Using evidence in practice

Precision Tinted Lenses

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Background

Claims that individually prescribed coloured filters aid reading[1] were well-publicised in the 1980s and remain controversial.[2,3] The initial method, developed by Irlen, has been criticised because the system has not been fully described in the scientific literature,[4] does not systematically sample colour space,[5,6] and is not typically administered by eyecare professionals. A newer system using the "Intuitive Overlays" (IO), the "Intuitive Colorimeter", and Cerium Precision Tinted Lenses was developed by Wilkins at the MRC Applied Psychology Unit. This system is fully described in the scientific literature,[5,7,8] systematically and efficiently samples colour space,[5,7] and has been shown to have the properties required for an appropriate method.[9-11] Furthermore, this system is used by eyecare professionals. This is important to ensure that symptoms due to optometric conditions are alleviated before colour is used.[12,13] For these reasons, the present document reviews evidence from research using the Wilkins (MRC) system.

The condition that is purportedly helped by coloured filters has been given various names,[14] most recently Visual Stress[15] or Pattern Related Visual Stress (PRVS).[16] Visual Stress has another meaning,[17-19] so PRVS is used here. PRVS is characterised by symptoms of asthenopia and visual perceptual distortions when viewing striped patterns, including lines of text.[20] The prevalent view on the aetiology of PRVS is that the patterns caused by text[21] over-stimulate a hyper-excitable visual cortex.[22] It is hypothesised that by altering the spectral composition of the retinal image with coloured filters cortical activity[23] can be rearranged so as to avoid strong local excitation in hyperexcitable orientation columns of the visual cortex.[24] Research continues investigating this hypothesis and the nature of visual discomfort.[25-34]

This document is based on a literature search for controlled trials of the treatment of PRVS with individually prescribed coloured filters using the Wilkins (MRC) system.

PRVS and reading difficulties

Reading difficulties, dyslexia, and PRVS

A comprehensive review (the Rose report) defined dyslexia as a learning difficulty that primarily affects the skills involved in accurate and fluent word reading and spelling. The Rose report highlights the characteristic features of dyslexia as difficulties in phonological awareness, verbal memory and verbal processing speed.[35] These non-visual factors are likely to be causes of the poor reading. The report acknowledges that sensory or motor co-ordination difficulties can occur alongside dyslexia and includes PRVS among these conditions, but stresses that there is no evidence of a causal link between PRVS and dyslexia. This is also the conclusion of the present review. It is therefore not appropriate for optometrists to claim that they can treat dyslexia. The term "visual dyslexia" is inappropriate, at least as regards optometric use.[35] Since dyslexia is an educational problem it is not appropriate for optometrists to claim that they can diagnose dyslexia. Similarly, it is advisable for optometrists when they treat PRVS to advise that they are not treating reading difficulties but rather a visual condition that may co-occur with and in some cases contribute to reading difficulties.

The Rose report indicates that PRVS co-occurs with dyslexia and the two studies that investigate this hypothesis find a higher prevalence of PRVS in dyslexia than in good

readers.[36,37] In both studies the statistical significance was marginal. A third concordant study (also lacking statistical power) indicates that PRVS is more likely to be problematic when it co-occurs with dyslexia.[38] It is clear from the literature that most people with dyslexia do not have PRVS and therefore studies investigating the effect of coloured filters on samples selected as having dyslexia[39] suffer from selection bias and will be underpowered.

Diagnosis of PRVS

PRVS is suspected when patients report symptoms of visual perceptual distortions, eyestrain, or headaches during reading. Four approaches have been used to detect PRVS:

1. Questionnaire-based rating scales.[33,38,40]
2. Pattern Glare Test (PGT),[16,41-43] which in one study was found to be more reliable than a symptom questionnaire.[42]
3. Sustained voluntary use of IO.[6,44,45]
4. Improvement in reading (typically, with Wilkins Rate of Reading Test; WRRT)[46,47] or task performance[16,37] with IO.

