



## **North East Treatment Advisory Group**

Intraocular telescope by VisionCare™  
for age-related macular degeneration

William Horsley  
©NETAG, October 2012

## Summary

The intraocular telescope from VisionCare™ is a miniature device which is implanted into the eye and is used to improve vision in patients with advanced age-related macular degeneration. The telescope is implanted into only one eye of suitable patients during a procedure that takes about 45 to 60 minutes.

The implant projects a magnified image onto the retina which leads to a gain in visual acuity. However this gain comes at the expense of peripheral vision which is substantially reduced in the implanted eye. Patients are required to undergo visual rehabilitation and training to adapt to using the implanted eye for central vision, both near and distance, and using the non-implanted eye primarily for peripheral vision. Spectacles for simple refractive error are usually still required by patients.

The VisionCare™ intraocular telescope has been evaluated in one large study in which the non-implanted eye acted as the control. Outcomes with up to two-year follow-up have been published, and up to five-years follow-up has been made available for this appraisal. The evidence demonstrates that implanted eyes have statistically and clinically significant gains in visual acuity and quality-of-life measures.

The VisionCare™ intraocular telescope is associated with a relatively low rate of adverse events and patient selection criteria have since been updated to reflect experience gained in clinical studies. A small number of patients do not adapt to the resulting differences in visual function between their implanted and non-implanted eyes and there were a small number of device removals in clinical studies. However a more rigorous patient selection process may reduce this rate in practice. Patients will require post-implantation visual rehabilitation and training to adapt to the implant and this is provided at no charge by VisionCare™.

Each VisionCare™ intraocular telescope implant costs £10,000. Associated clinical costs including pre- and post-operative assessment and the implant procedure are estimated at about £3,000 per implant therefore the total cost is estimated at about £13,000 per implant. Patients will still require spectacles for simple refractive error and a proportion of patients may still require use of low vision aids. The alternative for many patients would be continued low-vision therapy consisting of specific low-vision aids and rehabilitation, estimated at about £160 per patient per year.

The patient population has been estimated at up to 80 patients per annum within NHS North East, although a provider trust has stated that initial use would be limited and reviewed after 24 patients had received an implant.

The intraocular telescope has demonstrated significant and substantial benefits in terms of visual acuity however total visual function is made up of other factors such as contrast sensitivity, colour perception, visual field, and depth perception amongst others. The intraocular telescope has demonstrated significant benefits in overall vision-specific quality-of-life measures with 12-month's follow-up.

## Introduction

Macular degeneration is an eye disorder that affects central vision. If it occurs later in life, it is described as age-related. Age-related macular degeneration (AMD) is the commonest cause of irreversible blindness in industrialised countries. It is associated with degeneration of the macula, the small area at the centre of the retina responsible for central vision and appreciation of fine detail and colour. There are two main types of AMD the most common of which is atrophic or 'dry' macular degeneration. Dry AMD is characterised by thinning of the macular retina. It develops slowly, causing a gradual loss in central vision. The other type is neovascular or 'wet' AMD which is characterised by the growth of new blood vessels behind the retina causing retinal bleeding and scarring. The onset and disease progression in wet AMD is much faster than in dry AMD. Both types of AMD usually affect both eyes, although one may be affected before the other. Dry AMD can also progress to the more aggressive wet form of the disease. 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. <sup>1,2</sup>

Patients with dry or wet AMD may benefit from optical aids such as magnifying glasses for reading and other tasks involving fine detail. Treatment options for wet AMD depend on the disease subtype and the location of lesions in the central part of the macula. More commonly used treatment options for wet AMD include laser photocoagulation, photodynamic therapy and intravitreal injections of anti-vascular endothelial growth factor agents. All these treatments may require several treatment and follow-up episodes. Less common treatment options for wet AMD include thermotherapy, macular translocation surgery and radiotherapy. There is currently no treatment for dry AMD. <sup>1</sup>

