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Recommended Changes to Standard of Care for Monitoring of Cortically Blind Fields

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Abstract

Global incidence of stroke has risen 70% in the last 30 years, affecting approximately 25% of adults throughout the course of their lives. Up to 60% of stroke survivors will suffer visual impairments, which significantly reduce quality of life and independence. Despite the high prevalence, patients are hugely underserved by the medical and research communities. Clinical care is variable throughout the United States and United Kingdom, with only 57% of patients receiving visual field assessments and 61% stating their need for support has not been fully met. Additionally, unlike stroke survivors with motor or language deficits, those with vision loss are rarely offered visual rehabilitation. This is despite recent research into the efficacy of visual training and the propensity for the visual deficit to worsen in the absence of an intervention. This article reviews common gaps in patient care and proposes policy changes to increase awareness of the condition, foster clinical and scientific advances in treatment, and enhance patient outcomes.

Keywords

stroke, vision, rehabilitation, perceptual learning, standard of care, hemianopia

Social Media Post

Stroke-induced vision loss is a prevalent and debilitating condition that remains underserved by the medical and scientific communities. This article aims to illuminate the hurdles patients faced and what policy changes may help alleviate these burdens.

Highlights

- Vision loss following stroke is a debilitating condition that affects 30–60% of stroke survivors.
- Current clinical care leaves patients feeling frustrated and abandoned. A lack of proper assessment and follow-up care seems to be universal.
- A plethora of scientific work suggests a capacity for recovery in this condition. However, clinical deployment of potential therapies is uncommon.
- Regulatory support for minimally invasive, low-risk treatment options is necessary to speed development of new therapies.
- Formation of a consortium comprising patients, caretakers, researchers, policy makers, and clinicians is critical for deciding a path forward for this field.

Introduction

Vision loss following stroke is a prevalent source of visual impairment. Every year, over 12 million people in the world suffer from stroke, affecting one in four adults during their lifetime (Feigin et al., 2022; Study, 2018). Of these, an estimated 30–60% develop visual deficits (Gray et al., 1989; Rowe, 2013; Terecoasa et al., 2022), leading to 1% of the population over the age of 49 living with this type of vision loss (Gilhotra et al., 2002), and an additional 100,000 new cases each year in the United States and Europe (Sahraie, 2007). This vision loss is associated with impaired quality of life (Gall et al., 2009, 2010; Papageorgiou et al., 2007) and increased mortality (Sand et al., 2017). Despite its prevalence, patients are rarely provided with adequate clinical care, are offered limited rehabilitation options, and receive little follow-up or monitoring (Rowe, 2013). This is largely due to a lack of standardized protocols for assessing and monitoring visual impairment following stroke. As a result, many patients report being unsatisfied with their level of care (Rowe, 2013). This article reviews the causes of stroke-related vision loss and the current standard of care, identifies gaps in coverage and treatment options, and makes recommendations to improve patient outcomes.

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In the human visual system, information travels from each eye, along the optic nerve to the optic tract and through subcortical regions before reaching the primary visual cortex (known as V1). Due to the organization of the visual system, each cortical hemisphere processes visual information from both eyes representing the opposite (contralateral) visual field. As a result, damage to later stages of the visual pathway, for example, V1, causes a loss of vision on one side of the visual world in both eyes. The size and location of the visual deficit can vary widely, depending on the extent and location of the damage to V1 or the inputs to it. Patients may exhibit visual field deficits that represent anything between a small scotoma, to a single quadrant ("quadrantanopia") or a full hemifield ("hemianopia"). This condition is referred to by many names, including hemianopia (Ajina et al., 2015), partial hemianopia (Ali et al., 2013), quadrantanopia (Elgin et al., 2010), cortical blindness (Huxlin et al., 2009), cortical visual impairment (Cavanaugh & Huxlin, 2017), or visual field loss poststroke (Townend et al., 2007).

The clinical gold standard for detection and assessment of stroke-induced vision loss is automated visual field tests, typically in the form of Humphrey visual fields. During these visual field tests, patients perform a luminance detection task, indicating if they detect a spot of light while maintaining fixation over the course of 10–15 minutes. This task can be difficult to conduct in recent stroke patients, as fatigue, cognition, and fixation abilities are typically impacted by the stroke. Alternatively, confrontation visual fields, in which patients identify simple movements or count fingers in different quadrants of their visual fields, may be used. However, the simplicity of this task and lack of fixation control make detection of vision loss difficult and unreliable (Townend et al., 2007).