An additional criterion is to exclude patients with an optometric problem that may account for their symptoms. This is important for clinicians and is part of the College Guidelines on this topic. This criterion is not always adopted in research studies but is unlikely to be a significant confounder because optometric factors are infrequent correlates of PRVS.[20,48-50]

PRVS seems to lie on a spectrum from mild to highly symptomatic. Large studies with coloured overlays show that about one third of those choosing overlays read >5% faster with the overlay whilst 5% read >25% faster.[51] An early tendency to use >5% as a cut-off is likely to over-diagnose PRVS[36] and a recent analysis indicates that >15% is likely to be the most appropriate criterion, at least for children.[52] A re-analysis of data on prevalence[36] using this criterion suggests PRVS occurs in about 20% of children with dyslexia. This indicates that Irlen's approach, which can detect PRVS in close to 80% of people with reading difficulties,[53] over-diagnoses the condition. The diverse range of approaches used to diagnose PRVS in the literature is undesirable. Combining these may improve diagnostic accuracy and minimise over-diagnosis and a Delphi study with this goal is currently underway.

Research with coloured overlays

The strongest evidence for the effectiveness of any therapeutic intervention is obtained from randomised controlled trials (RCT) in which participants with the target condition are randomised to receive either the treatment under investigation or a comparator. Ideally, neither the patient nor the treating clinician should be aware which therapy is received. It is not possible to mask the participant in a trial comparing coloured overlays with a control (e.g., grey) as the participant will be aware, and so there are no double-masked RCTs with IO.

Table 1 evaluates, using CASP criteria,[54] studies of the effect of IO on reading, or related performance, in populations selected as having PRVS. Studies are included if they applied at least one of the above four diagnostic criteria for PRVS. Studies that investigated samples whose sole indicator for PRVS is reporting an immediate improvement in perception with an overlay are not included because this will over-diagnose PRVS, selecting about 50% of the population.[6,44,45,47,50] The exclusion of these studies (all of which found improved performance with IO)[6,36,45,55-57] means that several studies often cited as supporting the use of IO are not included in Table 1. Three of the papers cited in Table 1 were not designed to be clinical trials but rather to assess prevalence of PRVS.[6,44,45] These papers each contained several studies, most including placebo controls of one kind or another, but only those studies that meet the selection criteria outlined above are included in the table. It should be acknowledged that taken together the studies that make up these large bodies of work are more compelling than the studies cited individually in Table 1.

Research with Intuitive Colorimeter and Cerium Precision Tinted Lenses

Table 2 evaluates all controlled trials using the Intuitive Colorimeter (IC). All three studies and others[10,11] support the notion that different individuals need different colours and the colour at least in some cases needs to be prescribed with a precision that is unlikely to be attributable to colour memory.[10] The IC allows for placebo effects to be controlled and this was used in one double-masked RCT.[58] The disadvantage of such a study is that the control tints are not necessarily inert but rather are similar in colour to the optimal tint, which might reduce the likelihood of a significant finding. This 20 year old study should be repeated with modern selection criteria, a larger sample, an appropriate reading test[47] (the reading test used at the time is now known to be insensitive to PRVS),[46,47,51] and a proper implementation of the intention-to-treat principle.[59] It is, however, notable that there were 7 participants who individually had significantly fewer symptoms with one pair of coloured lenses and in every case this was the lenses with the optimal colour, despite the fact that participants were masked and remained unaware throughout the study as to which pair contained the optimal colour.[58]

Conclusions

Table 1 and 2 reveal limitations of the research, principally limited control of the placebo effect. These potential confounders are likely to increase the chance of a study finding that filters are helpful. In contrast, the tendency to over-diagnose PRVS in these studies[52] reduces the likelihood of a positive result. The extent to which these biases offset one another is unquantifiable. There is complete concordance in the outcome of these studies, all finding that filters alleviate symptoms or improve performance in PRVS.

Three additional CASP[54] criteria are to ask whether: (1) the results apply to other populations, (2) all clinically important outcomes are considered, and (3) the benefits are worth the harms and costs. Concerning the first point, there is some evidence that PRVS is prevalent in other conditions in which cortical hyperexcitability is likely to occur:[60] migraine,[61] epilepsy,[62] autism,[63] MS,[64] and stroke.[65-67] One outcome that has not been quantified is the psychological effect of using coloured filters. In some children the filters may play a positive role in helping them attribute their underachievement to a condition rather than a lack of intelligence, but for others coloured filters may draw unwelcome attention to the child. The cost of coloured overlays is small, but precision tinted lenses are more expensive.

