Argus II™ Retinal Prosthesis System for peripheral retinal degeneration

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**The Argus™ II Retinal Prosthesis System** is an artificial vision restoration system designed for patients with severe sight impairment due to peripheral retinal degeneration, such as in *retinitis pigmentosa*. It includes an implant designed to sit on the surface of the retina and stimulate the healthy cells of the retina. The implant receives information from a patient-worn video processing unit, which in turn receives signals from a miniature video camera housed in a pair of glasses. By learning how to interpret these signals, patients may potentially be able to continue using visual cues to guide their activities and maintain independent living for longer.

**Background**

Peripheral retinal degeneration is present in many retinal diseases, by far the most common of which is *retinitis pigmentosa*, a group of degenerative diseases usually caused by a wide variety of genetic mutations. These diseases all affect the layer of the retina containing cells called photoreceptors, which convert the light entering the eye into electrical signals that are sent to the brain. These cells are lost (leaving behind dark pigment deposits) as the disease progresses. The cells in the peripheral (outer) retina are usually affected before, and more severely than, those in the centre. Early in the disease, patients usually experience difficulties seeing in low-light conditions, have sensitivity to light and difficulty adjusting between different light levels. Later in life, most people experience loss of peripheral vision. Much later, some people experience loss of central vision in daylight conditions. In most cases the disease takes several decades to progress to profound loss of sight, though this can vary greatly between individuals. The loss of peripheral vision can greatly diminish an individual’s ability to live independently as walking or driving safely can be very difficult and the later stages of *retinitis pigmentosa* often leave patients with only a very narrow field of vision. Complications include cataracts (clouding of the lens) and macular oedema (excess fluid and protein in the central retina). In 20-30% of patients *retinitis pigmentosa* may be part of a syndrome which includes other symptoms such as deafness and renal disease.

There are an estimated 20-25 people with *retinitis pigmentosa* per 100,000 individuals in England and Wales, which equates to 11,000-13,750 people. In a study of 1,000 *retinitis pigmentosa* patients over the age of 45, 25% had a visual acuity of 2/200 or worse, 12% had a visual acuity of “count fingers or worse” and 0.5% had no light perception at all in both eyes. One commercial estimate is that there will be approximately 1,000 patients with severe sight impairment (2 patients per 100,000 individuals) in England who would be eligible for a retinal implant such as the one described here.
Current Practice

There is currently no treatment for retinitis pigmentosa, retinal degeneration or for severe sight impairment, though sometimes attempts are made to slow down the degeneration process through the use of dark glasses and vitamin A and E supplements. To manage light sensitivity, the use of yellow-orange glasses and lateral protection of the eyes from light is sometimes used. Treatment of complications such as cataracts, macular oedema and inflammation may offer some improvement in quality of life, as may learning Braille, improving social support, the use of guide dogs or a white cane. The Argus II Retinal Prosthesis System is the first commercially available retinal device for this condition, although others are in development.

New Technology

The Argus II Retinal Prosthesis System by Second Sight Medical Products Inc is designed for the treatment of severe sight impairment in patients with peripheral retinal degeneration and the implant component is implanted surgically in the back of the eye. It is intended for adults 25 years and over with some residual light perception or ability to respond to electrical stimulation of the retina; with functioning optic nerves and visual cortex (the part of the brain that processes visual information) and with a previous history of useful vision.

A miniature video camera housed within a pair of special glasses captures images which are sent to a small video processing unit that is worn by the patient. The video is converted into signals which are sent back to the glasses via a cable and transmitted wirelessly to a receiver in an implant sitting on the surface of the retina. The signals are then sent to a 60 electrode array which emits small pulses of electricity to stimulate the healthy photoreceptor cells in the retina. These stimulate the optic nerve to the brain, causing the perception of patterns of light which patients may learn to interpret and use in their daily lives.

The Argus II Retinal Prosthesis System was CE marked in February 2011 and the company anticipate launch in two UK centres in late 2011-early 2012. The cost of the device is estimated to be £66,000 excluding VAT. Additional costs estimated by the company include £6,200 for surgery and £3,600 for clinical follow-up.

Clinical Studies and Research Questions

A prospective, open-label study of 26 retinitis pigmentosa patients and 1 patient with chorioideremia (published results to date) using the Argus II Retinal Prosthesis System is in progress. Results have been presented in a journal article, a conference paper and several conference abstracts.

Patients who had bare-light vision and no recordable visual acuity (worse than 20/15887) prior to implantation of the device, were asked to perform a task locating a square on a screen. Feedback enabled the patients to improve their performance of this task. Of 27 patients, 26 showed significantly better improvement task completion with the device switched on, than with it switched off (and the glasses removed) (p<0.05).

Results from other tasks performed by the first 17 patients who had been implanted with this device (6 months prior to testing) were also published. In a task locating a door in a room, the proportion of times any part of the door was located was 59% with the device switched on and 32% with it switched off. When walking along a
20ft line, 44% of patients finished the task on the line with the device switched on (26% with it switched off).

Adverse event data from the product insert is detailed below and data from a subset of these patients have been published previously. Of 30 patients followed up for 6-32 months (average 18 months), 4 experienced erosion of the conjunctiva, or a reopening of the surgical cut, requiring explantation of the device in one case, surgical intervention in one case and stitches in two cases. Surgery was required for three cases of hypotony (lowered eye pressure) and two cases of retinal detachment. Two patients required the device to be reattached with a stitch and five patients underwent elective revision surgery. One small retinal tear required laser treatment and there were three cases of endophthalmitis (inflammation of the main cavity of the eye) or undefined severe inflammation which required antibiotics or steroids. Ten patients had conjunctival congestion, one required medication. The company also reports a wide range of non-serious adverse events in up to 25% of patients. There were more adverse events reported in those enrolled earlier in the trial and the company states that surgical techniques and design of the device were improved as the trial progressed.

Other tests of vision for the same group of patients were reported in abstracts at conference. Trials of an earlier, 16 electrode array version of the device (Argus16 Retinal Prosthesis System) are also available.

More data on the effectiveness of this device, including on independent mobility, falls and accidents are needed to determine the extent of benefits for patients. Longer-term collection of adverse event data is awaited.

**Potential Impact**

The Argus™ II Retinal Prosthesis System may offer benefits to patients with peripheral retinal degeneration, who currently have no treatment options. If the device proves to be safe and effective, it may provide a way for patients to maintain their independence, employment and mobility for longer. The cost to the NHS of the device plus surgery exceeds £75,000. Additional costs will include the training needed for surgeons to implant this device, probably in specialist centres. Healthcare professionals may also require support to train the patient in its use. Major benefits are likely to be societal, with public sector savings largely among social care and support services.

**References**


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