reports of corneal transplant (cumulative probability 4.1%, 95% confidence interval 0.4%, 7.7%). Corneal transplant is a subset of persistent unresolved corneal edema.
- Only cornea specialists should implant the intraocular telescope. A cornea specialist is an ophthalmologist who had fellowship or other specialty training in diseases and surgery of the cornea and who regularly performs corneal surgical procedures such as penetrating keratoplasty.
- The potential for the device to alter intraocular pressure and long-term risk of glaucoma, anterior synechiae, and pigment dispersion are unknown.
- Surgical difficulties at the time of cataract extraction might increase the potential for complications, including persistent bleeding, significant iris damage, uncontrolled positive pressure, or significant vitreous prolapse or loss.
- Secondary surgical intervention may be necessary and include intraocular telescope repositioning, removal, corneal transplant, or intraocular telescope replacement.
- A small percentage of patients (< 4% in the clinical trial) may be dissatisfied to the point that they request and have the device explanted.

- Thermal lasers should be used with extreme caution around the device and never through the glass optical portion. Accidental focus of the laser beam on any glass part could cause glass fracture.
- Patients must be informed that participation in visual training/rehabilitation is necessary to maximize the benefit of the change in visual status.
- The intraocular telescope protrudes slightly through and above the plane of the iris. Patients must be informed that eye rubbing must be avoided due to risk of endothelial cell loss. Patients who are persistent eye rubbers are contraindicated.
- The intraocular telescope restricts the patient's peripheral field. The functional field of view will be generally limited to that of the non-implanted eye.
- The intraocular telescope implant is MR-Conditional (see "Note" in Section 2.0 for conditions).

7. PRECAUTIONS

PROVIDING INFORMATION TO THE PATIENT AND OBTAINING THE PATIENT'S AGREEMENT

- Before a patient decides whether to have implantation of the intraocular telescope, he or she should be given a copy of the Patient Information Booklet and advised to read it or have it read to him or her by a family member or friend. The patient should be given sufficient time to consider whether he or she wishes to have the procedure. The patient should be given ample opportunity to ask questions and get answers from his/her referring ophthalmologist, the surgeon, eye care professionals at their offices, and family and friends.

- A physician or other health care professional should assess whether the patient is able to consider the benefits and risks of the intraocular telescope. The patient should be implanted with the intraocular telescope only after the patient, with full opportunity for consideration of the Patient Information Booklet, has signed the Acceptance of Risk and Informed Decision Agreement.

- Since the effectiveness of the preoperative screening and postoperative visual training/rehabilitation programs used in the clinical trial were not systematically investigated in the IDE clinical trial, their ability to predict candidates who will benefit from intraocular telescope implantation is unknown.

PRECAUTIONS CONCERNING THE RISKS OF IMPLANTATION OF THE INTRAOCULAR TELESCOPE

- The effects of the intraocular telescope on the corneal endothelium beyond five years have not been established. Patients should undergo an eye exam at least once a year. This examination should include specular microscopy, to determine whether the cornea is at risk of edema. Physicians should use clinical judgment regarding any interventions related to endothelial cell density changes. The clinical study results for outcomes associated with explantation of the intraocular telescope should be reviewed.

- Intraocular telescope dimensions necessitate a 12 mm limbal incision and 7 mm capsulorhexis for implantation. Special care should be taken to minimize the risk of endothelial cell loss including attention to proper patient selection and appropriate surgical techniques.
- As with any surgical procedure, risk is involved. Potential complications accompanying crystalline lens removal and intraocular telescope implantation surgery may include, but are not limited to: cornea endothelial cell loss leading to corneal edema, corneal transplant, choroidal detachment, choroidal hemorrhage, microbial infection, retinal detachment, vitreous loss, posterior capsular rupture, intraocular inflammation, uveitis, etc.
- Inaccurate or unreliable measures of corneal endothelial cell density should be avoided. A non-contact specular microscope should be used for determining central corneal endothelial cell density. The images should provide distinct countable cells and contain a minimum of 100 identifiable cells. Three images of the central cornea should be taken and the results averaged. The instructions provided by the microscope manufacturer for taking images and endothelial cell density calculation should be followed.
- Patients with corneal endothelial cell coefficient of variation >0.45 may have a stressed endothelial cell layer, and may be prone to greater than normal endothelial cell loss if implanted with the intraocular telescope.
- Patients with corneal endothelial cell percent hexagonality <45% may have stressed endothelial cell layer, and may be prone to greater than normal endothelial cell loss if implanted with the intraocular telescope.
- Vision-related quality of life may not improve. 48.2% of patients did not report a clinically significant improvement in the NEI VFQ composite score. 22.3% of patients (43/193) lost at least 5 points in VFQ-25 composite score from baseline and 25.9% (50/193) of patients reported no significant change (i.e., change within ± 5 points).

Surgical techniques and other factors that may lead to increased ocular complications or cornea endothelial cell loss include, but are not limited to:

- Forcing the intraocular telescope into the anterior chamber through an incision that is too small.
- Corneal endothelial touch with surgical instruments, the intraocular telescope, or other intraocular matter.
- Excessive stretching (e.g., 'tenting') of the cornea.
- Inadequate intra-operative anterior chamber space management or peri-operative wound management leading to shallow chamber.
- Placing one or both carrier haptics outside of capsular bag (i.e., sulcus); this may result in a tilted device and greater risk of endothelial cell loss.
- Inadequate use of ocular viscoelastic devices.

Monocular intraocular telescope implantation will result in the following visual effects:

- The size difference in the retinal images in the central field will be too great to fuse binocularly.

- Non-corresponding images in the two eyes will produce either double vision or binocular rivalry and suppression effects whenever both eyes are open. The differences in image size, motion, and brightness in the two eyes may promote diplopia by disrupting the normal neural mechanisms and feedback circuits that control binocular eye position and movements. Diplopia was reported in 4 (1.8%) of the subjects implanted with the intraocular telescope. Some subjects may find it difficult to judge the true position of objects in the environment under these conditions.
- Implantation of the intraocular telescope will limit the effective field of view in the implanted eye to the intraocular telescope field of view to 24° (WA 2.2X) or to 20° (WA 2.7X).
- The binocular temporal field will be obstructed on the side of the intraocular telescope implanted eye, and the limits of the binocular field are the same as those of the monocular field of the fellow eye.
- When the intraocular telescope field suppresses the overlapping region of the fellow eye field, vision will be obstructed in the annular region of the binocular visual field between the unmagnified and magnified outer limit of the intraocular telescope field, i.e., between eccentricities of 12° and 26.4° for the WA 2.2X model and 10° and 27° for the WA 2.7X model.
- Beyond the image projected onto the retina, approximately 55°, the intraocular telescope implanted eye will experience a permanent loss of patterned input to the peripheral retina. The implications of this are unknown.
- The magnified retinal image in the intraocular telescope implanted eye will move faster than the retinal image in the fellow eye during consensual eye movements. The impact of this motion discrepancy is unknown. While nystagmus, disorientation and loss of balance were not reported by subjects implanted with the intraocular telescope in the clinical trial, the impact of intraocular telescope implantation on the vestibular system was not evaluated.
- Retinal illuminance in the intraocular telescope implanted eye will be reduced by the transmission times the inverse square of the power. For the 2.2 power and 2.7 power telescopes, the respective attenuation factors are about 0.8 and 1.0 log units, comparable to wearing a monocular sunglass. Although the impact of this attenuation on visual performance was not evaluated in the clinical trial, it can be expected to reduce both contrast sensitivity and acuity in dim light conditions in the intraocular telescope implanted eye.

8. ADVERSE EVENTS IN THE INTRAOCULAR TELESCOPE CLINICAL TRIALS

Data for evaluation of the intraocular telescope were provided by prospective, multi-center clinical trials; IMT-002, a pivotal study, and protocol IMT-002-LTM, a long-term safety study in which patients implanted under protocol IMT-002 were followed through 5 years. The objective

of the 2-year, prospective, 28-center IMT-002 study (n=217) was to evaluate the safety and effectiveness of the intraocular telescope for the improvement of visual acuity and vision-related quality of life in patients with bilateral moderate to profound central vision impairment (BCDVA between 20/80 and 20/800) due to untreatable, end-stage age-related macular degeneration.

Rates of significant adverse events reported in clinical studies IMT-002 and IMT-002-LTM are shown in Table 3.

TABLE 3
SIGNIFICANT OCULAR ADVERSE EVENTS
OPERATED EYES (N=217)
STUDIES IMT-002 AND IMT-002-LTM

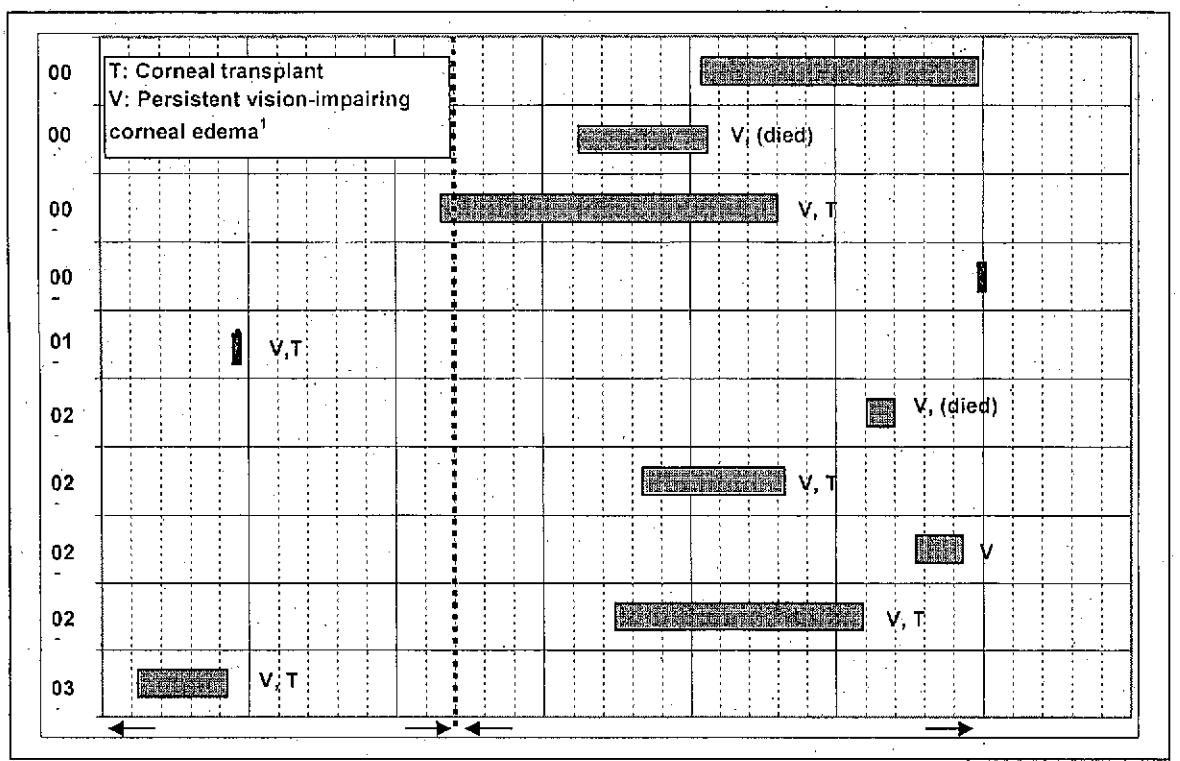
Significant Adverse Event – Device Related or Potentially Device Related	n	% (n/217)
Corneal transplant (subset of persistent vision-impairing corneal edema)	5	2.3%
Persistent[1] vision-impairing[2] corneal edema (subset of persistent unresolved corneal edema)	8	3.6%
Device failure	2	0.9%
Intraocular telescope removal	12	5.5%
Decrease in BCDVA[3]	15	6.9%
Persistent[1] unresolved corneal edema (subset of corneal edema reported > 30 days after surgery)	10	4.6%
Corneal edema reported > 30 days after surgery*	14	6.5%
Intraocular telescope dislocation	4	1.8%
Significant Adverse Event – Others		
Choroidal neovascularization	5	2.3%
Endophthalmitis	0	0%
Retinal detachment	0	0%
Retinal tear	0	0%

