

APPENDIX 14

PATIENT INFORMATION BROCHURE



**AMD TELESCOPE PROSTHESIS
(IMPLANTABLE MINIATURE TELESCOPE, IMT™ BY DR. ISAAC
LIPSHITZ)
FOR AGE-RELATED MACULAR DEGENERATION (AMD)**

**FACTS THAT YOU NEED TO KNOW ABOUT THE
AMD TELESCOPE PROSTHESIS**

PATIENT INFORMATION BROCHURE

For Central Vision Impairment Associated with Age-Related Macular Degeneration

Please read this entire brochure. Discuss its contents with your doctor so that you have all your questions answered to your satisfaction. Ask any question you may have before you agree to undergo surgery.

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FOR AGE-RELATED MACULAR DEGENERATION (AMD)**

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TABLE OF CONTENTS

	<u>PAGE</u>
1.0 INTRODUCTION.....	6
1.1 NORMAL VISION.....	6
1.2 CENTRAL VISION IMPAIRMENT.....	7
1.3 CURRENT OPTIONS FOR CENTRAL VISION IMPAIRMENT.....	7
2.0 HOW DOES THE DEVICE CORRECT CENTRAL VISION IMPAIRMENT?	8
3.0 CONTRAINDICATIONS	9
4.0 WHAT ARE THE BENEFITS OF DEVICE IMPLANTATION?	10
5.0 WHAT ARE THE RISKS OF DEVICE IMPLANTATION?.....	11
6.0 WARNINGS	13
7.0 PRECAUTIONS	13
8.0 ARE YOU A GOOD CANDIDATE FOR DEVICE IMPLANTATION?.....	13
9.0 WHAT TO EXPECT WITH THE PROCEDURE?.....	14
9.1 BEFORE THE SURGERY.....	14
9.2 THE DAY OF SURGERY.....	15
9.3 AFTER THE SURGERY.....	15
9.4 VISUAL TRAINING/REHABILITATION AFTER SURGERY.....	16
9.5 WHEN TO CONTACT YOUR DOCTOR/SURGEON.....	17
10.0 QUESTIONS TO ASK YOUR DOCTOR.....	17
11.0 CLINICAL STUDY DATA.....	17
11.1 STUDY DEMOGRAPHICS AND BASELINE CHARACTERISTICS.....	18
11.2 VISION RESULTS (WITH GLASSES).....	18
11.3 PATIENT QUALITY OF LIFE QUESTIONNAIRE.....	19
12.0 PATIENT ASSISTANCE INFORMATION.....	20
13.0 INDEX.....	21

GLOSSARY

This section summarizes important terms used in this information booklet or that your eye doctor may discuss with you. Please discuss any related questions with your doctor.

Anterior Chamber: front chamber of the eye, anterior chamber depth is the thickness of the chamber.

Atrophic: decrease in size or wasting away of tissue.

Axial length: overall length of the eye.

Binocular vision: the manner in which two eyes work together.

Cataract: clouding of the natural lens inside the eye that can blur vision.

Choroid: layer of tissue lying under the retina.

Choroidal neovascularization: the growth of new, abnormal blood vessels into the choroid. Often referred to as 'wet' macular degeneration.

Contraindication: any special condition that results in the treatment not being recommended.

Contrast Sensitivity: a measure of the ability of the eye to detect small lightness differences between objects and the background in daylight and in dim light. For example, black lines on a gray background are easier to see than gray lines on a gray background. Objects in daylight are also easier to see than in dim light. Contrast sensitivity is a way to determine how well you can see in poor contrast conditions such as very dim light, rain, snow or fog.

Cornea: clear front portion, or 'window', of the eye. It covers the iris and the **pupil**.

Corneal decompensation: A clouding of the usually clear front surface of the eye (cornea), when there is too much swelling.

Corneal edema: abnormal fluid build-up/swelling in the cornea. The condition is usually temporary after surgery with no significant effect on vision. Persistent corneal edema may be indefinite.

Corneal endothelium layer of cells lining the inside surface of the cornea.

Corneal endothelial cell loss: loss of cells on the inner surface of the cornea. Endothelial cells are essential in keeping the cornea clear and healthy.

Corneal Transplant: removal and replacement of the cornea.