Natural History

Within the first 6 months poststroke, approximately 50% of patients with vision loss show some form of spontaneous perimetric recovery (Zhang et al., 2006). Most of these improvements are seen in the first 3 months (~50–60% of patients), with a marked drop off between 3 months and 6 months (~20% of patients). This is consistent with other studies that have shown that most recovery occurs in the first 10 days, with maximum recovery occurring within the first 48 hours (Gray et al., 1989; Pambakian & Kennard, 1997). However, less than 10% of patients recover their full visual field, with only 50% showing partial recovery (Pambakian & Kennard, 1997). This research has led to the belief by many scientists and clinicians that after this 6-month period of potential spontaneous improvement the condition is stable and permanent and is therefore referred to as the "chronic" period (Saionz et al., 2022). However, more recent evidence suggests the visual field remains unstable and in fact continues to decline over time (Cavanaugh & Huxlin, 2017; Fahrenthold et al., 2022; Saionz et al., 2022). This worsening may be caused or exacerbated by the well-documented retrograde degeneration that occurs post-stroke (Fahrenthold et al., 2021; Jindahra et al., 2012).

Current Standard of Care

As discussions with stroke survivors attest, the current standard of care after stroke is highly variable and depends on the hospital and country. A large proportion of the scientific literature attesting to this has been conducted by Rowe and colleagues, who focused on the U.K. health system, though to the best of our knowledge, the same issues are present globally. The major limitations in current care include failure to diagnose early, limited visual testing or assessment in hospitals after diagnosis, and a lack of follow-up after discharge.

Early detection of stroke is critical for patient survival and outcomes. Treatments such as thrombolysis to dissolve clots require early administration (i.e., within 4.5 hours) and if provided in time can significantly reduce disabilities post-stroke (Campbell et al., 2019; Strbian et al., 2012). This is difficult in stroke patients with isolated vision loss, as diagnoses are often delayed (e.g., up to 3 days in younger patients; Rowe, 2013). Delays are likely caused by a lack of awareness in the general population about the connection between vision loss and stroke, as well as inadequate recognition by medical providers (Raty et al., 2017). Furthermore, even when stroke is detected early, thrombolysis may be withheld as a treatment option in cases of isolated vision loss, with one report finding only 72 incidences in a database of 45,000 thrombolysis-treated stroke survivors (Strbian et al., 2012).

In addition to lack of awareness for patients, clinicians are often provided with limited training in visual deficits post-stroke (Colwell et al., 2021), with 20% of healthcare providers reporting fair or poor knowledge of visual problems, many of whom were stroke team professionals (Rowe et al., 2015). Although 80% of respondents thought their knowledge was good or very good, approximately 40% requested more information to enhance knowledge (Rowe et al., 2015). This suggests that knowledge about visual deficits poststroke is variable across clinicians, which may contribute to failures in early identification of visual strokes. As such, clinicians and the general public are likely to mislabel visual deficits caused by a stroke as other conditions, such as migraine (Rowe, 2013). This especially seems to impact younger patients (Rowe, 2013) or those presenting with visual symptoms alone (Rowe et al., 2020b). Migraine is commonly known to cause visual disturbance, so it is understandable that many initially mischaracterize these symptoms. However, misdiagnosis of visual loss poststroke delays intervention, which can close the narrow window during which thrombolysis options can be administered (Gladstone & Black, 2001; Raty et al., 2017).

Moreover, after diagnosis, there appears to be variability in the assessments provided to patients, likely due to the lack of standardized pathways of care. In 2015, only 46%

of departments in the United Kingdom followed a designated care pathway for stroke survivors with visual problems (Rowe et al., 2015), which highlights the potential for each hospital to follow different procedures and guidance, leading to variability in patient care. In addition, although 93% of departments in the United Kingdom (out of 317 that responded) provided vision assessments poststroke, only 45.5% of these were provided as part of the stroke unit (rather than as outpatients in the eye clinic), and only 32.9% were reported to be funded (Hepworth & Rowe, 2019). This also reflects patient-reported experiences in which some receive immediate referral to ophthalmic services after stroke diagnosis, while others (especially those with visual field deficits) have a late referral, have no referral at all, or were simply discharged and encouraged to contact their local optometrist for assessment (Rowe & Group, 2017). Finally, after patients are discharged from hospital, follow-up appointments show some discrepancy. Patients report that the information provided depends on the expertise of hospital staff, with some providing no poststroke care, while others offer multiple out-patient appointments (Hanna et al., 2020). Typically, follow-up is carried out for less than 3 months, although a large number of patients are not followed up at all (Rowe et al., 2015).

