

OdySight: Real-World Data Analysis of a Mobile Medical Application for Ophthalmology

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Article Info

Article Notes

Received: March 20, 2020

Accepted: April 23, 2020

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Keywords:

Tilak healthcare

OdySight

AMD

Visual acuity

Amsler grid

Digital health

Tele-ophthalmology

Remote monitoring

Mobile medical applications

Abstract

Digital tools for remote monitoring have revolutionized the current landscape of healthcare delivery. With the advent of smartphones and tablets, the development of mobile medical applications (apps) has created a new dimension in telemedicine. While there are a variety of “wellness apps” available to the general public, only some of them have undergone rigorous human factors testing and clinical validation and require the recommendation of a clinician to be used for remote monitoring. In this article, we specifically review the utility of a mobile medical application called OdySight, which is being recommended by ophthalmologists throughout France for patients with chronic eye diseases.

Introduction

Digital healthcare is attractive to clinicians as a form of telemedicine, to enable and promote patient remote management^{1,2}. The remote monitoring tools embedded within digital healthcare apps³ are uniquely positioned to tackle many current and upcoming challenges⁴. Digital health companies provide technologies that support the delivery of care virtually and are uniquely suited to expand the capacity of our strained healthcare system⁴⁻⁹. With the COVID-19 public health crisis, the need for remote monitoring tools cannot be over-emphasized⁴. Hospitals and health systems across the world are witnessing a huge increase in virtual clinic visits, and it's expected that this trend will only continue¹⁰. With in-person visits being transitioned to virtual ones¹¹, ophthalmologists are challenged to assess patient health without a physical exam or the imaging technology relied upon in the clinic.

In overburdened hospitals and clinics, worldwide, smartphones and tablets are key to keeping patients out of the clinic when they do not need to be there, and to bring them in, earlier, when they do. For ophthalmology¹², in particular, clinical assessment via smartphones¹³ has existed for several years already¹⁴, and teleophthalmology is becoming more popular^{15,16}. There has been a steady rise in the development of home/remote monitoring¹⁷⁻¹⁹ systems^{14,20,21} over the last few years^{5,22}. It has also been suggested that “gamification techniques are likely to increase compliance with self-monitoring, leading to earlier detection in the next generation of patients with neovascular AMD”²²⁻²⁴.

Tilak Healthcare creates mobile medical applications that include a video game with the intent of engaging and entertaining patients, yet require a certain level of commitment and accountability from the patient^{24,25}. Tilak Healthcare's first app is for the remote monitoring

of chronic eye diseases¹⁹- the intended use is to assist with the planning of follow up care, between scheduled clinic visits, for patients with age-related macular degeneration, diabetic retinopathy and other similar, treatable causes of blindness. Patients can now use their mobile devices and be active participants in their care, which will hopefully decrease the chance that they will lose their vision prematurely¹⁹.

Since September 2018, 152 ophthalmologists across France have recommended OdySight for patients with chronic eye diseases and 950 patients have downloaded the app.

OdySight App

OdySight is designed to monitor clinically relevant visual parameters for patients with chronic eye diseases. OdySight (which comes from the word “odyssée” in French and odyssey in English) was so-named because the player embarks upon an adventure, putting together the pieces of a puzzle with each video game that they play. The patient first completes one, monocular eye test (a digitalized version of Visual acuity or Amsler grid) to boost their “energy” points, allowing them to then play the video game. The puzzle game keeps patients engaged and encourages them to visit the app regularly^{10,11,13}. The patient is limited to a 10-15 minute session each day.

Access and installation of OdySight

In France, the OdySight application is only available by prescription from an ophthalmologist. During a consultation, if the ophthalmologist thinks that OdySight might be useful for a patient, they can create an account for the patient by logging into their clinic dashboard, and completing a form containing the following fields :

- First name of the patient
- Last name of the patient
- Patient’s phone number
- Patient’s email address
- Patient’s visual acuity (for each eye)
- Patient’s eye disease diagnosis (for each eye)
- Patient’s gender
- Patient’s birthdate

After the form is validated by the doctor, the patient receives an email and an SMS containing a link to download the app, as well as a personal code. The clinic staff may assist the patient in installing the app on their device and explain the details of the application. The patient will also receive a small box which contains written instructions for downloading and using the app and contact information for the OdySight support team. The box itself converts into

a stand to hold the patient’s phone stationary while they perform visual tests.

