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Real-life evaluation of the home vision monitoring application Odysight® in primary and secondary prevention of exudative maculopathies

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ABSTRACT

Objective: To assess the performance of the Odysight® self-monitoring tool for primary and secondary prevention of exudative maculopathies.
Methods: A one-year retrospective evaluation was conducted in a private practice. An alert was considered significant (SA) when patient was symptomatic, and non significant (NSA) when the patient was asymptomatic and the VA drop was refuted by an additional test carried out the next day.
Results: Of the 92 patients who received a prescription, 44 (48%) downloaded and used the application and were analyzed. At the end of the year, there were 24 (55.8%) active patients. 29 alerts were generated, 13 were considered as NSA, and no anticipated appointment was given. The remaining 16 alerts were SA, 6 (21%) of them were true positive, i.e, revelealed a disease activity on OCT, leading to anticipated injection (representing 9.3% of the patients). 83% of the true positive alerts were generated by eyes with retinal vein occlusion (RVO). Eleven false negative events occurred (6 (55%) for AMD, 4 (36%) for RVO, 1 (9%) for myopic MNV). No primary exudation occured, although 7 false positive alerts were generated. The overall sensitivity of alerts for detecting OCT recurrence was 35.3% (95% CI [12.6; 58]), specificity was 93% (95% CI [90.3; 95.8]), positive predictive value was 20.7% (95% CI [6; 35.7]), and negative predictive value was 96.5% (95% CI [94.5; 98.6]). Sensitivity was higher for RVO (55.6% (95% CI [26.7; 81.1]) than for AMD (14.3% (95% CI [2.6; 51.3]).
Conclusion: In this real-life experimentation of Odysight, half of the patients used the application after initial prescription. Participation was low among diabetics. Odysight® allowed about 10% of the cohort to receive earlier intravitreal injection, albeit with a high number of false positives. Sensitivity was low in secondary prevention for AMD, and better for patients with RVO. Additional use in primary prevention may be questionable.

Introduction

Patients with macular diseases such as diabetic macular edema (DME), age-related macular degeneration (AMD), retinal vein occlusion (RVO), and myopic neovascular maculopathy face a threat of visual loss. However, prognosis has significantly improved since the introduction of intravitreal injections (IVI) [1], especially new anti-VEGF agents, such as Aflibercept HD, Faricimab and Brolucizumab, carrying some hope to decrease the burden of those diseases.

While for AMD, the Treat and Extend (T&E) regimen appears superior to the pro re nata (PRN) regimen in terms of visual outcomes [2], both regimens seem equivalent for DME [3]. In RVO, PRN is as effective as the fixed monthly regimen [4] and T&E regimen allows to space intervals [5]. In PRN regimen, the patient undergoes a high frequency of visits, leading to a risk of non-compliance and undertreatment, whereas in T&E, it is possible to decrease the number of visits by extending the intervals between appointments. However, in the latter strategy, there is a risk of overtreatment but also of recurrence of disease when

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prolonging the interval between two IVI. Additionally, visual acuity (VA) irreversibly decreases during the course of the disease, despite treatment.

Real-world outcomes for chronic maculopathy treatment with IVI are often disappointing and not reproducible compared to large clinical trials [6]. Several reasons may account for this observation: reduced patient mobility or comorbidities limiting appointment attendance; lack of healthcare access in certain geographical areas; asymptomatic nature of VA loss due to frequently unilateral involvement or initial low VA. Thus, developing solutions to address these various issues poses a major challenge. Home self-monitoring tools to detect the onset or recurrence of macular pathologies have been developed. Self-use optical coherence tomography (OCT) systems is the gold standard to detect anatomical exudative recurrence at home, [7,8]. However, it is expensive, complex to implement, and is not currently approved by health authorities in France. There are several mobile applications for self-monitoring VA, the most common being those using a dot alignment test (Alleye™, Ocular medical Inc, Zurich, Switzerland) [9] or shape discrimination (myVisionTrack™, Vital Art and Science, Inc, Dallas, TX, USA) [10], or visual field analyzer based on hyperacuity (ForeseeHome, Notal Vision Inc, USA) [11]. However, they are not yet available in France. Finally, the Amsler grid, which is the most well-known and straightforward to use, has a heterogeneous sensitivity [12].