Nonbiological Intervention

While early intervention to reverse stroke damage results in the best patient outcomes, development of therapies to restore lost vision in the subacute (<6 months poststroke) and chronic (>6 months poststroke) phase of the stroke is also necessary for the large number of patients living with poststroke vision loss. Unfortunately, interventions to address this vision loss are limited in both scope and availability. It is likely that the reasons for this are based on the outdated belief that the visual system has limited plastic potential, and no recovery after damage to the visual system is possible. Therefore, the majority of patients are discharged from the clinic without treatment and are simply instructed to adapt to their deficit (Hanna et al., 2020). During interviews, the authors' patients shared that they were told "there was nothing they could do" and there was "no therapy for vision deficits." This prevailing dogma within the clinic leaves most patients feeling disheartened, abandoned, confused, and hopeless (Hanna et al., 2020). In the rare instances where therapy is available, patients are presented with three options: compensation, substitution, and restitution. All three therapeutic approaches have been investigated in the laboratory setting, with mixed results on a limited number of studies.

Compensation. In compensation therapy, patients are taught to move their eyes and head to better capture visual information falling within their deficit. Over time, patients are able to make more effective eye movements into the blind field (Zihl, 1995). Studies have found that visual search training can improve reading (Aimola et al., 2013; Keller & Lefin-Rank, 2010), activities of daily living (Keller & Lefin-Rank, 2010), visual search (Mödden et al., 2012; Nelles et al., 2001; Roth et al., 2009; Sahraie et al., 2020), and quality of life (Rowe et al., 2017). In addition, it may expand the visual fields (Mödden et al., 2012) and improve disability scores (Sahraie et al., 2020). Despite this research, a Cochrane review concluded that there was limited, low-quality evidence that compensatory scanning training improved quality of life or activities of daily living in randomized controlled trials (Pollock et al., 2019).

Substitution. In substitution therapy, a device, most often a prism lens, is used to shift visual information that would normally fall within the deficit to superimpose over the sighted field. Prism lenses accomplish this by attaching to standard eyeglasses and bending light, increasing the visual field by up to 20 degrees (Peli, 2000). Prism lenses may improve mobility (Bowers et al., 2014; Peli, 2000), visual function (O'Neill et al., 2011; Peli, 2000), and quality of life (O'Neill et al., 2011), although Rowe et al. (2017) found no evidence of improvement in visual function or quality of life. Moreover, the Cochrane review mentioned above also concluded that there was low-quality evidence that prisms improve quality of life or activities of daily living (Pollock et al., 2019). Many patients struggle to integrate the information, resulting in problems with navigation, double vision, and visual confusion (Rowe et al., 2017). There are also higher reports of adverse events, such as headaches, for prisms compared with other therapies such as visual search (Rowe et al., 2017). These reasons may explain why few patients continue to use prisms long-term (Giorgi et al., 2009; Rowe et al., 2013).

Restitution. Currently, no clinically or commercially available restitution therapies reliably restore vision loss following a stroke. However, a number of laboratories have developed therapies designed to restore lost visual abilities and have investigated their efficacy (Melnick et al., 2016; Saionz et al., 2020a). These interventions involve making a decision regarding visual information presented in and around the visual deficit, typically a detection or discrimination task:

Detection. A stimulus is presented somewhere within the participant's visual deficit, and they are asked to simply indicate if they detected the presence of the stimulus. These tasks have been conducted with static spots of light, drifting Gabors, and flickering gratings. Results from detection training have been mixed. Visual restitution therapy (VRT), introduced by NovaVision Inc. in 2002, reached commercial availability and received FDA approval for treatment in the United States. However, subsequent studies failed to replicate the promising results of VRT (Horton, 2005; Reinhard et al., 2005), and the product has since fallen out of favor. While additional studies have reported success with detection training (Bergsma et al., 2012; Raemaekers et al., 2010), none have done so with a rigorously controlled clinical trial. The need to tightly control fixation, light scatter, and presentation timing and to avoid training effects on perimetry has made detection training difficult to properly implement.