After downloading the app, the patient will read and accept the terms of use, enter the personal code they received by SMS/Email, and select a personal password. A short tutorial will show them how to do a test, how to do a puzzle, and how to contact the clinic if an alert is triggered. The patient is completely autonomous and can play the puzzle game and perform visual tests. Each time the patient does a test, their results are automatically displayed on the doctor’s dashboard. If a loss of visual acuity is detected by the OdySight algorithm, the patient and the doctor will be notified and the patient will be encouraged to contact the clinic. The doctor will then decide, according to the data available on the dashboard, to include an additional clinic consultation for the patient, or to have the patient wait until their next scheduled visit.

Medical modules

OdySight currently has two medical modules: 1. Visual acuity; and 2. Amsler Grid; both of which are CE marked and included within the app for the remote monitoring of visual function.

i. Visual acuity module:

The Visual Acuity Module is inspired by the standard Early Treatment Diabetic Retinopathy Study (ETDRS) and the “tumbling E” test. It is a short and interactive test during which the patient needs to indicate the orientation of the letter “E” by sliding their finger in the corresponding direction (up, down, left, or right) (Fig. 1 a). Several sizes and orientations of the letter “E” are displayed, one by one, sequentially on the screen. The orientation and the size of the letter changes after each patient’s response. The orientation of the letter is random but its size changes according to a predefined algorithm. If the patient does not respond by sliding their finger, then the app will display a button that says “NOT SURE,” and the patient may tap that button. The first time a patient performs the test on each eye, there is an initial screening phase that allows the app to do a ‘threshold’ evaluation of the patient’s visual acuity. Subsequent test sessions will then be much shorter in duration, and more precise based on the patient’s baseline visual acuity. At the end of each test performed, the app displays the patient’s visual acuity test results for that test only. The test stops at the defined threshold for the respective test and this threshold is converted to the corresponding logmar score, which is then translated to the score displayed on the patient’s screen within the app. (eg, logmar 0.0 → decimal value 1.0 → Snellen fraction 10/10 displayed on the app).

When a decrease of the near visual acuity is detected, a pre-alert/alert is triggered, as per the alert algorithm described below.

ii. Amsler grid module:

The Amsler Grid Module is a digitalized version of the traditional Amsler grid paper test for the patients who have macular diseases to detect changes in their central vision. In the app, the Amsler grid is displayed in 3 parts on the screen and the patient is required to draw the anomalies they see using their finger instead of a pencil (Fig. 1 b).

There are no alerts with the Amsler grid, but the clinician can visualize the Amsler grid in the dashboard and compare the latest result with the previous tests.

Algorithms for distance to screen and ambient light detection

To ensure that the tests taken using the OdySight modules are precise and reproducible, unique technology (patent filed) has been developed by Tilak Healthcare, including a proprietary algorithm calculating the distance from the patient’s eye to screen and an algorithm for automatic detection of ambient lighting.

In order to continually assess how far the screen is from the patient’s eyes, a special formula is used based on: (i) the interpupillary distance (average or measured on the patient); (ii) the size of the camera feed and current frame;

