

Introduction

Importance and Credibility:

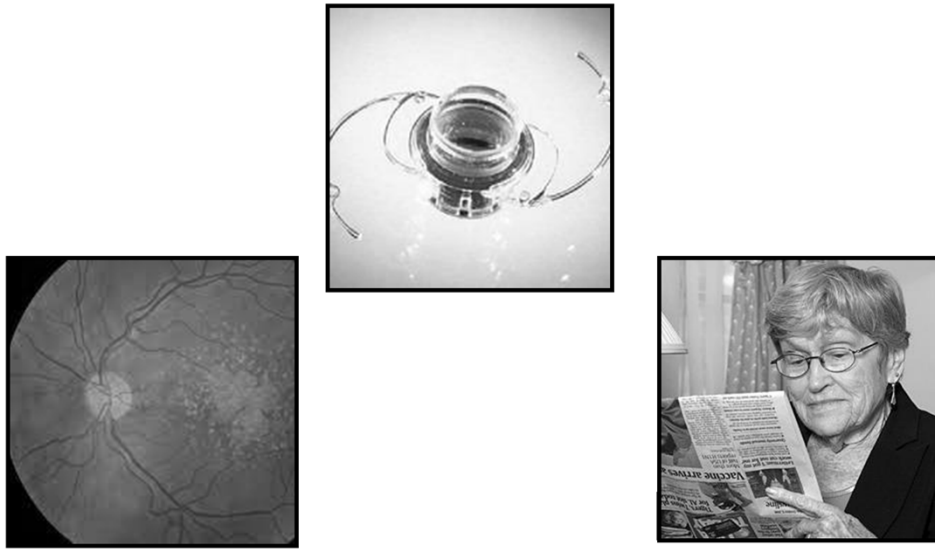
As the baby boomer generation reaches retirement age, we will see the largest senior citizen generation the country has ever experienced. Coupled with an increasing life expectancy, health concerns of the elderly will be a much greater problem facing those in healthcare. Among these concerns is age-related macular degeneration, the leading cause of legal blindness in the United States. AMD will see its patient count double by 2050. This is a problem which our generation will be expected to deal with.

Transition: But there is currently no effective solution to the vision loss caused by AMD.

http://www.centrasight.com/img/chart_amd_population.gif

¹ Rein DB, Wittenborn JS, Zhang X, et al. Forecasting Age-Related Macular Degeneration Through the Year 2050: The potential impact of new treatments. *Arch Ophthalmol*. 2009;127:533-540

The IMT is an effective solution to vision loss in end-stage AMD patients



Thesis Statement and Limitations: In this talk I will discuss a new technology innovation that addresses the needs of end-stage AMD patients called an implantable miniature telescope.

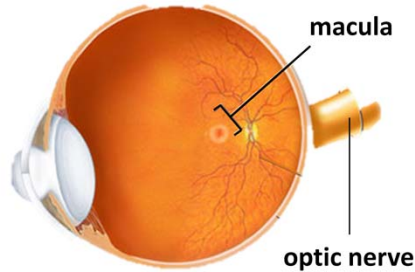
When approaching this topic, I will be excluding cost as a factor and I will only be considering end-stage AMD patients for this presentation, meaning those who are within the range of legal blindness or severe vision loss in both eyes.

Mapping:

I'll explore this topic in three stages. First, I'll talk about what an IMT is and how it works. Then I'll talk about the physical improvements in a patient's vision as a result of the implant. Finally, I'll describe the positive impact the device has on a patient's quality of life.

Transition: I'll start by talking about what an implantable miniature telescope is.

AMD affects the macular cells that allow the eye to interpret detail in central vision



[FocusClinic]



[WillsEye]

Main Point 1. AMD is a disease that targets the part of the eye responsible for central vision and is most prominent in those over the age of 65.

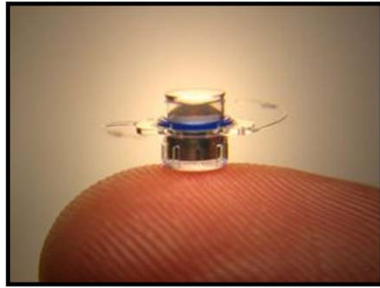
A. Vision is the result of your brain interpreting signals sent to your brain by the retina. The macula is the region of cells of the retina that are responsible for central vision.

