



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

**FACTS THAT YOU NEED TO KNOW ABOUT THE AMD DEVICE:
Implantable Miniature Telescope (IMT™ BY DR. ISAAC LIPSHITZ)**

PATIENT INFORMATION BOOKLET

For Central Vision Impairment Associated with Age-Related Macular Degeneration

Please read this entire booklet. 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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1. INTRODUCTION

The purpose of this booklet is to provide you with information regarding the Implantable Miniature Telescope (IMT™ by Dr. Isaac Lipshitz), hereafter referred to as “AMD implant”. Please read this entire book carefully to learn more about this device. Please see the “Glossary” (Section 12) for an explanation of words shown in *italics*. Discuss all your questions with a doctor trained in implantation of this device and in the care of implanted patients. You need to understand the benefits and risks of this procedure before you make a decision to undergo surgery.

1.1 NORMAL VISION

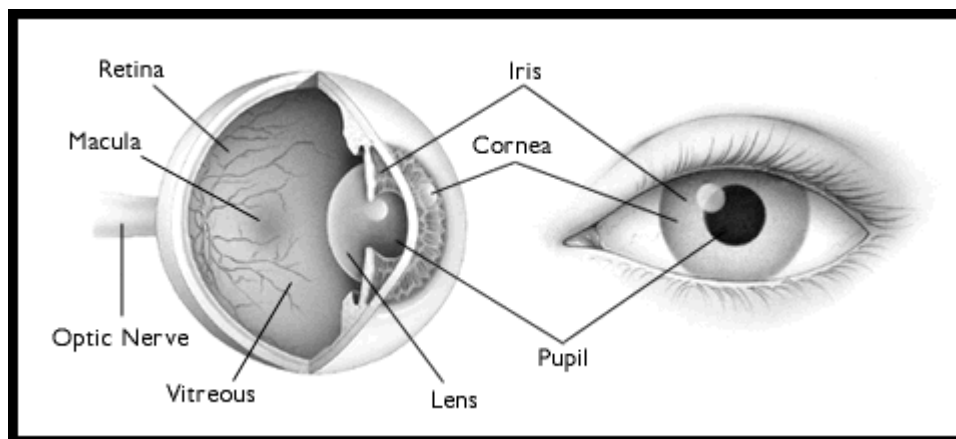


Figure 1: Diagram of the Eye

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.

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 makes up only a small part of the retina, it is much more sensitive to detail than the peripheral retina. The macula is responsible for focusing 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.

1.2 CENTRAL VISION IMPAIRMENT

Age-related macular degeneration (AMD) is the most common form of macular disease. Macular degeneration refers to the breakdown of cells in the macula, which is the central part of the retina responsible for good vision. Some degeneration is an inevitable

consequence of the aging process. However, when it is coupled with the loss of sight in the central part of the field of vision (Figure 2), a blind spot forms in the impaired eye.



A. Normal Vision



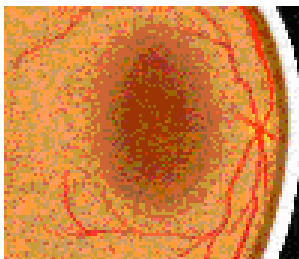
B. Blind Spot Created by Central Vision Impairment

Figure 2: Central Vision Impairment

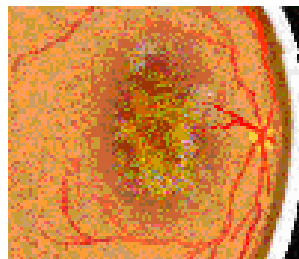
AMD is the leading cause of irreversible vision loss and legal blindness in individuals over the age of 50. Although people with AMD do not generally go completely blind, it can be difficult to read, recognize people, drive, and perform other daily functions that require central vision. Side or "peripheral"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

1.3 THE DEVELOPMENT OF AMD

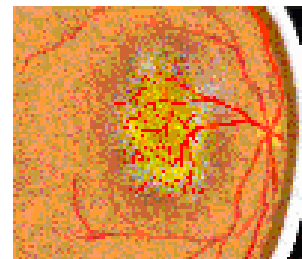
There are two basic types of macular degeneration: **dry** and **wet**. **Dry (atrophic) AMD** accounts for approximately 90% of all cases of macular degeneration.