Discrimination. A stimulus appears within the visual deficit, and the participant is asked to discriminate a feature of the stimulus, such as its direction of motion (Huxlin et al., 2009), orientation (Das et al., 2014), or shape (Chokron et al., 2008; Raninen et al., 2007). All of the assessed discrimination types were able to improve patient performance within the impaired visual field, on the given task. In addition to improving performance on the trained task, discrimination training studies have reported a reduction of the visual deficit in terms of total size (Bergsma et al., 2017; Cavanaugh & Huxlin, 2017; Chokron et al., 2008; Elshout et al., 2021) and an improvement in quality of life (Cavanaugh et al., 2016). The exact mechanism underlying this visual improvement remains uncertain but may be mediated by spared neurons within V1 (Barbot et al., 2021).

Results within the laboratory have been largely positive, suggesting restitution techniques are effective in improving visual impairment poststroke; however, these techniques have not yet been adapted for clinical practice. A major roadblock to clinical deployment is the limited scope of the studies conducted so far, with the majority relying on small cohorts. Moreover, a lack of randomized, multi-site, double-blind, placebo-controlled clinical trials (RCTs) has prevented potential therapies from gaining regulatory agency approval. A 2019 Cochrane review of RCTs found only three studies meeting their inclusion criteria that investigated visual training following stroke (Pollock et al., 2019), and only one of these, representing 19 participants, assessed the impact of training on the perimetric visual deficit. Since then, an additional clinical trial was conducted on 46 participants (Cavanaugh et al., 2020); however, this study did not yield conclusive evidence of a difference in visual field size between the two randomized training arms.

Policy Recommendations

Poststroke visual impairment has been highlighted as an under-researched area. In 2013, neuro-ophthalmology was named one of the top 10 research priority areas by the James Lind Alliance. Despite recent significant improvements in care provided to stroke survivors with visual deficits, even 10 years later, this field is still under-researched and underfunded. In 2010, a Stroke Association survey (Rowe, 2013) reported 61% of patients felt their needs had not been fully met. This suggests current research and clinical practice are failing stroke survivors with this condition. Further exacerbating this issue, research for cortical vision loss is relatively limited, compared with other vision-related conditions: approximately 5,000 PubMed results for "hemianopia" compared to 83,000 for "glaucoma" or 10,000 for "amblyopia." Additionally, adoption of research advances into clinical practice typically takes >10 years (Morris et al., 2011), making it unlikely clinical care will improve rapidly without directed action by stakeholders. To improve standard of care for patients: (1) increase awareness of visual field deficits poststroke, (2) develop a more effective definition, (3) develop and use standardized pathways of care, (4) administration of high-quality visual fields, (5) deployment of training interventions, and (6) organize a consortium to discuss the future directions and impacts of research.

Increased Awareness of Visual Field Deficits Poststroke

Clinicians, researchers, and the general public must become more aware of visual deficits poststroke. Increased awareness provides numerous benefits for patients and medical providers, including reducing treatment delays, better funding for visual impairment research, and providing patients with more information and options regarding their condition. To increase awareness of visual problems in stroke, a more comprehensive acronym such as BE FAST (Balance, Eyes, Face, Arm, Speech, Time; Aroor et al., 2017) should be adopted in place of the commonly used FAST. Additionally, multiple screening tools, including the Visual Screening Assessment Tool (Rowe et al., 2020a), the Stroke Vision App (Quinn et al., 2018), and the Stroke and Vision Defect Screening Tool (Courtney-Harris et al., 2022), have been developed in recent years to allow paramedics and first responders to quickly assess visual deficits during call-outs for suspected stroke. Increased deployment of these screening tools may help detect vision loss earlier poststroke, making administration of thrombolysis safer and more effective.