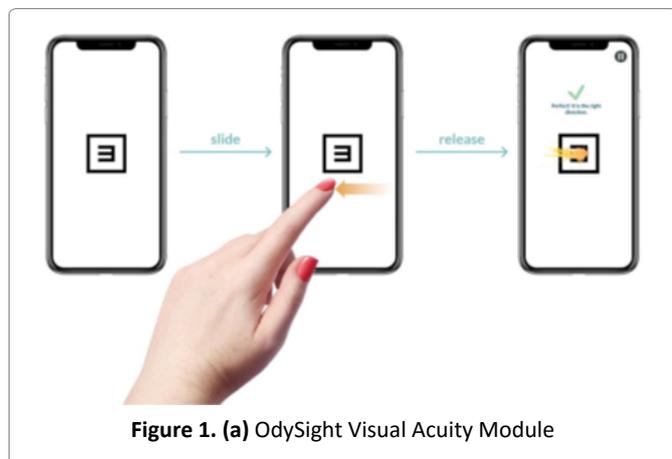


Figure 1. (a) OdySight Visual Acuity Module

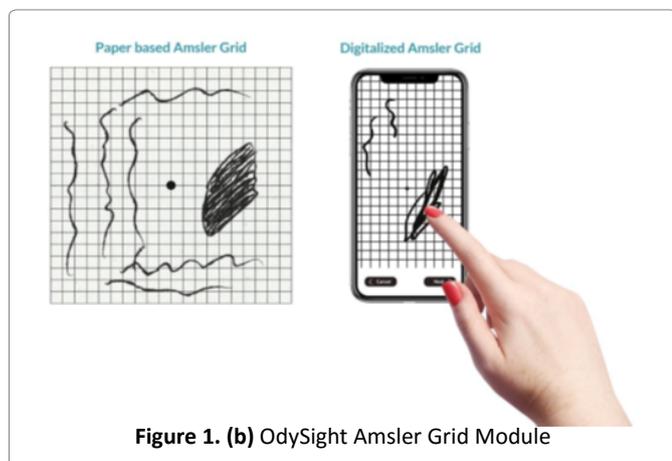


Figure 1. (b) OdySight Amsler Grid Module

and (iii) the camera properties (sensor physical size, pixel size, and focal-length) for the particular smartphone being used.

To ensure accurate and reproducible test results, the minimum requirement for screen size is 4.7” with dots per inch (DPI) over 260 or even 320 in case one of the eyes has a visual acuity greater than 6/10 (20/32). This recommendation helps to address the impact of different platforms and mobile screen sizes on the score and the repeatability of tests performed on the app.

Algorithm for alerts

Changes in performance for the visual acuity module of OdySight are assessed by an algorithm with a 2-step alert system – if between two tests, there is a change of 5 or more letters in the number of letters correctly identified, then a pre-alert is generated (Fig. 2). The app will automatically prompt the patient to re-do the visual acuity module on the same eye the following day. If, when the visual acuity module is repeated, the user’s performance on that test is the same as the previous day, up to 2 letters better, or worse, then an alert is triggered by the app. In this case, both the patient and clinician (via the secure server and dashboard) will be notified simultaneously that an alert has been triggered. The user is notified by SMS, email, and via the app that they should schedule a visit with their clinician.

Limitations and contraindications for OdySight

OdySight is recommended for adults at least 18years of age. It is contraindicated for users who suffer from epilepsy or seizures and for those with:

- i. Binocular vision worse than logMAR 0.5 (20/63).
- ii. No access to a compatible smartphone and/or tablet.
- iii. No valid email address or phone number which are required to create an account and receive alerts.
- iv. A lack of competence to use the app and complete the test modules remotely, without the guidance of a clinician.

Clinical Validation of OdySight

Overview

The framework under which digital therapies need to be designed is not too different from how traditional medications are studied and tested. Clinical validation of the modules of OdySight was therefore undertaken with 122 eyes (88 patients) in France in 2018^{19,25}.

TIL-001 clinical trial summary

The clinical study was designed to evaluate OdySight’s medical modules by comparing them directly to the

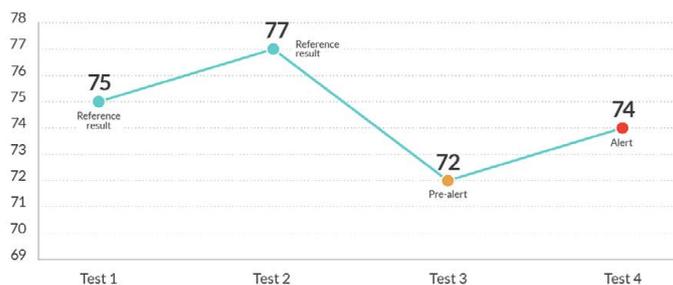


Figure 2. Algorithm for the alert system in OdySight

gold standard tests for visual acuity, contrast sensitivity, and Amsler Grid. The results of this study demonstrate good agreement with statistical significance, for the measurements taken by two of OdySight’s medical modules (visual acuity and Amsler grid) when compared to present-day gold standards (ETDRS Sloan near visual and distance ETDRS charts and paper Amsler Grid, respectively) (Fig. 3) in the majority of the study population¹⁹. OdySight was validated to be a good alternative to traditional clinical tests and a powerful tool for remote monitoring of vision between clinic visits, and could potentially assist in follow-up planning.

The study is similar to the results from other studies^{16,17,21} in which remote monitoring apps were validated and to those that compared apps with existing gold standard tests^{21,22,26}.

Real-World Use of OdySight

OdySight users based on eye disease

OdySight has been most commonly recommended for patients with a diagnosis of wet age-related macular degeneration (AMD) (35% of all patient downloads) (Fig. 4).