A variety of external visual aids are available for patients with advanced dry or wet AMD. These include high-plus lenses and external telescopes or binoculars. These devices use magnification to increase the size of the image on the retina. High-plus lenses have the disadvantage of a short focal length making them inappropriate for a large number of visual tasks. External telescopes and binoculars are generally cumbersome, cosmetically unappealing, and provide a very narrow visual field. Patients may also experience nausea with external telescopes because of the need to scan the visual field using head movements rather than natural eye movement. <sup>2</sup>

The intraocular telescope (IT) from VisionCare is a miniature prosthetic telescope device designed for patients with advanced dry or wet AMD. It measures about 4½ mm in length and weighs about 60 mg *in situ*. It 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 IT and the cornea together function as a telephoto lens providing 2.7 times magnification on the retina. The implanted eye provides enhanced central vision while the non-implanted eye provides peripheral vision for orientation. A structured visual-rehabilitation program is

recommended for patients following surgery to help them adjust to unequal images in their eyes.<sup>2</sup>

Other intraocular lens devices are also approved in Europe. The IOL-VIP system (Veni Vedi) uses two separate lens implants in the same eye to redirect slightly magnified images to an undamaged part of the retina.<sup>3,4</sup> Like the VisionCare IT, the Lipshitz macular implant (OptoLight Vision Technology) also provides telescopic magnification but, it is claimed, without impairing peripheral vision in the implanted eye.<sup>5</sup>

The NHS North East Treatment Advisory Group has been requested by a member organisation to conduct an appraisal and cost analysis of, and issue a recommendation for, the VisionCare IT for use within its approved indication in the treatment of AMD.

NICE issued interventional procedure guidance regarding 'implantation of miniature lens systems for advanced age-related macular degeneration' in August 2008.<sup>6</sup> The accompanying evidence overview prepared in January 2008, included details of only five studies of which three related specifically to the VisionCare device.<sup>1</sup> This appraisal report is intended to serve as an update the NICE appraisal with the addition of a cost analysis.

NICE interventional procedure guidance number 272: Implantation of miniature lens systems for advanced age-related macular degeneration (August 2008)<sup>6</sup>

1.1 Evidence on the efficacy of implantation of miniature lens systems for advanced age-related macular degeneration (AMD) shows that the procedure can improve both vision and quality of life in the short term. Short-term safety data are available for limited numbers of patients. There is currently insufficient long-term evidence on both efficacy and safety. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake implantation of miniature lens systems for advanced AMD should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand the need to adapt to having a lens system implanted into one eye, the risk of early complications and the uncertainties about long-term efficacy and safety. They should provide clear information. In addition, the use of the Institute's information for patients is recommended.
- Audit and review clinical outcomes of all patients having implantation of miniature lens systems for advanced AMD.

1.3 Patient selection is crucial and should include detailed assessment to predict the patient's ability to process visual stimuli following the operation.

1.4 Further publication of safety and efficacy outcomes would be useful, specifically with regard to longer term follow-up. The Institute may review the procedure upon publication of further evidence.

## Clinical evidence and safety

The principal source of evidence for the VisionCare IT, and indeed the largest published study of any of the implantable lens devices for AMD, is the population first described by Hudson et al in 2006.<sup>7</sup> The one-year results of this study (n = 206) are described in the NICE evidence overview of 2008.<sup>1</sup> The two-year results were published after the NICE guidance was published and these are summarised here.<sup>8</sup>

Data is available from 174 eye-pairs of 188 available patients.<sup>8</sup> The missing data (n = 32) were mainly attributed to a loss-to-follow-up (n = 13) and death (n = 10). Eight patients had the device removed consisting of two device failures, two cases of corneal oedema, and four patient requests; three reported glare in bright light and the other reported reduced peripheral vision and depth perception.

The patient cohort received one of two different VisionCare IT devices which varied in the level of magnification provided, with one providing 2.2 and the other 2.7 times magnification; 56% of the cohort received the less powerful IT which is not commercially available. Reported outcomes are mean values for the entire patient cohort unless otherwise indicated. Visual acuity was measured according to the best corrected visual acuity achieved on a standard sight chart. Differences are between the untreated eye at baseline without the use of low vision aids and the implanted eye at the specified time point.