[1] Persistent – continuing
[2] Vision-impairing – decrease in BCDVA > 2 lines from baseline at the last available visit
[3] Decrease in BCDVA - decrease in BCDVA > 2 lines from baseline at the last available visit
*Corneal edema reported in 13 intraocular telescope-implanted eyes and in 1 operated eye not implanted with an intraocular telescope

Information on less serious adverse events and on complications associated with the intraocular telescope is provided in Section 12 (Clinical Study Results) of this professional use information.

The timing of observation of persistent unresolved corneal edema for the 10 intraocular telescope-implanted eyes is shown in Figure 1. Of these 10 eyes, 8 developed persistent vision-impairing corneal edema. When ECD levels fall too low (< 750 mm^2), the cornea may become edematous, thicken and lose transparency, and corneal transplantation may be needed. Five intraocular telescope implanted eyes underwent corneal transplantation. The endothelial cell density needed to maintain corneal transparency is unknown and varies from patient to patient.

FIGURE 1
INTRAOCULAR TELESCOPE-IMPLANTED EYES WITH PERSISTENT UNRESOLVED EDEMA
TIME OF OBSERVATION OF CORNEAL EDEMA



[1] Persistent vision-impairing corneal edema (continuing corneal edema leading to a loss of BCDVA > 2-lines from baseline level at last available visit)

As shown in Figure 1, most cases (8 of 10) of persistent unresolved corneal edema first appeared later postoperatively (at >18 months postoperatively), rather than in the early postsurgical time period.

RISK OF MAJOR EVENTS RELATED TO ENDOTHELIAL CELL LOSS, CORNEAL EDEMA, AND VISION LOSS

Using Kaplan-Meier survival analysis, the risk to an individual patient of some of the more serious adverse events was estimated for a 5-year postoperative period. (This analysis takes into account the loss to follow-up during the study.) As shown in Table 4, the cumulative probability of persistent unresolved corneal edema over 5 years was 9.2%. For persistent vision-impairing corneal edema, a subset of persistent unresolved corneal edema, the cumulative probability for this adverse event of 6.8%. Persistent vision-impairing corneal edema may require corneal transplant. There were 8 cases of persistent vision-impairing corneal edema in the study; 2 of these patients died without corneal transplant and 1 patient did not receive a transplant (reason unknown). There were 5 observed cases of corneal transplant in the study. The cumulative probability of corneal transplant over 5 years was 4.1%.

TABLE 4
CUMULATIVE NUMBER OF EVENTS AND PROBABILITY OF PERSISTENT UNRESOLVED CORNEAL EDEMA AND THE SUBSETS OF PERSISTENT VISION-IMPAIRING CORNEAL EDEMA AND CORNEAL TRANSPLANT
206 INTRAOCULAR TELESCOPE-IMPLANTED EYES
STUDIES IMT-002 AND IMT-002-LTM

Years from Implant	Persistent Unresolved Corneal Edema		Persistent Vision-Impairing Corneal Edema[1]		Corneal Transplant[2]	
	Cum # of Events	Cum % Prob[3] 95% CI of Cum Prob	Cum # of Events	Cum % Prob[3] 95% CI of Cum Prob	Cum # of Events	Cum % Prob[3] 95% CI of Cum Prob
1.0 Year (365 Days)	2	1.0% (0.0%, 2.4%)	2	1.0% (0.0%, 2.4%)	2	1.0% (0.0%, 2.4%)
2.0 Years (730 Days)	3	1.8% (0.0%, 3.8%)	2	1.0% (0.0%, 2.4%)	2	1.0% (0.0%, 2.4%)
3.0 Years (1095 Days)	5	3.4% (0.4%, 6.4%)	3	1.8% (0.0%, 3.9%)	2	1.0% (0.0%, 2.4%)
4.0 Years (1461 Days)	7	5.1% (1.3%, 8.8%)	6	4.6% (0.9%, 8.3%)	4	2.9% (0.0%, 5.9%)
5.0 Years (1914 Days)	10	**9.2%** (3.3%, 15.1%)	8	**6.8%** (2.1%, 11.6%)	5	**4.1%** (0.4%, 7.7%)

1 Persistent vision-impairing corneal edema with BCDVA loss > 2 lines from baseline at the last available visit. This is a subset of persistent unresolved corneal edema.
2 This is a subset of persistent unresolved corneal edema
3 Cum Prob = cumulative Kaplan-Meier probability that a patient experienced the event. For each reported event, the onset date (or the first reported date) was used for patient reported events. For patient without the events, the last available dates during the study were used and treated as censored records.
4 3 of the 8 patients with vision-impairing unresolved corneal edema did not undergo corneal transplantation (2 patients died before undergoing transplant and corneal transplantation was not performed in the third patient)

As shown in Table 5, the cumulative probability of persistent ECD <1000 cells/mm^2 or <750 cells/mm^2 at 5 years post intraocular telescope was 20.2% and 11.8% respectively. The cumulative probability of a patient experiencing a loss of greater than 2 lines of best corrected distance visual acuity over five years was 12.3%.

TABLE 5
CUMULATIVE NUMBER OF EVENTS AND PROBABILITY OF PERSISTENT ECD < 1000 CELLS/MM[1] OR < 750 CELLS/MM[2] BCDVA LOSS > 2 LINES AT LAST VISIT 206 INTRAOCULAR TELESCOPE-IMPLANTED EYES STUDIES IMT-002 AND IMT-002-LTM

Years from Implant	Persistent ECD < 1000 cells/mm²		Persistent ECD < 750 cells/mm²		BCDVA loss > 2 Lines at Last Visit	
	Cum # of Events	Cum Prob[4]	Cum # of Events	Cum Prob[4]	Cum # of Events	Cum Prob[4]
	95% CI of Cum Prob		95% CI of Cum Prob		95% CI of Cum Prob	
1.0 Year (365 Days)	23	11.5%	13	6.5%	4	2.0%
	(7.1%, 15.9%)		(3.1%, 9.9%)		(0.1%, 3.9%)	
2.0 Years (730 Days)	27	13.8%	17	8.6%	5	2.6%
	(9.0%, 18.7%)		(4.7%, 12.6%)		(0.3%, 4.8%)	
3.0 Years (1095 Days)	27	13.8%	17	8.6%	6	3.4%
	(9.0%, 18.7%)		(4.7%, 12.6%)		(0.7%, 6.1%)	
4.0 Years (1461 Days)	33	19.1%	18	9.5%	11	7.8%
	(13.0%, 25.2%)		(5.3%, 13.8%)		(3.2%, 12.4%)	
5.0 Years (1914 Days)	34	**20.2%**	20	**11.8%**	15	**12.3%**
	(13.8%, 26.6%)		(6.6%, 16.9%)		(6.2%, 18.5%)	

1 ECD < 1000 at two consecutive visits or at the last available visit.
2 ECD < 750 at two consecutive visits or at the last available visit.
3 BCDVA loss > 2 lines from baseline at the last available visit.
4 Cum Prob = cumulative Kaplan-Meier probability that a patient experienced the event. For each reported event, the onset date (or the first reported date) was used for patient reported events. For patient without the events, the last available dates during the study were used and treated as censored records.

Note that the risk for new events increased over time during the first 5 years and may continue to increase.

9. PATIENT SCREENING PROCEDURE

When it has been established that the patient may be a candidate for implantation of the intraocular telescope, patients will participate in pre-surgery training with low vision specialists, including use of an external telescope, and visual acuity testing with an external telescope will be performed using ETDRS (Early Treatment Diabetic Retinopathy Trial) charts. Patients must achieve at least a five letter improvement on the ETDRS chart in the eye scheduled for surgery with at least one of the external telescopes and sign the Acceptance of Risk and Informed Decision Agreement, in order to be allowed to proceed with the surgery. Patients who do not meet these criteria should not be implanted with the intraocular telescope.

10. DIRECTIONS FOR USE

DEVICE PREPARATION

Diagnostic testing, including corneal endothelial cell density and anterior chamber depth measurements, to determine if candidates meet minimum requirements should be performed preoperatively.

1. Check the label on the outer package for proper intraocular telescope model and expiration date. Inspect the packaging to insure it is not damaged. Open the external packages and remove the sterile barrier package.
2. In a sterile environment, peel to open the pouch to present the device case.
3. While keeping the container in a horizontal position, twist and remove the screw cap. The anterior aspect of the device is up, as it sits in the case. Do not re-screw cap back on case.
4. Use forceps to grasp clear carrier plate when removing device from case. Avoid grasping or handling of haptic loops and glass telescope.
5. Examine the intraocular telescope thoroughly to ensure it is free from debris, and examine the optical surfaces under magnification for other defects.

The optical portion of the intraocular telescope is comprised of fragile glass components. Do not impose any mechanical forces on the optical portion. Grasp the device only by the clear PMMA carrier plate. Do not re-sterilize the device by any method. Do not soak or rinse the device with any solution other than sterile balanced salt solution or sterile normal saline.

PATIENT PREPARATION

Induce anesthesia by retrobulbar or peribulbar injection. Administer mydriatic agents to ensure adequate pupil dilatation during surgery. Place a lid speculum on the eye to be implanted, to provide maximum cornea exposure. Position the operating microscope over or in front of the eye to be treated. Illumination from the operating microscope provides adequate visualization during the procedure.

INTRAOCULAR TELESCOPE IMPLANTATION

The intraocular telescope should be implanted in the capsular bag using a limbal insertion technique. The crystalline lens must be removed before the device can be implanted in the capsular bag. Lens extraction can be performed using the surgeon's preferred method with phacoemulsification. The device is intended for placement in an intact capsular bag with a 7 mm anterior capsulorhexis after extraction of the crystalline lens. Do not implant if there is zonular instability or inadequate capsular bag integrity.