Similarly, the cohort with the most active players are patients with wet AMD. (Fig. 4). Non-players are defined as those who did fewer than three sessions (performing eye tests or doing puzzles) or fewer than three puzzles, or those for whom the number of puzzles completed is less than 10% of their total number of sessions.

OdySight users based on age

Age cohort-based distribution among OdySight users reveals that the most frequent users are in the age cohort of 70-80 years, with the maximum number of players (vs non-players) also being in this cohort (Fig. 5). Overall, the maximum number of users are in the age range of 50-80. And, interestingly, even in the age cohort of >80 years, comprising 17.6% of the patient population, more than 50% of the cohort is defined as players (Fig. 5).

Retention rates based on age

Retention is a key component to the success of mobile technology. When the patient becomes bored or fatigued by a mobile application or game, they will likely stop being engaged and rarely restart gameplay again. The mobile applications with the best retention on the

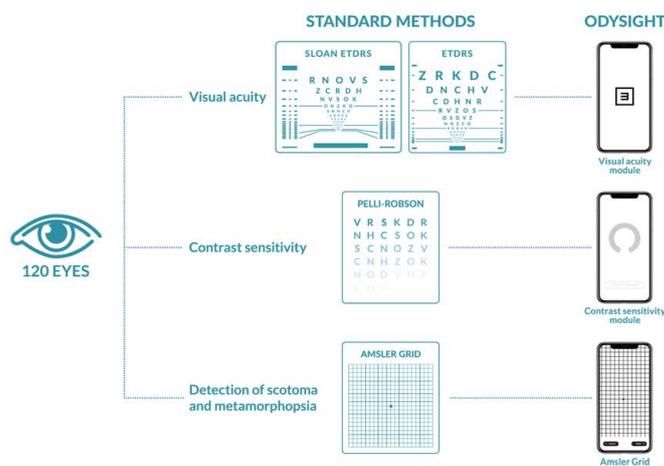


Figure 3. Evaluation of OdySight medical modules compared to Gold standard tests

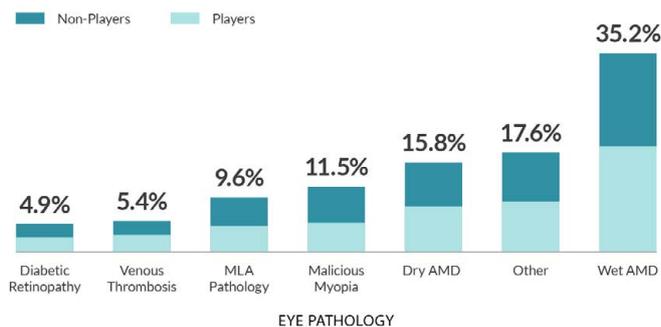


Figure 4. Eye Pathology among total OdySight user population in France by player/non-player profile

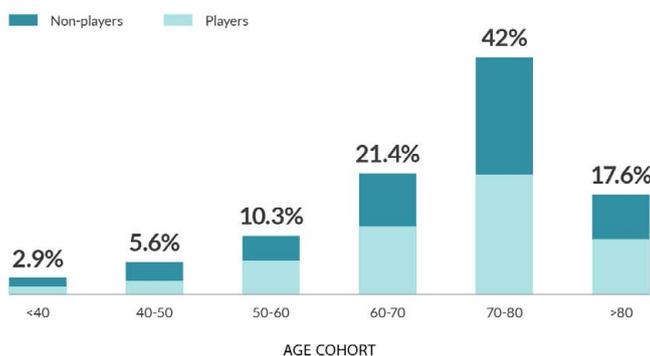


Figure 5. Age group cohorts among total OdySight user population in France by player/non-player profile

market are Instagram (70%) and WhatsApp (62%). OdySight has average retention of 43% for three months (Fig. 6 a). Patients who play the game regularly have the best retention (defined by the number of patients who use the application at least once over the given period). Also, it is worth noting that players have much better retention than non-players (63% vs 17% at three months) (Fig. 6 a).

Remarkably, patients in the age group, 80+ years, have three-month retention of 43% (53% for the age group 65-80 years) (Fig. 6 b).

