The Implantable Miniature Telescope (IMT™)

By

VisionCare Ophthalmic Technologies, Inc.

There is no doubt that, with the aging population, there will be a dramatic increase in individuals with low vision – with the most common cause secondary to age related macular degeneration. When an individual (patient) experiences a central vision loss, there are presently only a limited number of ways to improve his/her vision loss. No known cure is yet available and eye care specialists (low vision specialists) are resolved to helping these patients through the use of magnification along with rehabilitation services (i.e. rehabilitation teachers, orientation & mobility instructors, occupational therapists, etc.). A common visual concern for these patients is improvement of distance vision, for watching television, independent travel, identifying people at a reasonable distance, and in some cases – driving. To obtain magnification at distance there are generally 4 different ways to achieve this:

- Relative size – providing a larger object at a given distance (i.e. 2X magnification by switching a 20 inch screen TV to a 40 inch screen)
- Projection – projecting an enlarged image generally through electronics (i.e. projecting small print on a screen – slide presentation)
- Relative distance – getting closer to an object (i.e. walking closer to an individual to identify him/her or sitting closer to a TV)
- Angular – ratio of the angle subtended by the image to that subtended by the object with respect to a viewing point of reference (i.e. using a telescope to obtain magnification)

Telescopes are generally the most commonly prescribed system for achieving magnification at distance. When prescribing or recommending any telescope (or any low vision device) to a low vision patient, it is most important to initially determine the goals of that patient, since the patient's goals or visual concerns truly drive the examination. It is through the determination of these goals or concerns that will help determine the type of telescope (i.e. Galilean vs. Keplerian, spectacle mounted vs. hand held, etc.) and required magnification needed (to achieve the specific concern). When a patient could possibly benefit from a telescope but is unsure of any specific goals, it is widely accepted that 20/40 to 20/50 vision should be the "target acuity". It is expected that with this acuity the patient would be capable of distinguishing most distant objects at a reasonable distance (i.e. reading a street sign at a "normal distance" and in some states – driving a car, etc.).

In spite of the wide potential use of telescopes, there are a number of disadvantages that prevent total satisfaction with this type of device. Cosmesis (unattractive appearance), field of view, and in some cases weight (when spectacle mounted) may deter patients from using such a device. VisionCare Ophthalmic Technologies, through its Implantable Miniature Telescope (IMT™), is attempting to help eliminate the weight and cosmetic concerns. "The IMT™ is indicated for use in adult patients with bilateral, stable, untreatable, moderate to profound central vision impairment due to macular degeneration". It appears from the data presented by VisionCare that a number of subjects (patients) have been successfully surgically fitted with this type of telescope. It is reported that "with respect to safety, the incidence of complications and adverse events was relatively low and endothelial cell loss is the only parameter that did not meet the pre-specified protocol criterion". The data also presents with clinically significant

improvement in visual acuity with the patients tested over a 2-year period of time. It is further reported that "effectiveness outcomes exceeded the predefined targets identified in the study protocol. The majority of subjects (approximately 75%) achieved an improvement in best corrected distance acuity of at least 2 lines, with over 60% of eyes gaining 3 or more lines of acuity, 40% gaining 4 or more lines and 20% experiencing a gain of 5 or more lines of distance vision". These are certainly commendable results. There are, however, a number of concerns that I have regarding the approach and effectiveness of this reported research and the type of telescopic system utilized with respect to low vision rehabilitation.

1. If a patient is implanted with this telescope and his/her vision decreases to a point where he/she requires more magnification to achieve the visual goals, it would require surgical removal of the telescope. This would be more costly and a more risky procedure than what is presently done by merely switching one telescope for another (whether it be a hand held or spectacle mounted). In addition, more powerful telescopes (than 2.7X) are not available as implantable systems.

2. It does not appear that a patient's specific visual concerns were ever considered when implanting the telescope. If a patient's goals were never initially determined prior to implantation of the telescope, how was it determined which patient received the 2.2X telescope or the other 2.7X in this study? There must have been a rationale for prescribing one magnification system over the other since 115 eyes were implanted with the 2.2X and 91 eyes were implanted with the 2.7X.

   It is commendable that both a "Quality of Life" and "Activities of Daily Living" questionnaire was presented to each patient to qualify and quantify a patient's functional vision. However, the results of the "Quality of Life" questionnaire reports that the implantable telescope showed "general vision improvement" to be the greatest positive response followed by "near vision activities" and then "distance vision activities". Again this seems to reinforce the fact that the original use of the telescope was to provide overall improvement in visual acuity rather than provide improvement for specific visual concerns.

3. Driving is a common visual goal by many low vision patients and the IMT™ is not capable of providing any assistance in this area of concern.

4. The data supports improvement in visual acuity with magnification, however, I do question whether the majority of these improvements will allow the subject to achieve realistic goals. With magnifications of only 2.2X and 2.7X there appear to be only a limited number of patients that could truly benefit from such a system even though it is suggested for patients with moderate to profound vision loss (20/80 to 20/800).

