

LOW VISION

The Implantable Miniature Telescope Part Two: Patient Selection and Rehabilitation

BY ANNIE STUART, CONTRIBUTING WRITER

The Implantable Miniature Telescope (IMT), an investigative device developed by VisionCare Ophthalmic Technologies for patients with end-stage age-related macular degeneration, is garnering attention in the low vision community. The IMT is capable of fostering a three-line improvement in vision in patients with profound vision loss, though it may be an arduous process for physicians and patients to achieve this level of success.

Stephen S. Lane, MD, adjunct professor of ophthalmology at the University of Minnesota in Minneapolis, was a medical monitor for all phases of the IMT trials. He learned that, for the physician, a team approach is required to ensure the device's success. Typically, during the study, he said, a retina surgeon referred the patient to a cataract surgeon to do the IMT procedure. The retina or cataract physician would work pre- and postoperatively with a low vision specialist and occupational therapist to assess the patient's candidacy and to help the patient learn how to use their new vision in activities of daily living. Specifically, the telescopic eye is used for detailed central vision activities and the nontelescopic fellow eye for peripheral vision.

"I don't think people who do routine cataract surgery are going to want to get involved with this unless they

have a special interest in low vision because it is very different than routine cataract surgery," said Dr. Lane. "There's a lot of work involved in preoperative selection and postoperative patient rehabilitation. And there's certainly no 'wow' effect like that experienced with refractive surgery procedures. What's important is that everybody's expectations be tempered appropriately so that what we actually achieve is realistic on the part of all parties involved—families, patients and physicians."

Screening and Assessment

Patient selection for an IMT is critical. The ideal candidate is someone with end-stage disease and stable vision who is unlikely to need any further intravitreal injections because, once the telescope is in place, evaluating the macula is more difficult, said Baruch D. Kuppermann, MD, PhD, professor of ophthalmology and chief of the retina service at the University of California, Irvine. "This is in line with the clinical trial exclusion criteria, which required subjects to have no active wet AMD nor treatment of wet AMD in the previous six months," said Allen W. Hill, president and CEO of VisionCare. "Trial patients all had stable end-stage AMD—bilateral, nonfoveal sparing disciform scars or geographic atrophy." Henry L. Hudson, MD, lead author for one of the IMT trial reports¹ and retina specialist at Retina Centers in Tucson, Ariz., also considered a few other factors when selecting patients



for the IMT trials:

Screening for good outcomes. "I screened 68 people to get 25," said Dr. Hudson, who said that some other clinicians subsequently adopted the additional constraint he imposed—using a simple mathematical concept based on ocular dominance. "Your telescopic refraction in the treated eye has to exceed the nontelescopic refraction in the other eye by a meaningful amount—a minimum of five letters," said Dr. Hudson. "We have to drive your brain to use the telescopic eye so you get enough of a benefit. Then your bad eye becomes your good eye and your good eye becomes your ambulatory eye, which preserves the maximum ambulatory vision, untelescoped, coupled with a very significant visual gain telescoped. Then you have a happy patient."

Patient motivation. Dr. Hudson also emphasized that motivation is critically important because patients will need to jump over a series of

For part one of this story on the implantable miniature telescope, see www.eyenetmagazine.org and refer to the January issue.

hurdles throughout the process. This involves evaluation by multiple people, completion of a survey to determine their candidacy, and assessment of their willingness to do the postsurgical work necessary to achieve a result that's better than whatever they're currently achieving with low vision aids. "The best candidates are exactly what you would expect—people who have been using low vision aids and continue to use their eccentric viewing skills to function," said Dr. Hudson. "They continue to write their own checks. They might have a reading machine or a series of magnifiers that allow them to read large-print books. They make an effort to use their eyes as opposed to those who let their daughters or sons write all their checks and take them to the market."

A certain degree of optimism and psychosocial health is helpful, added Dr. Kuppermann, who found that his patients with more buoyant personalities seemed to fare better following the IMT trials.

Lylas G. Mogk, MD, director of the Visual Rehabilitation and Research Centers at the Henry Ford Health System in Detroit, agrees that candidates for IMT must actively participate in the process for it to be successful. "They can't be someone who just wants the surgeon to put it in and be done." Along with other low vision experts, Dr. Mogk helped develop, at VisionCare's request, a training manual to help systemize assessment and postsurgical rehabilitation.

Patient goals, abilities, needs. After a patient has expressed interest in the procedure, he or she should receive a low vision evaluation, and then be referred to an occupational therapist, said Dr. Mogk. The patient's balance, mobility and rehabilitation needs are all evaluated to increase the chances for success. "If the patient says, 'I want to drive and play tennis,' that's a goal that's not consistent with the implant," said Dr. Mogk. The goals need to line up with what the implant can provide them, she said.

