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Neurovisual rehabilitation of patients with geographic atrophy secondary to age-related macular degeneration with AvDesk system

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Abstract

Purpose: The aim of this study is to evaluate the efficacy of neurovisual rehabilitation using the AvDesk training system (Linari Medical, Pisa, Italy) in patients with geographic atrophy (GA) due to age-related macular degeneration (AMD) in their eye with better visual acuity.

Methods: This study employed a prospective, observational, single-centre case series design. All patients underwent neurovisual rehabilitation using an AvDesk device. The protocol included sessions twice a week for a duration of 3 consecutive weeks. Before and at the end of the protocol, all patients underwent a standardized ophthalmic examination. MAIA microperimeter was used to assess fixation parameters, using bivariate contour ellipse area (BCEA) at both 63% and 95% confidence intervals, and macular sensitivity (MS). Additionally, the NEI-VFQ 25 questionnaire was administered to evaluate the clinical response.

Results: 17 eyes from 17 patients were included in the study. The mean (SD) best-corrected visual acuity (BCVA) at baseline was 0.55 (0.28), improving to 0.39 (0.26) LogMAR ($p = 0.0002$), after completing the training. The mean (SD) MS did not change, ranging from 8.81 (6.08) dß to 8.60 (5.99) dß ($p = 0.30$). Following training, both BCEA 63% and 95% values exhibited a modest reduction, although these changes did not reach statistical significance ($p > 0.05$). Absolute scotomas remained stable (24.41 before treatment vs. 24.65 after treatment; $p = 0.83$). The NEI-VFQ 25 overall score improved from 55.05 to 62.18 post-treatment ($p < 0.01$).

Conclusions: The AvDesk training system is an effective tool for neurovisual rehabilitation in AMD patients with GA, yielding improvements in BCVA, fixation stability and quality of life.

Keywords

RETINA, SOCIOECONOMICS AND EDUCATION IN MEDICINE/OPHTHALMOLOGY, age-Related macular degeneration < RETINA, OPTICS / REFRACTION / INSTRUMENTS, retinal pathology / research < RETINA

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Introduction

Age-related macular degeneration (AMD) is the most common cause of blindness in developed countries, with an estimated prevalence expected to increase to 288 million by 2040.[1,2] Advanced AMD eventually progresses to geographic atrophy (GA), characterized by a progressive degeneration of photoreceptors and retinal pigment epithelium, leading to severe and irreversible loss of visual function.[3,4] Furthermore, difficulty in reading is the most common clinical issue for patients experiencing central vision loss, making it the primary focus for those pursuing visual rehabilitation.[5,6] Despite the recent introduction of new pharmacological approaches,[7,8] the lack of effective treatments to halt functional deterioration has led to a focus on visual rehabilitation strategies. These strategies aim to optimize the residual retinal function and improve the neurovisual response. Research on visual rehabilitation programmes has primarily targeted perceptual learning and eccentric viewing techniques,[9,10] as well as promoting the use of low-vision aids through an integrated and multidisciplinary approach in these patients.[11,12] However, there is currently no established standard for visual rehabilitation in individuals with AMD.

The AvDesk neurovisual training approach has previously been employed to enhance neurovisual performance in various neurological conditions affecting the visual pathways, including visual field defects in patients with epilepsy, stroke, and cerebral tumours, as well as in cases of unilateral spatial neglect.[13–15] Patients with AMD and GA typically experience central visual loss, often accompanied by other visual field defects that interfere with everyday activities such as reading, fixation, and spatial orientation.[16] As a compensatory response, many patients develop preferred retinal loci (PRL) outside the atrophic area to partially restore visual function.[17] Enhancing the efficiency and stability of PRL through AvDesk neurovisual training system could offer functional benefits in this population.. Given this context, we developed a pilot study to explore the feasibility and preliminary efficacy of a tailored AvDesk protocol in AMD patients with GA.

Thus, the aim of the present study is to analyze the effects of an AvDesk protocol designed to improve macular visual function and fixation in AMD patients, with the goal of optimizing both human and economic resources. This study seeks to evaluate the impact of AvDesk neurovisual training in patients with advanced-stage GA due to AMD in their better-seeing eye. The primary goal is to assess the efficacy of this intervention and to determine the extent of measurable improvements in visual function between clinical visits.