Table 1 Predicted Distance Visual Acuity Improvement:

	2.2X	2.7X
20/80	**20/36.4**	**20/29.6**
20/100	**20/45.5**	**20/37**
20/120	**20/54.6**	**20/44.4**
20/140	20/63.6	**20/51.9**
20/160	20/72.7	20/59.3
20/200	20/90.9	20/74.1
20/250	20/113.6	20/92.6
20/300	20/136.4	20/111.1
20/350	20/159.1	20/129.6
20/400	20/181.8	20/148.2
20/450	20/204.6	20/166.7
20/500	20/227.3	20/185.2
20/550	20/250	20/203.7
20/600	20/272.7	20/222.2
20/650	20/295.5	20/240.7
20/700	20/318.2	20/259.3
20/750	20/340.9	20/277.8
20/800	20/363.6	20/296.3

As table 1 shows, there are theoretically only a small number of improved visual acuities that fall within the 20/40 to 20/50 acuity range, which again is the recommended acuity range needed to achieve most patient's visual goals or concerns. Improving a visual acuity without solving a patient's visual concern is unproductive. **It is akin to a potentially new glaucoma medication (which is meant to work without any other combination of medications) that consistently lowers IOP by an average of 15 mmHG. It is then recommended, through the research study, that patients with "moderate to profoundly" high pressures would respond favorably to this medication, and indeed, patients with IOP's of 40 mmHG and 50 mmHg show a decrease in pressure of approximately 15 mmHg, with higher pressures demonstrating even a greater drop in pressure. Therefore, this study concludes that this new medication can be recommended for glaucoma patients with "moderate, severe, and profound" increases in IOP, since it does statistically demonstrate a significant drop in IOP .**

It should also be noted that visual function is more complex than just the ability to read letters or numbers on a chart. In fact, reading isolated high contrast optotypes in a dimly lit room (typical way acuity is taken) does not necessarily correlate well with a number of visual tasks that individuals have to perform on a daily basis.

Table 2 **Predicted Near Visual Acuity Improvement (Relative to a 16" or 40 cm distance):**

	2.2X @ 16"	2.2X @ 8"	2.7X @ 16"	2.7X @ 8"
20/80	**20/36.4**	**20/18.2**	**20/29.6**	**20/14.8**
20/100	**20/45.5**	**20/22.7**	**20/37**	**20/18.5**
20/120	20/54.5	**20/27.3**	**20/44.4**	**20/22.2**
20/140	20/63.6	**20/31.8**	**20/51.9**	**20/25.9**
20/160	20/72.7	**20/36.4**	20/59.3	**20/29.6**
20/200	20/90.9	**20/45.5**	20/74.1	**20/37**
20/250	20/113.6	20/56.8	20/92.6	**20/46.3**
20/300	20/136.4	20/68.2	20/111.1	20/55.6
20/350	20/159.1	20/79.5	20/129.6	20/64.8
20/400	20/181.2	20/90.9	20/148.1	20/74.1
20/450	20/204.5	20/102.3	20/166.7	20/83.3
20/500	20/227.3	20/113.6	20/185.2	20/92.6
20/550	20/250	20/125	20/203.7	20/101.9
20/600	20/272.7	20/136.4	20/222.2	20/111.1
20/650	20/295.5	20/147.7	20/240.7	20/120.4
20/700	20/318.2	20/159.1	20/259.3	20/129.6
20/750	20/340.9	20/170.5	20/277.8	20/138.9
20/800	20/363.6	20/181.8	20/296.3	20/148.1

As table 2 shows, there are theoretically again only a relatively small number of visual acuities (bold red print under telescopic devices) that would allow a patient with low vision to achieve reasonable visual goals or concerns (20/40 to 20/50 acuity range is the size of standard size print). It should again be noted that there is generally a significant difference between visual acuity and reading acuity. There are considerable differences between high quality visual acuity charts and poor quality print found in a newspaper. Also, individual optotypes (on an acuity chart) are easier to see than words and sentences in which spacing between letters (contour interaction) tend to pose a bigger problem as a low vision patient attempts to read at his/her threshold. Reading material may often lack uniformity in size and inking, as well as contrast between the inked letters and background when compared to visual acuity (and even reading acuity) charts. Therefore, even though newspaper print size may be equivalent to a 20/40 or 20/50 letter size, patients with low vision may require acuities of 20/30 or better to read a newspaper with comfort.

Contrast and illumination are also extremely important factors when reading. It does not appear that the study evaluated these parameters as it relates to reading with the IMT™. As a matter of fact, the illumination falling on the retina would be reduced greater when looking through a telemicroscope (telescope and reading cap) than when looking through an equivalent powered spectacle-reading lens. The reduced amount of light on the retina for many patients with low vision could mean all the difference between success and failure.

5. It was recommended, in the study, that if the best-corrected vision was better than 20/200 in either eye, the eye with worse visual acuity would be chosen for implantation. If the best-corrected vision was equal to or worse than 20/200, or the same in both eyes, the physician and patient decided which eye would be implanted. I question why the telescope would be placed in the poorer seeing eye if vision was better than 20/200 in either eye. I would expect that the patient, who may be a good candidate for this implanted telescope, would have the telescope placed in the better seeing eye to provide the maximum benefit. Of course, this would have to be determined only after a thorough medical, optical, and functional evaluation of the patient's mobility, with the better seeing eye aided by magnification. To accomplish this, I believe a team of specialists (i.e. surgeon, low vision M.D. or O.D. rehabilitation specialist, O&M instructor, O.T., etc.), along with the patient's input, would be required.