B. AMD is the buildup of waste products in the layers of macular cells which solidifies and effectively destroys the cells. This results in severe central vision loss while the peripheral vision remains intact. This progresses until it reaches the end-stage in which medicine and steroids are ineffective in stabilizing the condition.

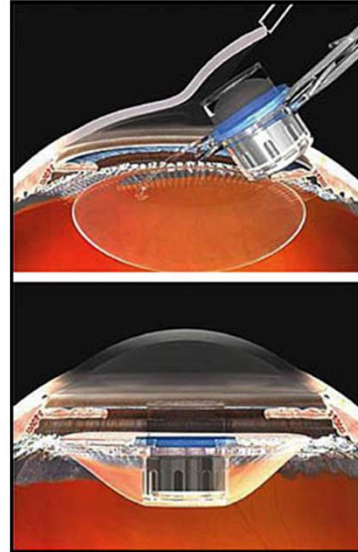
Transition: Treatment for end-stage patients is a limited practice.

The Visual Impact on Patients. *Centrasight*. VisionCare Ophthalmic Technologies, Inc 2013.
http://www.centrasight.com/visual_impact

**The telescope prosthetic is implanted into the eye
with the most macular tissue damage**



[Visioncare]



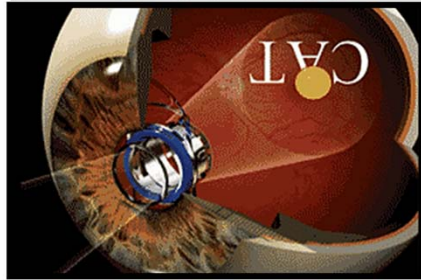
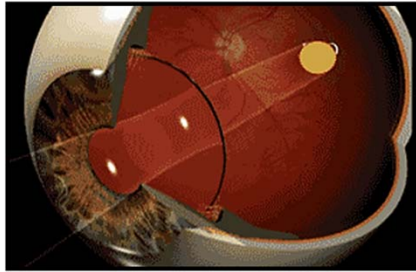
B. Device itself is 3.6mm in diameter (size of a pea) and made from polymethylmethacrylate, a synthetic polymer that will not be rejected by the eye tissue. To be a candidate for the prosthetic device, a patient must complete a thorough preliminary examination. This includes external eye tests to confirm that the IMT will aid in their vision. A patient must also complete screening, be at least 75 years old, and have a Snellen eye score of between 20/160 and 20/800.³

C. According to Centrasight, the company that is responsible for the IMT treatment program, implantation of the device involves a surgery that averages 2-3 hours. During this surgery, the cataractous natural lens of the eye is removed and the telescope prosthesis is placed where the lens had been, in the capsular bag of the eye. The device protrudes into the pupil, but is not in contact with the cornea of the eye. The haptic loops of the device anchor to the surrounding tissue, allowing no movement relative to the eye. This device is the only vision aid for AMD patients that allows the patient to use the movement of their eye as opposed to movement of their entire head in order to look at objects around them. This solves the problem associated with low-vision external aids which cause headaches and neck pain in patients.⁴

It is important to note that the surgery involved is almost identical to cataract surgery which is extremely common for the elderly in the U.S. The difference is that instead of replacing the natural lens with a standard artificial lens (intraocular lens), the IMT is implanted. Eye surgeons familiar with cataract surgery can easily be trained to perform the implantation.

Transition: So let us see how the device affects the visual acuity of the patient.

The telescope lets a patient use the surrounding undamaged retinal cells for central vision