The following steps have been identified as the appropriate surgical technique:

1. Maximally dilate the pupil. Create a 12-13 mm conjunctival incision and achieve hemostasis by cautery. Create 12 mm partial thickness limbal groove. Note: Less beveled incision allows advantageous device entry angle into anterior chamber.

   Do not make a smaller incision as it will make device implantation more difficult.

2. Create a paracentesis and inject ophthalmic viscosurgical devices (OVD) into the anterior chamber, e.g., "soft-shell technique." Coat endothelium with dispersive OVD and fill the anterior chamber (AC) with cohesive OVD.

3. After the incisions are made, create a continuous curvilinear capsular incision to achieve a 7.0 mm capsulorhexis.

   Do not make a smaller capsulorhexis as it makes intraocular telescope implantation more difficult.

4. Perform phacoemulsification to remove the crystalline lens utilizing settings that help preserve endothelial cells. Special care should be taken to remove any cortical remnants and polish the posterior capsular bag.

   Do not implant the intraocular telescope if capsule integrity is compromised - instead, insert an IOL.

5. Utilize the "soft-shell technique" to prepare the anterior segment, as follows. First, coat the endothelium with dispersive OVD (e.g., Viscoat); then inject cohesive OVD (e.g., Healon V or other viscoadaptive/cohesive OVD) to fill the AC and capsular bag. Note: lower viscosity OVDs may "burp" out during device insertion. Liberally coat the telescope (optical portion and leading haptic) with a dispersive OVD (e.g., Viscoat or equivalent). Enlarge the incision to 12 mm.

6. Using the dominant hand, grasp carrier plate of the intraocular telescope with forceps or a lens inserter while avoiding the glass optical apparatus. Damage (micro-cracks) to the glass optical apparatus can be induced during handling and manipulation. Do not grasp the glass optical apparatus. Compression of the optical element of the device resulting from improper handling by surgical instruments can also damage the device.

   The haptics are stiff - use of sharp forceps, when manipulated aggressively, can induce forces sufficient to damage or break the loops of the device.

7. Device implantation into capsular bag:

   a) Grasp the intraocular telescope by the device's clear carrier plate;

   b) Lift the cornea maximally while avoiding "tenting;"

   c) Liberally coat the telescope (optical portion and leading haptic) with dispersive OVD prior to insertion. Avoid corneal touch during the implant procedure. Iris damage increases the risk of endothelial cell loss. Use OVD appropriately to maintain a deep chamber.

   d) Insert the leading loop into the bag with the intraocular telescope at approximately 45 degrees to the horizontal plane;

   e) Both loops must be placed inside the capsular bag. Direct placement using a superior haptic compression technique should be employed.

      Dialing the trailing haptic into position should be avoided as the haptics are too stiff. A second instrument through the paracentesis incision may be helpful in holding the device steady during trailing haptic placement.

   f) Loops are bimanually rotated to the 12:6 o'clock position.

8. Once the intraocular telescope is in place, place several uninterrupted sutures to create water-tight incision and prevent shallowing of the anterior chamber. Constrict the pupil.
9. Irrigate and meticulously aspirate OVD to minimize post-operative IOP spikes. Special care is to be taken to remove OVD between the carrier plate and the capsular bag.
10. A peripheral iridectomy should be performed to reduce the risk of pupillary block.
11. Place additional sutures to close the wound, trim and bury the knots.
12. Test the incision carefully for leakage. Wound leakage and a resulting flat anterior chamber may cause significant endothelial cell loss and cornea edema leading to cornea decompensation.
13. Administer a sub-Tenon's injection of betamethasone depot (or appropriate substitute) at the end of surgery.

POSTOPERATIVE TREATMENT

1. Avoid external pressure on the eye. Use a plastic eye-shield for several days.
2. Avoid ocular hypotension.
3. Administer one drop of a topical ophthalmic antibiotic solution following surgery, and then continue as per product labeling for at least 2 days.
4. Administer one drop of Voltaren Ophthalmic (diclofenac sodium 0.1%, CIBA Vision Ophthalmics) following surgery, and then continue as per product labeling for at least 2 days.
5. Administer prednisolone acetate (1%) administered every 2 waking hours for the first 2 weeks post-implantation, followed by administration every 4 waking hours for 2 to 4 weeks.
6. Gradually taper prednisolone acetate (1%) over the next 4 to 6 weeks for a total duration of postoperative steroid treatment of approximately 3 months. Tapering may be performed over a shorter period of time, if deemed appropriate by the prescribing physician.
7. Administer homatropine 5% twice daily for 4 to 6 weeks postoperatively. If homotropine is inadequate to maintain cycloplegia, atropine may be used.

EXAMINATION AND TREATMENT OF POSTERIOR SEGMENT

Visualization and treatment of the posterior segment, including the fundus, can be accomplished following implantation of the intraocular telescope. The fundus can be visualized at the slit lamp using a 90D hand-held lens or a three mirror contact lens; approximately 50-60 degrees of the retina can be observed through the intraocular telescope with this approach. In eyes where fundus visualization is difficult when using a hand-held lens it is recommended a contact lens be employed to stabilize the eye and provide a clearer view.

Peripheral visualization can be performed by indirect ophthalmoscopy with the eye fully dilated, such that the examiner can observe the retina outside of the intraocular telescope. This view of the peripheral retina is limited in eyes in which full dilation is not possible, however, it should be

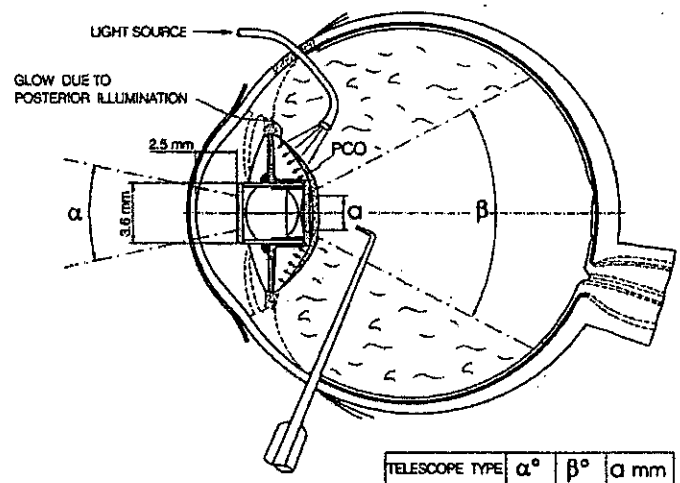
noted that even in a non-implanted eye, if dilation is limited, visualization of the peripheral retina may not be possible.

POSTERIOR CAPSULE OPACIFICATION

In the event visually significant posterior capsule opacification (PCO) occurs, a needling procedure may be used to treat PCO in patients implanted with the intraocular telescope along with cleaning of the PCO by rupturing a rhexsis on the posterior wall of the capsular bag.

Two patients implanted with the intraocular telescope successfully underwent treatment for PCO with needling; one of these cases employed a pars plana approach using a 25-gauge vitrector to engage the posterior capsule (capsulotomy performed using a combination of peeling and direct vitrectomy), as shown in Figure 2.

FIGURE 2
PARS PLANA POSTERIOR



TELESCOPE TYPE	α°	β°	a mm
2.2X	24.0	52.8	2.314
3X	20.0	54.0	2.052

11. ENVIRONMENTAL HAZARDS

If any of the following occurs, the product should be returned to the manufacturer immediately:

- If the package has been opened or damaged, as the intraocular telescope components or sterility of the device may be compromised.
- Damage to labeling that prevents clear identification of the printed labeling or the device.
- Damaged Tyvek® seal.
- Crushed/deformed package.

- Package exposed to temperatures higher than 54°C (129°F) and/or lower than -23°C (-9°F) for a period of more than 2 hours or stored at a temperature higher than 43°C (109°F) or lower than 0°C (32°F) for prolonged time.
- Package exposed to pressure higher than 1.2 atm (abs.) and/or lower than 0.5 atm (abs.).
- Do not store the device in direct sunlight or at a temperature higher than 43°C. Do not autoclave the device.
- Check the expiration date of the device before use. Do not use a device which is passed its expiration date.

12. CLINICAL STUDY RESULTS

Data from the intraocular telescope clinical trials, i.e., protocol IMT-002, a pivotal study and protocol IMT-002-LTM, a long-term safety study in which patients implanted with the intraocular telescope under protocol IMT-002 were followed through 5 years, are discussed in this section. The objective of the 2-year, prospective, 28-center IMT-002 study (n=217) was to evaluate the safety and effectiveness of the intraocular telescope for the improvement of visual acuity and vision-related quality of life in patients with bilateral moderate to profound central vision impairment (BCDVA between 20/80 and 20/800) due to untreatable, end-stage age-related macular degeneration. The results of these studies are presented.

DEMOGRAPHICS AND BASELINE CHARACTERISTICS

The demographic characteristics at baseline are presented in Table 6 for operated patients in IMT-002. At baseline, mean age was 75.6 and mean BCDVA was 20/312.

TABLE 6
DEMOGRAPHIC AND BASELINE CHARACTERISTICS
OPERATED PATIENTS (N=217)
STUDY IMT-002

217 Eyes of 217 Operated Patients	Number	Percentage
Gender		
Female	103	47.5%
Male	114	52.5%
Age (In Years)		
Mean (SD)	75.6 (7.3)	
Anterior Chamber Depth		
Mean (SD)	3.15 (0.38)	
Minimum	2.48	
Maximum	4.74	
Type of AMD		
Geographic atrophy (GA)	85	39.2%
Disciform scar	93	42.9%
GA & Drusen	11	5.1%
GA & Disciform scar	8	3.7%
Drusen & Disciform scar	13	6.0%
GA & Drusen & Disciform scar	7	3.2%
Best-corrected Visual Acuity		
Mean BCDVA	20/312	
(Range)	(20/873, 20/80)	
Mean BCNVA @8"	20/315	
(Range)	(20/1262, 20/50)	
Mean BCNVA @16"	20/260	
(Range)	(20/632, 20/63)	

For study IMT-002 196 (90%) of 217 enrolled patients were available for analysis for the 12-month visit and 174 (80%) for the 24-month visit. In study IMT-002-LTM, 85 patients were enrolled for the 36-month visit and 129 for the 48-month visit. 84 (99%) patients were available for analysis for the 36-month visit, 106 (82%) were available for the 48-month visit, and 84 (65%) returned for the 60-month visit.

IMT-002 POST-OPERATIVE CHARACTERISTICS AND RESULTS

Surgical complications led to 11 patients not being implanted with the intraocular telescope, leaving a cohort of 206 intraocular telescope-implanted patients. Table 7 shows the data for the eyes that were operated but did not receive the intraocular telescope. Of the 206 implanted eyes, 115 eyes were implanted with the WA 2.2X model device and 91 eyes were implanted with the WA 2.7X model device.