Mean BCVA improvement at two years was 2.8 lines with the 2.2 magnifier model and 3.6 lines with the 2.7 magnifier model (overall mean about 3.1 lines). Untreated eyes demonstrated a two-year mean BCVA improvement of 0.5 lines.<sup>8</sup> These results are similar to those achieved at one-year, where BCVA improvement was between 3 and 3.5 with IT and between 0.5 and 2.0 in untreated eyes depending on distance or near measurement respectively.<sup>7</sup> At two years 60% of IT eyes had gained three or more lines compared with 10% of untreated eyes, the corresponding figures for gains of two or more lines were 75% and 20% respectively. The proportion of eyes with deterioration in BCVA was significantly greater in untreated vs. IT eyes. No new major safety events occurred during the second year post-implant. Second-year events included four new cases of inflammatory deposits on device and three new cases of pigment deposits on device. Overall, there appeared to be few new adverse events in year two compared with the first 12 months following implantation. A particular concern of implant surgery is loss of epithelial cells in the cornea leading to corneal wasting or erosion. The rate of cell loss had stabilised between one and two years, increasing from a mean of 25% to 27% in IT eyes. Eyes with pre-existing structural abnormalities (specifically corneal guttae) demonstrated significantly greater and progressive endothelial cell loss to about 40% at two years compared with non-guttae eyes. Other potential predictive factors were investigated and demonstrated weak or absent associations.<sup>8</sup>

An earlier study of the VisionCare IT, described as a phase one study, involved 15 patients and reports 12-month results.<sup>9</sup> Intriguingly this study is not reported in the NICE evidence overview of 2008. All patients had visual impairment due to AMD and received the 2.7 times magnifier device, except one patient for whom surgery was aborted due to intraoperative complications associated with simultaneous cataract removal. 12-month outcomes are available for 13 patients with the missing patient due to unrelated fatality. Six patients experienced a near BCVA gain of  $\geq 2$  lines and seven patients experienced a distance BCVA gain  $\geq 2$  lines; three patients experienced near and distance BCVA gains of  $\geq 2$  lines. Mean epithelial cell loss was 13% (range; loss of 46% to gain of 15%). The dominant adverse event was inflammatory reactions including six of the 14 patients developing late onset ( $> 1$  month post-implant) inflammation. All cases resolved with topical steroid applications.<sup>9</sup>

No additional primary clinical research was identified however outcomes from the pivotal IT study beyond two years have been made available by VisionCare.<sup>10</sup> The data extends to follow-up of up to five years, although the number of patients still under observation decreases over time. Longer-term outcomes are summarised in table 1.

**Table 1.** Visual acuity (distance) outcomes in implanted eyes beyond two years.<sup>10</sup>

Outcomes at end of year:		Three	Four	Five
Participants (efficacy):		74	96	6
BCVA gain (lines)	$\geq 6$	2	7	1
	$\geq 5$	11	9	1
	$\geq 4$	26	27	2
	$\geq 3$	39	46	4
	$\geq 2$	51	65	5
	$\geq 1$	63	75	5
No change		9	17	1
BCVA loss (lines)	$> 2$	2	4	0
	$> 3$	2	4	0
	$> 4$	1	4	0
	$> 5$	0	2	0
	$> 6$	0	0	0
Mean change (lines)		2.74	2.48	3.57

Quality-of-life outcomes were reported for the pivotal IT study population at 12 months.<sup>7</sup> These results were summarised within the NICE evidence overview<sup>1</sup> and additional details have been provided for this appraisal by VisionCare.<sup>10</sup> The primary quality-of-life measure used was the (American) National Eye Institute 25-item visual function questionnaire (VFQ-25). The VFQ-25 has a range of 0 to 100 points with higher scores indicating better visual function. The minimum clinically significant change is 5 points.<sup>11</sup> At 12 months (n = 193) 52% (n = 100) of patients had demonstrated a change of  $\geq 5$  points, 26% (n = 50) had a change of between -5 and +5 points (i.e. no clinically significant change) and 22% (n = 43) had a loss of  $\geq 5$  points. The mean change in VFQ-25 was 6.0 points (95% confidence interval 4.0 to 8.1). The greatest gains and those with a lower 95% confidence limit of  $\geq 5$  points were seen in scores relating to dependency, near activities, mental health, and general vision.<sup>10</sup> A measure of overall health status showed a modest decrease over 12 months potentially indicating the underlying health state of a generally elderly and morbid patient population.<sup>1,7,10</sup>

