The Argus II™ retinal implant

English summary
This is the English summary of the guidance entitled L'implant rétinien Argus IIMC published in February 2019.

The complete version of this guidance (in French) is available on the website of INESSS in the Publications section.

Membres de l’équipe de projet

Auteures principales
Sylvie Arbour, Ph. D.
Sara Beha, M. Sc.
Julie Nieminen, Ph. D.

Collaborateurs internes
Olivier Demers-Payette, Ph. D.
Isabelle Ganache, Ph. D.
Karen Médina, M.D.
Geneviève Plamondon, M. Sc.

Coordonnateur scientifique
Yannick Auclair, Ph. D.

Directrice
Michèle de Guise, M.D., FRCPC

Repérage d'information scientifique
Caroline Dion, M.B.S.I., *bibli. prof.*
Mathieu Plamondon, M.S.I.
Lysane St-Amour, M.B.S.I.
Julien Chevrier, M.S.I.
Flavie Jouandon, *tech. doc.*

Gestion de l'information
Michèle Paré, M. Sc.
Mike Benigeri, Ph. D.

Soutien administratif
Christine Lemire
SUMMARY

Introduction
Retinitis pigmentosa (RP) is a rare hereditary disease that causes progressive degeneration of the photosensitive cells in the retina, which leads to profound visual impairment and, potentially, blindness. Currently, there is no treatment available for slowing the natural progression of the disease or restoring lost vision. Visual aids and rehabilitation services are patients’ only options. However, the development of retinal prosthesis system technology could restore some of the lost vision, this by means of an implant inserted on, under or in the retina. The Argus II™ retinal prosthesis (AIIRP; Second Sight Medical Products, Inc., California, United States) is currently the only retinal prosthesis system approved by Health Canada (2014). The field of retinal implants (RIs) is evolving rapidly, and many similar technologies are presently being developed and could be available in the near future.

The AIIRP is a system consisting of portable external components, namely, a pair of glasses fitted with a camera and a video processing unit (VPU), as well as a surgically implanted component on the retina (epiretinal implant). Data captured by the camera is transmitted to the electrode array by way of the VPU and stimulates retinal cells that are still active. This visual information is transmitted to the brain where it is perceived as patterns of light by the user. Since the system transmits different stimuli from those usually transmitted by a healthy eye, patients must learn to interpret them before regaining a certain level of visual functionality. Consequently, a 4-month postoperative rehabilitation period is essential and involves a multidisciplinary team of experts. The AIIRP is indicated for persons with severe to profound peripheral retinal degeneration who are left with little or no light perception.

In Québec, the CIUSSS de l'Est-de-l'Île-de-Montréal and the CISSS de la Montérégie-Centre have acquired the know-how for surgically installing retinal implants and for the rehabilitation involved, thanks to the few implementations that have been performed up to this point.

Mandate
INESSS was mandated by the Ministère de la Santé et des Services sociaux to assess the relevance of making the AIIRP available to patients with severe to profound peripheral retinal degeneration.

Methods
INESSS conducted a systematic review of the scientific literature to assess the efficacy, safety and efficiency of the AIIRP and its impact on the quality of life of implanted patients. This search was supplemented by a review of the grey literature. Contextual and experiential data were gathered from the stakeholders through committees and by means of questionnaires and individual interviews.
An economic model aimed at determining the AIIRP’s cost-utility in the Québécois context was developed. An analysis of the potential budget impact covering a 3-year period was performed as well.

Results

Most of the available data on the AIIRP are from one *single-arm* prospective, multicentre study involving 30 subjects that was sponsored by the manufacturer. The other two studies identified were case studies involving 6 and 11 subjects.

**Efficacy**

No standardized measure for evaluating visual function in patients with very low vision is available. The main results of interest for evaluating the efficacy of the AIIRP therefore include grating visual acuity (VA) measurements and tests aimed at determining visual function, orientation and mobility. The following results, which were obtained at 5 years, were reported:

- 38.1% of the subjects (8/21) had a VA of 1.6 to 2.9 logMAR\(^1\).
- The AIIRP also enabled 80.9% and 50.0% of subjects to better perform when visual functions were tested, namely object localization and detection of motion, respectively.
- Slightly more than 50% of the subjects were able to find a door and to follow a line while their device was on compared to a success rate of approximately 20% when it was off.

However, it is not possible to confirm the AIIRP was able to provide users with a real functional gain because most of the tests were carried out in a controlled environment. According to some of the experts consulted, the tests chosen served more to evaluate the abilities of the technology than the gains that patients might derive from it on a daily basis.

**Safety**

The results obtained 5 years post-implantation show frequent adverse events during the first 2 years. Nonetheless, most of them can be treated with current ophthalmic approaches. There were three explantations of the retinal prosthesis during the study. Additional data will be needed to assess the AIIRP’s long-term safety.

**Quality of life**

Very few data on the impact of the AIIRP on patients’ quality of life are currently available. Furthermore, there are very few tools for assessing the quality of life of people with very low vision. According to the currently available data, the AIIRP has a limited impact on patients’ quality of life.

---

\(^1\) Logarithm of the minimum angle of resolution.
**Patient perspective**

At the current stage of development of this technology, the few patients consulted expressed little interest in it. According to some, the gains in vision provided are not enough to have a real impact on their autonomy or quality of life.

**Efficiency**

The cost of this technology is approximately $196,000 at implantation, with an additional annual cost of $15,000. The average annual cost of usual care for RP is estimated at $4,900. Given the absence of demonstrated benefits, the AIIRP cannot be considered efficient.

**Potential budget impact**

According to INESSS’s estimates, the 3-year budget impact of the AIIRP on the health-care system for a potential 9 RP patients would be an additional cost of $1.8 million.

**Ethical considerations**

Different ethical and social considerations relevant to retinal implants in general were raised. For instance, the risk of short-term and long-term adverse events, patient selection and the importance of informed decision making bring various ethical principles into play. Furthermore, the fact that the surgery and rehabilitation services are centralized in the Montréal area could make it difficult for certain patients and their families to access this technology.

**Conclusions**

The findings of this evaluation indicate that, although promising, the AIIRP has certainly not achieved a sufficient level of maturity to be offered in a clinical program. A more robust demonstration of the scientific evidence, especially with regard to the improvement in the quality of life of implanted patients, is needed.

**INESSS’s RECOMMENDATION**

| **Given the available data, INESSS concludes that public coverage of the ARGUS II™ epiretinal prosthesis is not a fair and reasonable option. Further data are required in order to support the inclusion of this technology** |

| **INESSS’s RECOMMENDATION** |

| **Given the available data, INESSS concludes that public coverage of the ARGUS II™ epiretinal prosthesis is not a fair and reasonable option. Further data are required in order to support the inclusion of this technology** |