Of the 11 patients not successfully implanted, in 5 eyes the intraocular telescope was not implanted because of surgical complications and in 6 eyes intraocular telescope implantation was attempted but the device was removed at the time of surgery, also as a result of surgical complications. An intraocular lens was placed in these 11 eyes rather than the intraocular telescope.

TABLE 7
OPERATED EYES WITHOUT INTRAOCULAR TELESCOPE PLACEMENT
STUDY IMT-002

Number of Eyes	Surgical Complications
Cases with Intraoperative Contraindications for Intraocular Telescope Implantation	
3	Posterior Capsule Tear
2	Choroidal Detachment
Cases with Intraocular Telescope Placed and Removed Intraoperatively	
4	Posterior Capsular Tear
1	Zonular Dehiscence
1	Choroidal Hemorrhage

SAFETY RESULTS

Safety results from the intraocular telescope clinical trials, protocol IMT-002, a pivotal study, and protocol IMT-002-LTM, a long-term safety study in which patients implanted with the intraocular telescope under protocol IMT-002 were followed through 5 years, are discussed in this section.

The analysis of safety was based on subjects that had surgery for intraocular telescope implantation. Corneal endothelial cell density results, preservation of visual acuity, complications and adverse events are described below for the study population.

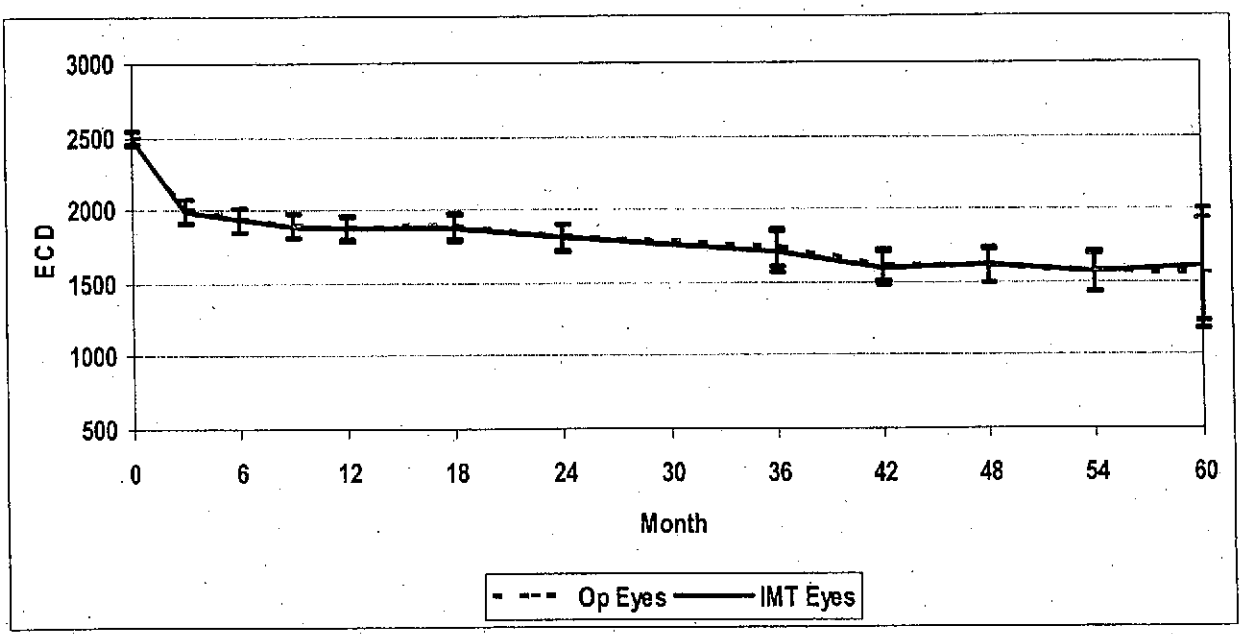
CORNEAL ENDOTHELIAL CELL DENSITY (ECD)

The IMT-002 protocol called for testing the hypothesis that population mean endothelial cell loss at one year did not exceed 17% in intraocular telescope implanted eyes. The mean ECD loss at 12 months was 25% (95% confidence interval 28% to 21%), thus failing to meet the ECD loss endpoint.

The most significant loss of corneal endothelial cells occurred from baseline to 3 months and from baseline to 6 months. This acute mean 20% (95% confidence interval 23%, 21%) ECD loss likely results from the 12 mm surgical incision required for insertion of the intraocular telescope, as well as the manipulation of the device during implantation. In the subset of eyes with visits available at both 6 and 48 months (n=85), the mean annual ECD loss was approximately 3% per year. The mean annual rate of ECD loss estimated from all eyes at all time points (through 48 months) was 4.8% (see discussion of biexponential model, page 26).

Figures 3 and 4 show the mean ECD and mean ECD percent change respectively over time for operated eyes and intraocular telescope implanted eyes. For intraocular telescope implanted eyes, mean ECD at baseline was 2496 cells/mm.^{2} At 3 and 6 months after implantation, mean ECD was 1995 cells/mm^2 and 1937 cells/mm^2 respectively; these changes in mean ECD translated into mean ECD percent loss from baseline of 20% and 22%, respectively. Mean ECD at 12 months after device implantation was 1871 cells/mm^2, a 25% loss from baseline. Mean ECD at 24, 36 and 48 months was 1808, 1713, and 1620 cells/mm^2, respectively, with associated mean percent losses of 28%, 31%, and 35%, respectively.

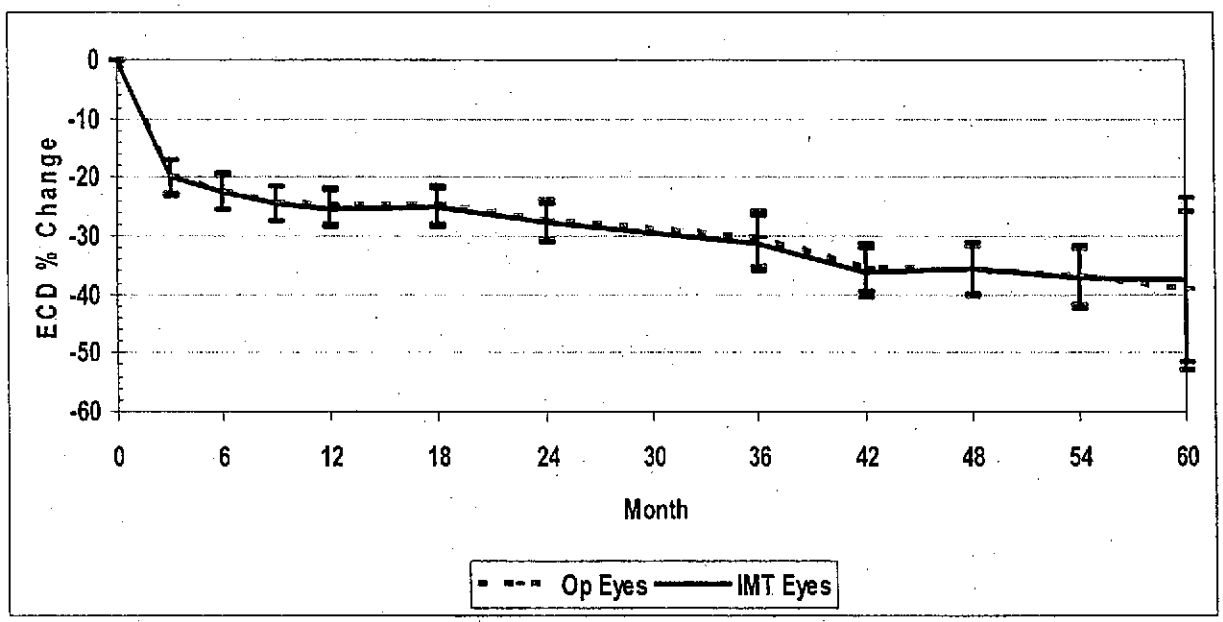
FIGURE 3
ECD (MEAN, CI)
OPERATED EYES AND INTRAOCULAR TELESCOPE IMPLANTED EYES
STUDIES IMT-002 AND IMT-002-LTM



		Preop	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months	30 Months	36 Months	42 Months	48 Months	54 Months	60 Months
Op Eyes	Mean	2498	2001	1936	1891	1881	1887	1813	1736	1612	1611	1572	1563
	95%CI	2451, 2546	1919, 2082	1855, 2016	1809, 1973	1795, 1967	1796, 1978	1723, 1903	1610, 1863	1505, 1720	1495, 1727	1439, 1706	1181, 1945
	N	216	198	200	190	190	182	173	79	110	94	65	18
	ECD<750*	0 (0%)	6 (3%)	8 (4%)	9 (5%)	9 (5%)	13 (7%)	12 (7%)	3 (4%)	9 (8%)	7 (7%)	5 (8%)	3 (17%)
IMT Eyes	Mean	2496	1995	1937	1891	1871	1878	1808	1713	1595	1620	1572	1616
	95%CI	2447, 2545	1912, 2078	1856, 2018	1809, 1973	1786, 1957	1787, 1969	1718, 1898	1576, 1850	1481, 1709	1499, 1741	1431, 1713	1227, 2005
	N	206	193	198	190	186	180	171	70	101	88	60	17
	ECD<750*	0 (0%)	6 (3%)	8 (4%)	9 (5%)	9 (5%)	13 (7%)	12 (7%)	3 (4%)	9 (9%)	7 (8%)	5 (8%)	2 (12%)

* ECD <750 – number and percent of eyes with ECD <750 cells/mm^2

FIGURE 4
ECD % CHANGE (MEAN, CI) FROM BASELINE
OPERATED EYES AND INTRAOCULAR TELESCOPE IMPLANTED EYES
STUDIES IMT-002 AND IMT-002-LTM



		Pre-op	3 Months	6 Months	12 Months	18 Months	24 Months	30 Months	36 Months	42 Months	48 Months	54 Months	60 Months
Op Eyes	Mean	0%	-20%	-22%	-24%	-25%	-25%	-27%	-30%	-35%	-36%	-37%	-39%
	95%CI		-23%, -17%	-25%, -20%	-27%, -21%	-28%, -22%	-28%, -21%	-31%, -24%	-35%, -26%	-40%, -31%	-40%, -32%	-42%, -32%	-53%, -26%
	N	216	198	200	190	190	182	173	79	110	94	65	18
IMT Eyes	Mean	0%	-20%	-22%	-24%	-25%	-25%	-28%	-31%	-36%	-35%	-37%	-38%
	95%CI		-23%, -17%	-25%, -19%	-27%, -21%	-28%, -22%	-28%, -22%	-31%, -24%	-36%, -26%	-40%, -32%	-40%, -31%	-43%, -32%	-51%, -24%
	N	206	193	198	190	186	180	171	70	101	88	60	17

Even patients who have baseline ECDs above the levels shown in Table 2 (page 7, Contraindications section) may experience low ECD leading to corneal edema if they have above average ECD losses at surgery, over time, or have longer than average life spans.

The range of ECD percent loss in intraocular telescope-implanted eyes is presented in Table 8.