Safety outcomes are extensively reported at up to five years in the same unpublished report from VisionCare.<sup>10</sup> These demonstrate twelve device removals; eight due to patient dissatisfaction at between 10 and 41 months, two device failures (condensation ingress) both at 1 month, and two patients who went on to have corneal transplants. In addition to the 12 post-operative removals, there were eight peri- or intra- operative removals two of which were due to device failure.

## Cost analysis

All costs include VAT at 20% where applicable, unless otherwise stated.

Each VisionCare IT device costs £10,000.<sup>12</sup> In addition to the cost of the device there will be a specific admission required for the device to be implanted. The manufacturer has indicated<sup>12</sup> that the device would be implanted according to the payment-by-results tariff code BZ02Z 'phacoemulsification cataract extraction and lens implant'.<sup>13</sup> This code has a cost of £748 for a day case admission<sup>13</sup> although the manufacturer has assumed an uplift factor of 2 to 3 fold to allow for the extra surgical time involved and therefore estimates an admission cost of between £1,500 and £2,250.<sup>12,14,15</sup> One identified potential NHS provider within NHS North East has indicated a procedure cost of £2,100 based on an approximate three-fold multiplier of the relevant 2012-13 payment-by-results tariff.<sup>16</sup> For the purpose of this analysis the procedure cost is assumed to be £2,100 per implant as indicated by the NHS provider. Therefore the total cost of implant plus procedure is estimated at £12,100.

A number of pre- and post-operative appointments may also be required although it is not clear whether all of these would be in addition to routine care for patients with pre-existing severe vision impairment due to AMD. The manufacturer states that patients will require two additional pre-operative appointments for selection and evaluation purposes.<sup>15</sup> The manufacturer also states that patients will require six post-operative check-up appointments; four follow-up and two refraction (optometric) visits although it may be possible to combine some of these appointments.<sup>15</sup> Each appointment can be assumed to fall under an outpatient follow-up tariff of about £65 so that total ex-operative appointment costs are estimated to be up to £520 depending on the actual number of appointments.<sup>13</sup> The identified potential NHS provider within NHS North East has estimated that the cost of two pre-operative assessment appointments and six post-operative appointments would cost about £950 per patient.

Specific visual rehabilitation training for patients is provided by VisionCare at no additional cost<sup>15</sup> and it is assumed that this is utilised. However if VisionCare is not used for providing visual rehabilitation then an additional cost for the provision of this service will need to be considered.

Therefore the total cost of the implant including the device, procedure and pre- and post-operative care is estimated at about £13,000, based on the stated costs of provision from one NHS North East provider.

The alternative management strategy for patients with low vision is assumed to consist primarily of low vision rehabilitation and aids such as portable magnifying lenses and in-the-spectacle lens adaptations.<sup>2</sup> Multiple low-vision aids may be provided to a single patient and devices may require periodic replacement due to wear, loss, or change in requirements. The cost of individual devices will likely vary substantially depending on the nature of the device and its source. It is possible that some or all of these costs will be met privately. VisionCare estimate that the cost of

