National Horizon Scanning Unit
Horizon scanning prioritising summary

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Implantable Miniature Telescope for the treatment of age-related macular degeneration

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ENQUIRIES ABOUT THE CONTENT OF THIS SUMMARY SHOULD BE DIRECTED TO:

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PRIORITISING SUMMARY

REGISTER ID: 000192

NAME OF TECHNOLOGY: IMPLANTABLE MINIATURE TELESCOPE

PURPOSE AND TARGET GROUP: IMPLANTABLE TELESCOPE FOR THE TREATMENT OF AGE-RELATED MACULAR DEGENERATION

STAGE OF DEVELOPMENT (IN AUSTRALIA):

- ☑ Yet to emerge
- ☐ Experimental
- ☐ Investigational
- ☐ Nearly established

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- ☐ Yes
- ☑ No
- ☐ Not applicable

INTERNATIONAL UTILISATION:

<table>
<thead>
<tr>
<th>COUNTRY</th>
<th>LEVEL OF USE</th>
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<td>Trials Underway or Completed</td>
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IMPACT SUMMARY:

This prioritising summary investigates the effectiveness of the Implantable Miniature Telescope, manufactured by VisionCare Ophthalmic Technologies, for the treatment of advanced age-related macular degeneration.

BACKGROUND

The Implantable Miniature Telescope (IMT) is designed to be a permanent solution for patients with advanced age-related macular degeneration (AMD). Advanced AMD is characterised by irreversible damage to the macula, or central retina, and an associated deterioration in central vision. Daily activities requiring detailed central vision, such as reading, watching television and recognising faces, become particularly difficult for people with advanced AMD. While central vision can be blurred or even missing, the peripheral vision of AMD patients generally remains intact. AMD can affect one or both eyes, and the disease can progress slowly or rapidly.
There are two distinct types of AMD, a dry or nonexudative form (geographic atrophy) and a wet or exudative form (neovascular). In the dry form of AMD, yellow deposits known as drusen form under the retina, interfering with the macula’s cell metabolism and ability to process waste. In the early stage of dry AMD, often referred to as age-related maculopathy, vision is generally unaffected and people are unlikely to know they have the condition. As the disease progresses however, the number of drusen under the retina increase and central vision slowly begins to deteriorate. Dry AMD can also progress to the more aggressive wet form of the disease. The wet form of AMD occurs when abnormal blood vessels develop behind the macula, the process often referred to as choroidal neovascularisation (CNV). The newly formed vessels are very fragile and can easily leak fluid and blood, leading to scar formation and permanent damage to the macula. Central vision can become distorted or entirely lost within a short period of time. Although the wet form of AMD is far less common than the dry form, it is responsible for the majority of cases of blindness or severe vision loss resulting from AMD (AIHW, 2005). Wet AMD has also been associated with increased depression, increased dependency and accidents, and an overall decrease in quality of life (Williams et al 1998; Tolman et al 2005).

Designed for patients with advanced dry and wet stage AMD, the IMT is a prosthetic telescope device measuring 4.4mm in length and weighing 46.1mg in an aqueous environment. The device is implanted behind the pupil in the posterior chamber of one eye during an outpatient surgical procedure that takes approximately 45 minutes. Once implanted, the IMT together with the cornea functions as a telephoto lens, providing three times magnification on the retina. The implanted eye provides central vision, while the non-implanted eye provides peripheral vision for orientation. A structured vision rehabilitation program is recommended for patients following surgery to help them adjust to the unequal images in the two eyes.

CLINICAL NEED AND BURDEN OF DISEASE

In 2004, a total of 147,000 Australians over the age of 55 years were estimated to have advanced AMD, a prevalence rate among this group of 3.1 per cent. A further 491,900 Australians over the age of 55 years were estimated to have age-related maculopathy (early stage AMD), bringing the total number of older Australians affected by AMD to 638,900. Although the prevalence of advanced AMD in older Australians is not high relative to other diseases of the eye, it is easily the most common cause of blindness. In 2004, 56100 Australians over the age of 55 years were estimated to be blind, with AMD accounting for just over 50 per cent of this number (AIHW 2005).

The most significant risk factor for AMD is age. The disease rarely affects people under the age of 50, and incidence rates increase with age. In Australia in 2004, 67 per cent of patients with advanced AMD were 80 years of age or older (AIHW 2005). Other notable risk factors for AMD include family history, hypertension and smoking (Klein et al 2004; Mitchell et al 2002).

DIFFUSION

VisionCare Ophthalmic Technologies, the company responsible for developing and marketing the IMT, has just completed a phase II/III trial demonstrating the effectiveness of the device. At this stage however, the company has not received regulatory approval from the FDA to market the device.

COMPARATORS

A variety of external visual aids are currently available to patients with advanced dry or wet stage AMD, including high plus lenses and external telescopes. Similar to the IMT, these devices use
magnification to increase the size of the image on the retina. High plus lenses have the
disadvantage of a very short focal length, making them inappropriate for a large number of visual
tasks. External telescopes are generally cumbersome and cosmetically unappealing, and the visual
field they offer is severely restricted (5 to 10 degrees, compared to 36 degrees for the IMT).
Patients can also experience nausea when using external telescopes because of the vestibular
ocular reflex conflict caused by the need to scan the visual field using head movement rather than
natural eye movement (Peli 2002).