6. It was reported in the FDA Executive Summary that the "sponsor argued that less than the theoretical improvement should be expected clinically because of the reduced central vision in the study subjects." This statement is far from accurate since all of the test subjects have reduced central vision and should demonstrate expected visual acuity improvements relative to the magnification. If the subject does not respond as expected there has to be an explanation. Some areas to evaluate are:
    a. Eccentric viewing
    b. Contrast and/or illumination differences with the visual acuity chart or exam room when comparing the initial acuity to the magnified acuity
    c. If different exam rooms are used, the chart may be at a slightly different distance if it is a portable ETDRS chart on wheels
    d. Different individuals recording the acuity since some test takers may push a subject harder
    e. The mood and willingness of the subject to respond
    f. Uncorrected refractive error
    g. Ocular complications

7. It is my understanding that the IMT™ is actually focused for 3 meters (10 feet). This may be a reasonable distance for many patients when watching TV and identifying people at a distance. However, if a distance of 6 meters (20 feet) or greater is required, a minus (concave) spectacle correction must be worn, which would decrease the overall magnification of the implant, thereby decreasing the visual acuity improvement to some extent.

   Blur created by an uncorrected refractive error would have to be prescribed so as to provide maximum clarity, since any vergence of light through a telescopic system would be amplified when not fully corrected. This **"Vergence Amplification"** refers to any divergent or convergent light, entering an afocal telescopic system, being magnified or amplified by approximately the magnification of the telescope squared (see formulas below). In addition, convex spectacle lenses would have to be fabricated for each specific near task that

requires a different working distance. For example, a patient wanting to read at 8" would require a different lens than when viewing a computer at 12" and another lens for identifying their food at 16". These varied distances generally require more lens changes when viewing through a telescope (less depth of focus) than without a telescope, again, because of vergence amplification.

Actual Vergence Amplification Formula: $A_{oc} = M^2U / 1\text{-}dMU$

Approximation Vergence Amplification Formula: $A_{oc} = M^2U$

8. It appears that no formal or clinical assessment of binocularity or bi-ocularity was performed, other then having the patient place a hand held telescope in front of one eye while performing certain tasks (i.e. watching TV, walking, etc.). It seems that the patients were left to work on their own or with friends and family members. I believe that both a <u>clinical</u> and <u>functional</u> binocular work-up would have been appropriate, especially as it relates to potential retinal rivalry and ocular suppression. In addition to an initial evaluation it is extremely critical that functional assessments and instruction by low vision rehabilitation specialists, such as orientation and mobility instructors and/or occupational therapists, should have been performed. This, I believe, is very important in lieu of the potential risk to a patient once fitted with the IMT™. In my opinion, some common risks factors are the following:
    a. Adapting to magnification in one eye since objects will appear to move quicker, appear closer, and appear larger through that eye.
    b. During mobility, a patient may not be fully capable (without instruction) of suppressing the eye with the IMT™ and using the non-magnified eye only.
    c. For most patients with low vision, mobility involving curbs and steps is difficult and in some cases dangerous. Even though there is generally a loss of contrast and true stereopsis, <u>binocular summation</u>, when present may be very helpful. For a patient utilizing the IMT™ system, it may become more dangerous and thereby require assessment and instruction.
    d. Since the patients in this study had to be 55 years or older, there may be a slower rate of adaptation with older patients, which might be improved with professional instruction.
    e. Since these patients tend to be older, greater complications (i.e. broken hip, etc.) may occur if the patient falls or bumps into an object when learning how to use the IMT™ system on his/her own.

In summary, the Implantable Miniature Telescope (IMT™) by VisionCare Ophthalmic Technologies, Inc. appears to be statistically successful for "general vision improvement". I do question, though, the benefit of this telescope as it relates to available magnification and ease in solving patient's visual concerns. I feel that it might be useful for some patients with moderate vision loss, since it may be capable

of providing adequate magnification to accomplish their common visual concerns (i.e. seeing TV more clearly, identifying peoples faces, etc.). How useful, however, is the telescope, as the macular degeneration progresses toward its end-stage (profound vision loss)? Granted, the system will continue to improve visual acuity, even with vision as poor as 20/1000, but is it capable of providing **quality** vision? **"The concept of low vision care emphasizes a person's ability to function visually and does not entail a numerical classification system. The service is directed at solving problems created for individuals by the impairment of their vision".** (Dr. Randall T. Jose in his textbook Understanding Low Vision, p 62)

The FDA requires that any potential researched product show **effectiveness,** and they define effectiveness as "reasonable assurance that, in a significant portion of the population, the uses and conditions of use (when labeled) will provide clinically significant results". Because of this, I truly believe that the panel should weigh my above concerns carefully when evaluating the effectiveness of the IMT™.

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