GIVE VISION

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SightPlus: what is the evidence?

Company White Paper

Vision Technologies Ltd., July 2018

SUMMARY

Since commencing early stage user evaluation sessions with now over 1000 visually impaired volunteers in 2016, GiveVision have completed a number of studies to provide objective evidence for wearable sight aid SightPlus. This report summarises three key activities conducted to test and verify the ecological validity of SightPlus while assessing clinically measurable improvements in sight and patient impact. Outcomes demonstrated large potential for SightPlus to improve ability to see and patient wellbeing:

- 83% of participants in a 2-week take-home evaluation reported improved ability to see compared to their best coping strategy/sight aid for an activity important to them.
- SightPlus enabled most stationary activities, covering near to distance vision.
- Visual acuity improved significantly by on average 0.86 logMAR (8 lines on a sight chart).
- Contrast sensitivity improved significantly by on average 0.55 log units (11 letters on a sight chart).
- 65% of long-term users reported being able to engage in activities which they could not do before.
- 68% of long-term users reported an increase in confidence and 59% reported an increase in independence.

1. TAKE-HOME EVALUATION

Introduction

Between 2016 and 2017, incremental iterations of the SightPlus prototype were demonstrated to over 1000 visually impaired people from around the UK in a variety of formats, ranging from ad hoc demonstrations to take home opportunities. After arriving at a final prototype version in 2017, GiveVision offered in-depth take home evaluation sessions to visually impaired volunteers with predominantly central vision loss. Results of these evaluation sessions, running between January and May 2017, are described in this report.

Methods

Screening and 1:1 demo sessions

After engaging with a number of charities and through exposure on the BBC, GiveVision invited 194 participants to attend a 1:1 demo session in 2017. These participants had been screened to use a magnifier or other low vision aid, have stable vision and not suffer from mental health issues to minimise risk of a negative impact on wellbeing.

The 1:1 demo session served to explain the SightPlus functionality in depth, including applied tasks resembling common recreational tasks, such as watching TV and reading a newspaper. Based on considerations of ability to see, comfort, confidence to operate SightPlus and personal needs, 92 participants

(47%) elected to take it home for a two-week period.

Participants

Of the 92 participants, 22% were aged <17 years, 39% were aged 17-64 years and 39% were aged 65+ years. The most common sight conditions were Macular degeneration, Hereditary retinal disorders and Albinism. Most participants did not know their visual acuity, and no sight charts were available to the time to estimate this. From descriptions and limited data, the vast majority of participants is assumed to fall within the WHO definition of low vision (acuity <6/18 to 3/60).

Task

Participants were instructed to use SightPlus for any and all activities which they wished to undertake during the two-week period. This explicitly excluded walking, driving and any other non-stationary or dangerous activity. Participants were advised to take regular breaks (every 30 minutes) and to discontinue use and contact the GiveVision team if there were adverse effects.

During the two-week evaluation period, participants agreed to be contacted a number of times for catch-up and support. Typically, this involved one call at the start of the evaluation period, followed by two to three calls throughout the period. Participants were provided GiveVision contact details and encouraged to call if their encountered any technical problems, side effects or other issues.

De-brief

At the end of the two-week period, participants agreed to participate in a comprehensive de-brief based on a structured interview. The same questionnaire was administered to all participants, in which they were asked to give feedback on SightPlus, provide scores for their ability to see during their two preferred tasks and provide input regarding future development.

The de-brief took the approach to compare SightPlus to the participant's best coping strategy, not their baseline ability to see. The rationale for this approach was the expectation that any future low vision aid would have to perform at least as well as current solutions in order to be competitive.

If at the end of the take-home period participants wished to keep SightPlus, they were able to do so for a nominal fee to ensure the true interest in the solution. Since then, SightPlus has been made free of charge to all participants.

Results

Improvement in ability to see

A total of 83% of testers reported that SightPlus improved their ability to see for any of their chosen use cases compared to their original coping strategy (**Figure 1**).