low vision aids is £271 per patient per annum with up to half of untreated patients requiring low vision aids.<sup>14</sup> A NHS Health Technology Assessment report of anti-VEGF treatments for neovascular (wet) AMD published in 2008 used a value of £150 per patient for low-vision aids and £259 per patient for low-vision rehabilitation based on the cost of occupational therapy (both 2005 prices).<sup>16</sup> Based on full uptake of low-vision rehabilitation and a subsequent uptake rate of  $\frac{1}{3}$  for low-vision aids, the mean cost of provision of low-vision therapy is estimated at £309 per patient. The HTA report also assumes that low-vision therapy may need repeating every two years, therefore the mean cost of low-vision therapy is estimated at £155 per patient per annum (£159 adjusted for inflation from 2005 to 2012).<sup>17</sup> Therefore the mean cost of low-vision therapy will be assumed to be £160 per patient per annum. It is not clear what proportion, if any, of IT-treated patients would also still require post-implant low-vision therapy. VisionCare estimates that 30% of patients who have had an IT implant will still require use of low-vision aids compared with 47% of untreated patients.<sup>14</sup> For the purpose of this analysis a liberal assumption of nil low-vision therapy following IT implant will be assumed.

Over a ten-year period low-vision care with an IT implant is conservatively estimated to cost about £13,000<sup>16</sup> per patient at a mean cost of £1,300 per patient per annum over the period. Over the same period the estimated cost of low-vision therapy is £1,600 at a mean cost of £160 per patient per annum. Therefore the incremental cost of an IT implant compared with low-vision therapy is conservatively estimated at £11,400 over ten years.

The life expectancy of adults at age 65 years in England and Wales is about 84 years.<sup>19</sup> In the pivotal IT study the mean age of participants was about 75 years.

Other costs could potentially be offset against the cost of the IT. A detailed cost effectiveness model provided by VisionCare includes off-set costs relating to reduced levels of nursing home care, (social services) home care, falls resulting in injury and hip replacement surgery, and other types of care. Utilisation rates are based on differences between patients with low vision and normalised vision. The model estimates that 47% of patients will use low vision aids, which reduces to 30% for IT implanted patients.<sup>14</sup>

The cost-effectiveness model provided by VisionCare estimates 780 new annual incident cases of late AMD cases suitable for IT implant within NHS North East, and similarly a prevalent population of 2,808 patients.<sup>14</sup> From this patient population it is estimated that there would be 166 implantations per annum. As stated previously, the model includes assumptions concerning health and social care outcomes and utilisation rates dependent on whether or not an IT has been implanted and the inferred level of visual function. These outcomes include, for example, injurious falls with and without hip fracture, depression, cataract surgery, nursing home care, home care, and use of low vision aids. Lower rates of health and social care outcomes and use are assumed for the cohort of patients implanted with an IT, for example the rate of injurious falls requiring hip replacement is reduced from 5% to 3%, and the rate of

patients requiring nursing home care is reduced from 10% to 5%. Although the specific rates in the base case are referenced it is not entirely clear from the source data exactly how the effects of the implant were estimated. Taking all of these direct and indirect health care costs into account the model estimates first-year costs of £37,800 in non-implant patients and £48,500 for IT-implanted patients, a difference of £10,700. For subsequent years the model estimates annual treatment costs of £36,600 per non-implant patients and £33,600 per IT-implanted patients, a difference of £3,000 per annum. Therefore the additional cost of an IT in year one would be recouped within five years of the procedure. The majority of cost savings attributed to the IT arise from 'home care' (i.e. social care services) and 'nursing home care' accounting for 56% and 33% of the actual difference respectively. The actual reductions modelled for these measures are from 90% to 60% and from 10% to 5% respectively, applicable to all patients in the respective cohorts. Although the data sources of the assumptions are referenced the magnitude of the effect of having an IT implant on individual components is less clear and it is not known on what basis these reductions have been assumed. It would appear that outcomes are inferred from assumed visual function under each treatment option.<sup>14</sup>