Odysight® is a French mobile medical application (Tilak Healthcare, Paris, France) that is currently being evaluated. This application measures VA at home using the Snellen E chart and provides optional access to an Amsler grid for monitoring metamorphopsia. It has been shown that comparable VA results to those achieved in clinical practice using the Sloan Early Treatment Diabetic Retinopathy Study (ETDRS) standard at 40 cm were obtained [13].

So far, Odysight® has only been studied for monitoring recurrence in patients already affected by maculopathy undergoing IVI treatment. The primary objective of this study was to evaluate the performance of this tool to detect a disease activity in patients with chronic maculopathy, in secondary prevention but also in primary prevention. The secondary objective was the ability to use the application in real life and private practice, to try to better characterize the target population likely to use the application optimally.

Material and methods

A retrospective real-life evaluation study of the Odysight® mobile application conducted during its first year of use at the (Centre Ophtalmologique Sorbonne Saint-Michel, Paris, France (COSS), a private practice dedicated to the treatment of vitreoretinal pathologies, one year after the start of its prescription. Medical files of patients using Odysight® between October 1, 2022, and October 15, 2023 were reviewed.

Eligible criteria for Odysight® prescription was: age 18 years or older, patients with chronic maculopathy (intermediate and late AMD, DME, RVO, and myopic neovascularization) with decimal binocular VA of 0.3 or greater and monocular VA of 0.1 or greater; possession of a touchscreen mobile phone with a camera and compatibility with the application. Exclusion criteria were: patient refusal of telemonitoring; physical or psychological inability to use the application; history of epilepsy. A patient could have both eyes tested provided they had a potentially bilateral pathology, even if only one of the eyes was treated with IVI. All patients received an Odysight® installation kit and usage instructions from the orthoptist. The patient's medical management was not affected by their use of Odysight®, except in the case of an alert, where an additional visit could be triggered. Oral informed consent was obtained from all participants after providing information about the study by a physician. The research was conducted in accordance with the Helsinki Declaration, and the ethics committee of the French Society of Ophthalmology approved the study (IRB Société Française d'Ophtalmologie IRB#1)

The Odysight® application, available on the Apple App Store® and Google Play Store®, must be downloaded onto a mobile phone and/or tablet and is only available through medical prescription. After being selected, the patient receives a text and an email to download the application. Once the account is created and the application downloaded, an initial calibration step is necessary. This step establishes the initial VA on each eye (score in ETDRS letters) and involves conducting a test examination to establish a score that will serve as a reference for subsequent examinations. Using the device's camera, the application continuously measures the distance between the patient and the test screen. All examinations are conducted monocularly and last on average five minutes. Subsequently, the patient can use the application regularly. With Odysight®, effective monitoring can only be achieved if patients perform these VA examinations at regular intervals (2 tests per week per eye). All results are sent in real-time to a platform reserved for the prescribing physician and the orthoptist in charge of the monitoring. The vision examination includes a VA test using the "tumbling E" and an optional Amsler's grid test. Only this test (and not Amlser's grid test) allows screening and will trigger an alert. The monitoring of near VA is governed by certain rules related to an integrated and patented algorithm, which sets a minimum threshold below which any value will be considered as a VA loss and triggers an alert. This threshold is individually set based on the confidence intervals of previous VA values, their trend, test frequency, and previous VA loss occurrences. It is estimated that the more tests the patient performs, the more reliable this value will be. Additionally, there is a separate Amsler grid divided into 3 parts and a puzzle-type game as a reward, offered at the end of a vision examination to enhance patient adherence. Alerts are triggered if the patient experiences a VA loss of more than 5 letters on 2 consecutive tests. The patient is immediately informed of the VA loss on the application and also receives an SMS and an email.