Diabetic retinopathy: damage to the back surface of the eye responsible for sensing light due to diabetes.

Dystrophy: a degenerative disorder.

Fluorescein angiography: a test used to view the blood vessels in the eye. A dye is injected into a blood vessel in the arm. The dye travels through the blood circulation to the eye. Photographs are taken of the eye while the dye travels through the blood vessels of the eye.

Hyperopia: farsightedness [people with hyperopia can see distant objects very well, but have difficulty seeing objects that are up close].

Intraocular Pressure (IOP): pressure measurement monitored in your eye.

Lens: A clear organ found in the front third of the eyeball that helps to focus light, or an image, on the retina. (The retina is like the film of a camera, the eye's lens is like a camera lens).

Macula: a small area in the center of the retina near the optic nerve. The macula is responsible for central vision in the eye, and it controls our ability to read, drive a car, recognize faces or colors, and see objects in fine detail.

Myopia: nearsightedness [people with myopia have difficulty reading highway signs and seeing other objects at a distance but can see for close-up tasks such as reading or sewing].

MR Conditional: A device or implant that may contain magnetic, electrically conductive components that is safe for operations in proximity to the MRI (magnetic resonance imaging) device if the defined conditions for safe operation are observed (such as 'tested safe to 3 Tesla').

Narrow angle: the angle between the iris and lens.

Peripheral: located away from a center or central portion.

Photodynamic therapy: use of low-intensity light to destroy tissue in a local area.

Prosthesis: an artificial substitute for a missing part of the body.

Pseudoexfoliation: flakes or deposits at the edges of the pupil of the iris and throughout the inner surface of the front of the eye.

Retina: The thin lining, or "film," at the back of the eye. It converts light images into nerve signals sent to the brain. (The area of the retina responsible for central vision is the macula).

Retinal degeneration: weakening/disease of the retina.

Visual Acuity: a measure of the sharpness of vision using a eye test chart.

1.0 INTRODUCTION

The purpose of this brochure is to provide you with information regarding the **Implantable Miniature Telescope** (IMT™ by Dr. Isaac Lipshitz), also called an AMD telescope prosthesis. Please read this entire brochure carefully to learn more about this device. You can refer to the glossary on pages 3 and 4 for an explanation of words shown in *italics*. You should discuss all your questions with your ophthalmologist (eye doctor) who is trained in implantation of this device and the care of implanted patients. You need to understand the benefits and risks of the surgical procedure for the AMD telescope prostheses before you decide if you want to undergo this surgery.

1.1 NORMAL VISION

Figure 1 provides a diagram of the eye. The *cornea*, pupil, and *lens* are clear, allowing light rays to pass through. The cornea and lens focus the light onto the retina, a layer of light-sensitive cells lining the back of your eye. The retina converts light rays into signals that are sent through the optic nerve to your brain, where they are recognized as images.

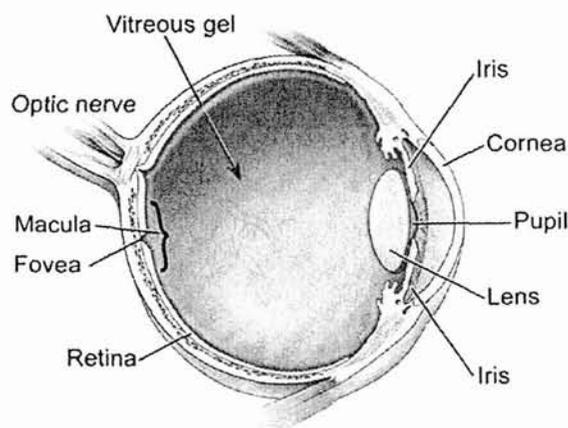


FIGURE 1: DIAGRAM OF THE EYE

The *retina* consists of two areas: the *macula* and the peripheral retina. The macula is a small area in the center of the retina near the optic nerve. Even though the macula is just a small part of the retina, it is the only area responsible for detailed central vision. The macula is needed for seeing objects clearly and for everyday tasks such as reading, watching television, recognizing faces, and driving a car.

