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Assessing the Efficacy of Artificial Vision in Advanced Retinitis Pigmentosa - A Systematic Meta-analysis

Sama Elzambily[1], Malek Telal Ahmed[2], Hosam A. Ibrahim Elzembely[3]

[1]*Saint Louis University (Orcid: 0009-0005-6006-2005)*

[2]*Minia University (Orcid: 0000-0002-5500-3458)*

[3]*Minia University (Orcid: 0000-0001-7836-3475)*

Corresponding Author: Hosam A. Ibrahim Elzembely, Minia University.

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Abstract

Introduction: Retinitis pigmentosa (RP) is a hereditary degenerative eye disorder characterized by progressive retinal degeneration, leading to symptoms such as night blindness, peripheral vision loss, and, ultimately, complete vision impairment.

Study design: a literature review and systematic meta-analysis

Aim of the study: to address the effects of artificial vision on visual functions in patients with severe retinitis pigmentosa in comparison to other treatment modalities (Medical and Gene therapy).

Methods: Eligibility criteria of were established prior to the screening process. Studies were included if they were peer-reviewed articles, clinical trials, systematic reviews, or meta-analyses that focused on RP and artificial vision devices such as the Argus I and Argus II systems or other retinal prostheses.

Conclusion: conventional methods of treating Retinitis Pigmentosa are ineffective in dealing with optic nerve atrophy or outer retinal dysfunction due to advanced Retinitis Pigmentosa. Artificial vision is the only known way to improve vision in such patients although the degree of improvement is not huge, nevertheless, this is only the beginning of a vast field of research that carries tremendous potential for the treatment of such a group of patients.

Artificial vision is unique compared to conventional or common methods for treating Retinitis Pigmentosa. It stems its peculiarity from the fact that it is dealing with a stage of Retinitis Pigmentosa in which all other methods stand helpless.

Introduction

Retinitis pigmentosa (RP) is a hereditary degenerative eye disorder characterized by progressive retinal degeneration, leading to symptoms such as night blindness, peripheral vision loss, and, ultimately, complete vision impairment. With a prevalence of approximately 1 in 4,000 individuals, RP presents significant challenges in both diagnosis and treatment.[1-3] This systematic review aims to explore the current landscape of RP management. RP is a multifaceted condition associated with a range of genetic mutations and variable phenotypic presentations. Despite extensive research, definitive treatment options remain limited. The strategic approach to addressing RP encompasses three key temporal frameworks:

1. Prevention and early detection, emphasizing genetic research to curtail transmission within affected families and utilizing advanced imaging techniques for timely diagnosis.
2. Management of the disease and exploration of novel therapeutic interventions aimed at decelerating the progression of the disorder.
3. Addressing the sequelae of advanced RP stages by implementing solutions for visual impairments, particularly through symptom management approaches such as low vision aids.

Ongoing advancements in gene therapy hold promise for future interventions; however, the inherent complexity and genetic heterogeneity of RP pose significant hurdles to successful therapeutic outcomes. Recent innovations in artificial vision technologies,

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specifically retinal prostheses, demonstrate potential in restoring visual function for RP patients. Nonetheless, comprehensive understanding of AV application and its implications for vision recovery remains incomplete. The full review will encompass an in-depth analysis of existing literature, highlighting the need for continued research in both therapeutic strategies and technological innovation to improve the lives of those impacted by this debilitating disorder. Therefore, This systematic review aims to focus on disease progression and the emerging role of artificial vision (AV) technologies in enhancing visual outcomes and synthesize available evidence on artificial vision technologies in the management of retinitis pigmentosa, specifically evaluating retinal prostheses such as Argus I/II, Alpha IMS/AMS, and cortical implants. The review highlights their clinical efficacy, safety, accessibility, and cost-effectiveness, while identifying gaps in knowledge that guide future therapeutic innovation.[4-7]

Aim of the study

This study addresses the research question:

To what extent will artificial vision affect the visual function in patients with severe retinitis pigmentosa, in comparison to other treatment modalities (Medical and Gene therapy)

Literature review of the therapeutic options of Retinitis Pigmentosa:

Retinitis Pigmentosa in its early stages is treated by one of three modalities; ***medical treatment, gene therapy, and artificial vision.*** The aim of any Retinitis Pigmentosa treatment is to preserve the remaining vision as the damage of the optic nerve from Retinitis Pigmentosa is usually ***irreversible.***

Medical Modality:

Vitamin A and lutein are essential nutrients known for their role in maintaining eye health, particularly in relation to Retinitis Pigmentosa (RP). These compounds are believed to slow down the progression of RP by supporting the function of photoreceptor cells in the retina. Vitamin A, in the form of retinol, is crucial for the synthesis of rhodopsin. Lutein, a carotenoid found in high concentrations in the retina, acts as an antioxidant, helping to protect the eyes from oxidative damage. While these nutrients show promise in retarding the effects of RP by promoting overall eye health, it's important to note that they do not offer a complete cure for the condition. RP is a complex genetic disorder, and while nutritional support can be beneficial, it is not a substitute for comprehensive medical management or gene therapies currently under development.[8]

Gene Therapy:

Gene therapy is an evolving field in medicine and ophthalmology that offers potential promise for the treatment of RP. Luxturna is the only approved gene therapy for RP, and it is only authorized for the treatment of a small sub-population of patients who have the RPE65 gene mutation, which represents 0.3–1% of all RP cases.[9] The RPE65 gene is a gene that encodes a protein crucial for proper vision, especially implicated in the visual cycle, turning light into electrical impulses required for both rod and cone-mediated vision.

Researchers are developing a gene therapy that could stop vision loss in people with RP and Usher syndrome. Other gene therapies are also being tested, including RNA antisense oligonucleotide therapy and XLRP gene therapy. RNA antisense oligonucleotide therapy is a therapeutic strategy that employs short DNA or RNA molecules to attach to particular RNA molecules, limiting their capacity to create proteins or function in other ways, and thereby modifying gene expression. — While XLRP gene therapy, is a cutting-edge treatment that uses a modified virus to transfer a normal type of gene into retinal cells, with the goal of slowing or halting the degeneration that leads to vision loss in X-linked retinitis pigmentosa (XLRP), a hereditary illness that causes blindness predominantly in men. — These treatments could help patients avoid debilitating vision loss due to retinitis pigmentosa.[10]

Stem Cell Therapy :

Stem cell therapy for retinitis pigmentosa involves using stem cells to replace damaged or degenerated retinal cells, particularly photoreceptors, which are essential for vision. These stem cells can be derived from various sources, including embryonic stem cells, induced pluripotent stem cells (iPSCs), or adult stem cells. While early-stage clinical trials have shown some promising results, including improvements in visual acuity and light sensitivity in some patients, challenges remain,including : Overcoming immune rejection of transplanted cells ,Ensuring the safety and long-term efficacy of the treatment and Addressing variability in patient response and disease progression.

https://stemcellres.biomedcentral.com/articles/10.1186/s13287-023-03526-x

Artificial Vision:

Artificial vision, also known as retinal prostheses or bionic eyes, is another approach to treating retinitis pigmentosa (RP) by bypassing damaged retinal cells and directly stimulating the remaining healthy cells or the visual processing centers of the brain.

The loss of vision due to the affection of the optic nerve secondary to Retinitis Pigmentosa is ***irreversible***. Ophthalmology has yet to find a way of overcoming said obstacle, though recently, multiple plans have been suggested in order to tackle the issue at hand. Within the recent ideas that have been proposed, stem cell research and artificial vision are two of the emerging fields that deal with Retinitis Pigmentosa.[12]

Artificial Vision (AV): The system

Artificial Vision (AV) proved to be a promising modality in dealing with optic nerve atrophy. Artificial Vision (AV) basically involves a multi-disciplinary approach; A collaboration between biology, biotechnology, electronics, and optics. It simply implies using a camera mounted on a glass frame on the patient's eye, a computer chip inserted under the retina of the patient, and an electrode implanted in the visual area of the brain. Connecting the three components presumably should construct an Artificial Vision (AV) loop that mimics the normal visual pathway.[13] **See Figure 1**

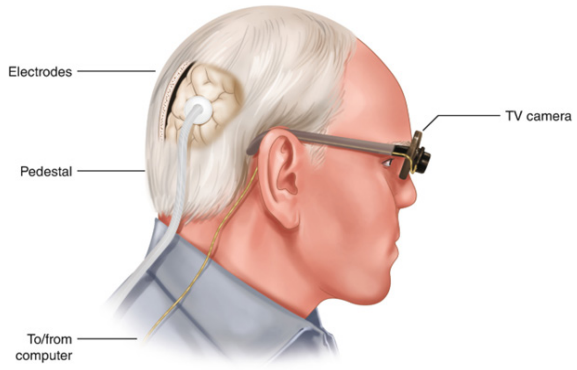

Figure 1: Dobelle cortical visual prosthesis[13]

The two most significant AV systems are Argus I and II, though their success is still guarded and their costs are immense, argus I's cost isn't fully known as it was mainly used for a small number of patients, mainly in clinical trails. Argus II costs $150,000 USD, which does not include surgical and rehabilitation costs, however, argus II is no longer an option since it has been discontinued. Patients may start to see shadows of individuals passing in front of them without the fine details.