Summary

OdySight was developed to address the growing need for remote monitoring of visual function among patients suffering from AMD and other chronic eye diseases. As a mobile medical application, it is simple for clinicians to recommend during a patient visit and for patients to download and use the app remotely. OdySight has shown good retention in all age groups analyzed and, particularly, in elderly patients. Players demonstrate better retention which implies that the puzzle game keeps patients interested and engaged (Fig. 7).

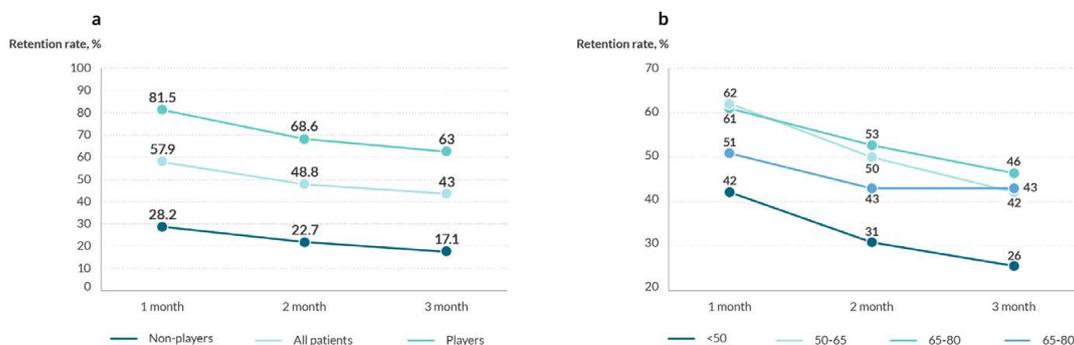


Figure 6. Retention rates among OdySight user population in France; (a) by total population and player/non-player profile; (b) by age

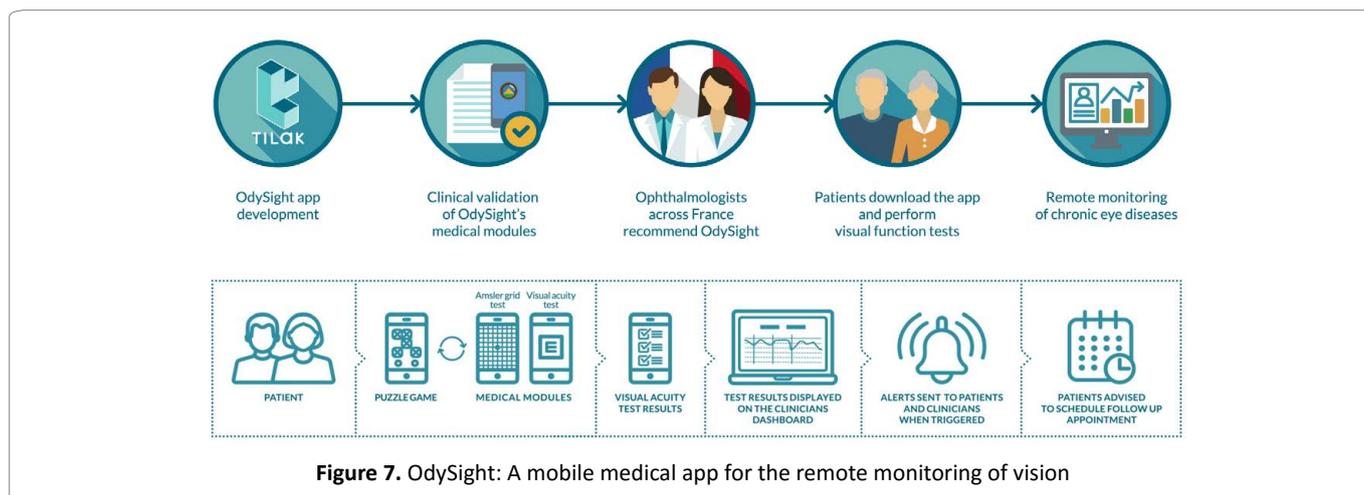


Figure 7. OdySight: A mobile medical app for the remote monitoring of vision

The Future of OdySight

The value of mobile, remote monitoring comes from an accurate alert system. Tilak is now planning a randomized controlled trial to assess the sensitivity and specificity of the unique alert algorithm of OdySight. OdySight is now available in the Apple and Android application stores in France and the US for free download and a 30-day trial. A clinician must provide a code to the patient for data exchange to occur and to allow the use of the app for more than 30 days. Tilak Healthcare’s second mobile medical application will be for mental health disorders, particularly addiction.

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