1.2 CENTRAL VISION IMPAIRMENT

Age-related macular degeneration (AMD) is the most common disease of the macula. Macular degeneration refers to the breakdown of the macula, which is the central part of the retina responsible for detailed, 'straight-ahead' vision. Some degeneration of the macula is normal during aging. However, when macular degeneration is severe, it can result in loss of sight in the central part of the field of vision. As shown in Figure 2, this causes a blind spot to form.



A. Normal Vision



B. Blind Spot Created by Loss of Central Vision

FIGURE 2: CENTRAL VISION IMPAIRMENT

AMD is the leading cause of permanent vision loss and legal blindness in people over the age of 50. Although people with AMD do not generally go completely blind, it can be difficult to read, recognize people, drive, and perform other daily functions that require central vision. Side or "peripheral" vision is rarely affected.

1.3 CURRENT OPTIONS FOR CENTRAL VISION IMPAIRMENT

Central vision loss cannot be corrected with glasses, contact lenses, or surgically implanted intraocular lenses (also known as IOLs). People with this problem may use devices such as special magnifying eyeglasses or a telescope in order to make images bigger and somewhat easier to see. Magnifiers and external telescopes which can be worn like eyeglasses can help AMD patients, but these devices can be inconvenient for a number of reasons. Patients often find the external devices difficult to use since the area of vision is very narrow, and peripheral vision is limited. In addition, these devices are difficult to use during activities, and they are often bulky, uncomfortable and unattractive. To use these external devices, the patient has to move his/her entire head to see anything other than the image immediately in front of the eye. This sometimes causes a queasy feeling.

The AMD telescope *prosthesis* is different from low vision devices such as magnifiers and external telescopes since it is implanted completely inside the eye. A picture of the AMD telescope prosthesis is shown in Figure 3. The AMD telescope prosthesis is intended to be implanted inside one eye in place of the natural lens (behind the colored iris).

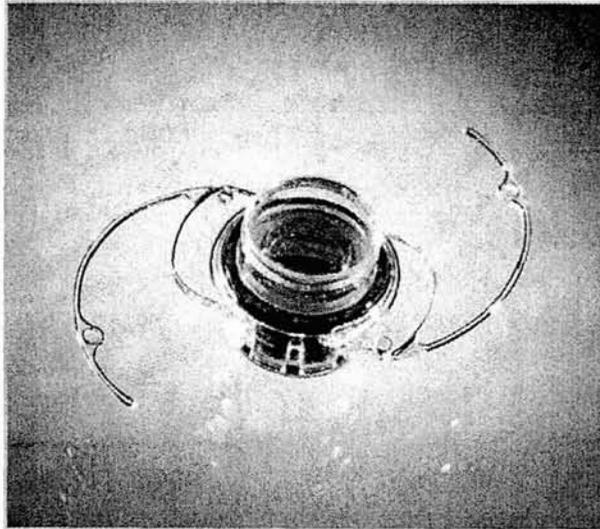


FIGURE 3: AMD TELESCOPE PROSTHESIS

2.0 HOW DOES THE DEVICE CORRECT CENTRAL VISION IMPAIRMENT?

The AMD telescope prosthesis helps enlarge images coming into the eye approximately double to triple their normal size, depending on the device model used. As shown in Figure 4, light from the central view of the eye becomes enlarged on the retina.

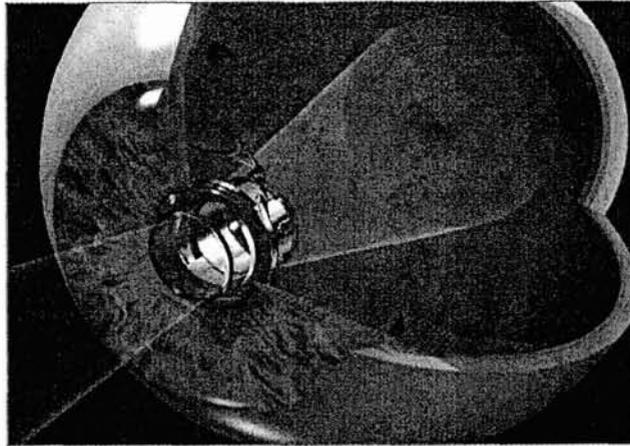


FIGURE 4: WIDE-ANGLE PROJECTION OF CENTRAL VISUAL FIELD

The telescope magnification allows images to be projected onto healthy areas of the retina, instead of the central retina alone where breakdown of the macula and loss of vision has occurred. This helps reduce the 'blind spot' and improves the patient's ability to recognize images that were either difficult or impossible to see.

