Technology Assessment Program

Office of Patient Care Services

OPTICAL DEVICES FOR ADULTS WITH LOW VISION: A SYSTEMATIC REVIEW OF PUBLISHED STUDIES OF EFFECTIVENESS

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A SUMMARY FOR HTA REPORTS

The VA Technology Assessment Program is a member of the International Network of Agencies for Health Technology Assessment (INAHTA) [www.inahta.org]. INAHTA developed this checklist© as a quality assurance guide to foster consistency and transparency in the health technology assessment (HTA) process. VATAP will add this checklist© to its reports produced since 2002.

This summary form is intended as an aid for those who want to record the extent to which a HTA report meets the 17 questions presented in the checklist. It is NOT intended as a scorecard to rate the standard of HTA reports – reports may be valid and useful without meeting all of the criteria that have been listed.

VA Technology Assessment Program Report
Optical devices for adults with low vision:
A systematic review of published studies of effectiveness
(MAY 2003)

Item	Yes	Partly	No
Preliminary			
1. Appropriate contact details for further information?	√		
2. Authors identified?	√		
3. Statement regarding conflict of interest?			√
4. Statement on whether report externally reviewed?	√		
5. Short summary in non-technical language?	√		
Why?			
6. Reference to the question that is addressed and context of the assessment?	√		
7. Scope of the assessment specified?	√		
8. Description of the health technology?	√		
How?			
9. Details on sources of information?	√		
10. Information on selection of material for assessment?	√		
11. Information on basis for interpretation of selected data?	√		
What?			
12. Results of assessment clearly presented?	√		
13. Interpretation of the assessment results included?	√		
What Then?			
14. Findings of the assessment discussed?	√		
15. Medico-legal implications considered?		√	
16. Conclusions from assessment clearly stated?	√		
17. Suggestions for further actions?	√		

TABLE OF CONTENTS

Figures 1 and 2 show that in FY 2002, several optical low vision devices were among the top 12 blind aids furnished to veterans in terms of either high unit costs (eg. 2,047 CCTVs prescribed at an average unit cost of $2,047) or high prescribed volume (eg. 21,524 hand held devices prescribed at an average unit cost of $75).

Figure 1. National Prosthetic Patient Database: Top 12 Blind Aids by Total Cost (Raw Data) for FY 2002

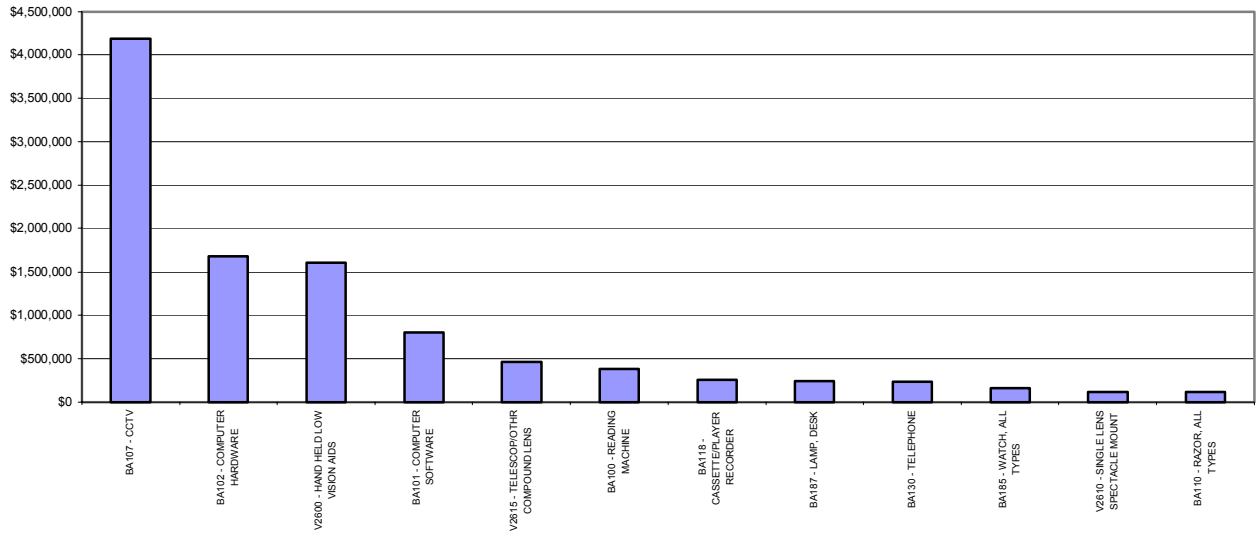
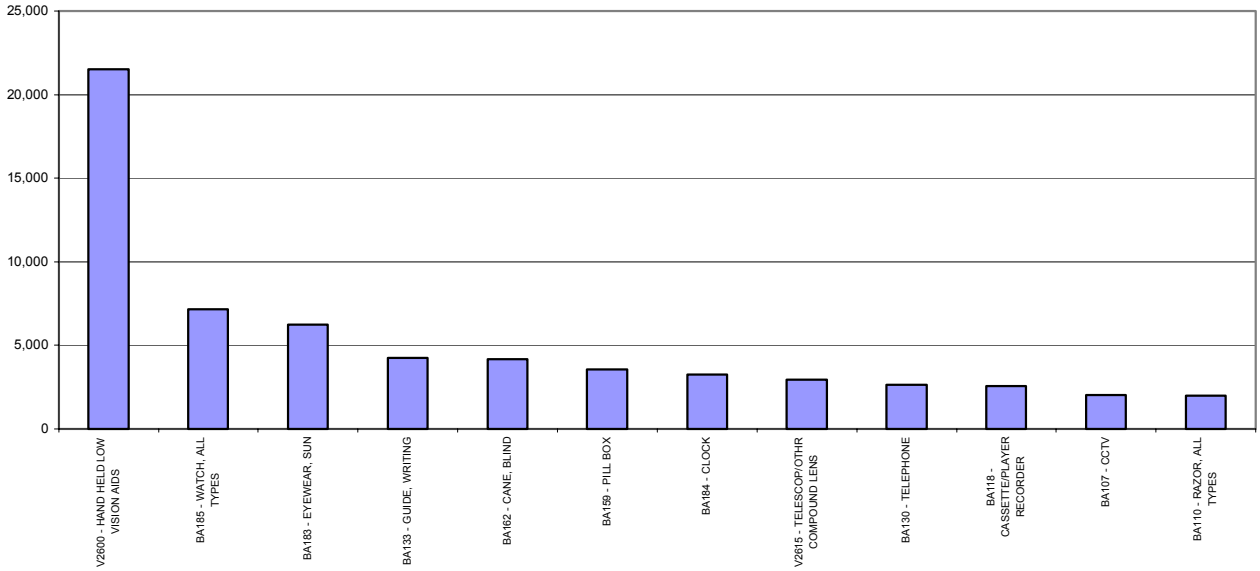