Methods

The study design is a prospective single-centre interventional investigation conducted at the Ophthalmological Department of Vita-Salute San Raffaele University. Consecutive patients diagnosed with GA due to AMD were recruited between August 2023 and March 2024. All patients received detailed information about the study objectives and provided informed consent before participation. The study protocol was approved by the Ethical Committee (MIRD2020) of IRCCS San Raffaele Scientific Institute and conformed to the principles outlined in the Declaration of Helsinki.

Patient recruitment and study design

Inclusion criteria were as follows: participants must have a confirmed diagnosis of GA attributable to advanced AMD, defined according to the criteria established by Ferris et al.,[3] without any history of macular neovascularization (MNV); GA was assessed using 30° fundus autofluorescence (FAF) imaging of the posterior pole and quantified with the Heidelberg Region Finder software. It was defined as the presence of unifocal or multifocal areas of sharply demarcated outer retinal atrophy, with at least one lesion measuring $\geq 1.25\ mm^2$,[18] with or without foveal sparing. Moreover partecipants must have best corrected visual acuity (BCVA) ranging from 20/200 to 20/40 Snellen in the better-seeing eye; willingness to actively participate in the study; no prior participation in any visual rehabilitation programme; and documented stability of AMD status for at least 12 months preceding enrolment, specifically showing no significant changes in visual acuity, considering the progressive nature of AMD and the potential for fluctuating visual acuity. Stability of GA during this period was additionally confirmed through FAF imaging, with no evidence of lesion enlargement. The decision to focus on patients with AMD was guided by two primary considerations: firstly, the necessity of establishing a homogeneous study cohort to enhance the robustness of the results; secondly, this population is the most representative in terms of epidemiological data related to central macular disturbances. In addition, participants had to be pseudophakic, as the presence of cataracts could have impacted the training. Exclusion criteria were: concurrent ocular or systemic conditions causing significant visual impairment, as well as advanced joint disorders like arthritis that might interfere with the handling of study devices; use of electronic low-vision aids; medications known to impact retinal development or function; and a previous clinical diagnosis of mental health conditions such as depression.

Before beginning the rehabilitation protocol and at its conclusion, all patients underwent a complete ophthalmic examination. This included assessment of BCVA using Early Treatment Diabetic Retinopathy Study (ETDRS) charts, biomicroscopic examination and microperimetry, performed using the Macular Integrity Assessment (MAIA; CenterVue, Padua, Italy). The final visual tests

were conducted immediately after the completion of the visual rehabilitation, enabling us to attribute the observed changes directly to the therapy and minimizing any bias from the natural progression of the disease.

Furthermore, patients filled out the National Eye Institute Visual Function Questionnaire (NEI-VFQ-25), which is a validated patient-reported outcome measure specifically designed to evaluate visual function in everyday tasks.[19–21] The NEI-VFQ 25 has been validated across various eye conditions, such as AMD, across several countries globally.[22,23]

The primary outcome of the study was the change in BCVA following the training sessions. Secondary outcomes encompassed mean retinal sensitivity (MS) measured via microperimetry, fixation parameters assessed using bivariate contour ellipse area (BCEA) at both 63% and 95% confidence intervals, the incidence of absolute scotomas (defined as MS <0 dß),[24] and responses from the VFQ-25 questionnaire assessing visual function in daily activities.

Avdesk neurovisual rehabilitation and other parameters measured

Upon referral, the patients were initially diagnosed by retinal experts (SDF, MBP and AN), followed by an evaluation from an orthoptist (JB), who then provided training to the patient's better-seeing eye.