The AMD telescope prosthesis is implanted by an eye surgeon during an outpatient surgical procedure. The device is implanted in only one eye. The implanted eye provides central vision by enlarging images immediately in front of the patient, while the other eye, which does not have an implant, provides peripheral or side vision. Since the AMD telescope prosthesis is implanted completely inside your eye, it is considered to be permanent and a second surgery would be required if it were ever necessary to remove it from your eye.

After the surgical procedure, you will be instructed to participate in a vision training/rehabilitation program so you can learn how to use the central vision from the implanted AMD telescope prosthesis to perform your daily activities.

3.0 CONTRAINDICATIONS

You should **NOT** undergo implantation of the AMD telescope prosthesis if you have:

- Evidence of 'wet' AMD (*active CNV or choroidal neovascularization*). Your eye doctor would see this on *fluorescein angiography* (photographs of the blood vessels of the eye).
- If you have had treatment for 'wet' AMD within the past six months.
- Any eye condition that decreases your peripheral vision (side vision) in your non-implanted eye.
- A history of frequently rubbing your eyes.

- Previous eye surgery of any kind in the eye intended for implantation, including any type of surgery for either refractive (near or far-sightedness) or therapeutic purposes.
- Prior or expected eye related surgery within 30 days preceding AMD telescope prosthesis surgery.
- A history of steroid-responsive rise in intraocular pressure, or uncontrolled glaucoma
- Pregnancy or lactation (breastfeeding).
- Known sensitivity to post-operative medications related to the eye surgery.
- If your planned operative eye has any of the following conditions:
 - *Myopia* > 6.0 D
 - *Hyperopia* > 4.0 D
 - An *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
 - An ocular condition that predisposes the patient to eye rubbing
 - Anterior chamber depth < 3.0mm
 - Inadequate *endothelial cell density* as determined by grid of patient age and endothelial cell density.

Your doctor will determine if you have any of these contraindications. In addition, if you think that you have any contraindications, please discuss these with your doctor.

4.0 WHAT ARE THE BENEFITS OF DEVICE IMPLANTATION?

The AMD telescope prosthesis improves distance and near visual acuity (sharpness of vision) in the implanted eye. It also improves the ability to recognize and respond to images, and improves quality of life in most, but not all, of patients implanted with the device. Visual acuity improved by 3 lines on the eye test chart in approximately two-thirds (66%) of patients, i.e., improving from 20/320 to 20/160. Approximately 80% of patients achieve a 2-line improvement in visual acuity, i.e, improving from 20/200 to 20/125. These 3-line and 2-line improvements are considered important changes in visual acuity. Approximately 5% of patients experience a worsening of visual acuity.

Compared to external telescopes, the AMD telescope prosthesis does not restrict natural eye movements, and does not require you to move your entire head, as is required with external telescopes.

The AMD telescope prosthesis allows you to use natural eye movements to scan the environment, for both up close and far away viewing, such as reading printed materials or watching television. The peripheral (side) vision in the eye implanted with the AMD telescope prosthesis will be restricted, but your peripheral vision will stay the same as before the surgery in your non-implanted eye. Also, you will need to wear eye glasses to bring objects into focus and may need to use a hand-held magnifier to read or see small details clearly. However, in general, less magnification will be needed after your surgery.

The AMD telescope prosthesis is small and may be barely noticeable in your eye.