Figure 2. National Prosthetic Patient Database: Top 12 Blind Aids by Total Quantity (Raw Data) for FY 2002



(Spitzberg 1995; Kuyk 1990), of which Spitzberg had a proprietary interest in a new prototype under study.

All studies included in this review were relatively small studies of less than 40 subjects with low vision. Of those reporting causes of visual impairment, age-related macular degeneration was the primary ocular condition. Four studies did not report the ocular conditions represented in their patients. Recruitment sources in the Stelmack (1991) and Goodrich (2001) studies included subjects enrolled in VA Blind Rehabilitation Centers or low vision clinics in VA and the private sector.

Rossi (1990) and Stelmack (1991) randomized all subjects to study groups. As mentioned earlier, blinding was not done due to the nature of the intervention, but Stelmack (1991) and Spitzberg (1995) randomized device order to balance the presentation of devices, thus lessening the potential effects of bias from not blinding. Three studies (Kuyk 1990; Spitzberg 1995; Cheng 2001) did not report on randomization in the study design, and Lavinsky (2001) exposed all subjects first to the conventional telescope before the contact lens telescope. All but Rossi (1990), who used a separate control group, used a "within subjects design" where subjects served as their own internal controls. This allowed for direct comparison of outcome measures using different devices. All subjects were accounted for in the design and analysis of each study, as was similarity across groups with respect to characteristics and treatment. The effect of training was accounted for as a potential confounder in each study.

Outcomes included objective or performance-based measures in all studies. Goodrich (2001) and Lavinsky (2001) presented statistical analysis for some performance data. Kuyk (1990) and Spitzberg (1995) included anecdotal data on subjective measures of preference, ease of use, and satisfaction; small study size limited the extent to which data could achieve statistical significance in the presence of an association. None of the included studies evaluated measures health-related quality of life or costs associated with the provision of the devices.

Of the seven studies, Stelmack (1991), Goodrich (2001), and Rossi (1990) represent the most rigorous with respect to study design and reporting. The strongest evidence of optical LVDs for improving reading performance in adults was in subjects age 50 years or older with severe vision loss primarily from age-related macular degeneration. These subjects had undergone extensive visual rehabilitation, including visual skills for reading and training on low vision aids, either prior to the study or as part of the study protocol. The studies were carried out in a controlled indoor setting. In this group:

- Performance with CCTV was superior to other optical aids.
- Subjects preferred stand-mounted CCTV to hand-held CCTV or other optical aids and preferred new prototype magnifiers to existing commercial models.
- Results suggested that cost, ease of use, technological design, motivation and age may influence satisfaction, routine use of these devices, and ultimately quality of life.

Table 4. Prospective controlled primary studies of low vision device effectiveness

Note: Shaded areas indicate deficiencies in the conduct or reporting of the study. Such deficiencies may introduce bias into the study or limit the reader's ability to generalize the results to other populations. Because of the nature of the intervention, none of the studies blinded patients, personnel or health care professionals to treatment groups; blinding (or unmasked) treatment assignment was not considered for this review. None of the included studies evaluated HRQOL or costs as outcome measures.

	Study attributes										Outcome measures			
Study	**Devices**	**N**	**Ocular conditions**	**Random-ized**	**Controlled**	**All subjects accounted for**	**Blinding**	**Group similarity**	**Groups treated equally**	**Training effect minimized**	**Objective/ Performance**	**Preferences**	**Ease of use**	**Satisfaction**
Kuyk 1990	• Prototype telescope • Keplarian telescope	15	Not reported	Not reported	I	Yes	No	Yes	Yes	Yes	**Target spotting & Identification**	√	√	
Rossi 1990	• 15-diopter Fresnel prisms • standard stroke rehab	39	HHA VN	S	C	Yes	No	Yes	Yes	Yes	**Visual perception ADL Falls**			
Stelmack 1991	• CCTV • Illuminated stand magnifier • Spectacle reading glasses w/ microscope • Prism half eyes	37	Post-disciform stage ARMD Ocular histoplasmosis	S, DP	I	Yes	No	Yes	Yes	Yes	**Reading speed Reading duration**			
Spitzberg 1995	• 4 prototype magnifiers • COIL stand magnifier	39	Not reported	DP	I	Yes	No	Yes	Yes	Yes	**Reading speed**	√		
Goodrich 2001	• Stand-mounted CCTV • Handheld CCTV • Microscopic lenses • Illuminated stand magnifiers	22	ARMD DR, CRVO, MH, Dystrophy	Not reported	I	Yes	No	Yes	Yes	Yes	**Reading speed Reading duration**	√		
Lavinsky 2001	• Conventional telescope • Contact lens telescope	15	Not reported	No	I	Yes	No	Yes	Yes	Yes	**Visual field**		√	√
Cheng 2001	• CR39 prisms • Fresnel prisms	15	Not reported	Not reported	I	Yes	No	Yes	Yes	Yes	**Acuity**			

ADL, activities of daily living
ARMD, age-related macular degeneration
C, separate control group
CRVO, central retinal vein occlusion
DP, device presentation randomized
DR, diabetic retinopathy
HHA, homonymous hemianopia
I, internal control (within subjects design)
MH, macular hole
S, subjects randomized to study groups
VN, visual neglect

Primary data—driving
The VATAP did not identify any evidence of the effectiveness of optical LVDs for driving that met criteria for inclusion in the review.