Colour adaptation means that the Intuitive Colorimeter can be used for a double-masked trial[58] and a large RCT with this instrument is a priority for future research. Colour adaptation is also likely to explain why a person's optimal colour of overlay and lens will differ.[68]

Although beyond the scope of this review, the evidence for other optometric factors (e.g., binocular instability) co-occurring with dyslexia is also modest.[69] Learning in the school or college environment requires clear and sustained distance and near vision and the absence of vision screening in many schools means that visual problems can go undetected. These may add to the burden that children with dyslexia or other learning difficulties experience. It would seem a sensible precaution for children who struggle at school to have an eye examination to exclude visual problems that may be contributing to their difficulties. Such testing should not just address refractive error but also binocular and accommodative function.[70-74] It is important for optometrists to appreciate that any interventions (e.g., refractive corrections, eye exercises, coloured filters) carry a cost to the patient & family in terms of expense, time, and raised expectations. For interventions where the evidence for the benefit is weak (e.g., coloured filters, small refractive errors) then the practitioner should be particularly careful not to overstate the case for an intervention because the parents and patients themselves might be vulnerable to the suggestion that any intervention may help.

Many schools, special needs teachers, and dyslexia organisations test and dispense coloured overlays and some of the users who benefit from these will ask optometrists for coloured lenses. Until larger trials are completed, a conservative clinical approach is to follow the

College guidelines. These recommend that before coloured lenses are prescribed practitioners should exclude other optometric problems, assess the effect of overlays with the WRRT, and undertake a trial with overlays.

Study	Design	Population appropriate?	Interventions appropriate?	Randomised?	Outcomes appropriate?	Groups matched?	ITT?	Results: size of treatment effect?	Statistical significance & precision	Interpretation
Wilkins, Jeanes, Pumfrey, Laskier (1996)[47]	Case control with repeated measures	Yes. PRVS indicated by sustained (8 week) use of IO a 15 chose & frequently used IO b 17 chose & infrequently used IO c 6 chose & did not use IO d 39 did not choose IO. No optometric testing.	Prone to placebo effect. IO v no overlay	Yes	Yes. WRRT	No	Data from 2 children incomplete & rejected	a 7.2% faster b 1.1% faster c 2.7% slower d 2.0% faster with overlay cf without	a p<0.01 b NS c NS d NS	IO improved reading performance in group with PRVS but poor control of placebo effect
Jeanes, Busby, Martin, Lewis, Stevenson, Pointon, Wilkins (1997)[6] Study 4	Case control with repeated measures	Yes. PRVS indicated by sustained (10 month) voluntary use of IO. Primary school children 11 PRVS 19 controls No optometric testing	Prone to placebo effect. IO v no overlay	Not stated, but Note 1 likely to apply	Yes. WRRT	No	Not stated	PRVS group read 8% faster with overlay cf without. Control group read 1% slower with overlay cf without	P=0.022 in PRVS group. Small sample size.	IO improved reading performance in group with PRVS but poor control of placebo effect
Wilkins Lewis (1999)[44] Study 4	Case control with repeated measures	Yes. PRVS indicated by sustained (6-9 months) voluntary use of IO. Children aged 7-11y a 36 chose & used IO b 43 chose & stopped using IO c 55 did not choose IO. Minimal optometrist testing: excluded if not 6/6	Prone to placebo effect. IO v no overlay	Yes	Yes. WRRT	No	Not stated	a 10.7% faster b 2% faster c 4% faster with IO cf without	a p=0.00002 b p=0.004 c p=0.02	IO improved reading performance in group with PRVS but poor control of placebo effect
Lightstone, Lightstone, Wilkins (1999)[68] Study 2	Repeated measures	Yes. PRVS indicated by symptoms & sustained benefit from IO. 17 children with PRVS Optometric testing & optometric anomalies treated first.	Moderate control of placebo effect. IO v none & control tint v none	Yes	Yes. WRRT	Yes (repeated measures)	Yes, all finished	10.2% faster with IO cf without 6.0% faster with control tint cf without	P<0.05 p>0.05 small sample size	IO improved reading performance in PRVS, some control of placebo effect
Wilkins, Lewis, Smith, Rowland, Tweedie (2001)[45] Study 3	Case control with repeated measures	Yes PRVS indicated by symptoms & sustained (8 months) benefit from IO. Children. a 136 chose & used IO b 124 chose & stopped using IO. No optometric testing.	Prone to placebo effect. IO v no overlay	Note 1	Yes. WRRT	No	Yes, all finished	a 13.3% faster b 2.5% faster with IO cf without	a p<0.0001 b p<0.05	IO improved reading performance in group with PRVS but poor control of placebo effect
Northway (2003)[75]	Case control with repeated measures	Yes. PRVS indicated by sustained (12 weeks) use of overlays. Dyslexic children in eye clinic. 40 with PRVS 14 no PRVS (no overlay selected) 10 no PRVS (overlay chosen not sustained use) Orthoptic testing & excluded any with orthoptic problems.	Prone to placebo effect. IO v no overlay	Note 1	Yes. WRRT & digit reading task	No, but mean age NS different	Yes, all finished	PRVS group read 10.1% faster with overlay than without. Control groups read 2.4% and 4.4% slower with overlay than without. Similar but stronger effects for digit reading.	P<0.01	IO improved reading performance in group with PRVS but poor control of placebo effect