5.0 WHAT ARE THE RISKS OF DEVICE IMPLANTATION?

Complications may occur during or after implantation of the AMD telescope prosthesis. These complications include:

- bleeding in the eye
- infection inside the eye
- elevated pressure in the eye
- *corneal edema*
- worsening of your vision
- decrease in *contrast sensitivity*
- double vision
- the need to explant the AMD telescope prosthesis due to medical or visual complications
- dizziness
- changes in depth perception
- no improvement in vision
- complications during surgery preventing implantation of the device
- damage to the cells that line the inside of the cornea during the surgical procedure; loss of these cells may cause your cornea to become cloudy, decreasing vision and possibly requiring removal of the AMD telescope and additional surgery
- reduction of light in the implanted eye
- cloudy or hazy vision
- complications that are unknown at this time

There is a chance of complications occurring during the procedure that will prevent implantation of the AMD telescope prosthesis. If the AMD telescope prosthesis can not be implanted or if the device is removed due to a complication, your vision may be worse than before the surgery. Eleven of the 217 patients (5.1%) that underwent surgery could

not be implanted due to complications that occurred during the procedure. A standard intraocular lens used in cataract surgery was placed in these eyes.

After surgery, your peripheral (side) vision will be restricted in your implanted eye. However, your peripheral vision will stay the same as before the surgery in your other eye.

Five percent (5%) of the study patients lost 2 lines of vision at 12 months and 6% at 24 months which was better than the safety limit of 10%.

There were two cases of *corneal decompensation* during the 2-year study, and two additional cases in a 4-year study. These resulted in a *corneal transplant* surgery. During these four corneal transplant surgeries, the AMD telescope prostheses was left in place in two cases and was removed in the other two cases.

Potential complications are not limited to those reported during the clinical study.

Out of the 206 patients implanted with the AMD telescope prosthesis, 2 devices (1%) were surgically removed due to device malfunction. The devices were replaced with standard intraocular lenses used in cataract surgery. As mentioned earlier, two devices (1%) were removed at the time of corneal transplant and were also replaced by intraocular lenses. Four patients (2%) reported dissatisfaction with the AMD telescope prosthesis and requested the devices be surgically removed. These patients also received standard intraocular lenses. An additional four patients (3%), who were followed in a long-term study to 4 years after surgery, requested removal of the AMD telescope prosthesis due to dissatisfaction.

6.0 WARNINGS

- The long-term effects of the AMD telescope prosthesis have not been determined; therefore you should be checked by your doctor on a regular basis.
- If you are unable or do not participate in the vision training/rehabilitation program before and after the surgery, the potential benefits of the procedure may be greatly reduced.
- You will need to avoid rubbing your implanted eye.
- The AMD telescope prosthesis limits your peripheral vision (vision outside the center). Therefore, you need to use your non-implanted eye for peripheral vision.

The AMD telescope prosthesis is considered MR Conditional – Please indicate that you were implanted with AMD telescope prosthesis prior to any MRI procedure

Please notify your family members that the AMD telescope prosthesis is considered MR Conditional.

7.0 PRECAUTIONS

The safety and effectiveness of the AMD telescope prosthesis implantation has NOT been established in:

- patients under 65 years of age
- patients with an eye condition other than AMD and mild *cataract*
- patients with active *choroidal neovascularization (active wet AMD)*
- patients who underwent previous intraocular surgery or corneal surgery, including refractive or therapeutic surgery

8.0 ARE YOU A GOOD CANDIDATE FOR DEVICE IMPLANTATION?

To determine if you are a good candidate to receive the AMD telescope prosthesis, your vision will be tested using an external telescope to help simulate what your vision may be like if an AMD telescope prosthesis were to be implanted inside your eye. You will also participate in several evaluation and training sessions.

It is recommended that you try two external telescopes of different magnification power to help decide if the effect of the magnification in one eye may be useful to you. You will be asked if the external telescopes help you identify objects in the center of your straight-ahead vision (e.g., facial features, watching TV, looking at moving objects or moving from bright to dim lighting environments).

When testing with the external telescope simulator, it is important to understand that, if the AMD telescope prosthesis is implanted in your eye, you will be using one eye for central vision (the eye with the device) and the other eye for peripheral (side) vision. It is important to understand the eye implanted with the AMD telescope prosthesis will permanently have an enlarged image and restricted peripheral vision. The non-implanted eye's vision is not affected.

A vision training specialist will discuss the potential for improved performance of activities of daily living, and any of your specific functional goals, that have been limited because of central vision impairment.

It is very important that you attend a vision training/rehabilitation program before and after device implantation, as recommended by your eye doctor, so that you can maximize your ability to perform daily activities and reach your functional goals.