Prior reviews of effectiveness of low vision devices or low vision rehabilitation
Literature reviews with explicit methods can help integrate large amounts of literature and identify knowledge gaps for rational decision-making. Existing reviews of the effectiveness of low vision rehabilitation may include outcomes related to provision of LVDs and, therefore, may inform the appraisal of evidence for this review.

VATAP identified four high quality reviews with explicit methods to include in the report (Eperjesi 2002; Owsley 1999; Raasch 1997; Stelmack 2001). To synthesize findings all used qualitative methods. A summary of the findings is presented in Table 5, and details of these reviews are abstracted in Table 7.

Table 5. High quality reviews of low vision device effectiveness

Review	Findings
Effectiveness of low vision devices	
Eperjesi 2002	• Improvement in visual function or of superiority of tinted lenses with spectral characteristics over neutral density filters or conventional sunglasses was inconclusive; some subjective improvement reported but no consistent objective benefit
Owsley 1999	• The effectiveness of bioptic telescopic spectacle use on driving performance or safety is inconclusive • Few controlled studies of important patient outcomes such as crash risk among drivers using bioptics have been done and the effect of self-regulated driving habits among bioptics users is unknown. • Well-designed studies are needed to assess the driving safety of low-vision drivers using bioptics and of monocular vision impairment or blindness, as well as the effectiveness of vision rescreening after initial licensure
Effectiveness of low vision rehabilitation	
Stelmack 2001	• Self-reported QOL is a significant outcome measure for low-vision rehabilitation • Low vision services are associated with increased self-reported functional status and QOL
Raasch 1997	• Self reported results suggest low vision intervention has a significant impact on activities of daily living and can be highly valued by patients • Impact of low vision intervention on QOL is unknown

Effectiveness of low vision devices. Eperjesi (2002) reviewed the evidence of effectiveness of tinted lenses and filters for persons with low vision. Despite using broader inclusion criteria than in this VATAP review (non-peer reviewed sources, all study sizes, and all ages of subjects), the authors found no conclusive evidence regarding the effectiveness of commercially available tinted lenses and filters for various tasks. While subjective improvement was reported among some subjects, there was no conclusive evidence of a consistent objective benefit, improvement in visual function, or

of superiority of tinted lenses with spectral characteristics over neutral density filters or conventional sunglasses.

The available research was inconclusive regarding the effectiveness of bioptics for driving, notwithstanding a sizable body of literature on the topic (Owsley 1999). The main limitations of the available evidence were: using the general population as the control group; the unknown contribution of the bioptics' restricted field of view and/or severely impaired visual function to elevated crash rates; and the unknown effect of self-regulated driving habits among bioptics users.

Effectiveness of low vision rehabilitation. Raasch (1997) reviewed studies of performance and satisfaction with low vision services, and Stelmack (2001) evaluated effectiveness of low vision services using quality of life measures. The conclusions from these two reviews represent the general state of the evidence of effectiveness of low vision rehabilitation: *current evidence shows a lack of systematic, comparative evidence of effectiveness of low vision interventions*.

Most research measured patient satisfaction or successful use of a LVD to measure change as a result of low vision intervention, but throughout the literature a consistent definition of success had been lacking (Raasch 1997). Many factors such as ocular diagnosis, vision needs, training, self-modification, home or family support, preferences and types of services may have influenced satisfaction and use, but their influence on other outcomes of low vision intervention such as quality of life was unknown.

Raasch (1997) noted that improved performance with a LVD might be expected to translate into improved quality of life, but a direct link between the two was not always apparent or had not been studied, and performance measured in a clinical setting may not generalize to function in the home or workplace. As Stelmack (2001) succinctly points out:

> *"It is important to recognize improvement in quality of life without improvement in performance with low-vision devices and improvement in performance of device use without improvement in quality of life."*

Stelmack (2001) found an improvement in functional status and quality of life after low vision interventions. Validated general health and disease-specific HRQOL instruments, such as SF-36, NEI-VFQ 51-Item Field Test, VF-14, NEI-VFQ-25, and BRS FOS instruments, had been used or modified to measure vision-specific HRQOL, but they were limited in their ability to assess outcome measures adequately for low vision rehabilitation or across specific populations. A version of the NEI-VFQ-25, was adapted for use in more frail, elderly populations. Prosthetic low vision devices used in low vision rehabilitation programs were found to be feasible for comparing outcomes of low vision programs in a veteran population.

VATAP identified an ongoing RCT comparing the effectiveness and cost-effectiveness of three models of low vision service delivery for subjects with newly diagnosed age-

related macular degeneration (Russell 2001). The results of this trial will be used to inform a national strategy for low vision services in the United Kingdom. It incorporates several generic and vision specific quality of life instruments. While this trial did not meet criteria for inclusion (it compared models of low vision rehabilitation rather than specific low vision devices), the preliminary findings support the need for a range of outcome measures to characterize quality of life in subjects with age-related macular degeneration: physical functioning; knowledge of eye condition; attitudes to and feelings towards visual impairment impact of low vision on daily life; task analysis and patterns of LVD use; and satisfaction with low vision services.

Limitations of this review

This review employed discrete inclusion criteria with respect to subjects, devices and their uses, and study attributes. The reader should be aware that changes in these criteria might alter the findings.

Children, adolescents and patients with total blindness were excluded from review, as were non-optical low vision aids. Tasks other than reading and driving were not considered, although review of the search retrieval showed a preponderance of evidence for reading.

VATAP only considered controlled prospective primary studies for inclusion in this review. The sizable amount of available non-experimental (observational) data, which is considered weaker evidence of effectiveness, was not included. It is possible that information from these studies may have contributed to the findings in this report. However, the findings from the included high quality reviews that did summarize non-experimental data in their topic areas would not change this report's conclusions.