The Argus II epiretinal prosthesis is a device that received CE marking which is a certification that allows medical devices to be sold in the European Union and other parts of the world after meeting specific standards set by the EU in 2011 and FDA approval which allows medical equipment to be sold in the United States and exported worldwide after fulfilling severe FDA requirements in 2013. It is the most commonly used retinal prosthesis worldwide, with over 250 patients having it implanted. The system consists of two components: an external part and an implantable part.[15] **See Figure 2**

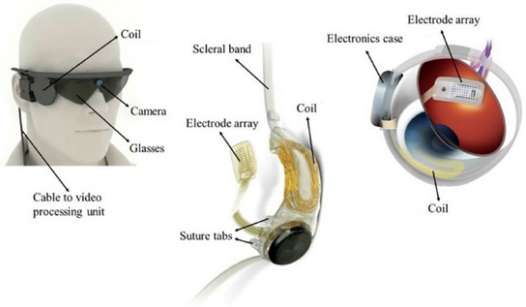

Figure 2: The Argus II Retinal Prosthesis System. Source: Adapted from Second Sight Medical Products, Inc., Sylmar, CA, USA.[15]

The external component includes a glasses-mounted camera connected to a portable visual processing unit. This unit processes the image and sends it to an external communication coil, which transmits power and data wirelessly to a silicone scleral buckle via radiofrequency telemetry. The internal matching coil receives the signal, decodes it, and sends an electrical signal to an intraocular retinal stimulator.[16]

In a phase II multicenter trial that was done by the researchers Yvonne Hsu-Lin Luo, and Lyndon da Cruz in 2015, 30 subjects were implanted with the Argus II to assess safety and effects on visual function. The results showed improved performance on visual tasks when the device was turned on compared to when it was turned off.[17-20] Over a 5-year period, subjects consistently performed better with the device on. The methods used in the assessment of the visual functions or the visual acuity were grating visual function, square localization, direction of movement, orientation, and mobility.[21-22] Grating visual function involves the ability to distinguish the elements of a fine grating composed of alternating dark and light stripes or squares.

Methods

This systematic review was conducted using a structured and transparent approach to identify, evaluate, and synthesize the available evidence on artificial vision technologies for retinitis pigmentosa (RP). A comprehensive literature search was performed across multiple electronic databases, including PubMed, Scopus, and Google Scholar, covering publications from [e.g., 2000–2025]. Keywords and Medical Subject Headings (MeSH) included retinitis pigmentosa, artificial vision, retinal prosthesis, bionic eye, Argus I, Argus II, retinal implant, and vision restoration. Boolean operators (AND, OR) were applied to refine the results and ensure that the search captured all relevant studies.

Eligibility criteria were established prior to the screening process. Studies were included if they were peer-reviewed articles, clinical trials, systematic reviews, or meta-analyses that focused on RP and artificial vision devices such as the Argus I and Argus II systems or other retinal prostheses. Non-English publications, conference abstracts without full text, studies unrelated to artificial vision, and papers focusing exclusively on other retinal diseases were excluded.

The study selection process occurred in two stages. First, titles and abstracts were screened to eliminate irrelevant studies. Second, full texts of potentially eligible papers were reviewed in detail to confirm inclusion. To ensure objectivity, two reviewers independently assessed all studies, and any discrepancies were resolved through discussion and consensus.

Data were then systematically extracted from the included studies using a standardized extraction sheet to maintain consistency and accuracy. The information gathered included study design, sample size, patient demographics, device or technology evaluated, primary outcomes such as visual acuity and functional vision, patient-reported outcomes, complications, and cost-related data. The methods used to assess visual function across the studies commonly involved grating visual function, square localization, direction of movement, orientation, and mobility tests. Grating visual function in particular refers to the ability to distinguish fine alternating patterns of dark and light stripes, providing a reliable measure of spatial resolution.