In the event of an alert, the patient was called in by the physician and questioned about the symptomatic nature of the visual decline. If a decrease was felt, the patient was sommoned for a complete ophthalmological medical examination within 48 h and the alert was considered as "significant" (SA). If the patient was asymptomatic, or declared having realized that they had performed the last tests incorrectly (inattention, tiredness or forgetting to wear glasses for the test), they were asked to repeat the test the next day (and the day after in case of VA drop $\geq$ 10 letters). If the results showed a significant increase in VA of at least 5 letters with each new test over 48 h, the patient was not sommoned before the date of his next appointment, and the alert was considered as non significant (NSA). On the contrary, in case of confirmed VA loss, a prompt medical appointment was then arranged, and the alert was considered as significant. Fig. 1 summarizes the algorithm used to sort alerts.

During this visit at the office, VA was measured and slit lamp examination as well as OCT were performed, to evaluate disease's activity. Apart from an alert, the patients continued their usual follow-up with a medical appointment rhythm established by the practitioner. The number of true positive (TP), false positive (FP), true negative (TN) and false negative (FN) alerts were collected.

Statistics: The results were expressed using median or means $\pm$ standard deviations. The non-parametric Yates chi-square test was used to test the independence of two variables in contingency tables. The parametric Student's t-test was used to compare two means, and the nonparametric Mann-Whitney U test was used to compare the central tendency of two groups. For all tests, a significance threshold (α) of 0.05 was chosen. It is worth noting that all included patients were retained, thus avoiding attrition bias.

Primary Objective: To evaluate the effectiveness of Odysight in detecting disease activity, both in secondary prevention (eyes undergoing IVI treatment) and primary prevention (non-decompensated maculopathy, never treated). Primary outcome measures were: sensitivity of Odysight for detecting disease activity on OCT (i.e., probability of receiving an alert in case of disease activity on OCT), specificity for detecting the absence of disease activity on OCT (i.e., the absence of

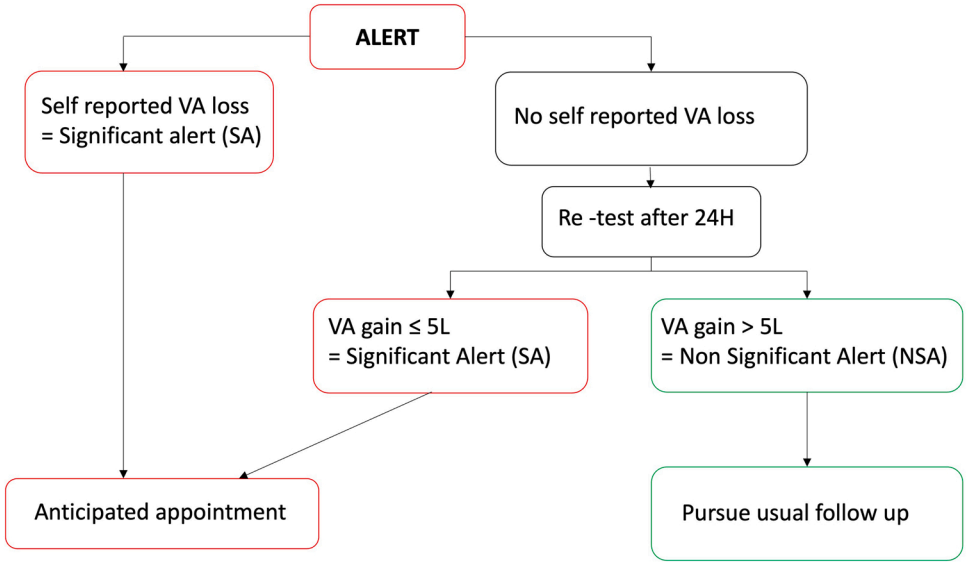

Fig. 1. Algorithm used to sort alerts.

alert in case of no disease activity on OCT), positive predictive value (PPV, i.e., the probability of disease activity on OCT in case of an alert), and negative predictive value (NPV, i.e., the probability of no disease activity on OCT in case of no alert).