A. Normal Macula



B. Drusen formation under the macula.



C. Macula with abnormal blood vessels

Figure 3: Macular Degeneration

Dry AMD is usually evident as a collection of small, white-yellow fatty deposits called *drusen*, which accumulate under the macula (Figure 3B). This condition results in deterioration of the macula from the aging and thinning of macular tissue. Late stage dry AMD is called geographic atrophy. This condition accounts for many of the new cases of legal blindness due to AMD each year in the US. It is also responsible for a

significant portion of permanent vision impairment associated with AMD. There are currently no accepted therapies for dry AMD.

Wet (*exudative*) AMD is caused by the growth of abnormal blood vessels, or *choroidal neovascularization* (CNV), under the macula (Figure 3C). These abnormal vessels are fragile and leak fluid and blood under the macula, and may cause permanent scarring of the macula. Wet AMD develops in only 10 to 15 percent of individuals with AMD, but usually dramatically affects vision. The end stage of wet AMD is called *disciform* scar and is often associated with permanent central vision loss. Current and investigational therapies for wet AMD focus on slowing or halting the progression of the disease and include *laser photocoagulation*, *photodynamic therapy* (PDT), and drugs injected into the eye.

No viable treatments are currently available for the many individuals whose vision degrades to permanent moderate to severe central vision loss due to late-stage dry, atrophic AMD and end stage wet AMD with disciform scar.

1.4 CURRENT TREATMENT OF CENTRAL VISION IMPAIRMENT

Central vision loss cannot be corrected with eyeglasses or contact lenses. People with this problem are often prescribed external, non-permanent low vision appliances such as special eyeglasses and head-mounted or hand-held telescopes, which magnify images onto the retina. These appliances are widely available but have only limited acceptance by patients. Patients often find these appliances of limited utility, since they provided a very limited field of view, are difficult to use during activities, and are often bulky, uncomfortable and unattractive. In addition, use of external telescopes requires suppression of natural eye movements. Instead, the patient has to learn to scan the visual field by moving his/her entire head which can sometimes cause a nauseous feeling.

VisionCare's Wide Angle Implantable Miniature Telescope (IMT™ by Dr. Isaac Lipshitz) is an implant for patients with central vision loss in both eyes due to AMD (Figure 4). The device is intended to be implanted in one eye in the same anatomical position as the natural lens.

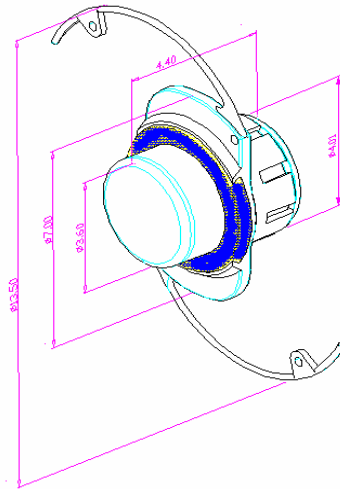


Figure 4: Implantable Miniature Telescope

2. HOW DOES THE DEVICE CORRECT CENTRAL VISION IMPAIRMENT?

The AMD device, together with the cornea, acts as a telephoto system to enlarge images approximately 3.0X or 2.2X, depending on the device model used. The telephoto effect allows images in the central visual field ('straight ahead vision') to not be focused directly on the damaged macula, but over other healthy areas of the central and peripheral retina. This generally helps reduce the 'blind spot' impairing vision in patients with AMD, and improves their ability to recognize and respond to images that were either difficult or impossible to see.

This AMD device is implanted by an ophthalmic surgeon in an outpatient surgical procedure. The device is implanted in one eye, which provides central vision as described above, while the non-implanted eye provides peripheral vision for mobility and navigation. The AMD device is intended to be a permanent implant. After the surgical procedure, the patient participates in a visual rehabilitation program to learn how to maximize their ability to perform daily activities using their changed visual status. Situated in the eye, the device allows patients to use natural eye movements to scan the environment, for both up close and farther away, such as reading printed materials or watching television. Peripheral vision in the eye implanted with the AMD device will be very limited, but peripheral vision will be retained in the non-implanted eye.

3. WHAT ARE THE BENEFITS OF DEVICE IMPLANTATION?

The AMD device may be able to reduce your central vision impairment and may improve the ability to recognize images.

CLINICAL STUDY DATA

A clinical study has been performed to evaluate the benefits and risks of the AMD device in patients with central vision impairment associated with age-related macular degeneration. A total of 206 patients were successfully implanted with the device.