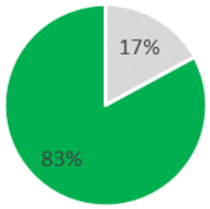
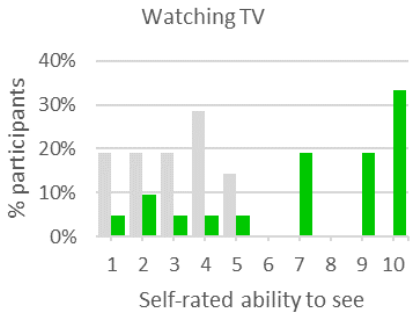


Figure 1. *Percentage of participants reporting improvement in ability to see with SightPlus compared to their original coping strategy for any task important to them.*

The most commonly performed activities were watching TV (77%), reading (42%), engaging in a hobby (39%) and working or studying (17%).

For these most common uses, the proportion of participants reporting a better ability to see with SightPlus compared to their original coping strategy was as follows (also see **Figure 2-3**):

- 70% of testers for watching TV
- 51% of testers for reading (e.g. newspapers, magazines, books)
- 78% of testers for a hobby or some other activity (e.g. playing a musical instrument, sight-seeing, checking dials in the kitchen etc)
- 75% of testers for studying or working (e.g. looking at a whiteboard, correcting student's homework, working on a PC, attending meetings / presentations)



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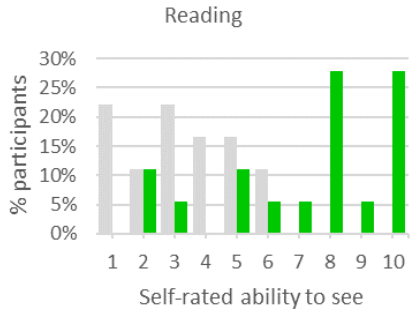

b)

Figure 2. *Self-rated ability to see with original coping strategy (grey) and SightPlus (green) when watching TV (a) or reading (b). 1-can't see, 10-can see clearly.*

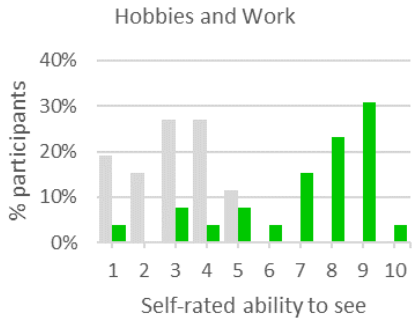

Figure 3. *Self-rated ability to see with original coping strategy (grey) and SightPlus (green) when engaging in hobbies or work. 1-can't see, 10-can see clearly.*

Retention

At the end of the take-home trial, 36% of home testers (17% of testers attending an initial 1:1 testing session) chose to keep SightPlus. All those who chose to keep SightPlus reported an improvement in ability to see to a self-rated 7 out of 10 or higher for activities important to them.

Of those who returned the device, 48% did not keep it because it was too inconvenient to use, for example too heavy, bulky or blocked the periphery. The remaining participants indicated insufficient improvement in ability to see to justify use and other reasons.

When controlling for age, 50% of children (aged <17) who tested SightPlus at home chose to keep the device compared to 32% for people aged 17+ years.

Discussion and Conclusions

This take-home evaluation session showed that SightPlus can support a wide variety of activities of daily living. Ratings for ability to see during commonly performed tasks increased substantially. Certain activities

showed room for improvement, for example motion blur confounding reading and display interference confounding working on some PC screens. In general, SightPlus performed better than participants' current coping strategies, demonstrating both the need for and potential of the device. While not all participants elected to keep SightPlus after the testing session, GiveVision anticipates that those testers who returned it for reasons of inconvenience may take up a proposed 2nd generation device which will address identified issues.

There was a notable fraction of participants in both, the 1:1 demo sessions and the take home sessions, who felt that SightPlus could not sufficiently improve their ability to see. In the future, it will be important to explore the scope and limitations to sight enhancement using the methods incorporated in SightPlus. In this study, participants were not screened out based on their diagnosis or ability to see, as the study aimed at exploring the potential of the device. In the future, it may become apparent that certain patient groups or sight loss profiles may benefit more from sight enhancement than others. At present, GiveVision is not aware of thresholds in acuity (patients with acuity 3/60 were able to read) or contrast sensitivity. However, there may be a level of retinal damage which is too substantial to be compensated for through sight enhancement. At the same time, there is potential to re-learn certain visual function with extended device use, even if there is no immediate effect. This includes the use of peripheral vision and finding the preferred retinal locus. These are questions which will need to be addressed in the future in order to scope out which patients are most likely to benefit from a device and to develop solutions for those patients who currently do not benefit.