Because of the heterogeneity in study designs, populations, and reported outcomes, a qualitative synthesis was undertaken rather than a pooled statistical analysis. Extracted data were categorized thematically under mechanisms of action of artificial vision devices, clinical outcomes and patient-reported experiences, limitations and complications, and cost-effectiveness. This structured methodology ensures transparency, reproducibility, and a comprehensive evaluation of the role of artificial vision in the management of RP.

In a systematic review study published at Pub Med in 2021, analyzing the safety and effectiveness of Argus || patients with retinal disability due to retinitis pigmentosa, it showed a 54% significant improvement in detecting the direction of moving objects. This study is a milestone study as it analyzed 926 records from 12 different studies on that subject.[23]

A ten-year follow-up study conducted in 2019 provided significant insights into the efficacy of Argus II implants in patients with retinitis pigmentosa when the device was activated. The study assessed various metrics, including letter reading capabilities, performance on grasping tasks—which simulate real-life scenarios such as picking up objects, opening doors, or sorting items to evaluate the individual's functional use of objects—real-world functional activities, and the perception of distinct color combinations during electrode stimulation. The findings revealed that 24% of participants could accurately recognize a square, while 50% were able to identify a large triangle. Furthermore, 46% of patients demonstrated reading abilities with the device active, compared to 20% who could read when the device was turned on, with no individuals able to read when the device was deactivated. Importantly, 83% of patients completed grasping tasks with enhanced speed and accuracy when the device was ON. Additionally, 100% of participants experienced improvements in their ability to locate and interact with a table setting while using the device. The study also noted that 50% of patients were capable of locating and traversing a doorway, and 60% were able to walk along a marked walkway. Finally, 10% of patients successfully identified at least one color, either red or blue. This comprehensive analysis underscores the potential of the Argus II implant in augmenting visual function and enhancing quality of life for patients affected by retinitis pigmentosa.

Overall, the Argus II has demonstrated positive outcomes in improving visual function for individuals with retinal impairments. [24-29] Furthermore, the Alpha IMS is a subretinal implant that received CE marking in 2013. It consists of a photovoltaic array called a multi photodiode array (MPDA) that converts ambient brightness into an electrical signal. Unlike other similar devices, the Alpha IMS is an active device that amplifies the signal using an external power source.[30]

The implant is connected to an external power supply through a silicone wire that is wrapped under the orbit and connected to a subdermal coil attached to the cranial bone. A detachable external coil magnetically connects to the subdermal coil, allowing for power induction and adjustment of contrast sensitivity and brightness.[31,32]

However, there are some challenges with the placement of the device. The coordination between different surgical teams is required, resulting in longer operating times. Additionally, degeneration of the retinal pigment epithelium (RPE) and retinal adhesion can make it difficult to place the device correctly.[33]

A clinical trial conducted from 2010 to 2014 examined the impact of the Alpha IMS on daily living, mobility, visual function, and object identification. The results varied among participants, with some reporting excellent experiences such as recognizing letters or unknown items, while others reported no improvement at all. Most participants were able to perceive light after the implantation, with improvements in light localization and motion detection.

In 2016, another version of the implant called Alpha AMS gained CE clearance. It is larger and consists of 1600 photodiode complexes. See Figure 3

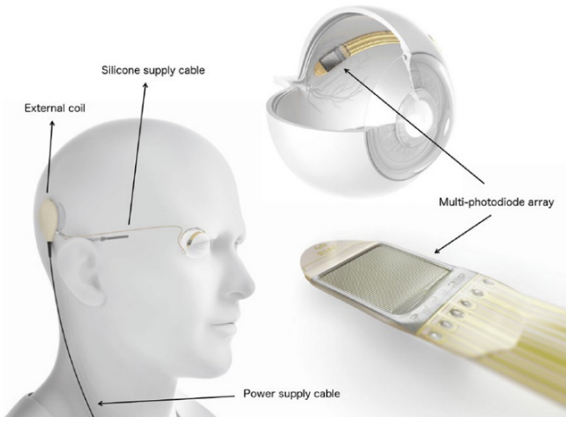

Figure 3: The Retina Implant Alpha AMS System. Source: Adapted from Retina Implant AG, Reutlingen, Germany. [34]

There is a debate whether we should spend the tremendous amounts of funding on research and development (RD) of such technology or halt and look for another innovative idea. The initial research can range from $205 million to $3 billion. [14] When discussing an issue like "blindness," several different perspectives should be addressed. Of course, the long-term effect of AV will be beneficial globally and the countries that circulate it, which requires FDA regulation that can cost as high as $500,000. However, the concern here is how a country can propagate such contemporary technology at a cheap or even medium cost. It's difficult to determine whether a country can achieve such an achievement in the history of science and technology. The cost of launching such a device can range from hundreds of thousands to over $30 million. From a national standpoint, it may be difficult to achieve the particular reason for this circumstance. The costs are now too expensive, and every country may have its priorities at the present time.