STUDY DEMOGRAPHICS

Table 1 shows the gender, race, and age of patients in the study. Most patients were Caucasian. The average age at implant was 75.4 ± 7.2 years, and ranged from 55 to 93 years of age. Slightly more male patients than female patients underwent implantation of the device.

Table 1: Demographic Information

206 Eyes of 206 Enrolled & Implanted Subjects			
		Number	Percentage
Gender	Female	98	47.6%
	Male	108	52.4%
Race	Caucasian	198	96.1%
	Black	3	1.5%
	Hispanic	4	1.9%
	Asian	1	0.5%
Age (In Years)			
Mean \pm Standard Deviation		75.4 ± 7.2	
Range		55-93	

VISUAL ACUITY WITH GLASSES

Visual acuity measures the sharpness of vision using a letter chart. The more lines a patient can read on a visual acuity chart, the better the vision they have. Both distance and near visual acuity were measured in the clinical study. Before the study started, it was determined that the AMD device would be considered a success if at least 50% of all patients were able to read with glasses two additional lines on the letter chart at either distance or near test ranges 12 months after the surgery. This cut-off was chosen since it is clinically relevant, i.e., this amount of benefit is important to patients with moderate to profound vision impairment in both eyes due to AMD.

Table 2 shows the visual acuity with glasses after surgery. One year after implantation, 90.1% of the study patients gained at least 2 lines in distance **OR** near visual acuity, indicating that the AMD device is very effective. Over time, through the second year of patient follow-up, the improvement in visual acuity remained good, with a gain of 2 or more lines of distance or near vision reported for 87.2% of patients at 18 months and 85.7% at 24 months after implantation of the device.

Data were also analyzed to calculate the proportion of patients that gained at least 2 lines in near visual acuity **AND** distance visual acuity; this proportion was 73.4% at 12 months, 70.9% at 18 months and 67.3% at 24 months after the surgery. Approximately 50% of patients gained 3 lines of both distance and near visual acuity. Thus, visual acuity at near and distance improved in a high percentage of patients following implantation of the AMD device.

Table 2: Visual Acuity with Glasses after Surgery

Time after surgery	6 Month	12 Month	18 Month	24 Month
Overall Success Rate Patients who gained at least 2 lines in distance or near visual acuity	89.1%	90.1%	87.2%	85.7%
More Stringent Success Criteria Patients who gained at least 2 lines in distance and near visual acuity	68.7%	73.4%	70.9%	67.3%
Most Stringent Success Criteria Patients who gained at least 3 lines in distance and near visual acuity	49.8%	52.8%	49.7%	51.0%

Patient age at the time of surgery did not have any effect on the success rate. In other words, the ability to have better vision following surgery is independent of the age at implantation. Also, patients had improved visual acuity with either model of the device, i.e., 2.2X or 3.0X.

PATIENT QUALITY OF LIFE QUESTIONNAIRES

Study patients completed two different questionnaires at several time points including before implantation of the device and 12 months after implantation.

The Activities of Daily Life (ADL) questionnaire asked questions regarding everyday visual tasks such as watching television, reading numbers on the telephone pad, handling money bills, distinguishing facial features, reading a newspaper, reading street signs etc.

The other questionnaire, the National Eye Institute's Visual Function Questionnaire (VFQ) 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 both questionnaires, 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 results from both questionnaires are outlined in Table 3. The mean score of the ADL and VFQ questionnaires increased from baseline to 12 month after surgery, indicating that patients rated their vision higher/better following implantation of the device than before the surgery.

Table 3: Patient Questionnaires

Timing	Before Surgery	12 Month after Surgery
Overall Activities of Daily Life score (Mean \pm Standard Deviation)	41.4 \pm 15.6	55.9 \pm 19.6
Overall Visual Function Questionnaire score (Mean \pm Standard Deviation)	44.0 \pm 13.3	50.3 \pm 14.7

4. WHAT ARE THE RISKS OF DEVICE IMPLANTATION?

Complications may occur during or after implantation of the AMD device. These complications include bleeding in the eye, loss of transparency of the front of your eye (the cornea), infection inside the eye, elevated intraocular pressure, decrease or loss of vision, or the need to explant the device. Additionally, as a result of having the AMD device in your eye, you may experience difficulties seeing simultaneously with both eyes, double vision, and dizziness. Depth perception may be affected due to the loss of binocularity [the manner in which two eyes work together]. Peripheral vision will be restricted in the implanted eye and peripheral vision will be limited to that of the non-implanted eye. Near and/or distance vision did not improve in a small percentage of patients.