This report confined retrieval to full text articles in English. In all, VATAP excluded 28 citations based on these criteria. Review of available title and abstracts shows that one additional study in German by Rohrschneider (1997) may have met inclusion for review (see excluded studies list in end references). This study compared visual acuity with glasses, telescope and the Low Vision Enhancement System (LVES)[16]. They reported improved visual acuity and contrast sensitivity and reduced glare with LVES over correction with glasses or telescopes, but regular use of LVES in the majority of patients was unlikely. These findings would not have changed the conclusions in this review.

Finally, only the most recent or comprehensive study published by the same study group for the same purpose was included. This was done to provide a best estimate of the true study base available for inclusion. Redundancy can be found in the peer reviewed literature when investigators publish research findings that overlap with previous publications or when they publish the same findings in multiple sources. In the end, VATAP did not exclude any studies based on this criterion.

[16] a battery-powered portable vision enhancement device worn like goggles and tailored to each patient. Developed by the Johns Hopkins Wilmer Eye Institute in collaboration with the National Aeronautics and Space Administration and the VA.

SUMMARY

Adults with low vision can experience a range of difficulties in their daily lives as a result of their vision impairment. Among older adults—the primary emphasis of this review—vision loss can have a profound effect on their lives. Low vision is associated with a variety of co-existing medical conditions, limitations in activity and performance, and lower quality of life. Demographic trends forecast a dramatic increase in the prevalence of age-related causes of vision loss in the veteran population. With this trend is an increasing need for low vision services targeted at detecting visual impairment and mitigating the functional consequences associated with age-related vision loss to improve quality of life.

Provision of low vision services to veterans is a priority area for VA. To meet the needs of an increasingly geriatric veteran population, VA is complementing its inpatient service delivery with outpatient services that include furnishing a range of low vision devices (LVD) to eligible veterans. The highest demand (and the most costly LVDs for veterans) is for electronic optical devices, such as CCTV and computer assistive technologies, and nonelectronic hand–held models. Veterans have shown substantial interest in CCTV in particular for its reported ability to improve a range of functional deficiencies caused by loss in visual acuity and visual field.

Advocates for visually impaired veterans have expressed concern over the quality of the scientific evidence supporting the use of many LVDs, particularly newly emerging electronic devices. This systematic review on existing evidence of effectiveness of low vision devices from the peer-reviewed published literature will inform a multidisciplinary task force of VA vision care experts charged with developing a process for evidence-based new technology evaluation and dissemination of information in VA.

This review considered controlled prospective studies of adult subjects with limited residual vision as a result of moderate to significant irreversible vision loss and all optical devices available to eligible veterans. This review considered outcome measures encompassing objective measures of performance and use, subjective measures of satisfaction and preference, efficiency, and health-related quality of life measures. Reviews of the effectiveness of low vision rehabilitation addressing the effectiveness of LVDs were also included.

The best available evidence comparing the relative effectiveness of optical LVDs is seven small, prospectively controlled clinical studies comparing the performance of low vision devices for reading tasks at various distances in an indoor setting. Evidence suggests that among extensively trained patients with age-related macular degeneration, reading performance with either stand-mounted or handheld CCTV was superior to prescribed optical devices (stand magnifiers, coil stand magnifiers, and microscopic lenses). Compared to standard rehabilitation alone, Fresnel prisms added to standard rehabilitation improved performance on visual perception tests but not on

activities-of-daily-living function in post-stroke inpatients with homonymous hemianopia or visual neglect.

Anecdotally, CCTV was preferred to spectacle reading glasses and illuminated stand magnifiers, and prototype magnifiers were preferred to conventional devices, but the reasons behind the preferences were not systematically examined. Anecdotal evidence identified cost of the device, design, age and motivation as factors that might have affected sustained use of a device. Sustained use of these devices in the subject's life setting, resources in terms of costs and training associated with each alternative, and the link between device use and health related quality of life were unknown.

KNOWLEDGE GAPS AND RECOMMENDATIONS FOR FUTURE RESEARCH

This review identified knowledge gaps that may help direct future research. These gaps concentrate on candidacy for low vision devices, suitable prescription of these devices, and measuring their effectiveness.

Diagnosis, visual acuity, and pattern of visual field loss are initial considerations in the prescription of low vision aids, as they provide a fair degree of predictable, objective information about the effect of the visual impairment (Faye 1976). However, these measures alone may be inadequate for the adult with age-related causes of vision loss (particularly those age 75 or older), who frequently complain of visual difficulties under everyday, sub-optimal conditions despite satisfactory results on standard testing (Brabyn 2001).

As yet, no single testing battery has been identified that is sufficiently sensitive or practical to administer to these patients. A testing battery that is easy to administer to a growing elderly population and is sensitive to real-world conditions might assist clinicians in (Legge 1992; Rubin 1997; Brabyn 2001):

- identifying the circumstances under which vision aids should be prescribed;
- optimizing prescription regimens;
- monitoring disease progression;
- predicting individuals at risk for future serious vision loss;
- referring patients to specialized low-vision clinics;
- freeing up resources associated with more labor-intensive special testing.

Current practice relies on direct measurement of performance in the clinical setting as a proxy measure for continued device use in the patient's life setting, but ideally performance should be measured for tasks encountered under everyday conditions. Low vision research has identified an array of visual and nonvisual factors that may influence both the performance conducted in a clinical setting and continued use of the LVD, but the value of these factors as predictors of performance or successful use in everyday indoor and outdoor conditions requires further study. Studies are needed with sufficient power to detect the presence of an association and to analyze intra-subject as well as intra- and inter-group variation. Research is also needed to differentiate the

physiological from psychological basis of visual improvement and to identify the visual and non-visual skills required for specific tasks. Identifying predictive factors from robust research may help clinicians develop a practical, sensitive testing battery for improving diagnosis and candidacy.

To inform choices about appropriate device provision, research is needed on the *relative* effectiveness of low vision devices using rigorous methods under conditions and for tasks similar to those found in the real world, and along the continuum of visual impairment and disability. Sufficient power is required to detect the presence of associations and to permit statistical analysis of intra-subject as well as intra- and inter-group variation. The methods should be transparent to allow the reader to determine applicability of the results to his or her patients, and the methods should employ patient-focused functional outcome measures and subjective measures appropriate to the desired goal of rehabilitation.