Assessing Functional Outcomes for AV Systems

The difficulty in the widespread use of prosthetic retinal devices lies in determining their effectiveness and functionality for patients. Many studies have used performance-based metrics and self-reporting questionnaires to assess the impact of visual characteristics on everyday tasks for visually impaired individuals. Visual function, visual field, and contrast sensitivity have been found to be significant factors in daily visual functioning.[35-39] Simulation studies, in which stimuli are used to elicit a reaction in a subject, can help evaluate the visual requirements for prosthetic systems to ensure suitable picture quality and range of view for relevant activities. A spatial resolution of 3-4 pixels per degree is considered adequate for pointing, manipulation, mobility, and object recognition activities, with even higher resolution needed for reading. [40-43]

While self-reporting and performance-based testing provide some indication of qualitative gain in functional outcomes, there is currently no widely accepted functional outcome measure for persons with ultra-low vision (ULV) whose visual acuity ≤ 20/1600.[44,45] Functional vision tests for ULV should not only be valid, reliable, and repeatable but also have ecological validity, meaning they should correspond to real-world task performance improvement. Additionally, these tests should be responsive to treatment response and allow for the calculation of a quantifiable meaningful difference that indicates useful functional improvement.[46]

Many functional tests have limitations in ecological validity, as they do not mimic real-world settings. Real-world functional assessments also lack a standardized metric for measuring functional benefit across different subjects. One solution is using standardized simulated real-world environments, although this can be costly. Salience maps, which are organized maps that show the visual saliency of a related visual scene by emphasizing locations that are more relevant or conspicuous to the human visual system. These maps can identify the spatial allocation of visual attention towards objects of interest. Simulated tests of picture and face discrimination have shown promising results, with individuals demonstrating an ability to detect prominent characteristics and a learning effect during retesting.

To establish a meaningful metric of functional improvement, the field of restorative visual medicine relies on the validation of a standardized test battery that includes both objective and subjective measurements of visual task performance. It is predicted that this demand will be addressed as more patients with ULV receive new therapies.

Discussion

It's evident from the previous literature review that medical treatment in the form of vitamin A and other nutritional substances may have a beneficial role in retarding the progression of retinitis pigmentosa. Nevertheless, it has never been proven that this medical treatment has an effect on curing the disease.

As regards gene therapy, it has been proven great success in curing, unfortunately, a tiny segment of the disease about 1% of those affected with RP. The future of gene therapy is promising as different forms of gene therapy may arise to cure different forms of RP. Concluding, gene therapy has the potential to treat all kinds of RP but only in mild and

moderate cases. In advanced cases of RP with optic nerve atrophy, gene therapy is constrained as it has no role in bypassing the failure of the outer retinal layers.

For Advanced Retinitis Pigmentosa and outer retinal layer failure, the only option that proved to be viable in such cases is Artificial Vision as proven by many studies starting from the year 1986 till now.[47]

Advanced Retinitis Pigmentosa refers to advanced irreversible damage of the optic nerve fibers, blindness as a result of advanced Retinitis Pigmentosa is incurable. Hence, Artificial Vision technologies are a lighthouse that diffuses some of the darkness caused by optic nerve damage due to progressive Retinitis Pigmentosa.

These technologies, despite their limited success so far, seem to be promising. Tracking the trajectory of these technologies may lead to success within the artificial vision field, with that being said success or enlightenment is considered the ultimate goal for blind patients suffering from optic nerve atrophy (O.N.A). Enlightening in this case is the ultimate goal and the long-waited hope for millions of blind patients due to optic nerve atrophy. This enlightening encompasses the use of both the eye and the brain in an artificial sophisticated connection, such connection would never have been possible without the true enlightening of the scientific revolution.