Hollis Allen (2006)[42]	Case control with repeated measures	Yes. PRVS indicated by symptoms & PGT. Adults. a 20 with PRVS b 18 borderline c 20 controls. No optometric testing	Prone to placebo effect. IO v no overlay	Note 1	Yes WRRT	No	Yes, all finished	a 12% faster b 7% faster c 4% slower with overlay cf without.	Change in speed significantly different in PRVS group cf control group ($p<0.05$).	IO improved reading performance in group with PRVS. Moderate control of placebo effect as colour not used in selection.
Singleton Henderson (2007)[37]	Case control with repeated measures	Yes. PRVS indicated by ViSS. Children. a 9 high PRVS + dyslexia b 5 high PRVS + no dyslexia c 13 low PRVS + dyslexia d 17 low PRVS + no dyslexia No optometric testing	Moderate control of placebo effect. IO v grey overlay	Note 1	Yes, WRRT	Yes, for reading age	Yes, all finished	a+b 17.3% faster c+d 4.1% faster with overlay cf grey. Greatest improvement when PRVS combined with dyslexia	P<0.01 Small sample size.	IO improved reading performance in group with PRVS. Moderate/good control of placebo effect as colour not used in selection & control overlay.
Allen, Gilchrist, Hollis (2008)[16]	Case control with repeated measures	Yes. PRVS indicated by symptoms & PGT. Adult students. 14 with PRVS 14 controls. No optometric testing	Prone to placebo effect. IO v no overlay	Yes	Yes. WRRT & VST	No, but reading rate & accuracy NS different in groups	Yes, all finished	PRVS group read 20 wpm faster with overlay: control group did not read faster with overlay. No significant effects with search task.	P<0.001 Fig. 3 shows little overlap between groups. Small sample size.	IO improved reading performance in group with PRVS. Moderate control of placebo effect as colour not used in selection.
Allen, Hussain, Usherwood, Wilkins (2010)[76] Experiment 1	Case control with repeated measures	Yes. PRVS indicated by PGT. Adult students. 11 with PRVS 11 controls. Optometric testing & excluded cases with confounding optometric anomalies or migraine.	Prone to placebo effect. IO v no overlay	Note 1	Yes. WRRT	Yes, for age, gender, refractive error.	Yes, all finished	PRVS group read 15 wpm (10%) faster with overlay: control group 0.5% faster. .	P<0.001 Small sample size	IO improved reading performance in group with PRVS. Moderate control of placebo effect as colour not used in selection.