Secondary Objective: To evaluate the usability of the application in everyday practice. Secondary Outcome Measures: Conversion rate (i.e.,

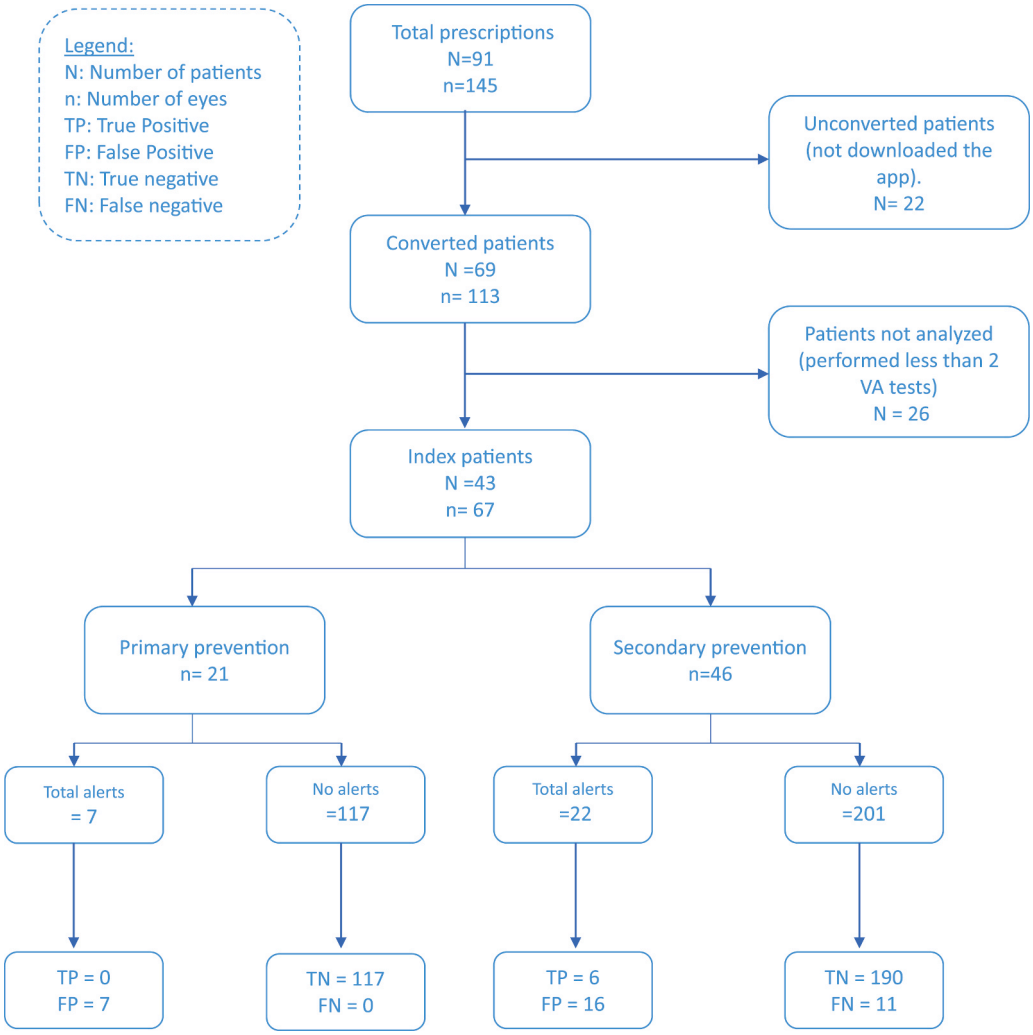

Fig. 2. Flow chart of inclusion, number and type of alerts, related to the presence of disease activity on OCT.

upload of the application and completion of at least 1 test in addition to calibration tests), retention rate (i.e., use of the application more than 3 months after the initial use).