In the clinical study, 11 patients (5.1%) could not be implanted with the device due to complications during the surgery and 8 patients had the implant removed. Some of the patients who had the implant removed were dissatisfied with the device. For the most part, the complications and adverse events reported for the study patients were similar to events reported after cataract surgery with intraocular lens implantation, or other intraocular surgical procedures.

The AMD device is a relatively large visual prosthesis, the surgery is more difficult than conventional cataract surgery, and there is risk of damage to the cells that line the inside of the cornea during the surgical procedure. Additionally, eyes implanted with the AMD device may experience a higher rate of loss of cells lining the cornea over time than the non-implanted eye. If cell loss is too high, removal of the device and corneal transplant may be required. There were two patients who required corneal transplantation after experiencing longer-term complication from surgery.

Telescopes reduce the amount of light entering the eye. Implanted patients may experience a reduction in illumination in the implanted eye and a reduction in contrast sensitivity in low lighting settings. The non-implanted eye is unaffected.

The eye implanted with the telescope will have little or no light projected onto the outer portion of the retina. Implications for the loss of light transmission to the portion of the retina obstructed by the AMD device in the implanted eye are unknown.

4.1 SECONDARY CATARACT

Following implantation of any intraocular lens that replaces your natural lens, vision may start to become cloudy or hazy. This may be caused by secondary cataract and refers to the clouding of the membrane that surrounds the implant. This clouding of the membrane can also occur in eyes implanted with the miniature telescope. A laser or surgical procedure may be used to make an opening in the membrane behind the implant, which may improve vision. The laser procedure is usually performed in the office. The procedure takes only a short time and does not require anesthetic. This procedure is known as a YAG capsulotomy. Your physician may decide the cloudy membrane is not suitable for laser treatment and may perform an outpatient surgical procedure using conventional surgical instruments that requires local anesthetic.

5. CONTRAINDICATIONS

You should NOT undergo implantation of the device if you:

- have any impairment or restriction of peripheral vision in the eye not targeted for implant.
- have evidence of active choroidal neovascularization, or wet AMD, or had treatment for wet AMD within the past six months.
- have a severe communication impairment or severe neurological disorder.
- have a history of steroid-responsive rise in intraocular pressure, glaucoma, or preoperative intraocular pressure >22 mm Hg.
- have undergone previous intraocular or corneal surgery of any kind in the operative eye(s), including any type of surgery for either refractive or therapeutic purposes.
- are pregnant or nursing.
- have had or are expected to have ophthalmic related surgery within 30 days preceeding device implantation.

6. WARNINGS

Discuss with your physician if your planned operative eye has:

- myopia > 6.0 D
- hyperopia > 4.0 D
- axial length less than 21 mm
- endothelial cell density < 1600 cells/mm²

- narrow angle less than Schaefer grade 2.

AMD device implantation is not recommended in any of those circumstances.

7. PRECAUTIONS

The safety and efficacy of device implantation has **NOT** been established in:

- patients under 55 years of age
- patients with ocular pathology other than *cataract*
- patients with active choroidal neovascularization
- patients who underwent previous intraocular surgery or corneal surgery, including refractive or therapeutic surgery

Safety and efficacy have not been studied for periods longer than 24 months.

<p>The IMT™ (by Dr. Isaac Lipshitz) is MR unsafe – poses hazards in all MR environments.</p>

8. ARE YOU A GOOD CANDIDATE FOR DEVICE IMPLANTATION?

To determine if you are a good candidate for device implantation your vision will be tested using an external telescope to see if this improves your vision, since it works in a similar manner as the miniature AMD implant. During the screening examination, you will be tested to see if your visual acuity improves using an external telescope. If your visual acuity is not improved while using the external telescope, it means you are not a potential candidate for implantation of the device.

You will be able to try two external telescopes of different magnification to help decide if the effect of 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 field of view (e.g., facial features, watching TV, looking at moving objects or moving from bright to dim lighting environments). When testing the external telescope, it is important to understand that, if the miniature telescope 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 vision. If you feel you cannot become accustomed to the difference in vision between your eyes, you may not be a good candidate for this device. However, if your visual acuity and ability to distinguish objects improved with the external telescope, and you feel you can become accustomed to the difference in vision between eyes, you will undergo a thorough eye examination to make sure that you are a good candidate for device implantation.