Performance should take into account adaptation, setting, compensatory strategies, training and exposure. Subjective self-reported measures of usage and satisfaction should be considered. Preferences should be measured in a way that is valid, useful for benchmarking, and relevant to inform decision making about uses in patient care as well as purchasing. With respect to measures of efficiency, the full range of resources (e.g. costs associated with devices, access to low vision services and training) associated with device use should be considered, both from the perspectives of the patient and the health care system.

Ultimately, the goal of low vision rehabilitation, including use of assistive technologies, is to improve the patient's quality of life. To some extent the impact of low vision devices on a patient's quality of life can be dramatic and may seem obvious. However, outcome measures are needed that capture the type and magnitude of the change in function and HRQOL in a way that allows comparison of outcomes across low vision interventions and with outcomes of treatment of other disorders. Research is needed to identify appropriate functional outcome measures for low vision rehabilitation and to develop and validate instruments of HRQOL for use in the low vision population. Existing evidence suggests that a range of outcome measures is needed to characterize quality of life in subjects with age-related visual impairment: physical functioning; ocular condition; attitudes towards and perceptions of visual impairment; impact of low vision on daily life; task analysis and patterns of LVD use; and satisfaction with low vision services.

In the realm of assistive technology (AT) outcomes measurement, a number of proprietary and publicly funded initiatives exist or are under development. Among the federally funded, VA researchers are actively investigating many areas of blind rehabilitation including developing functional outcomes measures and measuring the impact of blind rehabilitation on quality of life (VA BRS 2002). Findings from the VA

Blind Rehabilitation Outcomes Project[17] may assist providers in improving greater efficiency and effectiveness of low vision interventions in VA (De l'Aune 1999). For example, VA researchers developed and validated a 13-item instrument to measure the impact of a comprehensive rehabilitation program. With further modification it may be suitable as a measure of change in overall functional independence associated with use of low vision devices.

The Consortium for Assistive Technology Outcomes Research (CATOR)[18] was established in 2002 as a five-year project to conduct research on AT outcomes and impacts to determine the effectiveness and usefulness of AT and the implications for use/discontinuance of AT devices [http://www.atoutcomes.com/]. Results from this project may inform outcome measurement needed for low vision technologies.

CONCLUSIONS AND RECOMMENDATIONS

This review reveals the paucity of high quality evidence available in the peer-reviewed published literature to inform choices about the provision of optical low vision devices in VA. The absence of compelling evidence and a standard taxonomy of what constitutes desired outcomes make it difficult to clearly recommend one device over another. Therefore, clinicians must continue to rely on industry literature, patient self-reporting, clinical observations, and real-world trials in determining appropriate provision of low vision aids. Unfortunately, industry is motivated by profits and has no regulatory impetus (aside from mandates from federal funding sources) to produce such information. Only in recent years have low vision specialists been held to a higher standard of accountability to the health systems in which they provide care. Neither alone has had sufficient resources to conduct all of the research needed to inform these choices.

Nonetheless, health care providers and assistive technology communities have the responsibility to determine which practices and technologies are most appropriate for an expanding market of individuals with age-related visual impairment. By virtue of its large visually impaired population and concentration of low vision expertise, VA stands poised as the nation's largest health care system to make significant strides in evaluation and provision of high quality low vision services to veterans and the nation.

- ***VA practitioners should use an evidence-based framework in evaluating evidence of effectiveness.***

  Evaluating outcomes associated with use of low vision service delivery requires systematic evidence-based data collection to provide reliable data. To that end,

[17] VA Rehabilitation R&D Center, Atlanta, GA 30033; Pittsburgh Vision Services, Pittsburgh, PA. Funded in part by the VA Office of Rehabilitation Research and Development. http://www.varrd.emory.edu/brc/link.html

[18] funded by the National Institute on Disability and Rehabilitation Research (NIDRR), United States Department of Education

- ***In the meantime, VA practitioners need information that improves and standardizes <u>current</u> prescription practices.***

  VA provides a range of electronic and non-electronic optical devices to its veterans. Electronic devices tend to receive most of the attention because of their popularity among consumers and high unit costs. Non-electronic devices may be overlooked, even though they are the most commonly prescribed. To note, in fiscal year 2002, hand-held low vision aids were the most commonly prescribed low vision aid and had the third highest expenditure for aids to blinded veterans.

  Frequently manufacturers of non-electronic "low tech" devices report optical parameters of their devices based on arbitrarily chosen standards. Standardized information is needed to allow clinicians to predict accurate improvement in patients' visual performance with the device. Bailey (1994) measured and tabulated key optical parameters of 92 stand magnifiers and 53 hand-held magnifiers using a standardized formula. Information such as this may assist practitioners by translating existing disparate information from manufacturers into standardized, usable information on which to base more rational prescription decisions, particularly of some high volume, "low tech" optical devices.

Table 6. Primary studies that met inclusion criteria for review

Study attributes	Kuyk 1990	Rossi 1990	Stelmack 1991	Spitzberg 1995
Study objective(s)	• Demonstrate feasibility of constructing a simple motorized focus telescope using off-the-shelf components • Compare performance in spotting and identification of near and distance targets using a prototype motorized focus telescope (MFT) and a hand focus telescope (HFT)	To assess the efficacy of 15-diopter Fresnel prisms for treatment of homonymous hemianopia (HHA) or unilateral visual neglect (VN) after stroke	• Compare reading speed and duration using CCTV, spectacle reading glasses, and illuminated stand magnifiers	Compare reading speed and preferences for 4 prototype magnifiers to a commercially available stand magnifier
Study size	N = 15	N = 39	N = 37	N = 39
Recruitment source	VA facility but details not reported	Inpatient stroke rehabilitation unit	• Patients admitted to Central Blind Rehab Center, Hines VAMC for low vision rehabilitation	• Patients from 5 low vision clinics, including one in VA • Selection process not defined
Inclusion criteria	• Visually impaired subjects • Experienced users of manual telescopes • Informed consent	• Diagnosed with stroke with either HHA or VN • Free of disabling cardiac, pulmonary, or rheumatologic problems that may preclude rehab efforts • Informed consent	• Age 50 or older • Diagnosed with post-disciform stage age-related macular degeneration or ocular histoplasmosis	• Volunteers • Need for 3X magnification to read 1.0M or 1.5M print
Exclusion criteria	Not reported	• Best corrected visual acuity worse than 20/200 • Unable to comprehend and cooperate with visual field assessment	• Pathophysiologic changes w/in and in neurosensory or pigment epithelial retinal layers immediately surrounding the macula • Nutritional optic atrophy including glaucomatous, ischemic or toxic that would compromise central visual function • Significant cataract formation including posterior subcapsular cataracts of > 1+, cortical vacuoles > 2+, nuclear sclerosis > 2+ • Media changes decreasing view of fundus details to < 20/40 equivalent	None reported