Develop a More Effective Definition

A roadblock to awareness of vision loss following stroke is the use of many terms to describe the same condition. The most common term is "homonymous hemianopia": "hemianopia" describes a loss of vision in half of the visual field, while "homonymous" reflects that it equally affects both eyes. However, "hemianopia" is often used to describe patients with any amount of unilateral vision loss caused by damage to V1. Not only is the name difficult to pronounce for patients and clinicians, it is nondescriptive and inconsistently used. Other terms are used interchangeably by researchers and clinicians to refer to the same condition, including hemianopia, hemianopsia, quadrantanopia, partial hemianopia, cortical blindness, cortical visual impairment, and visual loss poststroke, all of which simply describe some amount of visual field loss. This makes searches of the literature and clinical trial databases difficult, as different names can be used, and it is often unclear the amount of visual field loss patients' experience. For example, a PubMed search found that "hemianopia" produced 5,010 articles; "hemianopsia" produced 3,945; "quadrantanopia" 4,114; "cortical blindness" 1,516; "cortical visual impairment" 244; and "cerebral visual impairment" 266. These search terms also share significant overlap, with all terms yielding a total of 7,000 articles. This may represent the presence of mixed populations in single studies or uncertainty by researchers as to the appropriate terminology to use.

We therefore propose that researchers, patients, and clinicians decide on an effective term for this condition that is accurate and informative. Recently, "specific language impairment" was renamed "developmental language disorder" via consortium (Bishop et al., 2017). During this discussion, it was agreed that too many terms were used for the condition, which might cause lack of awareness or understanding (Bishop, 2017). It is likely that the same problem exists for cortically induced vision loss, with different, and sometimes inaccurate, terminology used to describe the same type of deficit. We believe that a descriptive term that is both easy to pronounce and understand will allow patients to discuss their conditions with friends and families more easily, while for researchers and clinicians, agreeing on a consistent term will allow research articles and clinical trial registrations to have greater and wider impact.

Develop and Use Standardized Pathways of Care

We additionally propose that standardized care pathways need to be adopted across countries and hospitals to ensure that all stroke survivors with visual loss are diagnosed and treated as effectively as possible. Visual screening undertaken by orthoptists on the stroke ward has been highlighted as the gold standard, suggesting that this should be the standard procedure for all patients (Rowe, 2013). A recent U.K. stroke guideline not only highlights visual deficits poststroke but also recommends visual screening poststroke using a standardized approach ("National Clinical Guideline for Stroke for the UK and Ireland," 2023). This suggests that awareness of the condition is increasing. Recently, focus groups involving eye care professionals, stroke team professionals, and stroke survivors were organized with the aim of developing a care pathway for stroke-related visual impairments (Rowe et al., 2020b). This pathway is now freely available from the VISION research website (www.vision-research.co.uk). This care pathway highlights how stroke survivors can access healthcare and/or appropriate referrals to vision services within the United Kingdom, based on their condition. This pathway not only raises awareness that visual deficits occur poststroke but if used will begin to reduce inequalities in health provision, as all stroke survivors should receive the same access to vision services. This care pathway should be used more widely and similar schemes created globally.

Administration of High-Quality Visual Fields

Over the past 30 years, improvements in visual field test methods have resulted in better algorithms that reduce patient fatigue and testing time while improving reliability and accuracy (Pierre-Filho et al., 2006). However, the majority of these methods have focused on documenting ocular diseases, with special focus on the early detection and monitoring of glaucoma. As a result, patients are tested with visual field patterns and algorithms optimized for retinal disease features, rather than cortical organization (Goodwin, 2014). These commonly administered visual fields therefore fail to capture key aspects of stroke-induced vision loss and can be made more accurate and faster to administer in this population by applying principles of visual pathway organization. As such, we propose the development of new perimetric methods and algorithms specifically designed to detect and monitor cortical visual impairment.

The deployment of such fields will not only provide patients with a better understanding of their visual impairment and residual abilities but will also make monitoring visual field change a more feasible option for clinicians. Due to a lack of available interventions and the assumption that the visual field will not change 6 months poststroke, there has been little attention given to visual perimetry in chronic stroke survivors. However, the potential for degeneration of visual pathways poststroke (known as retrograde degeneration) and an associated decline in vision over time warrants increased monitoring (Cavanaugh & Huxlin, 2017; Fahrenthold et al., 2022; Jindahra et al., 2012; Saionz et al., 2022). Furthermore, as visual restoration therapies move nearer to clinical deployment, monitoring of visual deficits will become critical to assess the efficacy of these interventions and to adjust treatment course.

The standardized collection of visual perimetry poststroke will also serve to generate a robust dataset currently lacking in the field. Population studies relying on large databases of demographic and clinic information are rapidly gaining recognition as a critical method for enhancing patient outcomes. These meta-analyses allow for detection of subtle differences in incidence, treatment indication, and monitoring of disease progression. Given the demographic variability of stroke survivors, it is likely that population differences may emerge in terms of spontaneous recovery and natural history, as well as efficacy of intervention. As the majority of studies currently rely on small sample sizes, the development of such a database will provide a new avenue to assess and evaluate visual recovery that currently does not exist.