2. CLINICAL VALIDITY

Introduction

Moorfields Eye Hospital NHS Foundation Trust London, UK, will commence a device study to assess SightPlus in a clinical setting from August 2018 to March 2019. In a pilot study for this upcoming work, GiveVision, in partnership with a supporting clinician, prepared pilot sessions to gather feedback on the chosen methodology and study design while getting a first estimate of anticipated effect sizes.

In this pilot work, visually impaired volunteers (main indication central vision loss) participated in an assessment of their vision with and without the SightPlus device. This represented an opportunistic sample and was conducted as part of an ongoing user study run by GiveVision at WAYRA London in Spring 2018. Results have since been published in 'VisionNow'. A small increase in sample size since publishing the VisionNow article means that data reported here may slightly deviate from this published data.

Methods

Participants

Participants comprised 13 adults with central vision loss resulting from various conditions. Not all participants were able to complete all tasks. Mean (SD) visual acuity without a sight aid was 1.24 (0.27) logMAR across participants. This is equivalent to acuity worse than the top line of the sight chart.

Baseline and intervention

A number of standard vision tests were performed without SightPlus to gather baseline data for ability to see without a low vision aid. This was followed by a repeat of these tests with the SightPlus device using the

participant's preferred zoom and viewing option. All tests were performed binocularly using habitual spectacle correction (if any). Applied vision tests were:

- Visual Acuity (logMAR, measured on externally illuminated ETDRS chart);
- Contrast Sensitivity (log units, using a Pelli Robson chart);
- Reading related metrics using MNREAD parameters (peak reading speed, critical print size, reading acuity; iPad version).

Results

Visual acuity

Results (**Figure 4**) demonstrated a mean improvement in visual acuity of 0.86 logMAR (8 lines on the sight chart) with SightPlus compared with not using the device (n=13). Visual acuity improved significantly from 1.24 logMAR to 0.38 logMAR, p<0.001.

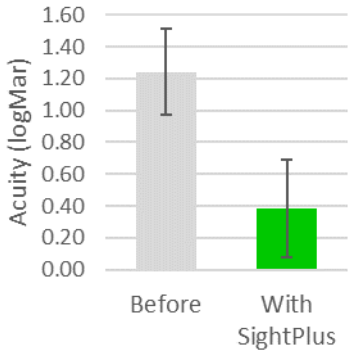

Figure 4. *Mean ± SD for visual acuity (logMAR chart) before using SightPlus (visual baseline, no vision aid) and with SightPlus.*

Contrast sensitivity

There was a mean improvement in contrast sensitivity (**Figure 5**) by 0.55 log units (11 letters on the sight chart) with subjects using SightPlus compared with not using the device (n=13). Contrast sensitivity improved significantly from 0.87 log units (13.5%) to 1.42 log units (4%), p<0.001.

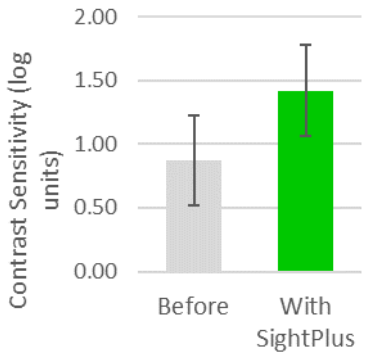

Figure 5. *Mean ± SD for contrast sensitivity (Pelli Robson chart) before using SightPlus (visual baseline, unsupported) and with SightPlus.*

Reading performance

Reading acuity improved from N16 to N8 (p<0.05), and critical print size (the smallest print that can be read with maximum fluency) improved from N35 to N17; both changes were significant, p<0.01 (n=9, where n=1 declined test due to dyslexia, n=1 did not complete the test and n=2 were not measurable with device). The peak reading speed decreased a little with SightPlus from 93 to 75 words per minute, a change which was significant at p<0.05.