The AvDesk training system utilized the AvDesk device (Linari Medical, Pisa, Italy), which employed two lines of 12 horizontally equally spaced RGB LED light stimulations with a 6 mm diameter presented on semicircular panels covering the central 66° of the field of view at a radius of 61 cm. For each pair of LEDs, a sound speaker was installed. In front of the patient, a red LED was illuminated to serve as a fixation point, assisted by an artificial intelligence (AI) with a head and eye tracking system that halted the stimulation sequence when the patient's position was outside the programmed range. The system required patients to initially fixate on the red LED light positioned at the centre of the machine's central panel. Following this, an audio stimulus was presented in conjunction with a corresponding visual stimulus that activated one of the 24 available LED lights. Upon perceiving both stimuli, the system requested the patient to press a button as quickly as possible. Then, this cycle was repeated for a predetermined number of stimuli. Therapy protocols and response data were managed by Linari Medical Cloud platform. The AvDesk protocol consisted of 30-min in-hospital sessions conducted twice a week for three consecutive weeks (Figure 1). Our specific protocol involved two daily consecutive sessions, each comprising 250 light stimulations, totalling 500 stimulations per day. Patients were given a break of less than 5 min between sessions. Before starting the protocol, patients were administered 25 trial spots to ensure optimal cognitive response. The protocol was consistently conducted by the same trained personnel (JB and NA). Although the rehabilitation could be performed at home independently, it was important to clarify that the role of medical professionals in the protocol was limited to conducting ophthalmic examinations, administering questionnaires, and overseeing the procedure. Due to the lack of available literature data, the administration and number of stimulations were determined arbitrarily. All session details, including specific characteristics of the device, were documented in Supplementary Table 1. MAIA microperimetry was conducted using a mesopic 4–2 staircase threshold strategy with achromatic stimuli (400–800 nm). A 68-stimuli pattern was used to cover the central 10° of the macula, allowing for the evaluation of MS. The light intensity ranged from 1 to 0.25 asb, corresponding to a sensitivity range of 0 to 36 dß. Fixation parameters were quantified using the BCEA, representing the ellipsoidal area of the fixation distribution at 63% and 95% BCEA. In addition, absolute scotomas were also evaluated.

Statistical analysis

Analyses were run using Microsoft R Open Version 4.3.1 (R Foundation for Statistical Computing, Vienna, Austria; https://mran.microsoft.com/open) and the add-on package lme4. Continuous variables were described using means, standard deviations, median and IQR, while categorical variables were reported as frequencies and percentages. Statistical analyses were conducted using the Wilcoxon rank-sum test. P-values less than 0.05 were considered statistically significant.

Results

Overall, 24 patients with GA secondary to AMD were recruited for the study. However, the completion rate was 71%, with 17 patients successfully finishing the training protocol. Among the dropout cases, 5 patients cited compliance issues, while 2 patients were excluded due to fixation losses exceeding 20% during microperimetry. Specifically, these 5 patients were unable to attend the scheduled training sessions due to their low visual acuity and insufficient caregiver support.

Mean age (SD) of the 17 patients was 81 (8) years, with 8 (47%) males. Demographic and clinical characteristics of patient are detailed in Table 1. The mean (SD) baseline GA area was 4.01 (5.33) mm^2. The mean (SD) BCVA at baseline was 0.55 (0.28) LogMAR (approximately 20/60 Snellen), which improved to 0.39 (0.26) LogMAR (approximately 20/50 Snellen) after completing the training, with a statistically significant difference ($p = 0.0002$;), as shown in Figure 2.