Results

Flow chart and characteristics of included patients

Fig. 2 summarizes the flowchart of patient's inclusion in the study, and the alerts according to primary or secondary prevention follow-up. Of the 91 prescriptions initially issued, 69 patients (76%) downloaded the application. Among these 69 patients, 43 performed more than two VA tests and were thus included in the present analysis (mean age: 68.9 years [35–92]), representing 47% of the initial cohort, and allowing the evaluation of a total of 67 eyes. 21 eyes (31.3%) were followed in primary prevention and 46 eyes (68.7%) were followed in secondary prevention. Ten of 43 (23%) patients had both eyes included in the study.

Table 1 analyzes patients' conversion rate and number of alerts according to the type of disease. Among the eyes included, AMD was the most prevalent disease (55.2%), followed by RVO (19.4%), DME (13.4%), and myopic macular neovascularization (MNV) (6%).

Diabetic patients had the lower conversion rate (27.8%) and triggered no alert.

Table 2 depicts VA of included eyes at time of prescription, according to the disease and the type of prevention.

Alerts, specificity and sensitivity

Twenty-nine alerts were generated by 14 patients. Among these 29 alerts, 13 were NSA and no anticipated appointment was given. The mean (SD) interval between the NSA and the next consultation was 27.8 ± 19.1 days. All those NSA were considered as FP. The remaining 16 alerts (55%) were SA, leading to anticipated appointment. Among those 16 SA, 6 (21% of the total number of alerts and 37.5% of the SA) were TP alerts, revealing a disease activity on OCT, leading to anticipated IVI treatment (representing 9.3% (4/43) of the index patients, including 2 patients with 2 TP alerts a few weeks apart). In those TP alert, VA drop detected by Odysight was confirmed at the time of medical appointment (mean VA dropped from 0.6 to 0.3, ρ-value = 0.01 (95% CI)) (Table 3). The mean (SD) interval between the SA and the anticipated appointment was 4.7 days± 4.7 days. The TP/FP ratio was higher in RVO patients than in AMD patients (0.6 vs 0.08 respectively). Among the 6 TP, 5 (83%) occurred in secondary prevention in 3 patients with RVO (2 patients had respectively twice an anticipated IVT in the included eye), 1 occurred in secondary prevention in a patient with AMD.

Eleven false negative events occurred, i.e, no alert was triggered, and confirmation was made that no drop in VA was measured at scheduled appointment, despite a disease activity on OCT (Table 3). Among those false negative, 6 eyes (55%) had AMD, 4 eyes (36%) had RVO and 1 eye (9%) had myopic MNV. Mean VA of eyes with FN was high.

Overall results of are shown in Table 4 and revealed a sensitivity of 35.3% (95% CI [12.6; 58]), a PPV of 20.7% (95% CI [6; 35.7]), a specificity of 93% (95% CI [90.3; 95.8]) and a NPV of 96.5% (95% CI [94.5; 98.6]). Patients who generated false positives were older than those who generated true positives (76.3 years ± 11 vs. 70.4 ± 13) (ρ value = 0.008 (95% CI [11.5; 26.5])).

The sub group analysis by pathology indicated a sensitivity of 55.6% (95% CI [26.7; 81.1]) in patients with RVO, and 14.3% (95% CI [2.6; 51.3]) in patients with AMD. For DME and other diseases, as no alert was triggered, no sensitivity and PPV could be calculated. For myopic MNV, 3 FP alerts were generated. In primary prevention, 7 FP alerts were generated, although no primary exudation occurred. Specificity and NPV were high for every subgroup.

Retention rate

At the end of the year, there were 24 active patients, accounting for 55.8% (24/43) of the included patients, 34.7% (24/69) of patients having uploaded the application, and 26.4% (24/91) of patients having received initial prescription. The average duration of use was 174 days (5.8 months). 26 patients (60%) used the application for at least 3 months. It is noteworthy that in the cohort, since not all patients were recruited on the same day, a short retention time did not necessarily mean that the patient had quickly stopped participating, but it could also mean that they were recruited late relative to the end of the study.