TABLE 8
RANGE OF ECD PERCENT CHANGE FROM BASELINE
INTRAOCULAR TELESCOPE IMPLANTED EYE
STUDIES IMT-002 AND IMT-002-LTM

	3 Months	12 Months	24 Months	36 Months	48 Months	60 Months
Maximum Loss	-85%	-88%	-81%	-84%	-80%	-81%
95th Percentile	-67%	-69%	-75%	-69%	-74%	-81%
75th Percentile	-30%	-37%	-40%	-43%	-49%	-56%
50th Percentile	-13%	-21%	-24%	-28%	-36%	-40%
25th Percentile	-6%	-9%	-11%	-16%	-19%	-13%
5th Percentile	+6%	+1%	0%	-5%	-6%	+2%
Minimum Loss	+18%	+13%	+28%	+11%	-2%	+2%
N	193	186	171	70	88	17

Negative sign (-) indicates decrease from baseline; positive sign (+) indicates an increase from baseline

Table 9 summarizes the number of eyes with last measured ECD <1000, <750, and <500 cells/mm^2. At the patient's last available visit (which varied among patients), 31 of 206 eyes (15.0%) had ECD < 1000 cells/mm^2. This included a subset of 18 eyes (8.7%) with ECD <750 cells/mm^2 and 7 eyes (3.4%) with ECD < 500 cells/mm.^{2} Limited numbers of patients were available for later visits. For the risk to the individual patient, please refer to the Kaplan-Meier analysis shown in Table 5.

TABLE 9
LAST AVAILABLE ECD < 1000, <750, <500 CELLS/MM^2
INTRAOCULAR TELESCOPE IMPLANTED EYES
(EXCLUDING RECORDS AFTER INTRAOCULAR TELESCOPE EXPLANTS AND CORNEAL TRANSPLANTS)
STUDIES IMT-002 AND IMT-002-LTM

ECD	N = 206		
	%	n/N	95% CI of %
ECD < 1000 cells/mm^2	15.0%	31/206	(10.5%, 20.7%)
ECD < 750 cells/mm^2	8.7%	18/206	(5.3%, 13.5%)
ECD < 500 cells/mm^2	3.4%	7/206	(1.4%, 6.9%)

In some eyes, ECD decreased to <750 cells/mm^2 in the early postsurgical period. In other eyes, ECD first decreased to this level later in the study period, up to and past 50 months postoperatively.

Patients should be advised of the potential risk of corneal edema leading to persistent vision-impairing corneal edema and the need for a corneal transplant due to loss ECD resulting from surgery and further advised that ECD will continue to decline at a rate significantly higher than the 0.6% annual rate of ECD loss in phakic eyes.

While long-term ECD data is available as described above, to characterize the rate of mean

annual ECD loss, a biexponential model (Predicting Endothelial Cell Loss and Long-Term Corneal Graft Survival, W. Armitage, A. Dick, W. Bourne, *Investigative Ophthalmology and Vision Science*, August 2003, Vol. 44, No. 8) was developed to fit the ECD pattern from baseline to 48 months after intraocular telescope implantation. For all intraocular telescope implanted eyes the mean annual ECD loss was 4.8% (90% confidence interval 3.4%, 6.2%).

Using the biexponential model described above, Table 10 predicts the percentage of eyes with ECDs <1000, <750, and <500 cells/mm^2 through 60 months postoperative.

TABLE 10
PREDICTED PROBABILITY OF ECD LESS THAN THRESHOLD BASED ON BI-EXPONENTIAL MODEL FOR INTRAOCULAR TELESCOPE IMPLANTED EYES ENROLLED IN IMT-002 OR IMT-002-LTM STUDY BASED ON DATA FROM BASELINE TO 48 MONTHS (EXCLUDING PREOPERATIVE RESIDUALS)

Time	Probability of ECD < 1000	< 750	< 500
3 Months	7.2%	2.8%	0.3%
12 Months	9.4%	5.0%	1.4%
24 Months	11.4%	6.7%	2.6%
36 Months	13.1%	8.2%	3.9%
48 Months	15.4%	9.6%	5.1%
54 Months	16.5%	10.4%	5.9%
60 Months	17.4%	11.4%	6.7%

The empirical frequency of residuals was used to estimate these probabilities.

There was no evidence from studies IMT-002 and IMT-002-LTM that rate of loss of ECD declined over time or that the rate of new cases of corneal edema declined.

When ECD levels fall too low (< 750mm^2), the cornea may become edematous, thicken and lose transparency, and corneal transplantation may be needed. The endothelial cell density needed to maintain corneal transparency is unknown and varies from patient to patient. Possible risk factors for endothelial cell loss are described in the following section.

IDENTIFICATION OF POSSIBLE RISK FACTORS FOR ENDOTHELIAL CELL LOSS

A number of possible risk factors associated with ECD loss, including presence of guttata in the eye, surgical specialty, and anterior chamber depth, were evaluated. Some possible risk factors are described in Table 11 below. These and other contraindications, precautions, and warning issues are discussed in the device labeling.

These potential risk factors were identified after the study, based upon inspection of the study data. They were not based upon testing protocol-defined hypotheses. This identification of risk factors is preliminary and not established by formal statistical testing. As a result, it is unclear how much, if at all, these factors may affect the loss of endothelial cells and associated rates of corneal edema.

TABLE 11
ENDOTHELIAL CELL DENSITY PERCENT LOSS — POSSIBLE RISK FACTORS
INTRAOCULAR TELESCOPE-IMPLANTED EYES
STUDIES IMT-002 AND IMT-002-LTM

	3 Months		12 Months		24 Months		36 Months		48 Months		60 Months	
	N	Mean	N	Mean	N	Mean	N	Mean	N	Mean	N	Mean
	95% CI		95% CI		95% CI		95% CI		95% CI		95% CI	
Intraocular Telescope-Implanted Eyes	193	20%	186	25%	171	28%	70	31%	88	35%	17	38%
	(17%, 23%)		(22%, 28%)		(24%, 31%)		(26%, 36%)		(31%, 40%)		(24%, 51%)	
Possible Risk Factors												
Guttata												
Not Present	167	19%	162	24%	150	26%	63	31%	76	34%	14	33%
	(16%, 22%)		(21%, 28%)		(23%, 30%)		(26%, 36%)		(29%, 39%)		(17%, 48%)	
Present	26	26%	24	32%	21	36%	7	34%	12	44%	3	60%
	(16%, 36%)		(22%, 42%)		(25%, 47%)		(20%, 47%)		(31%, 57%)		(7%, 100%)	
Surgeon Specialty												
Cornea Specialist	51	13%	52	19%	45	20%	18	24%	21	25%	3	40%
	(8%, 18%)		(14%, 24%)		(15%, 25%)		(17%, 30%)		(17%, 33%)		(-60%, 100%)	
Non-Cornea Specialist	142	23%	134	28%	126	30%	52	34%	67	39%	14	37%
	(19%, 26%)		(24%, 32%)		(26%, 34%)		(28%, 40%)		(34%, 44%)		(22%, 52%)	
Anterior Chamber Depth												
≥3 mm	116	19%	117	25%	106	26%	40	29%	50	34%	12	36%
	(15%, 22%)		(21%, 28%)		(22%, 30%)		(23%, 35%)		(28%, 40%)		(19%, 52%)	
<3 mm	77	22%	69	26%	65	30%	30	34%	38	37%	5	42%
	(17%, 27%)		(21%, 32%)		(24%, 36%)		(26%, 42%)		(30%, 45%)		(1%, 82%)	

GUTTATA

Corneal guttata has been shown to be a risk factor for endothelial cell loss following cataract surgery. The same risk may be present in intraocular telescope implantation surgery. The percent ECD loss at 3 months postoperatively was lower in non-guttata eyes (mean loss 19%, 95% confidence interval 16%, 22%) than in eyes with guttata (mean loss 26%, 95% confidence interval 16%, 36%). Accordingly, the presence of guttata is a contraindication to the use of the intraocular telescope.

SURGEON SPECIALTY

ECD loss at 3 months was lower for intraocular telescope implanted eyes operated by cornea specialists (mean loss 13%, 95% confidence interval 16%, 22%) than by non-cornea specialists (mean loss 23%, 95% confidence interval 19%, 26%). ("Cornea specialist" is defined as ophthalmologists who had fellowship or other specialty training in diseases and surgery of the cornea and who were at the time of the study regularly performing cornea surgical procedures such as penetrating keratoplasty.) Although the number of study subjects implanted by a cornea specialist is modest, there was lower ECD loss in these subjects of clinicians experienced in the medical management and surgical treatment of the cornea. Accordingly, there is a warning that only cornea

specialists should implant the intraocular telescope. The long-term ECD data for intraocular telescope implantation performed by corneal specialists is based on limited data from a limited number of investigation sites.

ANTERIOR CHAMBER DEPTH (ACD)

ACD ≥ 3.0 mm was associated with lower endothelial cell loss at 3 months postoperatively (mean loss 19%, 95% confidence interval 15%, 22%) as compare to patients with ACD < 3 mm (mean loss 22%, 95% confidence interval 17%, 27%). The finding of greater ECD loss in shallow anterior chambers (< 3.0 mm) at 3 months is likely the result of less working space in the anterior chamber and more surgical trauma to the corneal endothelial monolayer. Accordingly, the presence of an anterior chamber < 3.0 mm is a contraindication to the use of the intraocular telescope.

PRESERVATION OF VISUAL ACUITY

Protocol IMT-002 specified that preservation of visual acuity was to be assessed in terms of whether more than 10% of intraocular telescope-implanted eyes lost >2 lines of either BCDVA or BCNVA without a corresponding improvement in the other. This endpoint was met. At 12 months, 5% of eyes incurred such losses, and at 24 months, 6% of eyes incurred such losses.

At 36 months, 2 implanted eyes lost more than 2 lines of BCDVA, and 4 eyes (4.2%) lost more than 2 lines of BCDVA at 48 months. Over the 5-year period for studies IMT-002 and IMT-002-LTM, there were 15 cumulative reports of BCDVA loss of >2 lines from baseline at the last available visit.

OCULAR COMPLICATIONS AND ADVERSE EVENTS

Ocular complications were defined as events directly related to the surgical procedure for intraocular telescope implantation, whether successful or not, occurring in the operative and immediate postoperative period. Events occurring after the immediate postoperative period were classified as adverse events. Ocular complications and ocular adverse events reported for the IMT-002 and IMT-002-LTM studies are shown in Table 12 on the following pages, with the more serious events shown first in each table.

The intraocular telescope was not placed in 5 eyes due to surgical complications occurring prior to attempted implantation, primarily capsular rupture. The telescope was placed but removed intraoperatively in 6 eyes because of surgical complications (posterior capsule tear, zonular dehiscence, choroidal detachment). A standard intraocular lens was placed in these eyes.

Other significant ocular complications included corneal edema; iris damage and/or prolapse and transillumination defects; and vitreous loss (Table 12).