Discussion and Conclusions

These data from a small opportunistic sample show marked improvements in visual acuity and contrast sensitivity when using the SightPlus device. Although peak reading speed is slightly slower with SightPlus, significant improvements were seen in the smallest print

which can be read, and in the smallest print that can be read with maximum fluency.

While there are currently no published data in the peer reviewed literature on the effect of wearable sight aids on the market, results compared favourably with data presented at the ARVO 2017 conference by eSight: while SightPlus improved visual acuity by on average 0.86 log units, eSight reported improvements by 0.73 log units (Wittich at al., ARVO 2017). Similarly, while contrast sensitivity improved by on average 0.55 log units with SightPlus, eSight reported improvements by 0.60 log units (Wittich at al., ARVO 2017). This demonstrates that SightPlus is likely to offer at least the same benefit as eSight, with a potentially higher impact on visual acuity. In the past, the larger field of view and better image quality of SightPlus has in volunteer sessions consistently made it the preferred choice compared to eSight.

The assessment of the most common clinical indicators of ability to see showed a large measurable effect on both, visual acuity and contrast sensitivity, when using SightPlus. Comparison to state-of-the-art device eSight showed that SightPlus is equivalent in performance for these two metrics, improving vision to the same extent. It is concluded that SightPlus has the large potential to provide an effective clinical solution for patients diagnosed with central vision loss.

References

Wittich, Walter et al. 2017. eQUEST: The eSight QUality of life and Efficacy Study. Abstract Number: 4764, ARVO 2017, Baltimore, USA.

3. PILOT IMPACT ASSESSMENT

Introduction

Following the 2-week take-home evaluations sessions conducted between 2016 and 2017, those participants who wished to keep the SightPlus prototype were enabled to do so. After a prolonged usage time, it was however unclear what SightPlus usage pattern people had adopted and to what extent they benefitted from SightPlus in the long-term. To answer these questions, Give Vision followed up with these users by gathering follow-up data between November-December 2017 after 6 to 18 months living with SightPlus. While administering validated questionnaires in order to explore their sensitivity to changes in participants' lives, assessment focussed on the analysis of a bespoke questionnaire focussing on usage patterns and impact on everyday life. GiveVision prepared this work to also serve as a pilot study for a future health economic assessment, partially balancing the SightPlus intervention cohort (n=34) with a control cohort (n=9) to explore volunteer responsiveness and effect sizes. Results reported here refer to the intervention group only, unless specified.

Methods

Participants

Out of 42 long-term SightPlus users, 34 participated in this follow-up study. This intervention cohort was age-, gender- and condition balanced by a control cohort identified from GiveVision's volunteer network. However, a much-reduced response rate amongst this control cohort resulted in only 9 participants.

Forty-seven percent of the whole sample was aged 65+ years, with 20% being children (with

their parents answering on their behalf). Thirty-six percent were women. SightPlus testers had various sight conditions, most commonly macular degeneration, Stargardt's and ocular albinism.

Questionnaires

Data was gathered using two validated questionnaires widely used in assessing effectiveness of low vision aids:

- the Manchester Low Vision Questionnaire (MLVQ) to capture self-reported use patterns and difficulty using the SightPlus. This is the only instrument measuring low vision aid use.
- the National Eye Institute Visual Functioning Questionnaire (VFQ-39) to capture benefits of the SightPlus through a self-reported vision-related quality of life. Optional questions were included.

The VFQ-39 tool was modified to be applied retrospectively. The MLVQ list of activities was modified to add PC use and studying/working.

A bespoke questionnaire was designed to capture impact and functionality specific to SightPlus. This questionnaire was not administered to the control cohort.

Since questionnaires had not been administered when first providing SightPlus, this study took a retrospective approach, asking participants to provide ratings for the time before they had SightPlus and now. Based on the literature examining the impact of this retrospective design, the bias introduced is expected to be small. In the future, a prospective design will be adopted as it is the preferred method for impact assessment.