Discussion

The main objective of the study was to evaluate the effectiveness of Odysight® in detecting disease activity, both in secondary and primary preventions, in real-life conditions.

Over one year, 17 exudative recurrences occurred, 6 of them were

Table 1
Initial characteristics of patients and eyes at the time of prescription, conversion rate, type of prevention, and number of true and false positive.

Pathology	Number of prescriptions/N patients/n eyes (%)	Number of included patients N/n eyes (%)	Conversion rate %	Mean age of patient included ± SD	Primary prevention (%)	Secondary prevention (%)	Number of false positive alerts (FP)/number of true positive alerts (TP)/Total alerts
AMD	N = 38 (41.7) n = 71 (49)	N = 19 (44.2) n = 37 (55.2)	50%	74.89 ± 7.1	18/37 = 48.6	19/37 = 51.4	FP = 12 TP = 1 Total = 13
RVO	N = 20 (22) n = 20 (13.8)	N = 13(30.2) n = 13 (19.4)	65%	64.54 ± 10.8	0/13 = 0	13/13 = 100	FP = 8 TP = 5 Total = 13
DME	N = 18 (19.8) n = 35 (24.1)	N = 5 (11.6) n = 9 (13.4)	27.8 %	60.8 ± 10.8	0/9 = 0	9/9 = 100	FP = 0 TP = 0 Total = 0
Myopic MNV	N = 5 (5.5) n = 9 (6.2)	N = 2 (4.7) n = 4(6)	40%	64.5 ± 14.8	3/4 = 75	1/4 = 25	FP = 3 TP = 0 Total = 3
Other	N = 10 (11) n = 10 (6.9)	N = 4 (9.3) n = 4 (6)	40%	67 ± 6.7	0/4 = 0	4/4 = 100	FP = 0 TP = 0 Total = 0
Total	N = 91 n = 145	N = 43 n = 67	47%	68.9 ± 10.5	21/67 = 31.3	46/67 = 68.7	FP = 23 TP = 6 Total = 29

AMD = age related macular degeneration; DME = diabetic macular edema; RVO = retinal vein occlusion; Myopic MNV = myopic macular neovascularization; SD = standard deviation; FP: false positive; TP: true positive.
*The average time between prescription and download was 4.5 days.

Table 2
Visual acuity (VA) of included eyes at the time of prescription, according to the type or disease and prevention.

Baseline VA (decimal)	AMD primary prevention (n eyes = 18)	AMD secondary prevention (n eyes = 19)	RVO (n eyes = 13)	DME (n eyes = 9)	Myopic MNV Primary prevention (n eyes = 3)	Myopic MNV secondary prevention (n eyes = 1)	Other (n eyes = 4)
0.1	0	2	0	0	0	0	0
0.2	0	0	3	1	0	0	0
0.3	0	1	0	0	0	0	0
0.4	0	0	3	0	1	0	0
0.5	0	2	0	0	0	0	1
0.6	2	2	1	4	0	0	2
0.8	1	5	2	0	2	0	1
1	15	7	4	4	0	1	0

AMD = age related macular degeneration; DME = diabetic macular edema; RVO = retinal vein occlusion; MNV = macular neovascularization.

Table 3
Visual acuity (VA) measurements performed at the office, during regular visit or after alert, with respect to the nature of alert.