Study attributes	Kuyk 1990	Rossi 1990	Stelmack 1991	Spitzberg 1995
Characteristics of subjects	• Age ranged from 75-81 years • Visual acuity between 10/60 and 10/350	• Comparable demographically across groups with respect to gender, interval poststroke, lesion type, side of stroke, deficit type, modified mini mental status exam • Prism group older than control group Age (±SEM): control 63.3 yrs ± 2.5 vs. prism 72.6yrs ± 1.8 ($p < 0.01$)	• Gender not reported • Age range > 50 years, range not defined • Diagnoses: All with ARMD or ocular histoplasmosis • Eccentric viewing acuity ranged 10/60-10/600 • Magnification with ISM 3.5X to 10X • Power of spectacles +10.00D. to +32.00D. • Magnification with CCTV 4X to 22X	• Age range = 9 to 77 years • Other data not reported
Study devices	• Prototype MFT of 4, 6, and 8 X magnification • Keplarian type HFT monocular of 4, 6, and 8 X magnification	• 15-diopter Fresnel prisms • Routine stroke rehabilitation	• VTEK Voyager CCTV • Eschenbach illuminated stand magnifier • Prism half eyes or Aolite microscope spectacle reading lenses	• Spherical mirror magnifier • Cylindrical mirror magnifier • Reflecting prism magnifier • Zoom magnifier • COIL #5428 and #5123
Random assignment of either subject to group or order of device presentation	Not reported	Random assignment to study groups	Random assignment to one of 3 treatment groups; each group varied order of devices used	Order of presentation of devices rotated systematically
Controlled	Within subjects design used	Separate control group	Within subjects design used	Within subjects design used
Protocol	• Each subject trained in use of MFT for 15-30 minutes • First near and then far distance target spotting and identification tasks performed with each telescope of the same magnification power at seven distances between 8 and 80 feet in a well lit hallway using series of 4 black letters of varied size on a white background • Time to completion and number of identification errors recorded; data converted to time required to identify target • Questionnaire administered to elicit preferences, rate performance and design features on a 4-point scale, and rate confidence with device	• Prism group fitted and trained with prisms; visual adaptation and safety awareness demonstrated • All patients had general physical and neurologic exam and tested without prisms at baseline • All patients studies at baseline, 2 weeks, and 4 weeks with Modified Mini Mental Status Examination, Motor Free Visual Perception Test, Line Bisection Task, Line Cancellation Task, Harrington Flocks Visual Screener, Tangent Screen Examination, and Barthel ADL-Mobility Score • All patients participated in ADL training and table-top visual perception retraining tasks	• Each subject received extensive rehab training for visual skills for reading and one-hour training on each device • Within subject controlled = each subject tested with each device • Optimal magnification for spectacles and illumination magnifier = lowest power plus lenses needed to read “Life in These United States” excerpts from Readers’ Digest • Magnification for CCTV = lowest print size needed to read same excerpts with either black letters on white background or reversed	• Each subject trained daily with four low vision aids including at least two prototype devices for a minimum of 5 days • VA subjects trained for an additional 5 days • Order of presentation of devises systematically rotated among subjects • All subjects practiced reading and writing for ≥15 minutes each day with each device • Subject data collected included age, pathology, reading history prior to and after vision loss, visual acuity, and CSF • Daily collection of outcome measures for each device
Loss to follow-up/drop out	None	None	None	None

Study attributes	Kuyk 1990	Rossi 1990	Stelmack 1991	Spitzberg 1995
Intention to treat analysis[20] used	Yes	Yes	Yes	Yes
Outcomes	• Preferences • Performance and design features: overall focus speed; stability of the viewed scene during focusing; control of eye-target alignment of device; overall focus control; overall performance; weight; size • Confidence with device	• Testing measures • Number of falls • Demographic data of age and interval post stroke	• Reading speed and duration	• Daily change in reading speeds and subject preferences • Subject preference for aspects of device including cosmesis, portability, comfort, ease of use, field, and glare
Adverse effects	None reported	None reported	None reported	None reported
Results	• 73% preferred Motorized Focus Telescope vs. Hand Focus Telescope • Subjects rated confidence in device equally • Subjects rated weight and size of prototype motorized focus telescope below Hand Focused Telescope; improvements in design were warranted • Effect of motorized model on training time, learning curve and ability to correct alignment were under study	• Baseline evaluations of visual perception and activities of daily living function were similar for both study groups • At 4 weeks, prism group performed significantly better than controls on Motor Free Visual Perception Test ($p < 0.01$), Line Bisection Task ($p < 0.01$), Line Cancellation Task ($p < 0.02$), Harrington Flocks Visual Screener ($p < 0.01$), Tangent Screen Examination ($p < 0.01$) • No significant differences between study groups in Barthel ADL scores or number of falls • Steady improvement in perceptual task performance over study duration suggests a more complex response to prisms than simple adaptation • Recommended additional controlled studies to confirm results and to define the optimal prism strength, manner of application, and duration of benefit	Reading speed: • CCTV > stand magnifiers ($p < .001$) • Spectacle lens > stand magnifiers ($p < .001$) • CCTV v. spectacle lens were borderline significant (p not reported) Reading duration: • CCTV > stand magnifier ($p < .001$) • CCTV > spectacle lens ($p < .001$) • Stand magnifier v. spectacle lens (p = ns)	• Average reading speeds of subjects using prototype devices not significantly different from COIL stand magnifier (test of significance not presented) • 29 (74%) of subjects picked one of the new prototypes as aid of choice • Spherical mirror magnifier most frequently preferred (13/39) • Authors suggest that preferences are quite likely to change with increased knowledge about options
Comments	Supported by a DVA RR&D grant C962-PA	No proprietary interests reported	No proprietary interests reported	• Research sponsored by NEI given to Optical Designs, Inc (Houston, TX) • Author Spitzberg has proprietary interest in these products