The most common ocular complication was increased IOP requiring treatment ≤ 7 days (N = 59; 27.2%). (Increased IOP reported beyond 7 days and requiring treatment was classified

as an adverse event, not as an ocular complication.) Increased IOP classified as an ocular complication was likely associated with the liberal use of high molecular weight viscoelastic material (Healon V) in the eye. Other commonly reported (occurring at a rate of 5% or greater) ocular complications were corneal edema, posterior capsular opacification, iris prolapse, and corneal abrasions. Fourteen (14) cases (6.5%) of corneal edema occurred within 30 days of surgery; all 14 cases were first reported on postoperative Day 1 and three of these cases of corneal edema were still noted at the 1 month visit. Posterior capsular opacification was reported for 13 eyes (6.0%); surgical capsulotomy was successfully performed in one patient. Iris prolapse was observed in 12 eyes (5.5%) and 11 eyes (5.1%) had corneal abrasions.

TABLE 12
OCULAR COMPLICATIONS, OPERATED EYES (N=217)
STUDIES IMT-002 AND IMT-002-LTM

Significant Ocular Complications	n	% (n/217)
Aborted surgery	5	2.3%
Choroidal detachment	2	0.9%
Choroidal hemorrhage	1	0.5%
Corneal edema ≤ 30 days after surgery	14	6.5%
Iris atrophy ≤ 7 days after surgery	4	1.8%
Iris damage	9	4.1%
Iris incarceration	3	1.4%
Iris prolapse	12	5.5%
Iris transillumination defects ≤ 21 days after surgery	8	3.7%
Phthisis	1	0.5%
Posterior capsular rupture	10	4.6%
Vitreous hemorrhage ≤ 7 days after surgery	1	0.5%
Vitreous in anterior chamber ≤ 7 days after surgery	3	1.4%
Vitreous loss	3	1.4%
Vitreous loss - vitrectomy required	7	3.2%
Other Ocular Complications		
Afferent pupil defect	1	0.5%
Alternating exotropia	1	0.5%
Anterior chamber hemorrhage	1	0.5%
Anterior segment neovascularization	1	0.5%
Anterior synechiae	3	1.4%
Asthenopia	1	0.5%
Bleb	1	0.5%
Blepharitis	7	3.2%
Blurred vision	1	0.5%
Chalazion	2	0.9%
Conjunctival injection	4	1.8%
Corneal abrasion	11	5.1%
Corneal endothelial touch	3	1.4%
Corneal neovascularization	1	0.5%
Cortical remnants	2	0.9%
Cyclitic membrane ≤ 7 days after surgery	1	0.5%
Cyclodialysis cleft	1	0.5%
Descemet's membrane separation	3	1.4%
Dry eye	1	0.5%
Ecchymoses on eyelid	1	0.5%
Ectropion	3	1.4%
Endothelial folds	2	0.9%
Epithelial basement membrane dystrophy	1	0.5%
Esotropia	1	0.5%
Exotropia	2	0.9%

TABLE 12
OCULAR COMPLICATIONS, OPERATED EYES (N=217)
STUDIES IMT-002 AND IMT-002-LTM
(CONTINUED)

Flashes	1	0.5%
Flat anterior chamber ≤ 21 days after surgery	2	0.9%
Folds in corneal graft	1	0.5%
Glare	1	0.5%
Glaucoma	1	0.5%
Haze	3	1.4%
Hyphema	10	4.6%
Hypotony	2	0.9%
Increased IOP requiring treatment ≤ 7 days after surgery	59	27.2%
Increased IOP ≤ 15 days after surgery	3	1.4%
Iridotomy ≤ 7 days after surgery	3	1.4%
Iritis ≤ 30 days after surgery	2	0.9%
Meibomian gland dysfunction	1	0.5%
Ophthalmic migraine	1	0.5%
Peribulbar hemorrhage	1	0.5%
Peripapillary hemorrhage	1	0.5%
Posterior capsule opacification	13	6.0%
Significant anterior chamber bleeding	3	1.4%
Strabismus	1	0.5%
Strabismus surgery	1	0.5%
Superficial punctate keratitis	2	0.9%
Surgical mydriasis	1	0.5%
Suture rupture	4	1.8%
Treatment of PCO	1	0.5%
Uveitis	1	0.5%
Uveitis/vitritis	1	0.5%
Vitreous bulge	1	0.5%
Watery eyes	3	1.4%
Worsening of subretinal scarring	1	0.5%
Wound leak	3	1.4%
Zonular dehiscence ≤ 7 days after surgery	1	0.5%

% = n/N ×100.

Significant adverse events (Table 13) included persistent unresolved corneal edema (N=10, 4.6%), persistent vision-impairing corneal edema (N=8, 3.6%), corneal transplant (N=5, 2.3%), and decrease in BCDVA (N=15, 6.9%). Device failures, dislocation and removal are also significant adverse events.

Adverse events occurring at an incidence of 5% or greater included deposits or precipitates on intraocular telescope (N=71; 32.75%), guttae (N=22; 10.1%), posterior synechiae (N=21; 9.7%), corneal edema (N=14; 6.5%); iritis (N=12; 5.5%), iris transillumination defects (N=12; 5.5%), intraocular telescope removal (N=12; 5.5%), and distorted pupil (N=11; 5.1%) . In the majority

of eyes, deposits/precipitates on the intraocular telescope resolved over the course of patient follow-up and did not affect visual acuity. Pigment and inflammatory deposits were managed medically with a standardized course of anti-inflammatory agents, starting with a sub-Tenon's injection of betamethasone depot administered at the end of surgery followed by topical administration of prednisolone acetate 1% or equivalent tapering over 2-3 months. All remaining adverse events in study IMT-002 were reported at a frequency of less than 5.0%.

There were no cases of endophthalmitis, retinal detachment, or retinal tear in the study population.

TABLE 13
OCULAR ADVERSE EVENTS, OPERATED EYES (N=217)
STUDIES IMT-002 AND IMT-002-LTM

Significant Adverse Events	n	% (n/217)
Choroidal neovascularization	5	2.3%
Corneal edema > 30 days after surgery *	14	6.5%
Corneal transplant (subset of persistent vision-impairing corneal edema)	5	2.3%
Decrease in BCDVA	15	6.9%
Device failure	2	0.9%
Endophthalmitis	0	0%
Iris atrophy > 7 days after surgery	9	4.1%
Iritis > 30 days after surgery	12	5.5%
Persistent unresolved corneal edema (subset of corneal edema) > 30 days after surgery)	10	4.6%
Persistent vision-impairing corneal edema (subset of persistent unresolved corneal edema)	8	3.6%
Retinal detachment	0	0%
Retinal tear	0	0%
Subretinal hemorrhage	6	2.8%
Telescope dislocation	4	1.8%
Telescope removal	12	5.5%
Vitreous hemorrhage > 7 days after surgery	3	1.4%
Vitreous in anterior chamber > 7 days after surgery	5	2.3%
Other Adverse Events		
Anterior chamber inflammation > 30 days after surgery	7	3.2%
Anterior ischemic optic neuropathy	1	0.5%
Cyclitic membrane > 7 days after surgery	1	0.5%
Cystoid macular edema	1	0.5%
Diplopia	4	1.8%
Distorted pupil	11	5.1%
Dry eye	10	4.6%
Entropion	2	0.9%
Exposed suture	3	1.4%
Eye pain	3	1.4%
Flat anterior chamber > 21 days after surgery	1	0.5%
Floaters	3	1.4%
Focal striae	2	0.9%
Foreign body sensation	9	4.1%

TABLE 13
OCULAR ADVERSE EVENTS, OPERATED EYES (N=217)
STUDIES IMT-002 AND IMT-002-LTM

Guttae	22	10.1%
Increased IOP requiring treatment > 7 days after surgery	8	3.7%
Inflammatory membrane	1	0.5%
Iridotomy > 7 days after surgery	3	1.4%
Iris transillumination defects > 21 days after surgery	12	5.5%
Obstructed iridectomy	1	0.5%
Ocular allergy	1	0.5%
Pigment epithelium around the peripheral iridectomy > 30 days after surgery	1	0.5%
Posterior synechiae	21	9.7%
Precipitates or deposits on intraocular telescope	71	32.7%
Ptosis	5	2.3%
Secondary glaucoma	2	0.9%
Subconjunctival hemorrhage	9	4.1%
Synechiae	1	0.5%
Tearing	1	0.5%
Visual disturbance	1	0.5%
Vitreous flare	1	0.5%
Zonular dehiscence > 7 days after surgery	1	0.5%

% = n/N ×100.
*Corneal edema reported in 13 intraocular telescope-implanted eyes and in 1 operated eye not implanted with an intraocular telescope

CORNEAL EDEMA

There were 14 (6.5%) intraocular telescope-implanted eyes with corneal edema >30 days after implantation surgery. There were 10 (4.6%) intraocular telescope-implanted eyes with persistent unresolved corneal edema at the last available visit. When ECD levels fall too low (< 750mm^2), the cornea may become edematous, thicken and lose transparency, and corneal transplantation may be needed. The endothelial cell density needed to maintain corneal transparency is unknown and varies from patient to patient.

PERSISTENT VISION-IMPAIRING CORNEAL EDEMA AND CORNEAL TRANSPLANTATION

Persistent vision-impairing corneal edema may require corneal transplant. There were 8 cases of persistent vision-impairing corneal edema in the study; 2 of these patients died without corneal transplant and 1 patient did not receive a transplant (reason unknown). Five (2.3%) study eyes underwent corneal transplantation in the IMT-002 and IMT-002-LTM studies. All 5 cases involved surgical complications at the time of intraocular telescope implantation. In 2 of the 5 cases, the intraocular telescope was removed during corneal transplantation procedure and replaced with an IOL. Visual acuity returned to baseline levels in these 2 patients. The intraocular telescope was left in place in the other 3 cases of corneal transplantation; the initial improvement in visual acuity from the IMT-002 study was retained in these eyes.

CHOROIDAL NEOVASCULARIZATION

CNV was identified in one (1) eye in the IMT-002 study for an incidence of 0.5%, a rate consistent with that reported by Sunness et al., 1999.[i] An additional 4 cases of CNV were observed during the IMT-002-LTM study. These cases of CNV were successfully treated with thermal laser photocoagulation (Garfinkel et al, 2006)[ii], photodynamic therapy or intravitreal injection of anti-VEGF therapeutic agents.

DEVICE FAILURES, REMOVALS AND REPLACEMENTS – INTRAOPERATIVE AND POSTOPERATIVE

Table 14 summarizes the intraoperative and postoperative device failures, removals and replacements. Four device failures were reported in the IMT-002 study. Two of the intraocular telescope failures occurred during surgery and involved a broken haptic; one occurred before implantation and the device was not used, and one occurred during implantation, necessitating intraoperative replacement. The other 2 intraocular telescope failures involved condensation in the telescope portion of the device occurring one month postoperatively, resulting in device removal. No further device failures were reported over the course of follow-up through 4 years.