A visual rehabilitation specialist can also discuss the potential for improvement in performance of activities of daily living or other functional goals you may have. You may not be a good candidate for device implantation if there is limited chance of functional improvement in activities of daily living.

Following device implantation, it is very important to participate in a visual rehabilitation program recommended by the ophthalmologist to maximize your ability to perform daily activities and reach your functional goals. If you are unwilling or unable to undergo visual rehabilitation, you are not a good candidate for device implantation.

9. WHAT TO EXPECT WITH THE PROCEDURE?

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.

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 since you must not drive right after the surgery. Be sure to discuss all questions you might have regarding the surgery with your doctor prior to the procedure.

THE DAY OF SURGERY

The surgical procedure used to implant the device inside the eye requires several steps. Your eye will be anesthetized [numbed] at the beginning of the procedure so you will not feel any pain. Special eye drops will be administered to achieve adequate pupil dilatation [enlargement]; the effect of the eye drops is temporary. Your eye will be propped open with a lid speculum, and an operating microscope will be positioned in front of your eye. Your natural crystalline lens will be removed by a cataract surgeon. The AMD device will then be implanted in the same position in the eye as the natural lens. The effects of numbing will wear off after about 60 min.

AFTER THE SURGERY

After the device is implanted you will be provided with several types of topical ophthalmic medications for use when you return to your home. The schedule for using 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. It is important to adhere to the visual rehabilitation program since this is very important in helping you use your new visual status in activities of daily living. You will be asked by your physician to return after surgery for an eye exam, to make sure that your progress is as expected.

Use the eye medications as directed by your doctor. Your results depend upon you following your doctor's instructions.

DO NOT RUB your eyes after device implantation since irritation or damage to your eye may occur.

VISUAL REHABILITATION AFTER SURGERY

The goal of the visual rehabilitation program is to work with you to optimize your visual function and accomplish specific goals involving activities of daily living. Visual rehabilitation will provide you with the skills to adjust to your change of visual status and to its use in such a way that optimal function in distance and near visual activities is achieved in minimal time.

It is important to understand that side vision will be restricted in the implanted eye, your ability to judge distances may be affected, and you may not be able to adjust to and utilize your vision in the implanted eye effectively without full participation in visual rehabilitation.

Rehabilitation will be provided in five skills:

- Localizing (to locate an object of interest into the implant's field of view)
- Fixating (to fixate on the object to enable 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)

Visual rehabilitation exercises will include both static (seated) and dynamic (walking/moving) activities.

Since you are likely to experience reduced light reaching the back of the eye in the implanted eye, and therefore a reduction in contrast sensitivity in low lighting settings, you will be encouraged to use adequate lighting when indoors. You will be cautioned not to wear sunglasses in low light settings, and to use the fellow eye for navigation in low light settings.

In case you are experiencing double vision, you will be instructed to alternate viewing between the two eyes, or use one eye while suppressing the other eye (specifically, you will use the implanted eye for central vision and the other eye for orientation and mobility).

10. 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?
- Will I have to limit my activities after surgery and for how long?
- What are the benefits of the procedure for my degree of central vision impairment?
- Can the device be explanted if necessary?
- Can you provide more details regarding visual rehabilitation?

Discuss the cost of surgery and follow-up care with your doctor.

11. GLOSSARY

Atrophic: decrease in size or wasting away of tissue.

Binocular vision: the manner in which two eyes work together

Cataract: an opacity, or clouding of the lens inside the eye that can blur vision.

Choroid: layer of tissue lying under the retina.

Choroidal neovascularization: condition in which new, abnormal blood vessels grow into the choroid beneath the retinal pigment epithelium.

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

Cornea: the clear front layer of the eye.

Disciform: round or oval in shape.

Drusen: circular, yellowish bodies that appear on the choroid as a consequence of aging or in some retinal degenerations.

Exudative: leakage of substances from retinal tissue.

Laser photocoagulation: application of laser light that is converted to heat in order to seal off blood vessels.

Lens: a structure inside the eye that helps focus light onto the back surface (retina) of the eye.

Macula: a small area in the center of the retina near the optic nerve.

Peripheral: located away from a center or central portion.

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

Retina: the layer of nerve tissue at the back of the eye that captures images, similar to film in a camera, and sends information about those images to the brain. Light must be focused correctly on the retina to form clear images.

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

12. 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: _____

IMT™ (by Dr. Isaac Lipshitz) Manufacturer

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