VA (decimal), type and number of alerts (n)	VA at previous appointement		VA at last appointement		p-value
	mediane	Statistical range	mediane	Statistical range	α = 0.05
True positive (n = 6)	0.6	[0.2–0.9]	0.4	[0.1–0.6]	0.01
False positive (n = 23)	0.5	[0.3–1]	0.7	[0.4–1]	0.04
True negative (n = 307)	0.8	[0.2–1]	0.9	[0.2–1]	0.33
False negative (n = 11)	0.8	[0.4–1]	0.9	[0.4–1]	0.2

detected by Odysight, allowing 4 patients (9.3% of the cohort) to receive anticipated IVI. Two patients had respectively twice an anticipated IVT in the studied eye. The overall sensitivity was only 35.3%, and seemed better for patients with RVO (55.6%) compared to patients with AMD (14.3%). This low sensitivity did not mean that Odysight® was not able to detect VA loss with accuracy [13]; it means that no alert was triggered because no VA loss was induced despite recurrence of disease activity in 7 eyes, including 5 with AMD. In addition, predictive positive value was 20.7%, illustrating the high rate of false positive, especially in older patients.

Thus, the correlation between the presence of an Odysight® alert and the presence of a disease activity on OCT in patients with chronic maculopathies depends on the type and stage of disease. Pathologies such as RVO may seem suitable for its use, mostly because VA changes and presence of exudative signs on OCT are usually well correlated. On the contrary, in patients with advanced AMD, as well as in diabetic retinopathy, disease activity may be visible on OCT, without inducing a change in VA, due to a weak anatomo-functional correlation, partially induced by chronic retinal changes secondary to long-standing disease [14]. In addition, AMD patients were on average 10 years older compared to patients with other pathologies, leading to more frequent concomitant ocular comorbidities, which could explain VA loss secondary to extra retinal causes, such as cataract, posterior capsular opacification, or ocular surface disorders [15].

The very low number of patients with high myopia in our study do not allow to draw conclusions on this subgroup. No primary exudation occurred in non-treated eyes, although 7 FP alerts were generated. likely due to a short follow-up period and the small number of patients. This does not allow to draw conclusion about the use of Odysight in primary prevention. Of note, after 2 years, the risk of developing neovascular AMD in the contralateral eye when the first eye is already affected by exudative AMD is 12% [16]. No alerts were detected in diabetic patients or in the "other pathologies" group, possibly due to the small number of patients included in these categories.

Overall, we achieved a specificity of 93%, indicating a high probability of not receiving an Odysight® alert in patients without disease activity on OCT. We also observed a NPV of 96.5%, indicating a strong correlation between the absence of disease activity on OCT and the absence of Odysight® alert.

The high rate of false positives implies a strict algorithm to deal with alerts and rule out patients that don't need to prepone appointment, as proposed in the algorithm described in this study. The future updated version will include a technical support to call the patients in case of an alert, and to rule out NSA while performing additional VA check tests; this would help decreasing the burden for the medical team.

Our results of 47% conversion rate are consistent with those of other French teams (50% conversion rate in Kielwasser et al.'s study and 61% in Guigou et al.'s study [17,18]. Patients with RVO had the highest conversion rate (65%). The retention rate (34.7% at 12 months) was higher in our study, than in other French series (24% at 9 months in Guigou et al.'s study and 26% at 3 months in Kielwasser et al.'s study. Good retention thus required regular involvement of both physician and orthoptic team to establish frequent reminders and emphasize the importance of performing the tests. It was interesting to note that, despite their older age, patients with AMD had a decent conversion rate of 50%. The multicenter and retrospective study by Kielwasser et al. [17] over 2 years is consistent with our findings regarding the detection of disease activity by Odysight: sensitivity of 30.8% (95% CI [17.6; 44.0]) compared to 35.3% (95% CI [12.6; 58]) in our study, and specificity of 83.7% (95% CI [73.2; 94.3]) compared to 93% (95% CI [90.3;

Table 4
Sensitivity, specificity, positive and negative predictive values in detecting disease activity on OCT, overall, by pathology and by type of prevention.