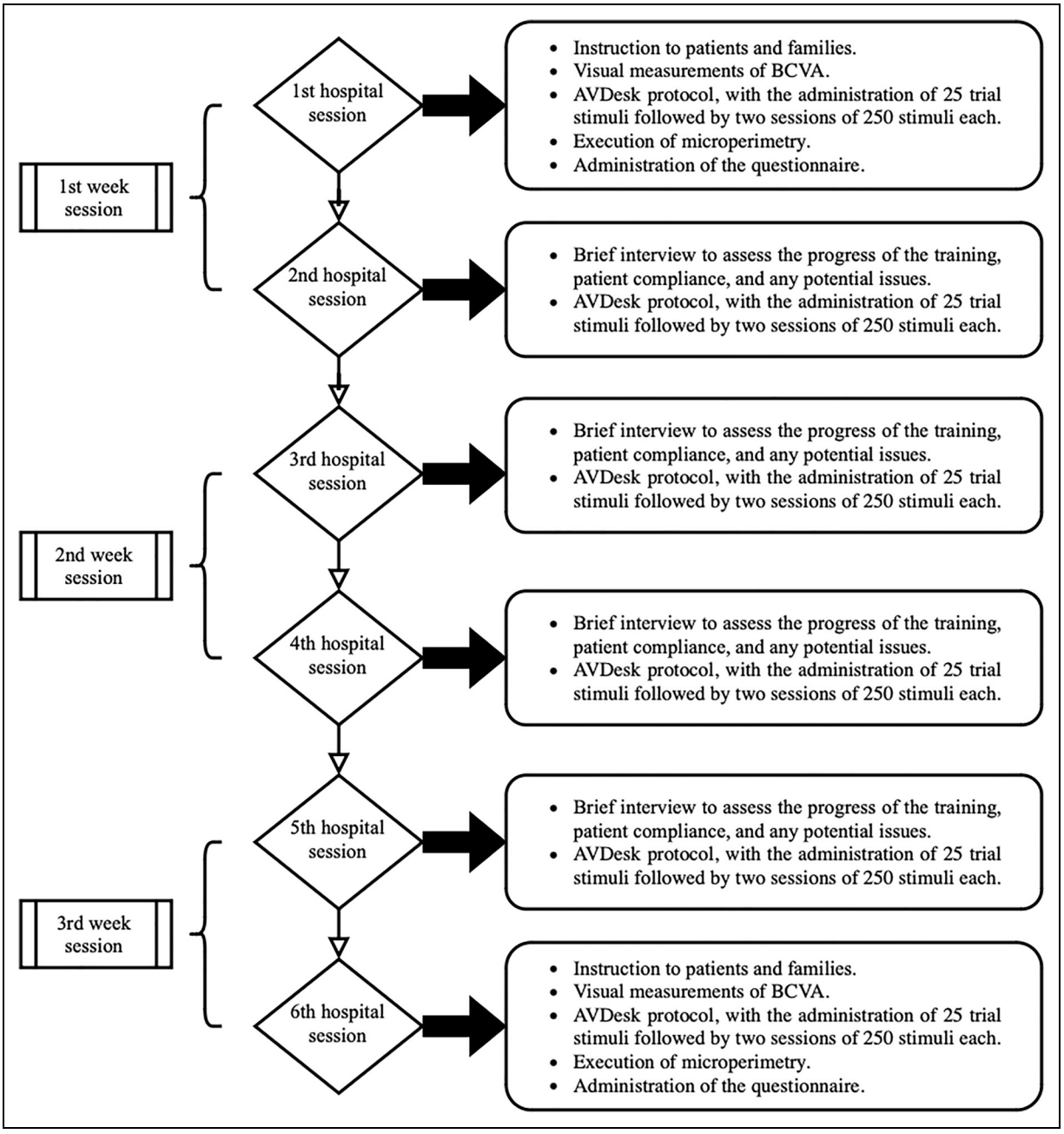

Figure 1. Avdesk protocol diagram. BCVA = Best-corrected visual acuity.

Mean (SD) MS remained stable over the course of the training, with a baseline value of 8.81 (6.08) dB and a post-training value of 8.60 (5.99) dB, showing no statistically significant difference ($p = 0.30$, Figure 3). Similarly, the BCEA 63% exhibited a modest reduction, with the mean (SD) decreasing from 12.72°² (8.73) at baseline to 12.07°² (6.70) after training. A comparable trend was observed for the BCEA 95%, with the mean (SD) decreasing from 38.17°² (26.16) to 36.23°² (20.06). Although none of these changes reached statistical significance ($p = 0.41$ for BCEA 63%, and $p = 0.39$ for BCEA 95%), a stratified analysis revealed a more substantial reduction in eyes presenting with higher baseline values—specifically, those exceeding 15°² for BCEA 63% and 46°² for BCEA 95%.

The mean (SD) number of absolute scotomas remained largely unchanged, with 24 (17) at baseline and 25 (18) at the final examination. Statistical analysis indicated no significant difference in absolute scotomas count ($p = 0.83$). Clinical results are showed in Table 2.

In addition, the mean overall score of NEI-VFQ 25 at baseline was 55.05 and 62.18 after the treatment ($p < 0.01$). All questionnaire results are reported in the Table 3.