You are **NOT** a candidate for implantation of the telescope prosthesis if you or your doctor find:

- your vision is not improved while using an external telescope
- you feel you cannot become accustomed to the difference in vision between your eyes
- a thorough eye examination reveals any contraindication
- there is a limited chance of useful improvement in activities of daily living
- your future vision goals are unrealistic or not achievable with the AMD telescope prosthesis
- you are unwilling or unable to fully participate in a vision training/rehabilitation program before and after the eye surgery

9.0 WHAT TO EXPECT WITH THE PROCEDURE?

9.1 BEFORE THE SURGERY

Before the surgery, your doctor needs to determine your complete medical and eye history and check the health of both your eyes. Your eyes should be tested with an external telescope simulator to determine if your vision improves enough to be eligible for implantation. You will also be asked to participate in one or two training/rehabilitation sessions with a low vision specialist who will help establish functional goals and discuss/assess realistic expectations. They will also demonstrate/simulate functional activities using the external telescope simulator, demonstrate eccentric viewing, and assign home activities - including eye patching to assess your ability to live with restricted peripheral vision in one eye.

Tell your doctor if you take any medication or have any allergies. Ask your doctor if you should eat or drink right before the surgery. You should arrange for transportation to return home. Be sure to discuss all questions you might have regarding the surgery with

your doctor prior to the procedure. You should plan on two to three hours time for surgical preparation, the surgical procedure, and a brief recovery period.

9.2 THE DAY OF SURGERY

The procedure is done in an outpatient surgical setting. The surgical procedure used to place the telescope prosthesis inside the eye requires several steps. Your eye will be numbed at the beginning of the procedure so you will not feel any pain. Special eye drops will be administered to enlarge your pupil; the effect of the eye drops is temporary. Your eye will be held open with a special instrument (lid speculum), and an operating microscope will be placed in front of your eye. Your eye's natural lens will be removed by a specially trained medical eye surgeon. The AMD telescope prosthesis will then be implanted in the same position in the eye where the natural lens once was. The surgical procedure will take approximately 1 hour. The effects of the numbing will wear off after about 60 min.

You should be aware that if there are complications during your surgery, your doctor may not be able to implant the AMD telescope prosthesis. This means that you may undergo surgery, but not be able to receive this device. If this is the case, your doctor will attempt to implant a standard intraocular lens, as in any procedure for cataract removal.

9.3 AFTER THE SURGERY

After the AMD telescope prosthesis is implanted you will be provided with several types of eye drops for use at home. These eye drops will prevent infection; reduce irritation, redness, burning and swelling, and will widen your pupil. When and how long you need to use these medications will be explained to you before you go home. You should expect improvement in central vision in the implanted eye to occur over a period of time, from weeks to months.

You will be instructed to schedule and participate in a vision training/rehabilitation program with a professional (see Section 9.4). You will also need to consult with a specialist who will help you so that you can move around and perform your daily activities. It is important to adhere to the vision training/rehabilitation program since it is important to get used to the vision from the AMD telescope prosthesis while performing your daily activities. You will be asked by your eye doctor to return after surgery for an eye exam within one week, to make sure that your recovery is proceeding as expected.

After the eye surgery, your doctor may provide you with a protective eye patch for use over the next several days (2 to 5 days). In addition, your doctor may tell you to limit specific activities for several weeks following the surgery.

Use the eye medications and/or eye patch as directed by your doctor. Follow your doctor's instructions.

DO NOT RUB your eye after the telescope prosthesis has been implanted in your eye. Irritation or damage to your eye may occur if the eye is rubbed. If you have a sudden worsening of your vision you should contact your doctor as soon as possible.

9.4 VISUAL TRAINING/REHABILITATION AFTER SURGERY

The goal of the vision training/rehabilitation program is to work with you to maximize your ability to use your vision and reach specific goals involving daily activities. Your program, over several weeks to months, is designed to provide you with the skills needed to use your vision from the telescope prosthesis.

It is important to understand that your ability to judge distances may be affected, and also peripheral (side) vision will be less in the eye with the AMD telescope prosthesis. You may not be able to completely adjust and use your vision in the implanted eye effectively in everyday activities without full participation in the visual training/rehabilitation program.