ARMD, age-related macular degeneration

[20] A strategy for analyzing data in which all participants are included in the group to which they were assigned, whether or not they completed the intervention given to the group. Intention-to-treat analysis prevents bias caused by the loss of participants, which may disrupt the baseline equivalence established by random assignment and which may reflect non-adherence to the protocol.

CCTV, closed captioned television
ISM, illuminated stand magnifier

Table 6 (continued)

Study attributes	Goodrich 2001	Lavinsky 2001	Cheng 2001
Study objective(s)	Compare differences in reading speed and duration using stand- or hand-mounted CCTV vs. prescribed optical devices	Evaluate the performance of a contact lens telescope (CLT) and conventional telescope	To compare high and low contrast acuity reduction with conventional CR39 versus Fresnel prisms
Study size	N = 22	N = 15	N = 15
Recruitment source	• Patients enrolled in residential rehab program at the Western Blind Rehab Center, Palo Alto VAMC • Selection process not defined	• Patients in the Hospital de Clinicas of Porto Alegre, Rio Grande do Sul, Brazil from October 1999 to April 2000	Not reported
Inclusion criteria	• All with legal blindness as defined by the ICD-9CM • Volunteers • Presence of central scotoma with intact peripheral field as determined by patient's reduced visual acuity and visual-field tests • Desire for reading rehabilitation	• Ophthalmological diagnosis of low vision • Visual acuity between 20/60 and 20/400 • Informed consent	Not reported
Exclusion criteria	• Cognitive defects • Current use of medications that would impair reading ability and/or illiteracy	Visual acuity < 20/60 or > than 20/400	Not reported
Characteristics of subjects	• 20 men; 2 women • Average age = 73.3 years, (SD 8.9 yrs), range 53-87 • Diagnoses: ARMD (16); DR with only central field involvement (2); central retinal vein occlusion (2); macular hole (1); dystrophy (1) • Average LogMAR visual acuity = 0.994, approx 20/200, (SD, 0.46), range 0.48-1.6 • Average Pelli-Robson contrast sensitivity = 0.89 (SD, 0.46), range 0.00 to 1.5 • No previous comprehensive rehab training • Most used magnifier, but none used CCTV	• 11 males; 4 females • age ranged from 13 years to 84 yrs (mean age = 60.7 years) • mean uncorrected visual acuity = 20/245; 8 patients with 20/200 • mean visual field without correction = 101 degrees (range 80-114 degrees) • mean corrected visual acuity = 220/105 • mean visual field with conventional telescope correction = 22 degrees • mean visual field with CLT correction = 52.1 degrees	• Healthy subjects • Age range 20-30 years • Spherical refractive error < 5.00 diopters • Cylindrical refractive errors < 1.00 diopters
Study devices	• Stand-mounted CCTV (Optelec Clearview or TeleSensory System Genie) • Handheld CCTV (Innoventions Magni-Cam Triad Color system) with 27 inch Daewoo TV • Prescribed optical device: Eschenbach stand magnifier (10); Coil stand magnifier (9); microscopic lenses (3)	• Sportieri® conventional telescope designed to produce 2.0X magnification with visual field of 25 degrees • Contact lens telescope system (CLT) = contact lenses (mediphacos, Belo Horizonte) plus spectacle lens designed to produce 2.0X magnification with a visual field of 50 degrees	• Conventional CR39 prisms • Fresnel prisms

Study attributes	Goodrich 2001	Lavinsky 2001	Cheng 2001
Random assignment of either subject to group or order of device presentation	Not reported	Each patient wore first the conventional telescope then the CLT	None
Controlled	Within subjects design used	Within subjects design used	Within subjects design used
Protocol	• Four instructors provided formal reading rehab training in all three devices • All subjects received eccentric viewing training before reading training • One training session/day for 5 sessions on each device • Reading speed and comprehension measured using randomly selected paragraphs printed by laser printer in Times Roman font rated at Flesch-Kincaid Grade 5 level difficulty • Reading duration defined as cumulative time subject spent reading during each training session	• Each subject wore the conventional telescope, obtained maximal focus, given a 10 minute period of adaptation • Visual acuity tested using Lighthouse Near Acuity Test at 2 m; best acuity defined as the line read with a maximum of two errors • Visual field testing with a Goldman perimeter at distance of 50 cm using a number III object of 4 mm^2 and intensity number 4 • Followed by same protocol using CLT	• Subjects' refractive errors corrected with trial lens to a visual acuity of 6/6 or better • Visual acuity of right eye measured with high and low contrast charts while wearing each prism at a vertex distance of 12 mm • Test distance of 4 m and chart luminance of 140cd/m^2 used
Loss to follow-up/drop out	None	None	None
Intention to treat analysis used	Yes	Yes	Yes
Outcomes	• Reading speed, duration and subjective preference	• Difficulty in device use using a 10 point scale • Overall satisfaction with devices using a 10 point scale • $P < 0.05$ considered statistically significant	Visual acuity
Adverse effects	None reported	None reported	None reported