Discussion

Neurovisual rehabilitation for patients in the advanced stages of AMD has several significant challenges. Central vision loss due to AMD severely affects visual performance,[17,25] leading patients to develop a PRL in the peripheral unaffected regions of the macula to compensate for their impaired central vision.[16,26,27] However, the PRL is often suboptimal, resulting in unstable fixation and reduced visual efficiency.[28,29] The implications of PRL development on visual perception are not fully understood. Recent research has explored crowding in AMD patients,[30] revealing that the crowding zone shape for targets at the PRL is similar to that of the fovea. This finding suggests possible reorganization at the cortical regions level associated with the PRL, indicating that the visual system retains a degree of plasticity which could be modified through experience.[28] It is well-established that accurate fixation is crucial for detecting object details, typically occurring at the fovea under normal circumstances. The literature suggests that improvement in fixation stability correlates with enhancements in visual capability.[31] Thus, interventions aimed at improving PRL fixation stability could potentially lead to significant gains in visual performance for AMD patients.

Given these insights, AvDesk training rehabilitation shows promising results. Our data indicate that after AvDesk training, improvements in BCVA and BCEA can be obtained. Although there are no published studies yet proving the effectiveness of this device for AMD patients, our results are comparable to those from studies on visual rehabilitation with the MP-1 and MAIA microperimeter. These studies have suggested that patients with AMD, myopic macular degeneration, inherited retinal diseases, and other macular disorders may experience improvements in visual acuity and fixation stability following visual rehabilitation interventions.[31–36] Additionally, we observed that patients with a larger BCEA, which indicates a more unstable fixation, showed greater improvements.. Consequently, if the enhancement of residual vision can be achieved through intensive training that improves neural plasticity, it is more likely to be effective in patients with less advanced stages of the disease. In our study retinal sensitivity did not show any improvement, nor did the number of absolute scotomas. Vingolo et al.[32] reported increased retinal sensitivity in a group of five patients with different macular diseases following microperimetry training. Similarly, Ratra et al.[36] found that 19 patients with various macular diseases experienced improvements retinal sensitivity using an acoustic biofeedback technique. However, the results of the first study are influenced by substantial sampling bias owing to the limited number of participants, whereas the second study faces challenges due to its considerable heterogeneity. According to Sivaprasad et al.,[37] the NEI VFQ-25 has been demonstrated as a reliable and valid tool for assessing the substantial impact of GA on visual function. Our findings are consistent with those of Künzel et al.,[38] who reported a median NEI VFQ-25 composite score of 70. The lower baseline scores in our study

Table 1. Demographic and clinical characteristics of the cohort.

Characteristics	Results
No. of partecipants	17
No. of eyes	17
Race	
Caucasians	100%
Age (yrs)	
Mean (SD)	81.06 (8,05)
Median	82
Sex	
Male	8 (47%)
Female	9 (53%)
Eye laterality	
Right eye	11 (65%)
Left eye	6 (35%)

Quantitative data were expressed as their mean (standard deviation); qualitative data are expressed as their absolute count and percentage proportion.

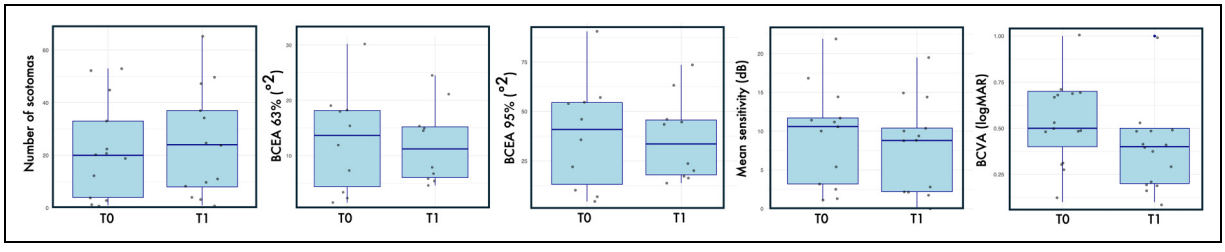

Figure 2. Visual outcomes and microperimetric parameters before and after AvDesk training system. Boxplots illustrating changes in visual acuity and microperimetric parameters before (T0) and after (T1) training with the AvDesk system. T0 refers to baseline measurements collected prior to the beginning of the training, while T1 indicates the results at the end of the training period. In each plot, the horizontal line inside the box represents the median value. The box itself spans from the 25th to the 75th percentile (interquartile range, IQR). Individual dots represent single observations.