Simulation screening. Ophthalmologists can consider each individual's

capacity to respond to the IMT based on a special simulation that involves a baseball-sized, handheld, external monocular telescope with a magnification and field of view similar to the telescope implant. This mimics what a patient can see once the telescopic device is implanted, including whether they may be able to see faces and specific contrast sensitivity factors. "We hope this can help health care providers assist patients in developing realistic expectations," said Mr. Hill. This presurgical "bionic boot camp" is a valuable adjunct to the assessment process, Dr. Hudson said.

After Surgery, More Work to Do

Because of the larger incision required, patients heal more slowly following this procedure than they do after standard cataract surgery. After about three weeks of recovery, they're still seen by the surgeon once or twice a year to check for any problems.

After surgery, patients participate in a structured vision rehabilitation program to maximize their ability to perform daily activities. They will see low vision optometrists and occupational therapists regularly for three months, said Dr. Mogk. "This new technology is of great interest to surgeons. So one of the benefits is that it brings to light the need for rehabilitation for all patients, not just for those who get the IMT. It raises awareness that people with low vision can do a lot with appropriate rehabilitation; it can greatly enhance their quality of life."

Making the Most of Monovision

Education and motivation are critical to the success of the telescopic device, which requires that patients adjust to an unusual type of monovision, said Dr. Kuppermann. "Using contact lenses—one for near vision and one for far—is trivial compared with this type of monovision," he said, which is harder to adapt to, particularly for older patients who may be grappling with extra physical and mental challenges.

Dr. Mogk said that seeing everything larger with one eye takes some getting used to but is doable for many

people. Patients may tolerate it at three months and be greatly improved at six months. "By about a year, they should have it down," she said, adding that it's largely a matter of consistent practice. "But a lot also depends on their general health and enthusiasm and incentive."

Training is an extended process.

Rehabilitation involves learning to do tasks at different distances, such as reading up close or playing a card game at arm's length, said Dr. Mogk. Some tasks require eye-hand coordination, others require patient mobility. So a patient might first practice sitting still and scanning still objects, then watch moving objects. The next steps might involve moving while watching a still object, then walking while fixating on moving objects.

Training starts with simple tasks and gradually builds skills by adding more complexity with a wide range of activities such as cooking or shopping. "This parallels what you might do in usual vision rehabilitation," said Dr. Mogk. But the strategies used are a little different because the telescope is inside, rather than outside, the eye.

Dr. Hudson emphasized that periodic refresher courses with the low vision specialist can help maximize results. "Some clearly use it and then stop using it," he said, "so we then put them through their paces and they start using it again."

Ancillary aids necessary. The telescope implant is used for both distance vision activities and near vision activities, the latter requiring standard near-add spectacles to focus on near materials like newspapers or cell phone pads.

Most patients will need additional low vision aids to complement the implanted telescope for more detailed tasks like reading prescription or nutrition information labels. They might need something portable for reading finer print and something different for smaller detail activities where they also need their hands free. "No specific low vision device does everything, which is sometimes difficult for patients to grasp," said Dr. Mogk. "They're used to glasses or contacts solving the problem."

The Patient Experience

Following the IMT trials, said Dr. Kuppermann, some study patients never adjusted to the tunnel vision effects of the telescoped eye, or they felt that the enhanced central view didn't justify their loss of peripheral vision in that eye. However, many have done very well. "Before surgery, one patient, an avid card player, had to hold cards right up to his face and stare intently for a prolonged time at the card," said Dr. Kuppermann. "Eventually he could tell me what was on the card. But after the implant, he could do it as fast as I could flip each card."

Dr. Hudson also described three patients who traveled "on their own nickel" to testify before the FDA in favor of the IMT. One spoke of identifying nieces, nephews and cousins in photos for the first time in 15 years. Another started painting again. A third—who was only at one week postop—watched from her car as her great-grandson dropped a ball at home plate.

"The telescope implant is a home run for three reasons," said Dr. Hudson. "One, it gives you a three- to four-line gain. Two, the IMT will be a covered service, thereby minimizing patient costs. Three, you'll provide a value-added service for a patient population that's been neglected." Integrating this into your practice, he said, allows you to better serve the community.

"At the end of the day," said Dr. Kuppermann, "our hope is that the need for this will be limited, that with retinal regeneration, whenever that day arrives, we'll be able to grow new retinas and have them back to 20/20 vision functionality without the need for telescopes. But, until that day comes, we're dependent upon drugs, devices and rehabilitation to improve the quality of our patients' lives."

Drs. Hudson, Lane and Mogk are paid consultants to VisionCare but have no financial interests in the IMT. Dr. Kuppermann served as a clinical investigator in the IMT trial.

1 Hudson, H. L. et al. *Ophthalmology* 2006; 113:1987–2001.

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