Intraoperatively, implantation of the intraocular telescope was attempted but unsuccessful in 6 eyes, as a result of surgical complications that included posterior capsule tear, zonular dehiscence, and choroidal hemorrhage (Table 14). A standard intraocular lens was placed in these eyes.

Postoperatively, the intraocular telescope was removed from 12 eyes. Eight (8) subjects requested removal of the intraocular telescope because they were dissatisfied with the device. As noted above, the intraocular telescope was also removed from 2 eyes due to device failures and in 2 eyes that underwent corneal transplantation.

[i]Sunness JS, Gonzalez-Baron J, Bressler NM, Hawkins B, Applegate CA. The development of choroidal neovascularization in eyes with the geographic atrophy form of age-related macular degeneration. Ophthalmol 1999;106:910-9.
[ii]Garfinkel RA, Berinstein DM, Frantz R. Treatment of choroidal neovascularization through the Implantable Miniature Telescope. Am J Ophthalmol 2006;141:766-67.

TABLE 14
INTRAOPERATIVE AND POSTOPERATIVE DEVICE FAILURES REMOVALS AND REPLACEMENTS STUDIES IMT-002 AND IMT-002-LTM

Intraoperative Removals (Number of Eyes)	
Broken Haptic	2*
Posterior Capsular Tear	4
Zonular Dehiscence	1
Choroidal Hemorrhage	1
Postoperative Removals Protocol IMT-002 and Protocol IMT-002-LTM (Number of Eyes)	
Condensation in the telescope portion of the intraocular telescope 1 month postoperatively	2
Dissatisfaction	8
Corneal Transplant	2

*1 broken haptic occurred before implantation

Table 15 provides ECD data for eyes that underwent postoperative intraocular telescope removal. In general, there was some ECD loss following intraocular telescope explantation, however there was considerable variability in the magnitude of loss. ECD loss was as high as 62%, but no lower than 13% in 6 eyes with data pre- and post-explantation.

TABLE 15
PREOPERATIVE & LAST AVAILABLE BCDVA AND ECD PRIOR TO & POST INTRAOCULAR TELESCOPE REMOVAL EYES THAT UNDERWENT POSTOPERATIVE INTRAOCULAR TELESCOPE REMOVAL (N = 12), STUDIES IMT-002 AND IMT-002-LTM

Patient ID	Months from Date of Implant	Preop BCDVA	Last Available BCDVA Post Explant	ECD Prior to Explant Cells/mm²	ECD Most Recent Visit Post Explant Cells/mm²	Comments
Subject Dissatisfaction						
001-XXX	31 Months	20/604	20/399	2544	1926	Patient dissatisfied
001-XXX	31 Months	20/551	20/726	1675	1454	Patient dissatisfied
004-XXX	22 Months	20/502	20/276	1772	666	Patient dissatisfied
008-XXX	10 Months	20/317)	20/289	1625	1100	Patient dissatisfied
008-XXX	12 Months	20/219	20/240	2891	2199	Patient dissatisfied
010-XXX	12 Months	20/381	NAV	1858	NAV	Patient dissatisfied
012-XXX	19 Months	20/276	20/166	2408	1389	Patient dissatisfied
020-XXX	41 Months	20/200	NAV	2258	NAV	Patient dissatisfied
Device Failure or Corneal Transplant						
013-XXX	1 Month	20/348	NAV	2316	NAV	Device failure
023-XXX	1 Month	20/348	20/458	2529	1234	Device failure
013-XXX	12 Months	20/303	20/348	463	1264*	Corneal transplant
031-XXX	08/10/2004	20/551	20/1002	385	1857*	Corneal transplant

NAV = not available.
*Post-PKP ECD

OTHER SECONDARY SURGICAL INTERVENTIONS

Seven secondary surgical interventions not involving intraocular telescope removal were performed during the clinical studies. These procedures consisted of one YAG laser treatment of the anterior surface of the intraocular telescope to eliminate pigment deposits; 4 YAG laser peripheral iridotomies; one surgical repair of a distorted pupil; and one removal of a cortical fragment resulting from inadequate cataract removal.

EFFECTIVENESS RESULTS

Effectiveness results from the intraocular telescope clinical trials, protocol IMT-002, a pivotal study and protocol IMT-002-LTM, a long-term safety study in which patients implanted with the intraocular telescope under protocol IMT-002 were followed through 5 years, are discussed in this section.

The intraocular telescope improved visual acuity and quality of life in most patients with end-stage macular degeneration. The primary effectiveness endpoint, a 2-line or greater gain in either distance or near BCVA at 12 months in at least 50% of study patients, was met and exceeded. The secondary effectiveness endpoint, improvement in quality of life, was also achieved. The WA 2.7X device provided somewhat superior results as compared to the WA 2.2X, an outcome that would be expected given the higher magnification of this model.

VISUAL ACUITY PRIMARY ENDPOINT

Ninety percent (90%) of intraocular telescope-implanted eyes achieved at least a 2-line or greater gain in either distance or near BCVA at 12 months, thus exceeding the 50% criterion specified for the primary endpoint. This improvement was maintained at 24 months.

CHANGE IN BCDVA AT 12 AND 24 MONTHS

The mean change in best corrected distance visual acuity was more than a 3-line improvement from baseline at both one and two years. At 12 months, 66% of patients had a gain of 3 or more lines of BCDVA, and 45% had a gain of 4 or more lines.

Change in BCDVA from baseline is shown in Table 16.

TABLE 16
BCDVA CHANGE FROM BASELINE AND MEAN CHANGE
ALL INTRAOCULAR TELESCOPE-IMPLANTED EYES
STUDIES IMT-002 AND IMT-002-LTM

	12 Months n* (%)	24 Months n (%)	36 Months n (%)	48 Months n (%)	60 Months n (%)
N	193	173	74	96	6
Gain ≥ 6 lines	21 (10.9%)	16 (9.2%)	2 (2.7%)	7 (7.3%)	1 (16.7%)
Gain ≥ 5 lines	49 (25.4%)	33 (19.1%)	11 (14.9%)	9 (9.4%)	1 (16.7%)
Gain ≥ 4 lines	87 (45.1%)	74 (42.8%)	26 (35.1%)	27 (28.1%)	2 (33.3%)
Gain ≥ 3 lines	128 (66.3%)	103 (59.5%)	39 (52.7%)	46 (47.9%)	4 (66.7%)
Gain ≥ 2 lines	155 (80.3%)	129 (74.6%)	51 (68.9%)	65 (67.7%)	5 (83.3%)
Gain ≥ 1 line	170 (88.1%)	146 (84.4%)	63 (85.1%)	75 (78.1%)	5 (83.3%)
No change	19 (9.8%)	24 (13.9%)	9 (12.2%)	17 (17.7%)	1 (16.7%)
Loss > 2 lines	4 (2.1%)	3 (1.7%)	2 (2.7%)	4 (4.2%)	0 (0.0%)
Loss > 3 lines	3 (1.6%)	1 (0.6%)	2 (2.7%)	4 (4.2%)	0 (0.0%)
Loss > 4 lines	2 (1.0%)	1 (0.6%)	1 (1.4%)	4 (4.2%)	0 (0.0%)
Loss > 5 lines	2 (1.0%)	1 (0.6%)	0 (0.0%)	2 (2.1%)	0 (0.0%)
Loss > 6 lines	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Mean Change (SD)	3.43 lines (SD 2.31)	3.15 lines (SD 2.19)	2.74 lines (SD 2.17)	2.48 lines (SD 2.60)	3.57 lines (SD 2.74)

N = number of non-missing BCDVA change from baseline.

As shown in Table 17, mean BCDVA improved from 20/312 at baseline to 20/141 at 12 months and to 20/149 at 24 months. Mean BCNVA at 8 inches improved from 20/315 at baseline to 20/181 at 12 months and to 20/190 at 24 months. Mean BCNVA at 16 inches improved from 20/262 at baseline to 20/149 at 12 months and to 20/157 at 24 months.

TABLE 17
MEAN BCVA AT BASELINE, 12 MONTHS AND 24 MONTHS
INTRAOCULAR TELESCOPE-IMPLANTED EYES, STUDY IMT-002

	Baseline		12 Months		24 Months	
	N	Mean	N	Mean	N	Mean
Mean BCDVA 95% CI	206	**20/312** (20/334, 20/291)	193	**20/141** (20/152, 20/131)	173	**20/149** (20/161, 20/138)
Mean BCNVA at 8" 95% CI	206	**20/315** (20/341, 20/291)	192	**20/181** (20/196, 20/167)	173	**20/190** (20/207, 20/174)
Mean BCNVA at 16" 95% CI	206	**20/262** (20/282, 20/244)	192	**20/149** (20/161, 20/138)	173	**20/157** (20/170, 20/145)

VISUAL ACUITY BY DEVICE MODEL

Improvements in BCDVA and BCNVA were achieved with both the WA 2.2X and WA 2.7X intraocular telescope models. A summary of improvement in visual acuity in terms of the primary effectiveness endpoint and percent of patients achieving at least a 2- and 3-line change are shown in Table 18.

TABLE 18
SUMMARY OF IMPROVEMENT IN VISUAL ACUITY
STRATIFIED BY INTRAOCULAR TELESCOPE MODEL, STUDY IMT-002

IMPROVEMENT IN VISUAL ACUITY	12 MONTHS		24 MONTHS	
	WA 2.2X % (n)	WA 2.7X % (n)	WA 2.2X % (n)	WA 2.7X % (n)
≥2 LINES GAIN OF BCDVA *OR* BCNVA	89.0% (97)	91.6% (76)	84.5% (82)	88.2% (67)
BCDVA LINES GAINED				
≥3 LINES GAIN OF BCDVA	60.0% (66)	74.7% (62)	52.6% (51)	68.4% (52)
BCNVA LINES GAINED (8 OR 16 INCHES)				
≥3 LINES GAIN OF BCNVA	64.2% (70)	72.3% (60)	58.8% (57)	68.4% (52)

LONG-TERM VISUAL ACUITY

Long-term follow-up data demonstrates that mean BCDVA improvements were generally retained over time in intraocular telescope-implanted eyes. There was a slight decline in BCDVA at 48 months (Table 19).