A number of non-optical treatments for AMD have also been developed. Photodynamic therapy,
approved by the FDA in 2000, has shown success in preventing further deterioration of vision in
patients with wet AMD. Unfortunately the treatment is expensive, difficult to access and is only
appropriate for patients with early stage wet AMD. In 2004, the FDA approved Macugen
(pegaptanib sodium injection) for the treatment of early stage wet AMD. Macugen is a vascular
endothelial growth factor inhibitor that attacks the vascular growth and leakage responsible for
vision loss in wet AMD. While Macugen may be effective in preventing further vision loss, it has
not been shown to improve visual acuity in patients. Furthermore, it only has a short-term effect
and must be re-administered every six weeks.

**Effectiveness and Safety Issues**

An early phase I study by Lane et al (2004) (level IV intervention evidence) evaluated the safety
and effectiveness of the IMT in a group of 13 patients with advanced dry and wet stage AMD. All
patients were 60 years of age or older (mean age 80 years), with best-corrected visual acuity
(BCVA) between 20/80 and 20/400 in both eyes. At 12 months, ten of the 13 patients who
underwent surgery gained two or more lines of either distance or near BCVA, while eight of 13
gained three or more lines. Mean endothelial cell density decreased by 13 per cent after 12
months, indicating that the corneal endothelium tolerated the procedure well. Finally, all adverse
events in the study were resolved with appropriate corticosteroid treatment.

In a similar study, Alió et al (2004) (level IV intervention evidence) assessed the safety and
effectiveness of the IMT in 40 patients suffering from advanced dry stage AMD. In the study,
patients were 60 years or older (mean age 77.1 years), with BCVA in the implanted eye between
20/80 and 20/200, and BCVA in the fellow eye of 20/80 or worse. In the operated eye, mean
uncorrected visual acuity (UCVA) from a distance improved from 0.9 logMAR (minimum angle
of resolution) prior to the operation to 0.6 logMAR 12 months later (p<0.001). Similarly, near
UCVA in the operated eye improved from 0.8 logMAR prior to operation to 0.4 logMAR one
year later (p=0.01). Few complications were reported during the course of the study. Seven
patients developed persistent complications in the form of persistent capsular opacification (n=4),
synechias (n=2) and fibrin deposition on the pupil (n=1).

VisionCare Ophthalmic Technologies recently released twelve month results of their multicentre
study (level IV intervention evidence) in which the IMT was implanted in 206 patients with
advanced dry and wet stage AMD (VisionCare, 2006). In the study, patients had a mean age of 76
years and reported moderate to severe levels of visual impairment prior to implantation, with
BCVA ranging between 20/80 and 20/800 in both eyes. Twelve months after IMT implantation,
patients demonstrated a mean improvement in the study eye of over three lines in both distance
and near BCVA. Preservation of vision was achieved in 95 per cent of patients (exceeding the
protocol-specified target of 90 per cent). Significant improvements in vision related quality of life
were also reported. Patients improved significantly from baseline (range 7-14 points, p<0.01) in
seven of eight vision-specific and psychosocial subscales of the National Eye Institute Visual
Function Questionnaire. Finally, mean endothelial cell density had decreased by 25 per cent at 12
months (protocol-specified target 17 per cent). Although two-year safety surveillance is now complete, results are yet to be published.

**COST IMPACT**

The specific cost of the IMT is yet to be determined. In addition to the device itself, the implantation procedure and associated rehabilitation would attract further costs. The implantation of the IMT is performed under local anaesthetic in an outpatient cataract surgery procedure that takes approximately 45 minutes. Following surgery, patients are encouraged to see a rehabilitation specialist for at least a month to help them adjust to the unequal images in the two eyes.

**ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS**

No issues were identified/raised in the sources examined.

**OTHER ISSUES**

No issues were identified/raised in the sources examined.

**CONCLUSION:**

AMD is the leading cause of blindness amongst older Australians. Patients affected by AMD, particularly its wet form, often experience difficulties performing daily activities that require detailed central vision. AMD has been associated with increased depression, increased dependency, and an overall decrease in quality of life. Given the extensive burden of the disease and the lack of current treatment alternatives, the implantable miniature telescope offers significant health benefits for patients with advanced AMD. The case series results reported by VisionCare Ophthalmic Technologies provide limited evidence for the effectiveness of the IMT, however questions remain regarding the long-term safety of the device, its overall cost impact and the timeliness of its availability in Australia.

**HEALTHPACT ACTION:**

Currently the evidence for the effectiveness of the implantable miniature telescope is questionable. Given the extensive burden of disease and lack of alternative treatment options, it is recommended that the technology be monitored.

**SOURCES OF FURTHER INFORMATION:**


**List of Studies Included**

Total number of studies

Level IV evidence

3

**Search Criteria to be used:**

- Macular Degeneration/diagnosis/*rehabilitation
- Lens Implantation, Intraocular/*methods
- Macular Degeneration
- Visual Fields
- Blindness/etiology/psychology

**Appendix**

20/20 vision is a term used to describe normal distance vision. The ‘20’ represents a distance of 20 feet, the standard testing distance used by optometrists. In metric countries such as Australia vision may be described as 6/6, where the six represents 6 metres. If an individual is described as having 20/40 vision, then that person must stand at 20 feet to see what a person with normal vision can see at 40 feet. 20/200 vision is the cut off for legal blindness. Conversely, an individual with 20/10 vision has above normal vision (Optometrist Australia, 2003).