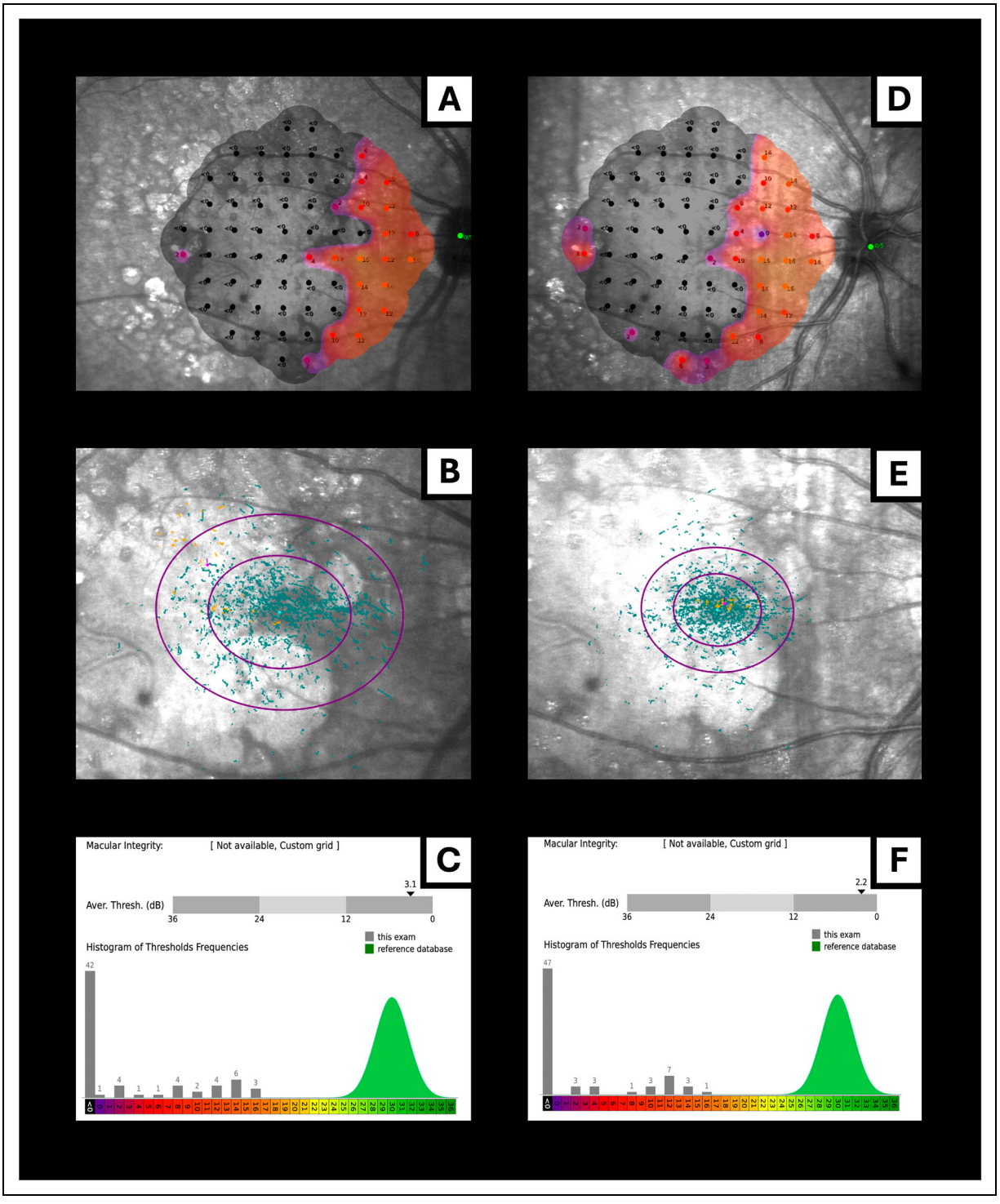

Figure 3. Microperimetry reports. Retinal sensitivity maps (A, D) and fixation plots with BCEA 63% and 95% (B, E) before and after treatment, respectively. Mean Sensitivity (MS) and the number of absolute scotomas before (C) and after (F) treatment.