To summarize, gene therapy will have the upper hand in treating mild and moderate cases of RP while AV will be preserved for severe cases of RP. Medical treatment in the form of vitamin A, antioxidants, and other nutritional substances will probably be available as an adjunctive therapy but never as a main line of treatment. **See table 1**

#	Points of Comparison	Medical Treatment	Gene Therapy	Artificial Vision
1	Suitable for	These compounds are believed to slow down the progression of RP by supporting the function of photoreceptor cells in the retina.	For patients who have the RPE65 gene mutation, which represents 0.3–1% of all RP cases.	All cases of Retinitis Pigmentosa
2	Degree of improvement	slowed the decline of ERG amplitude but did not show a significant difference in visual field area or visual acuity.[48]	All treated Phase 3 study participants improved their functional vision by 93% (27 of 29).[49]	Patients performed significantly better with the Argus II on than off on all visual function tests and functional vision tasks.[50]
3	Source	**(7)**	**(9)**	**(1)**

Table 1: Comparison of Treatment Modalities of Retinitis pigmentosa.

Research methods used in the essay:

Professional scientific resources from the World Wide Web that are specialized in science and medicine, such as PubMed. Keywords such as Retinitis Pigmentosa and retinal prosthesis systems are used in the search.[7]

Evaluation methods:

"There are multiple methods such as:

1. Visual function before and after treatment
2. Optic nerve examination before and after treatment
3. Visual field before and after treatment"

Evaluation

One of this study's major strengths is the utilization of thorough and dependable sources for literature research and data collecting. The use of material from credible sources such as PubMed and the National Eye Institute guaranteed that the study was founded on evidence-based research. These sources are well-known for their contributions to the area of ophthalmology, providing a solid basis for the study's background and bolstering the validity of the findings. Furthermore, using strong, dependable resources improves the research's reputation and helps its overall robustness. By drawing on well-established sources, the study enhances its theoretical framework and offers a strong foundation for investigating the impact of artificial vision on patients with severe retinitis pigmentosa.

Despite the advantages, some constraints limited the scope and complexity of the study. One major constraint was limited access to advanced data analysis tools as the topic is newly discovered. The lack of advanced statistical tools may have limited the intricacy of the data processing and subsequent interpretation. This constraint is noted because it may have influenced the precision and depth of the statistical analysis, thereby reducing the granularity of insights gained from the data. Furthermore, time limits were a significant obstacle. As a result of the study's time constraints, the amount of time allocated to analyzing the effects of artificial vision on retinitis pigmentosa was limited. Given the complexities of the issue, additional time spent on in-depth investigation may have resulted in a more thorough grasp of the intricacies involved in comparing alternative treatment modalities.

In the future, devoting more effort to a detailed analysis of artificial vision's influence on retinitis pigmentosa may have allowed for a more in-depth exploration of the research subject. As a result, it is noted that the study's conclusions may be restricted by the time allotted for in-depth examination. Future study in this area might benefit from a longer time frame to dive deeper into the complexity of the subject.

Risk of Bias (ROB) assessment:

We used a tool called AMSTAR2 which is a measure to assess systematic reviews appraising the methodological quality of systemic reviews. Table 2

Table 2: Shows the risk of bias assessment for meta analysis of two review articles

	PICO	prot ocol	Design Selection	Search Strategy	Study Sele ction	Data Extr action	Excluded Justifi cation	Included Details	RoB Tool Used	Funding (Included Studies)	Statistical Methods	RoB in Meta-Analysis	RoB in Dis cussion	Hetero geneity	publi cations bias	Conflict of Interest
Ostad-Ahmadi et al. (2021)	Yes	Yes	Yes	Yes	Yes	Yes	Partial Yes	Yes	Yes	Yes	N/A	N/A	Yes	Yes	No	Yes
Wu et al. (2023)	No	No	No	No	No	No	No	No	No	No	N/A	N/A	No	N/A	No	Yes

Conclusion

It's proven that all the conventional methods of treating Retinitis Pigmentosa are ineffective in dealing with optic nerve atrophy or outer retinal dysfunction due to advanced Retinitis Pigmentosa. Artificial vision is the only known way to improve vision in such patients although the degree of improvement is not huge, nevertheless, this is only the beginning of a vast field of research that carries tremendous potential for the treatment of such a group of patients.

Artificial vision is unique compared to conventional or common methods for treating Retinitis Pigmentosa. It stems its peculiarity from the fact that it is dealing with a stage of Retinitis Pigmentosa in which all other methods stand helpless. The technology of artificial vision is in its early stages yet it is steadily evolving. It carries the hope for millions of desperate patients with end-stage Retinitis Pigmentosa.

Disclosures

None of the authors has any financial interest related to the subject of research.

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