Results

Manchester Low Vision Questionnaire (MLVQ)

Eighty-eight of participants reported having used SightPlus in the last four weeks (**Figure 6**), with 12% indicating not having used it. Non-usage was for technical reasons that were resolved with follow-up support. Usage frequency showed that 41% of respondents used SightPlus daily, often multiple times per day. The remainder reported using SightPlus less frequently.

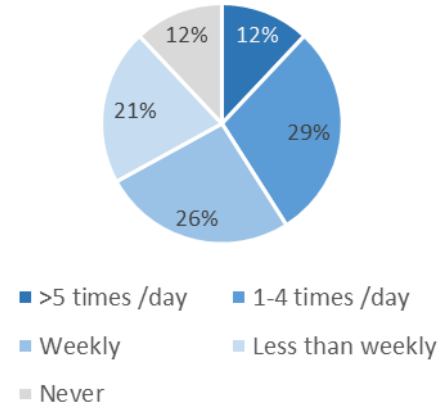

Figure 6. *Frequency of SightPlus usage 'during the last four weeks' – MLVQ inventory.*

The duration per session for which people used SightPlus varied: 30% of participants used SightPlus on average for 2 hours or more, while another 30% used it for 10 to 30 minutes and the remaining participants reporting usage durations in between. No participant reported typically using the device for very short tasks of less than 10 minutes.

Participants used SightPlus for a variety of different activities defined in the MLVQ (**Figure 7**), from reading different print sizes and materials to DIY, hobbies and watching sport events. The most common activities which

SightPlus was preferred for were watching TV (53%), studying / working (45%) and reading ordinary print (42%).

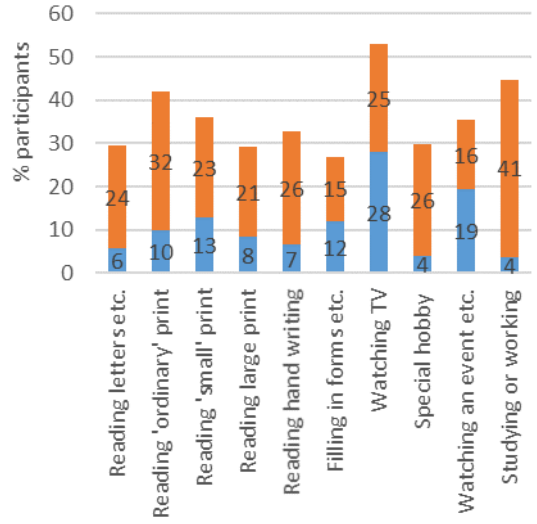

Figure 7. *Testers who can only do an activity with SightPlus (blue) and those who prefer SightPlus to their original coping strategies/low vision aids (orange), excluding those not interested in the activity. The figure shows the most common activities (at least 27% of all testers engaging in it). There were no activities out of the 22 activities listed on the MLVQ inventory that the testers did not do with SightPlus.*

National Eye Institute Visual Functioning Questionnaire (VFQ-39)

The VFQ-39 instrument was used to measure change in the quality of life after using the SightPlus compared to a life without it (**Figure 8**). There was a statistically significant (p=0.036) improvement for testers on this measure (48.7 points to 53.4, on a scale from 0 to 100). This improvement amounted to 4.7 points across all participants and 5.2 points for adults only. Furthermore, the control group reported a decrease in quality of life over a period of six months (from 46.5 points to 43.6), increasing the effect size of SightPlus on quality of life overall.

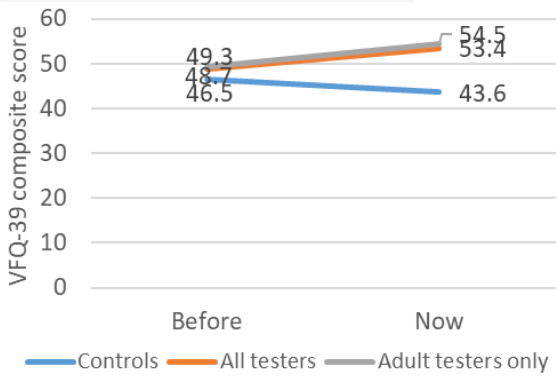

Figure 8. *Change in quality of life as measured by the VFQ-39: before SightPlus (or 6 months ago for controls) and 'now' (at the time of the survey). The control group indicated a small decrease in vision-related quality of life, while SightPlus users reported an improvement.*

The statistically significant improvements on the 10 VFQ subscales were those for near vision (improved by 11 points, p=0.005), distance vision (by 10 points, p=0.003) and role limitations, e.g. being limited by one's poor vision (by 6 points, p=0.024).