A published cost-effectiveness analysis provides absolute and incremental cost per quality-adjusted life-year values although from the perspective of an American healthcare service.<sup>20</sup> Nonetheless, the analysis is still informative and provides a number of relevant sensitivity analyses. Using an exchange rate of \$3 to £2 (approximately correct as of August 2012) the device and procedure costs are similar to those stated for the UK in this analysis. A range of other costs are included which wouldn't be entirely relevant to a UK-oriented analysis although the net effect of these is small as the overall implantation cost is heavily dominated by the cost of the IT device. The overall implantation cost is stated as about £12,200 compared with an estimated £13,000 for the UK, which indicates a good level of agreement in the main component of the cost. The efficacy of the IT within the analysis was based on the outcomes of the pivotal study which relied upon a comparison against untreated eyes and not against eyes managed with low-vision therapy.<sup>7</sup> The model included all relevant outcomes including the reversion rate and used an estimated lifetime of 12 years from date of implant, which could be considered generous. Offset costs included savings due to decreased incidence or prevalence of depression, injury, nursing care, nursing-home care, and a large contingency for unidentified costs associated with vision loss. Numerous scenarios are generated with the base case incremental cost per QALY estimated at £9,400. Only one alternative scenario yielded an incremental cost per QALY > £20,000 and this assumed a 50% loss of vision in the untreated eye between years 3 to 12 (incremental cost per QALY £22,000).<sup>20</sup>

Overall, there are deficiencies in the cost models<sup>14,20</sup> which diminish their relevance to NHS North East. In particular the comparator in both analyses appears to be untreated eyes and not eyes which are managed using low-vision therapy. The cost-effectiveness of the IT compared with the current standard of care has not been demonstrated.

## Points to consider

A single human eye typically has a field of view of about 155°. <sup>21</sup> The field of view provided by the IT is much reduced and is typically between 20° and 24°. <sup>10</sup> However, as the telescope is only implanted into one eye the brain can learn to compensate with the untreated eye providing peripheral vision and the implanted eye being used primarily for central vision. Visual training and rehabilitation is required to enable patients to achieve satisfactory overall binocular vision.

Studies of the VisionCare IT have focused primarily on visual acuity, which is an important but not sole component of overall functional vision. Also important to overall functional vision are contrast sensitivity, colour perception, visual field, and depth perception amongst others. <sup>22</sup> Even broader outcomes include the assessment of a patient's orientation and mobility in space, especially the areas of daily living and, where applicable, work environments. <sup>22</sup> Finally, a measure of a patient's overall quality-of-life is also important, <sup>22</sup> and indeed this has been demonstrated with the VisionCare IT device.

The IT has demonstrated clinically important efficacy in a range of outcomes for a large proportion of treated eyes however all comparisons were made against untreated eyes and not against eyes or patients managed with use of low vision aids. Therefore the incremental benefit of the IT over current management strategies, which will consist primarily of low vision aids, has not been demonstrated.

The IT may deliver several attendant health and social benefits from improved visual function which could potentially result in significant off-set savings from both health and social budgets. However these effects have not been directly demonstrated with the IT and it is still not clear whether patients managing their visual function using low vision aids would also achieve these outcomes.

The main safety concern is epithelial cell loss; device contraindications have been updated to reflect the clinical evidence in this respect. The rate of device failure or removal is relatively low and an enhanced screening programme has been designed to reduce the number of patients who opt for device removal.

The IT is a costly treatment estimated to be at least £13,000 per patient when procedure, device and follow-up costs are included. Patients will require spectacles to obtain maximum benefit and visual rehabilitation to manage the disparity in visual function between eyes. The alternative treatment is to manage patients using low vision therapies consisting of ophthalmic aids and rehabilitation estimated at about £160 per patient per annum.

The cost of low-vision therapy over ten years is estimated at £1,600 per patient. Therefore the incremental cost of an IT is about £11,500 over ten years. It may take many years before the initial treatments costs are recouped through attendant reduced healthcare consumption, if indeed there is any reduction, compared with low-vision therapy.

An NHS North East provider service has modified the standard VisionCare IT eligibility criteria and estimated that this would limit treatment to a maximum of 80 patients within NHS North East in any given year. In addition, the service provider has indicated their intention to audit and reappraise the treatment after 24 IT implants have been performed. Significant changes to the criteria include only selecting patients if they have not gained sufficient or significant benefit (undefined) with low vision aids and rehabilitation and patients who have a life expectancy which is not limited by severe diagnosed comorbidity. <sup>16</sup>

Guidelines from the Royal College of Ophthalmologists (2009) regarding age-related macular degeneration state that, for the management of non-neovascular (i.e. dry) AMD, 'treatment ... is limited and consists mainly of counselling and rehabilitation'. <sup>23</sup>

**Author's declaration:** The author has participated in advisory boards and other non-promotional meetings and events for the manufacturer of a leading medicinal product licensed for the treatment of (wet) AMD.