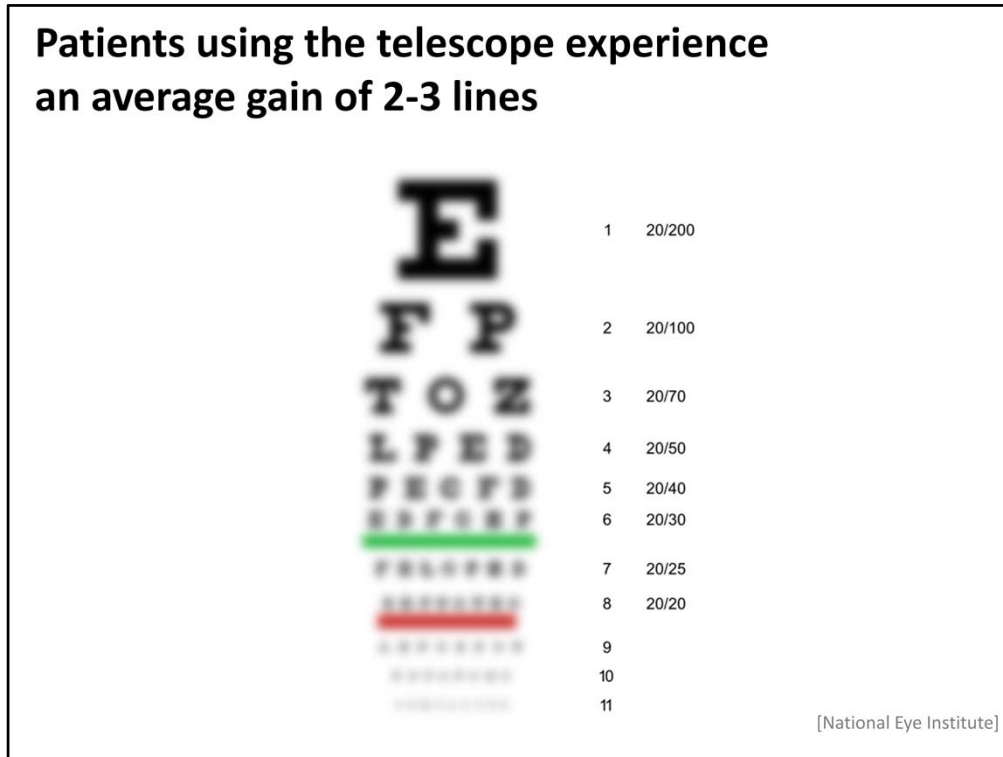
[ScienceDaily]

[National Eye Institute mod]

Main Point 2. The implantable miniature telescope works by using the retinal cells around the damaged macular area. (Toulmin)

- A. The IMT is produced by VisionCare Ophthalmic Technologies. Normally, light enters the eye and projects to the macula, the sensitive retinal cells responsible for detailed central vision. AMD destroys these cells resulting in central vision loss. The telescope prosthetic magnifies the incoming image 2.2-3X (depending on model), projecting an area that covers 36 degrees of the retinal surface of the back of the eye (as opposed to the original 5 degrees). The eye is then able to effectively limit the “blind spot” in a patient’s field of vision which restores central vision to the user of the device. It is important to note that the IMT does not cure the condition of AMD but drastically improves the visual acuity of the patient.²

Transition: Now we will look at how the device is implanted.



Main Point 3. Patients using the IMT device experience an average gain of 2-3 lines on the standard Snellen eye chart exam. (Rebuttal)

- A. According to the clinical trials discussed in the American Journal of Ophthalmology, patients gained 2-3 lines on this exam after successful implantation of the IMT device. This may not sound like much. Most people are familiar with the Snellen eye chart that is used to examine the visual acuity of a person. Normal vision is considered 20/20. Legal blindness is a score of 20/200 or worse. This is where most end-stage patients fall on the chart, even with corrective lenses. So when a patient gains 2-3 lines and moves to a mean of 20/100, they are able to read again and see the faces of people around them. Two to three lines allows them to navigate their own house or cross a street by themselves or dial a phone. ⁵

Transition: These are all differences that contribute to an increased quality of life in patients.

The telescope results in improvement in the quality of life of AMD patients



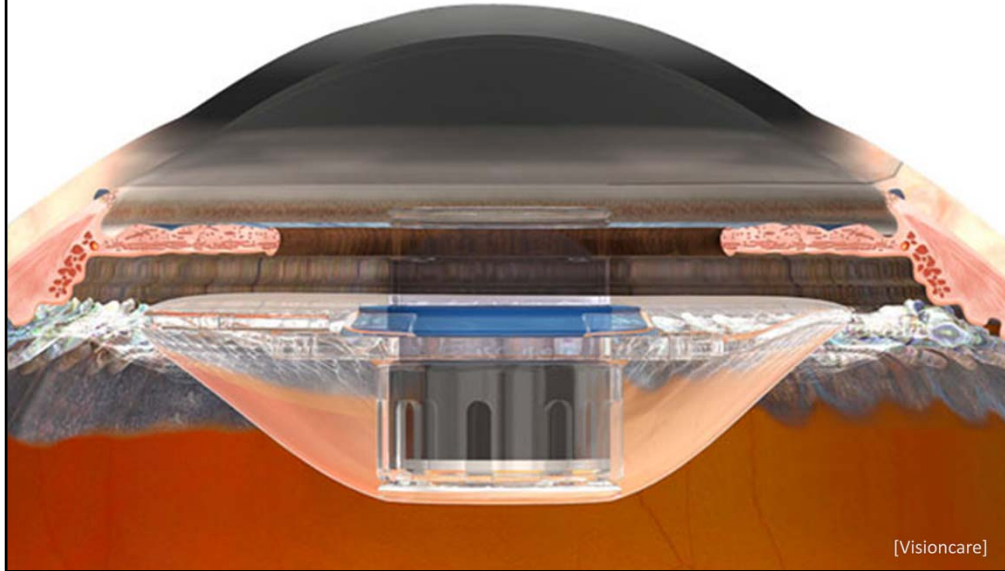
[Centrasight]