may suggest that our participants were in an advanced stage of the disease compared to the population examined in their study. While we observed statistically significant improvements in subscales such as general health, overall vision, social functioning, and mental health, these findings should be interpreted with caution. Given the short duration of the intervention and the absence of a control group. Unlike traditional rehabilitation methodologies, which often falter due to their hospital-based nature and the resulting impact on patient compliance,

Table 2. Variations in BCVA and microperimetric parameters after treatment with AvDesk.

	Before treatment	After treatment	p-value*
BCVA (LogMar)			
Mean§	0.55 (0.28)	0.39 (0.26)	<0.001
Median	0.5	0.4	
MS (dβ)			
Mean§	8.81 (6.08)	8.60 (5.99)	=0.30
Median	10.00	10.00	
BCEA 63% ($^{\circ 2}$)			
Mean§	12.72 (8.73)	12.07 (6.70)	=0.41
Median	13.65	11.2	
BCEA 95% ($^{\circ 2}$)			
Mean§	38.17 (26.16)	36.23 (20.06)	=0.39
Median	40.9	33.60	
Absolute scotomata			
Mean§	24 (17)	25 (18)	=0.83
Median	21	24	

BCVA: best-corrected visual acuity; MS: mean retinal sensitivity; BCEA: bivariate contour ellipse area.. *Wilcoxon rank sum test. § Mean (standard deviation).

Table 3. Summary and results of the VFQ-NEI 25 items.

	Before treatment	After treatment	P-value†
General health	44.64	55	
General vision	42.86	60	
Near Vision	52.95	53.31	
Distance vision	54.12	55.79	
Driving	10.82	29.74	
Peripheral vision	58.93	62.5	
Color vision	92.86	95	
Ocular pain	72.32	68.75	
Vision specific:			
Social functioning	79.46	90	
Mental health	36.43	50.63	
Role difficulties	50.89	55	
Dependency	64.26	70.47	
25-Item composite*	55.05 (53.54)	62.18 (57.90)	<0.01

The data are represented by the mean original numeric values obtained from the survey administered to each patien. All items are scored such that higher scores indicates better functioning. The possible range of scores is set between 0 and 100, with 0 representing the lowest and 100 representing the highest possible score. VFQ-NEI: national eye institute visual functioning questionnaire. †Wilcoxon rank-sum test. *Mean (standard deviation).

the AvDesk training system offers a different approach. We may propose that AvDesk training system could be offered to patients to perform a home-based rehabilitation exercise, thereby eliminating the need for constant medical oversight, improving patient compliance and clinical outcomes.

The present study acknowledges several important limitations that should be considered when interpreting its findings. Firstly, as a small-scale, uncontrolled, and short-term pilot study, the design itself limits the strength and generalizability of the findings. Secondly, the absence of a control group may complicate the interpretation of treatment efficacy. Specifically, it limits the ability to determine whether the observed improvements are attributable to the training itself or to non-specific effects related to study participation, including increased attention, patient motivation. Thirdly, variability in baseline fixation characteristics among participants introduces potential confounders that may impact the consistency of results. Additionally, the size and extent of GA were not analyzed in relation to training response, which limits the ability to explore potential correlations between structural damage and functional improvement. Lastly, the lack of long-term follow-up data limits our understanding of how treatment effects may evolve over extended periods.

In conclusion, the AvDesk training system may represent a potential approach to support visual rehabilitation in AMD patients with GA. Further controlled studies are necessary to validate these preliminary findings and to better define its clinical applicability based on patient-specific characteristics and optimized training protocols.

Authorship

All authors attest that they meet the current ICMJE criteria for Authorship.

Commercial relationships disclosure

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Declaration of conflicting interests

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Patient consent

Each study subject provided signed informed consent.

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Supplemental material

Supplemental material for this article is available online.

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