## References

1. National Institute for Health and Clinical Excellence. Interventional procedure overview of implantation of lens systems for advanced age-related macular degeneration. IP375, January 2008
2. Australian and New Zealand Horizon Scanning Network. Implantable miniature telescope for the treatment of age-related macular degeneration. National Horizon Scanning Unit Horizon Scanning Prioritising Summary 2006;13(3)
3. [www.veni-vidi.co.uk](http://www.veni-vidi.co.uk) Accessed August 2012
4. IOL-VIP patient information leaflet 'A new treatment for age-related macular degeneration: The IOL-Vip System'. Date unknown. Downloaded August 2012
5. <http://optolight.net/home> Accessed August 2012
6. National Institute for Health and Clinical Excellence. Interventional procedure guidance 272: Implantation of miniature lens systems for advanced age-related macular degeneration. August 2008
7. Hudson HL et al. Implantable miniature telescope for the treatment of visual acuity loss resulting from end-stage age-related macular degeneration: 1-year results. *Ophthalmology* 2006;113:1987-2001
8. Hudson HL et al. Implantable telescope for end-stage age-related macular degeneration: Long-term visual acuity and safety outcomes. *American Journal of Ophthalmology* 2008;146:664-73.
9. Lane SS et al. A prospective multicentre clinical trial to evaluate the safety and effectiveness of the implantable miniature telescope. *American Journal of Ophthalmology* 2004;137:993-1001
10. VisionCare Ophthalmic Technologies. VisionCare's implantable miniature telescope: Professional use information. Ref 060110.
11. Mangione CM et al. Development of the 25-item National Eye Institute visual function questionnaire. *Archives of Ophthalmology* 2001;119:1050-8
12. Personal communication, VisionCare (UK), August 2012
13. Department of Health. Payment by results tariff 2012-13. [www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_132654](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_132654)
14. VisionCare (UK). CentraSight™ treatment utilising the telescope implant, for end-stage age-related macular degeneration: Economic modelling to estimate financial impact of treatment on local health and social care. July 2012
15. VisionCare (UK). Implantable telescope technology for the treatment of end-stage age-related macular degeneration (AMD): Business case for NHS commissioners. August 2012.
16. Private communication, October 2012.
17. Colquitt JL et al. Ranibizumab and pegaptanib for the treatment of age-related macular degeneration: a systematic review and economic evaluation. *Health Technology Assessment* 2008;12(16)
18. Office for National Statistics. Consumer prices indices. [www.ons.gov.uk/ons/rel/cpi/consumer-price-indices/january-2012/cpi-time-series-data.html](http://www.ons.gov.uk/ons/rel/cpi/consumer-price-indices/january-2012/cpi-time-series-data.html) (medical services)
19. Office for National Statistics. Life expectancy by local areas in the United Kingdom, 2007-2009 - Results for England and Wales. [www.ons.gov.uk/ons/rel/subnational-health4/life-expec-at-birth-age-65/2007-2009/results-for-england-and-wales.xls](http://www.ons.gov.uk/ons/rel/subnational-health4/life-expec-at-birth-age-65/2007-2009/results-for-england-and-wales.xls)
20. Brown GC et al. Comparative effectiveness and cost-effectiveness of the implantable miniature telescope. *Ophthalmology* 2011;118:1834-43
21. Spector RH. Visual fields. Chapter 116 in: *Clinical methods: The history, physical, and laboratory examinations*. 3<sup>rd</sup> edition, Walker HK, Hall WD, Hurst JW (editors). Butterworths, Boston, 1990
22. Lepri BP. Is acuity enough? Other considerations in clinical investigations of visual prostheses. *Journal of Neural Engineering* 2009;6:035003
23. Royal College of Ophthalmologists. Age-related macular degeneration: Guidelines for management. RCO, London, 2009