Table 1. Summary of controlled trials of Intuitive Overlays (IO) in populations selected as having PRVS. Key CASP[54] critical appraisal criteria are detailed in the columns, with the exception of two CASP criteria: masking (it is not possible to double mask overlay studies) and it is assumed that groups were treated equally as all studies are repeated measures trials. Abbreviations: EE, eye examination; ITT, intention to treat (were all of the participants who entered the trial properly accounted for at its conclusion?); NS, not significant; PGT, pattern glare test; VDS, Visual Discomfort Scale; ViSS, computerised Visual Stress Screener; VST, visual search task; WPM, words per minute; WRRT, Wilkins Rate of Reading Test. P-values are two-tailed. Note 1: in these studies the WRRT was carried out as in recommended in the test instructions using an ABBA order to control for practice effects.[45]

Study	Design	Population appropriate?	Interventions appropriate?	Randomised?	Outcomes appropriate?	Masked?	Groups matched?	Groups treated equally?	ITT?	Results: size of treatment effect?	Statistical significance & precision	Interpretation
Wilkins, Evans, Brown, Busby, Wingfield, Jeanes, Bald (1994)[58]	Cross-over RCT	Yes. PRVS indicated by symptoms or difficulties when reading and sustained (3 week) benefit from overlay.	Yes, IC colour v similar colour. Good control of placebo effect but control tint sub-optimal rather than inert, reducing chance of significant result	Yes	Symptoms assessed thoroughly with diaries. Reading assessed with test now known to be inappropriate.[46,47,51]	Yes, double-masked	Yes (cross-over)	Yes (cross-over)	No. 68 started the trial but only analysed the 37 who completed	Symptom-free on 71% of days with optimal colour v 66% of days with sub-optimal colour. Effect on reading NS	Overall p=0.002. Individual data from symptom diaries shows 7 individuals had significantly fewer symptoms with one pair of glasses, all with the optimal colour.	IOPTL improve symptoms in some individuals with PRVS, but overall results limited by attrition. Good control of placebo effect
Lightstone, Lightstone, Wilkins (1999)[68] Study 2	Repeated measures	Yes. PRVS indicated by symptoms & sustained benefit from overlay. 17 children with PRVS Optometric testing & had treated any optometric anomalies.	Good control of placebo effect. ICPTL v none & control tint v none	Yes	Yes. WRRT	Uncertain. (unclear if participants could identify PTL from control tints)	Yes (repeated measures)	Assumed yes (repeated measures design)	Yes, all finished	12.7% faster with ICPTL cf none. 6.0% faster with control tint cf none. 6.4% faster with ICPTL cf control tint.	P<0.05 p>0.05 p=0.03 small sample size	ICPTL improve symptoms in PRVS. Moderate control of placebo effect.
Singleton Trotter (2005)[38]	Case control with repeated measures	Yes. PRVS indicated by VPPI. 20 adult students. 5 high PRVS + dyslexia 5 high PRVS + no dyslexia 5 low PRVS + dyslexia 5 low PRVS + no dyslexia No optometric testing	Prone to placebo effect. IC optimal colour v IC white light.	No, but counter-balanced	Yes. WRRT	No	Yes, for reading accuracy	Assumed yes (repeated measures design)	Not stated, but implied all finished	High PRVS + dyslexia group 16% faster with optimal colour. Other groups 3-4% faster with optimal colour.	P=0.046 NS Small sample size	Colour selected in IC improves reading performance in PRVS but poor control of placebo effect.

Table 2. Summary of controlled trials using Intuitive Colorimeter (IC) or Cerium Precision Tinted Lenses prescribed with the Intuitive Colorimeter (ICPTL) in populations selected as having PRVS. Abbreviations: ITT, intention to treat (were all of the participants who entered the trial properly accounted for at its conclusion?); NS, not significant; PGT, Pattern Glare Test; VPPI, Visual Processing Problems Inventory (instrument with 24 questions relating to symptoms of PRVS); VST, visual search task; WPM, words per minute; WRRT, Wilkins Rate of Reading Test. Note 1: in these studies the WRRT was carried out as in recommended in the test instructions using an ABBA order to control for practice effects.[45]

References (NB some papers include multiple studies, identified in Tables 1 & 2 and Study 1, 2, etc)

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