Deployment of Training Interventions

Directly after a stroke, stroke survivors with visual field deficits have higher quality of life scores than general stroke survivors (Gall et al., 2010). This suggests that directly after a stroke, these patients are less impaired. However, after 6 months, stroke survivors with isolated visual field deficits have a lower quality of life than general stroke (Gall et al., 2010; Rowe et al., 2013). This indicates that the quality of life of general stroke survivors increases over time, while those with visual deficits decrease. The difference in quality of life may be related to the lack of intervention or follow-up after discharge from the hospital. When intervention is administered, the most common options include vision advice (87.5%), functional advice (70.5%), prisms (54.5%), patching monocularly (53%), eye scanning (50%), and reading strategies (67%) (Rowe et al., 2015). These treatments are all compensatory rather than aiming to restore the visual field. Despite this, evidence indicates that visual training within the blind field can be effective at improving vision (Cavanaugh & Huxlin, 2017) is most effective when started early (Bergsma et al., 2017; Saionz et al., 2020b) and can even protect against stroke-induced neurodegeneration (Fahrenthold et al., 2021). We therefore propose that further research investigating restitution therapy is needed.

A long-term goal of this research would be the incorporation of visual training and rehabilitation in standard clinical care for all stroke survivors with visual field deficits. While there is a documented lack of large-scale randomized clinical trials for this condition (Pollock et al., 2019), an RCT may not be the appropriate standard by which to assess psychophysical interventions like the ones typically employed in restitution therapy. Masking to training conditions and use of a placebo intervention are nearly impossible when participants are able to see the stimulus they are training on. Moreover, given the minimal risk posed by psychophysics, these standards may be unnecessarily restrictive. Currently, psychophysical therapies are classified as medical devices and thus require RCTs to gain regulatory approval. Due to the complicated history of the field, industry sponsors are understandably wary of investing in the large-scale clinical trials necessary to establish efficacy. The newly developed "Basic Experimental Studies Involving Humans" designation by the FDA, as well as the rise in single-case statistical designs, may help alleviate this regulatory burden in the future.

Organize a Consortium to Discuss the Future Directions and Impacts of Research

Ultimately, the current gaps in care for patients with stroke-induced vision loss are too large to fix overnight. Priorities must be established so that those in the field can work in synchrony toward the specific goals that will most benefit patients. Likewise, numerous standards currently in the field, each with varying strengths and failures, should be evaluated and developed to provide the best possible outcomes. To make such decisions, the formation of a consortium would move the field forward and discuss the future directions of visual stroke research, the current gaps in the literature and knowledge, and directions for rehabilitation. In the general stroke literature, there have been several consortia discussing how to accelerate stroke recovery research (Bernhardt et al., 2017) and what research evidence should be prioritized in clinical practice (Eng et al., 2019). However, these consortiums have generally focused on motor stroke. The formation of a consortium to specifically address poststroke vision loss should instead focus on methods to detect and quantify vision loss and the development of interventions to reduce the burden of the condition and ultimately to unify a clear and consistent term for the condition.

Conclusion

Vision loss after stroke is a prevalent and debilitating condition that continues to grow more common as stroke survival rates increase. Despite its high prevalence and significant burden, this condition remains underreported and underserved in the medical and scientific communities. Quality care for this condition is currently hampered by a lack of awareness, inconsistent clinical pathways, and limited research. Evidence gathered from preliminary work in stroke-induced vision loss, as well as those gathered from other conditions, suggests that these obstacles to patient care can be overcome through combined efforts from patients, caretakers, researchers, policy makers, and clinicians. Many of the methods proposed here require minimal costs or risks but offer significant potential benefit to those suffering from stroke-induced vision loss. Awareness campaigns can improve patient understanding and clinical detection of the condition, while regulatory support for minimally invasive, low-risk interventions can expedite research and reduce disease burden. Due to the plethora of issues facing this field, deciding on the best path forward, and the order in which to address the identified issues, must first be carefully considered and agreed upon, with input from regulatory bodies and public health experts to guide efforts into improving patient outcomes. As such, the authors hold that these proposals are best addressed by a consortium of all stakeholders to ensure needs are met as fully as possible, with all voices and inputs considered.

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