Main Point 3. The implantable miniature telescope improves the quality of life of end-stage patients. (Toulmin)

A. The woman pictured here is Marian, a 79 year old woman from North Carolina. She was one of the patients involved in the FDA trials that began in 2003. She had end-stage AMD and decided she would take part in the study. With the IMT Marian is able to shop at the grocery store and be involved in her church. She was able to see her children and grandchildren again. The vision that is restored to AMD patients allows them to regain dependence in their lives. They no longer have to be checked in to nursing homes or be under constant supervision of family members. Tasks such as reading, crossing streets, cooking become possible again. This is just one of many IMT success stories.⁶

B. Preference-based comparative effectiveness is an analysis that quantitatively measures a person's quality of life. This analysis was performed on end-stage patients before and after they had the IMT implanted. The researchers were from universities across the country, including the Departments of Ophthalmology from University of Pennsylvania and University of Minnesota, two top ranking medical schools. The results indicated that patients using the IMT experienced an average increase in the quality of life of 12.5%. ⁷

In summary, the telescope device effectively reduces vision loss in end-stage AMD patients



Conclusion

Summary and Reinforcement of Thesis:

The IMT addresses the vision loss problem by magnifying the incoming image on the retinal cells that are unaffected by AMD. This limits the degenerated blind spot. Patients using the device experience an increase in visual acuity equal to 2-3 lines on the standard eye chart, allowing them to perform tasks such as reading and recognizing faces. This results in a 12.5% increase in the quality of life.

These factors show that the IMT is indeed an effective solution for end-stage AMD patients.

Closure:

In the previous presentation, I ended with the fact that AMD affects the age demographic that are grandparents are at and that our parents will eventually get to. It is comforting to know that leaps in technology such as this will help them continue to leave happy, healthy lives. It is amazing how such a small piece of technology can make such a huge difference in people's lives.

References

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2. Implantable Miniature Telescope for Age-Related Macular Degeneration. *ViscionCare Technologies*. http://www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4225b1_06_Patient%20Information%20Brochure%2001%2024%2006.pdf
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5. Implantable Telescope for End-Stage Age-related Macular Degeneration: Long-term Visual Acuity and Safety Outcomes. *American Journal of Ophthalmology*. Henry L. Hudson, R. Doyle Stulting, Jeffrey S. Heier, Stephen S. Lane, David F. Change, Lawrence J. Singerman, Cynthia A. Bradford, Robert E. Leonard 2008
6. Patient and Caregiver Stories. *Centrasight*. http://www.centrasight.com/Marians_Story 2011
7. Comparative Effectiveness and Cost-Effectiveness of the Implantable Miniature Telescope. *American Journal of Ophthalmology*. Gary C. Brown, Melissa M. Brown, Heidi B. Lieske, Philip A. Lieske, Kathryn S. Brown, Stephen S. Lane 2011

Images

Slide 1

http://www.visioncareinc.net/img/img_hcp_device_schematic.jpg

Slide 2

<http://www.fda.gov/ucm/groups/fdagov-public/documents/image/ucm219509.jpg>

http://www.centrasight.com/img/billy_closeup.jpg

http://www.centrasight.com/img/marian_news.jpg

Slide 3

<http://images.sciencedaily.com/2013/03/130321221315-large.jpg>

http://www.nei.nih.gov/health/images/normal_vision_color.jpg

Slide 4

<http://www.visioncareinc.net/img/image-telescope.jpg>

Slide 5

<http://www.uofmhealth.org/sites/default/files/healthwise/media/medical/hw/h9991086.gif>

Slide 6

http://www.centrasight.com/img/marian_news.jpg

Slide 7

http://www.centrasight.com/img/billy_closeup.jpg

http://www.centrasight.com/img/img_step_3.jpg

Slide 8 (optional)

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