TABLE 19
MEAN BCDVA AT BASELINE, 12, 24, 36, 48, AND 60 MONTHS
INTRAOCULAR TELESCOPE IMPLANTED EYES
STUDIES IMT-002 AND IMT-002-LTM

BCDVA	Baseline	12 Month	24 Months	36 Months	48 Months	60 Months
Overall						
N	206	193	173	74	96	6
Mean 95% CI	**20/312** (20/334, 20/291)	**20/141** (20/152, 20/131)	**20/149** (20/161, 20/138)	**20/156** (20/175, 20/139)	**20/171** (20/191, 20/152)	**20/103** (20/228, 20/47)
WA 2.7X intraocular telescope						
N	91	83	76	29	37	4
Mean 95% CI	**20/326** (20/359, 20/297)	**20/127** (20/140, 20/115)	**20/141** (20/159, 20/125)	**20/157** (20/194, 20/127)	**20/170** (20/206, 20/140)	**20/118** (20/422, 20/33)
WA 2.2X intraocular telescope						
N	115	110	97	45	59	2
Mean 95% CI	**20/301** (20/331, 20/273)	**20/152** (20/169, 20/136)	**20/155** (20/172, 20/140)	**20/155** (20/179, 20/134)	**20/171** (20/198, 20/148)	**20/80** (20/2E5, 20/0)

QUALITY OF LIFE

Quality of life, as assessed by the National Eye Institute's (NEI) Visual Function Questionnaire-25 (VFQ-25), was a secondary outcome measure. The VFQ-25 is a validated version of the NEI VFQ which measures vision-targeted health status for persons with chronic eye diseases including macular degeneration. A 5 point difference in subscale and/or composite scores may be interpreted as clinically significant. The VFQ-25 survey was administered at baseline and postoperatively. As shown in Table 20, implantation with the intraocular telescope improved quality of life in this study population.

VFQ-25 RESULTS

Outcomes for all subscales of the VFQ-25 and the composite score are summarized in Table 21. At 12 months, the mean VFQ-25 composite score increased by a clinically significant amount (an increase of 6 points at 12 months). Overall, seven of the VFQ-25 subscales improved by clinically significant levels (general vision, near activities, distance activities, social functioning, mental health, role difficulties, and dependency). In subscales where no improvement or a decline in performance was expected (color vision, driving, and peripheral vision), performance was stable or declined. Also, the mean score of the general health subscale declined by 5 points, likely reflecting the impact of other health-related events on the non-vision related general health of the elderly study population.

TABLE 20
MEAN SCORE CHANGE AT 12 MONTHS
NEI 25-ITEM VISUAL FUNCTION QUESTIONNAIRE (VFQ-25)
INTRAOCULAR TELESCOPE IMPLANTED EYES
STUDY IMT-002

VFQ-25 Subscale	Preop Mean Score (95%CI) N = 200	12 Months Mean Score (95%CI) N = 195	Change from Preop Mean Score (95%CI) N = 193
General Vision	35.3 (33.2, 37.4)	50.3 (47.5, 53.1)	14.1 (11.0, 17.2)
Near Activities	25.5 (23.6, 27.5)	37.3 (34.6, 40.0)	11.2 (8.4, 13.9)
Distance Activities	34.3 (31.7, 36.8)	42.4 (39.1, 45.7)	7.9 (4.4, 11.4)
Color Vision	63.9 (60.1, 67.8)	67.7 (63.9, 71.5)	3.4 (-0.2, 6.9)
Social Functioning	49.3 (46.0, 52.7)	58.3 (55.1, 61.4)	8.6 (4.8, 12.4)
Mental Health	39.8 (36.5, 43.1)	49.3 (45.5, 53.0)	9.3 (6.1, 12.5)
Role Difficulties	37.4 (34.2, 40.7)	44.8 (41.0, 48.5)	7.3 (3.5, 11.0)
Dependency	37.7 (34.0, 41.4)	48.3 (44.4, 52.2)	10.0 (6.1, 13.9)
Ocular Pain	88.2 (86.0, 90.4)	88.5 (86.1, 90.9)	0.6 (-2.1, 3.3)
Driving	2.3 (1.0, 3.6)	1.9 (0.6, 3.2)	-0.5 (-1.6, 0.5)
Peripheral Vision	67.6 (63.9, 71.3)	62.9 (59.7, 66.1)	-5.9 (-10.4, -1.5)
Overall Composite	44.0 (42.1, 45.8)	50.3 (48.2, 52.4)	6.0 (4.0, 8.1)
General Health	64.0 (60.8, 67.1)	59.7 (56.4, 63.0)	-5.1 (-8.1, -2.0)

VFQ-25 scores on a scale of 0 (low) to 100 (maximum).
95%CI = 95% Confidence Interval.
General Health not included in Overall Composite per NEI VFQ-25 scoring guidelines.

The relationship between ≥ 2 line improvement in both distance and near best corrected visual acuity (BCVA) and VFQ-25 overall composite score is shown in Table 21. In subjects that experienced a 2-line or greater improvement in both distance and near BCVA, 141 of 193 subjects (73%), the VFQ-25 mean composite score improved by a clinically significant 7.7 points at 12 months as compared to 2.4 points for subjects who did not experience that level of visual acuity improvement.

TABLE 21
RELATIONSHIP BETWEEN ≥ 2 LINE IMPROVEMENT IN BOTH DISTANCE AND NEAR BCVA IMPROVEMENT AND VFQ-25 SCORE COMPOSITE SCORE AT 12 MONTHS*
STUDY IMT-002

	N/%	Mean Change in Composite Score
≥ 2 line improvement in both distance and near BCVA	141(73%)	+7.7
< 2 line improvement in both distance and near BCVA	52 (27%)	+2.4

*Hudson, et al, Implantable Miniature Telescope for the Treatment of Visual Acuity Loss Resulting from End-Stage Age-Related Macular Degeneration: 1-Year Results, Ophthalmology, Vol 113, Number 11, 2006

Since a 5-point change in the VFQ-25 may be interpreted as clinically significant, change in VFQ-25 composite score at 12 month from baseline is summarized in Table 22. At 12 months, 51.8% (100/193) of patients gained at least 5 points, while 25.9% (50/193) of patients reported no change (i.e., change within ± 5 points), and 22.3% of patients (43/193) lost at least 5 points in VFQ-25 composite score from baseline.

TABLE 22
12-MONTH VFQ-25 OVERALL COMPOSITE SCORE CHANGE FROM BASELINE INTRAOCULAR TELESCOPE-IMPLANTED EYES AT 12 MONTHS
STUDY IMT-002

Change in VFQ-25 Composite Score	12 Months (N = 193)	
	%	n/N
Subjects with increase ≥ 5 points	51.8%	100/193
Subjects with change between -5 and 5 points	25.9%	50/193
Subjects with decrease ≥ 5 points	22.3%	43/193

As shown in Table 23, in subjects that gained 2-lines or more in best corrected distance visual acuity (BCDVA), 56% reported a clinically significant improvement in NEI-VFQ overall composite score. In subjects that had a < 2-line improvement in BCDVA, 37% reported a clinically significant improvement in NEI-VFQ overall composite score. 44% of subjects with a 2-line or more improvement in BCDVA did not report a clinically significant improvement in the overall composite score and 63% of subject that did not achieve a 2-line improvement in BCDVA did not report a clinically significant improvement in the overall composite score.

TABLE 23
RELATIONSHIP BETWEEN BCDVA CHANGE AND CLINICALLY SIGNIFICANT IMPROVEMENT IN VFQ OVERALL COMPOSITE SCORE AT 12 MONTHS
STUDY IMT-002

BCDVA Change from Baseline	VFQ Composite Score Change from Baseline		
	Clinically significant improvement (≥ 5 point increase)	No change or clinically significant decrease (< 5 point increase)	Total
≥2 line improvement	86/155 (55.5%)	69/155 (44.5%)	155/193 (80.3%)
<2 line improvement	14/38 (36.8%)	24/38 (63.2%)	38/193 (19.7%)
Total	100/193 (51.8%)	93/193 (48.2%)	193 (100%)

13. ADVERSE EVENT REPORTING

Physicians are specifically requested to report to VisionCare and/or the Food and Drug Administration (FDA) any serious adverse events and potentially sight-threatening adverse events and complications that may reasonably be regarded as device-related. This information is requested to aid in identifying problems with the device. These problems may be related to a single device, a specific lot of devices, or may be indicative of long-term problems associated with the intraocular telescope.

A serious adverse event is one that is life-threatening, results in permanent impairment of a body function or permanent damage to a body structure, or necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

You may also report non-serious adverse events and complications.

When you report, please be prepared to give your name, the lot number of the device, if possible (this can be found on the device case, the Tyvek® sterility barrier on the device package, or the patient registration card), a description of the adverse event or complication, whether the adverse event or complication required treatment and the results of the treatment, and information about how we can contact you if we need more information.

To report an adverse event to VisionCare, please call 1-408-872-9393. To report to FDA, please call FDA's MedWatch Adverse Event reporting program at 1-800-332-1088 or place the report online at www.fda.gov/medwatch/report.htm.

14. PHYSICIAN TRAINING PROGRAM

A surgeon training program has been developed to focus on the unique aspects of the intraocular telescope surgical procedure that differ from other intraocular implants. As outlined below, there are six components of the training program. Participation in two components, i.e., Physician-Led Training Session and the In-service Program, are required prior to implantation of the first intraocular telescope. The other components are optional and will be provided at the physician's request.

The training program consists of the following components:

- ***Physician-Led Training Session:*** A physician-led training session is required for all surgeons wishing to implant the intraocular telescope.
- ***In-service Program:*** An in-service training, conducted by a VisionCare representative, is required for surgical staff prior to the first intraocular telescope implantation procedure at their site.
- ***Surgical Technique Video:*** A video demonstrating the recommended surgical procedure for the intraocular telescope implantation is available to surgeons.
- ***Hands-on Simulation:*** A hands-on simulation experience is provided to assist the anterior surgeon with the required instrumentation for the proper handling and insertion of the device.
- ***Surgical Review:*** A review and recommendations for technique adjustment, based on the surgeon's video-recorded initial surgical cases, is provided by an experienced surgeon.
- ***Professional Education:*** Continuing education courses are offered at ophthalmic medical meetings.

15. HOW SUPPLIED

The product is supplied sterile in several stiff package layers. The device in its immediate packaging is EtO sterilized and should be opened only under sterile conditions. Attached to the device is the Patient Implant Card which shall be completed by the physician after implantation. This card must be given to the patient with instruction to keep it as a permanent record of the implant and to show the card to eye care practitioner seen in the future.

16. RECOMMENDED STORAGE AND TRANSPORTATION CONDITIONS

- Ambient temperature - 0° C to 43° C (32° F to 109° F)
- Relative humidity – 20% to 95%
- Barometric pressure – 0.5 atm to 1.2 atm (abs.)
- Illumination – Not specified
- Expiration date- specified on the package label.

Products not meeting the storage conditions specified in this document or damaged product packaging should not be used for clinical applications.

17. EXPIRATION DATE

The expiration date on the product package is the sterility expiration date. The device should not be implanted after the indicated sterility expiration date.

18. PATIENT REGISTRATION INSTRUCTIONS AND REPORTING REGISTRATION

Each patient who receives an intraocular telescope must be registered with VisionCare Ophthalmic Technologies, Inc. at the time of device implantation. Registration is accomplished by completing the Patient Registration Card that is enclosed in the device package and mailing it to VisionCare.

A Patient Implant Card is supplied in the device package. This card must be given to the patient with instruction to keep it as a permanent record of the implant and to show the card to any eye care practitioner seen in the future.

19. RETURN/EXCHANGE POLICY

Please contact VisionCare Customer Service regarding device return or exchange. Due to device fragility, it is recommended to keep one spare implant in house.

Manufactured for and Distributed by:
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