Number of eyes	AMD (n= 37)	RVO (n=13)	Myopic MNV (n=4)	DME (n=9)	Other (n= 4)	TOTAL (n= 67)	Primary prevention (n=21)	Secondary prevention (n=46)
Sensitivity	14.3% (95% CI [2.6; 51.3])	55.6% (95% CI [26.7; 81.1])	N/A	N/A	N/A	35.3% (95% CI [12.6; 58])	N/A	35.3% (95% CI [17.3; 59])
Specificity	94.3% (95% CI [90.4; 96.6])	90.7% (95% CI [82.7; 95.2])	83.3% (95% CI [48.7; 118])	N/A	N/A	93% (95% CI [90.3; 95.8])	94.3% (95% CI [90.3; 98.4])	92.2% (95% CI [87.8; 95.1])
PPV	7.7% (95% CI [1.4; 33.3])	38.5% (95% CI [17.7; 64.4])	N/A	N/A	N/A	20.7% (95% CI [6; 35.4])	N/A	27.3% (95% CI [13.2; 48.4])
NPV	97.1% (95% CI [93.8; 98.7])	95.1% (95% CI [88.1; 98.1])	93.8% (95% CI [79.8; 107])	N/A	N/A	96.5% (95% CI [94.5; 98.6])	100% (95% CI [0; 0])	94.5% (95% CI [90.5; 96.9])

AMD = age related macular degeneration; RVO = retinal vein occlusion; MNV = macular neovascularization.

95.8]) in our study. The PPV was low but slightly higher than that of our study (30.8% vs. 20.7%).

The study by Guigou et al. [18] revealed that 6 out of 19 alerts (31%) were true positives that resulted in IVI, compared to 6 out of 29 in our study (20.7%), which explains why the PPV is lower in our study; The 13 NSA were considered as FP alerts for the specificity and PPV calculations. However, when ruling out NSA, considering that they did not require an anticipated appointment and did not impact patient's follow-up, better results would be obtained regarding specificity (96.3% (95% CI [94.2; 99.5]), and PPV (37.5% (95% CI [18.8; 56.2]).

We have reached the same conclusion, namely, that patient profile selection is crucial to achieve good retention and optimal use of the application. However, the 6% of diabetic patients included in Guigou's study did not seem to be appropriate candidates, as we also observed. The difficulty in usage among diabetic patients may be related to the high daily mental burden induced by their pathology, making them hesitant to use an additional monitoring solution.

The main limitation of our study, in addition to its retrospective nature, is that the heterogeneity of included patients with a variable number depending on the pathologies and type of prevention, thus limiting the possibility of intergroup statistical comparisons.

Results from a recent study conducted in the UK suggest that no home-monitoring vision test provided satisfactory diagnostic accuracy to identify active AMD diagnosed in hospital eye service follow-up clinics [19]. Self-use OCT systems are the gold standard to detect the onset or recurrence of macular diseases at home. However, it is not yet approved by the French health authorities. In addition, although recent studies have confirmed its feasibility among patients with neovascular AMD, it appears time consuming and difficult to generalize. Therefore, home vision tests are presently the only solution that can help monitoring exudative maculopathies, especially when spacing out IVI, but obviously cannot replace a medical consultation.

Conclusion

In this real-life experimentation of Odysight®, half of the patients used the application after initial prescription. Participation was particularly low among diabetics. Odysight® allowed about 10% of the cohort to receive earlier intravitreal injection, albeit with a high number of false positives. Sensitivity was low in secondary prevention for AMD, and better for patients with retinal vein occlusion. No primary exudation occurred in non-treated eyes, although 7 FP alerts were generated, making the additional use in primary prevention questionable. The initial selection of patients and reminders of use by the healthcare team during follow-up were fundamental to ensure an optimal use of the tool.

CRediT authorship contribution statement

All authors attest that they meet the current International Committee of Medical Journal Editors (ICMJE) criteria for Authorship.

Informed consent and patient details

The authors declare that this report does not contain any personal information that could lead to the identification of the patient(s) and/or volunteers.

Human and animal rights

The authors declare that the work described has been carried out in accordance with the Declaration of Helsinki of the World Medical Association revised in 2013 for experiments involving humans as well as in accordance with the EU Directive 2010/63/EU for animal experiments.

Declaration of competing interest

The authors declare that they have no link of interest concerning this article.

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