Bespoke questionnaire

The majority of testers reported a positive impact of SightPlus on their wellbeing (see Figures for exact breakdowns):

- 68% of participants reported an increase in self-confidence (**Figure 9**), with no participant providing a rating indicating any level of decrease in confidence
- 59% of participants reported an increase in independence (**Figure 10**)
- 65% of participants reported being able to do activities which they were

not able to do without SightPlus because of their eyesight

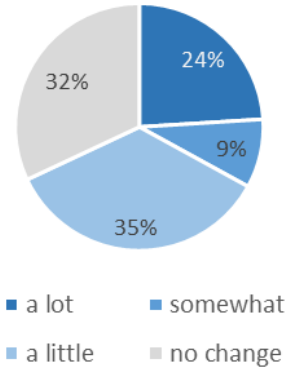

Figure 9. *Rating distribution for change in self-confidence with SightPlus after long-term use.*

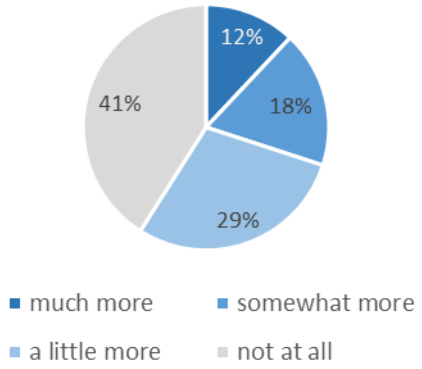

Figure 10. *Rating distribution for change in independence with SightPlus after long-term use.*

Discussion and Conclusions

This study achieved a response rate of 81% of current testers who had been using the device for 6 months to 1.5 years. Of them, the absolute majority (88%) reported still using the device, often daily (41%). The impact of the device included increased self-confidence, independence and being enabled to perform activities they could not do before due to their sight. Further, there were measurable and significant positive effects on validated inventories related to sight loss.

SightPlus was found to have a significant effect on quality of life as defined by the vision-related quality of life instrument VFQ-39. This change amounted to 5.2 points for adult testers. This effect matches the impact level of previous low vision interventions: for example, Scott et al. (1999) reported a statistically significant change on the general vision sub-scale that amounted to 3.4 points following 3 months work with Low Vision Services. Kuyk et al. 2008 reported an 8.2-point change after 6 months of extensive low vision rehabilitation.

SightPlus had greatest impact on the VFQ-39 sub-scales distance vision, near vision and role limitations. The sub-scales that showed less impact were those that fell outside the functionality range of SightPlus (e.g. colour and peripheral vision, ocular pain and general vision, which measures visual ability without any sight aids).

From working with a pilot control cohort, this study showed that there may be a decrease in quality of life during the period of intervention for controls. This shows the need to include controls in similar research in the future in order to estimate an accurate effect size relative to life without the sight aid.

The VFQ-39 is not a paediatric instrument and child participants reported little change (one point) in quality of life for that reason. Future work on impact should establish paediatric instruments to accurately capture the impact on children.

MLVQ and the bespoke questionnaire showed that there is no single pattern of SightPlus use: testers reported using it for various activities,

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various durations and in various combinations of its functional features. This indicates that SightPlus is a versatile sight aid providing lots of flexibility for its use.

References

Kuyk, Thomas et al. 2008. Health-Related Quality of Life Following Blind Rehabilitation. *Quality of Life Research* 17(4): 497–507.

Scott, Ingrid et al. 1999. Quality of Life of Low-Vision Patients and the Impact of Low-Vision Services. *American Journal of Ophthalmology* 128(1): 54–62.