The program will include teaching the following five skills:

- Localizing (locating an object of interest into the field of view of the operated eye)
- Fixating (focusing on an object in order to allow object identification)
- Scanning (the natural eye movement performed by the operated eye)
- Tracing (to follow a path between objects of interest)
- Tracking (the ability to follow a moving object)

Vision exercises will include both sitting and walking/moving activities.

Since the AMD telescope prosthesis will reduce the amount of light that is able to pass through the eye, you will be encouraged to increase lighting sources when indoors. You will be cautioned not to wear dark glasses in dim light settings, and to use your non-operated eye when moving around in dim light settings.

In case you experience double vision, you will be instructed to vary your viewing between your two eyes. For example, you may use one eye while not using the other eye (specifically, you will use the implanted eye for central vision and the other eye for moving around).

9.5 WHEN TO CONTACT YOUR DOCTOR/SURGEON

Please contact your doctor/surgeon immediately if you experience any of the following problems after surgery:

- extreme pain in your implanted eye
- sudden worsening of your vision
- itching, redness or blurred vision in your implanted eye

10.0 QUESTIONS TO ASK YOUR DOCTOR

You may want to ask the following questions to help you decide if this procedure is right for you:

- What are my other options to correct my central vision impairment (blind spot)?
- Will I have to limit my activities after surgery - which activities and for how long?
- What are the benefits of the procedure for my amount of central vision impairment?
- What are the risks of the surgical procedure?
- What are the long-term risks of having the AMD telescope prosthesis implanted in my eye?
- Can the device be taken out of my eye if necessary?
- Can you provide more details regarding the vision training/rehabilitation program?
- What is the cost of surgery and follow-up care?

11.0 CLINICAL STUDY DATA

A clinical study has been performed to evaluate the benefits and risks of the AMD telescope prosthesis in patients with central vision impairment associated with age-related macular degeneration. 217 patients were enrolled at 28 centers in the United States. 206 patients were implanted with the AMD telescope prosthesis. The 11 patients (5%) that were not implanted encountered surgical complications that prevented implantation of the AMD telescope prosthesis. An intraocular lens usually used after cataract surgery was implanted instead in these instances.

11.1 STUDY DEMOGRAPHICS AND BASELINE CHARACTERISTICS

Table 1 shows the gender, race, and age of the patients in the study. Most patients were Caucasian. The average age of the patients when they underwent the surgery was 76 years, and ages ranged from 55 to 93 years of age. Slightly more male patients than female patients received the AMD telescope prosthesis. Before surgery, the average distance visual acuity was 20/312.

**TABLE 1
DEMOGRAPHIC INFORMATION
ALL IMPLANTED EYES**

217 EYES OF 217 OPERATED SUBJECTS		
	Number	Percentage
Gender		
Female	103	47.5%
Male	114	52.5%
Race		
Caucasian	208	95.9%
Black	3	1.4%
Hispanic	5	2.3%
Asian	1	0.5%
Average Age	76 years	
Best-Corrected Visual Acuity (BCVA) Before Surgery		
Average Distance BCVA	20/312	
Average Near BCVA at 8 inches	20/315	
Average Near BCVA at 16 inches	20/260	

11.2 VISION RESULTS (WITH GLASSES)

Both distance and near visual acuity were measured in the clinical study. Before the study started, it was determined that the AMD telescope prosthesis would be considered a success if at least half (50%) of all patients were able to read, with glasses, two additional lines on the eye test chart at 12 months after the surgery in either distance or near vision. The goal of being able to read 2 more lines was chosen because this improvement is important to patients with vision impairment in both eyes due to AMD.

Table 2 shows the study subjects' vision (visual acuity) with glasses after surgery. One year after receiving the telescope prosthesis, 90% of the study patients improved at least 2 lines in distance or near vision, indicating that the AMD telescope prosthesis is very effective. Over time, through the second year of patient follow-up, the improvement in vision remained stable, with 2 or more lines of distance or near vision improvement reported for 86% of the study patients at 24 months after the AMD telescope prosthesis surgery.