Study attributes	Goodrich 2001	Lavinsky 2001	Cheng 2001
Results	Reading speed (effect size, d): • Stand-mounted CCTV > optical device; d = 0.45 • Hand-held CCTV > optical device; d = 0.57 • No difference between types of CCTV; d not calculated Reading duration: • Stand-mounted CCTV > optical device; d = 1.31 • Hand-held CCTV > optical device; d = 1.71 • No difference between types of CCTV; d not calculated Reading productivity (reading speed X duration = words per sitting): Hand –held CCTV (2820.5 WPS) > stand mounted CCTV (2745.8 WPS) > optical device (1442.3 WPS) For types of CCTV only: • 72% preferred stand-mounted to 23% for hand-held for most reading tasks • Patients were equally divided when asked to consider device cost	• 11/15 found conventional telescope easy to use vs. 6/15 for CLT • 11/15 were satisfied with CLT, but only 3/15 were satisfied with conventional telescope • Visual field increased 28.7% using CLT (P < 0.001) • 33% spontaneously decided to use CLT • 3 (100%) of patients under age 50 and 8 (67%) rated good satisfaction with CLT • Authors suggest motivation and age determined successful use	• Significant reduction of high and low contrast acuity occurred when power of CR39 prism and Fresnel prism reached 10 prism diopters and 5 diopters, respectively ($p < 0.05$) • Rate of acuity reduction with increasing prism power was greater with low contrast targets than with high contrast targets for both prisms (p not reported) • Rate of acuity reduction with increasing prism power was greater with Fresnel prism than with CR39 prism for both contrasts ($p < 0.05$) • Greater high and low contrast acuity reduction with Fresnel prisms is mainly the result of reflection from the prism facets, secondary refraction at the prism facet bases and diffraction of light by the grooves
Comments	No proprietary interests reported	No proprietary interests reported	No proprietary interests reported

Table 7. Literature reviews included in the report

Review attributes	Eperjesi 2002	Stelmack 2001	Raasch 1997	Owsley 1999
Topic	**Tinted lenses and filters**	**Low vision rehabilitation**	**Low vision rehabilitation**	**Driving with vision impairment**
Objective	• Evaluate effectiveness of tinted lenses and filters for people with low vision • Identify a scientifically-based prescribing protocol for adoption in clinical practice	• Evaluate effect of low vision on quality of life (QOL) • Evaluate effectiveness of low vision intervention on QOL	• Evaluate effectiveness of low vision interventions • Identify factors affecting effectiveness of low vision interventions	• Evaluate impact of eye diseases and conditions on driving habits, performance, and safety • Evaluate effectiveness of vision assisted driving using bioptic telescopic spectacles • Identify public policy issues and research challenges in studying driving and vision impairment
Methods	• MEDLINE searched for past 30 years using variety of key word combinations • Hand searching of reference lists of retrieved articles • Critical appraisal of study design outlined • Commercially available tinted lenses included: Corning photochromic filters®; UVShields® and NoIR® filters • Use of tinted lenses on progressive eye disease (e.g. Retinitis pigmentosa) excluded • Peer-and non-peer reviewed sources, no study size limit, children and adults included	• MEDLINE and PsychINFO searched from 1990-2000 using key words of vision or vision disorders, QOL, and low vision rehabilitation • Available research outlined but little critical appraisal beyond study focus, population studied and instruments used • Studies of adults with low vision or on QOL as an outcome measure in low vision rehabilitation included • Excluded were reports of instrument development, clinical trials, restorative treatments of vision, and community-based studies of sensory impairment	• Studies that examined patient satisfaction and performance with low vision services were tabulated • Description of subjects by study size, mean age, visual acuity; intervention, follow up, key findings and limitation of study were presented • Studies of prevalence of low vision, impact of low vision on affected individuals, and impact of low vision intervention on visual impairment included • Published studies ranged from 1986 – 1996 • Children and adults considered	• MEDLINE search from 1966-present using terms for vision, ocular, vision impairment, driving, accident and crash • Hand searching of end references of retrieved articles and authors' reprint collections were included • Full length articles only
Outcome measures	• Objective visual measures and subjective measures • Objective measures further analyzed by measure used	• QOL using validated instruments	• Patient satisfaction • Performance measured with low vision services	• Crash rate • Driving performance
Results	• Most results were equivocal • Some subjective improvement reported but no consistent objective benefit • Little conclusive evidence of improvement in visual function or of the superiority of tinted lenses with spectral characteristics over neutral density filters or conventional sunglasses	• Visual impairment significantly associated with decreased functional status, decreased self-reported QOL, and increased risk for depression • Decreased visual acuity, visual field, and occasional blurred vision are associated with decreased QOL • Low vision services are associated with increased self-reported functional status and QOL	• Low vision intervention can have a significant impact on patients' activities of daily living and can be highly valued by patients based on self reporting • Impact of low vision intervention on QOL is unknown • Training, diagnosis, and model of care may affect effectiveness of low vision services but their impact has not been studied	• Evidence of the impact of types of visual impairment on driving safety and performance is inconclusive • Peripheral vision may play a greater role than visual acuity • Visual attention and processing show promise as a method for identifying high-risk drivers • Evidence of the effectiveness of bioptic use on driving performance or safety is inconclusive
Conclusions	• Not possible to base tinted lens use on type of task or eye condition • Practitioners must continue to rely on marketing literature, subjective reports, clinic-based observations and real-world trials in determining appropriate prescription of devices in low vision	• Self-reported QOL is a significant outcome measure for low-vision rehabilitation • Instruments are needed that are more sensitive to rehabilitation services, patient needs and goals to facilitate development of rehabilitation plans and to compare techniques, devices, and programs • Measurement properties, validity, and reliability of instrument currently used and in development • Low vision services are associated with increased self-reported functional status and QOL	• Application of QOL instruments to low vision populations is needed for evaluation of outcomes of low vision services • Such a study is needed that establishes the type and magnitude of the change in functioning and QOL in a way that allows comparison with treatment of other disorders.	• Research challenges include accounting for the effects of driving exposure, age, and ocular disease in study design, classifying and defining outcomes that can be generalized across populations, and developing tests to identify unsafe drivers • Well designed studies are needed to assess safety of low vision drivers using bioptics or with monocular vision impairment or blindness, and the effectiveness of vision rescreening after initial licensure.

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