TABLE 2
SUMMARY OF IMPROVEMENT IN VISUAL ACUITY

IMPROVEMENT IN VISUAL ACUITY	12 MONTHS	24 MONTHS
≥ 2 LINES GAIN OF BEST-CORRECTED DISTANCE OR NEAR	90%	86%

The age of the patient at the time of surgery did not have any effect on the success rate of the surgery. In other words, the ability to have better vision following surgery does not depend on the patient's age at implantation. Also, patients had improved vision with either model of the device, i.e., 2.2X or 3X. Patients implanted with the 3X AMD telescope prosthesis improved somewhat more than those implanted with the 2.2X device.

11.3 PATIENT QUALITY OF LIFE QUESTIONNAIRE

Study patients completed a questionnaire about the quality of their life, in terms of their vision, before their eye surgery and at 1 year after the surgery.

The National Eye Institute's Visual Function Questionnaire (VFQ), the questionnaire used in the study, contains questions about visual activities and how a person feels about his or her vision. Questions asked include ability to perform visual activities that require seeing up close and farther away, needing assistance due to eyesight, being frustrated due to eyesight, picking and matching clothes, and questions regarding situations that may be affected by vision.

For this questionnaire the higher the score, the less difficulty the patient has in doing things and potentially the better/more satisfied the patient is with his/her vision.

The average score on the VFQ questionnaire was higher 12 months after implantation of the device compared to before surgery. This indicates that patients, on average, rated their vision-related quality of life higher/better following implantation of the device than before the surgery.

12.0 PATIENT ASSISTANCE INFORMATION

To be completed by you or your Primary Eye Care professional as a reference:

Primary Eye Care Professional

Name: _____

Address: _____

Phone: _____

Eye Surgeon

Name: _____

Address: _____

Phone: _____

Treatment Location

Name: _____

Address: _____

Phone: _____

AMD telescope prosthesis Manufacturer

Name: VisionCare Ophthalmic Technologies, Inc.

Address: 14395 Saratoga Avenue, Suite 150 Saratoga, CA 95070

Phone: 408-872-9393

Fax: 408-872-9395

13.0 INDEX**A**

Age-related macular degeneration (AMD), 1, 2, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 18
Atrophic, 3

B

Benefit(s), 2, 5, 8, 11, 14, 15, 16
Bleeding, 9
Binocular, 3, 9
Blind, 6, 8

C

Candidate, 2, 11, 12
Cataract, 3, 9, 11, 13
Central vision impairment, 1, 2, 6, 7, 14, 15
Choroid, 3, 4
Choroidal neovascularization, 3, 10, 11
Clinical study, 2, 15, 16
Cloudy, 8, 9
Complications, 9
Contraindication, 2, 3, 10, 12
Cornea, 3, 5, 7, 9, 10, 11

D

Daily functions, 6
Device, 1, 2, 4, 5, 6, 7, 8, 9, 11, 12, 13, 14, 16, 17
Dizziness, 9
Double vision, 9, 14

E

Examination, 12
External telescope, 8, 11, 12
Eye drops, 13

F

Focus/Focusing, 3, 5, 8, 14

G

Glaucoma, 10

H

Hyperopia, 3, 10

I

Implantation, 1, 2, 5, 8, 9, 10, 11, 12, 16, 17
Infection, 9, 13
Intraocular pressure, 10

L

Legal blindness, 6
Lens, 3, 4, 5, 6, 7, 10, 13
Letter chart, 4, 16
Lining, 5, 9
Light rays, 5
Loss of vision, 9

M

Macula, 3, 5, 6
Medication, 10, 12, 13
Myopia, 3, 10

N

Natural lens, 3, 7, 13
Normal vision, 2, 5, 6

O

Optic nerve, 3, 5, 10

P

Peripheral, 4, 5, 6, 8, 9, 10, 11, 12
Permanent vision loss, 6
Precaution, 2, 11
Pregnancy, 10
Pupil, 5, 13

Q

Questionnaire, 2, 17

R

Rehabilitation, 2, 13
Retina, 3, 4, 5, 6, 7, 8
Risk, 2, 5, 9, 14, 15

S

Safety, 11
Study demographics, 2, 15
Surgery, 1, 2, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17

T

Therapy, 4
Therapeutic, 10, 11
Transparency, 9
Training, 2, 8, 11, 12, 13, 14, 15

V

Visual acuity, 2, 4, 16
Vision, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17