

**A REVIEW OF THE ADLENS “WHITE PAPER” ON THE SALE OF  
ADJUSTABLE FOCUS SPECTACLES: OCTOBER 1st 2015**

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## 1. Introduction

In their recent “White Paper” entitled “*Adjustable Focus Eyewear: Why expanded access to new lens technology is in the public interest*”, the **adlens** company outlines its reasons for believing that over-the-counter sale of such eyewear should be allowed in the UK (adlens, 2014). The present report outlines the background to this proposal and comments on the potential advantages and disadvantages of its acceptance. In preparing this report, the references included in the “White Paper” were all considered, with the exception of references 1, 14, 17, 42-45, 50, 51, which the GOC were unable to provide.

## 2. Background

Conventional corrective spectacles have three main possible functions:

- (i) The correction of spherical and cylindrical refractive errors (myopia, hypermetropia, astigmatism) for distance vision. Right and left eyes may have different refractive errors (anisometropia).
- (ii) The provision of a positive near addition to supplement or replace the failing ability (presbyopia) of the older individual to change ocular focus (accommodate) to see near objects clearly
- (iii) Less commonly, the introduction of prismatic effects to correct possible problems in binocular vision.

In practice, a substantial fraction of the population of all ages will require a correction if they are to obtain good distance vision. Fig. 1 shows some recent data for the distribution of refractive errors in adult Europeans. Although precise figures are open to debate, most would agree that unaided vision would be expected to be compromised in all those with errors  $E$  lying outside a range of about  $-1.00 \text{ D} < E < +1.00 \text{ D}$ , the hyperopic limit being dependent upon the age of the individual. Note that a large fraction of individuals are myopic (short-sighted, needing a negative lens to correct their vision).

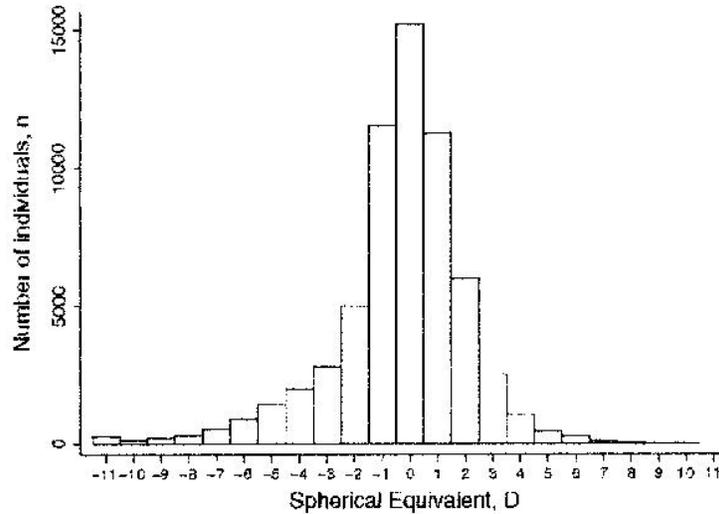
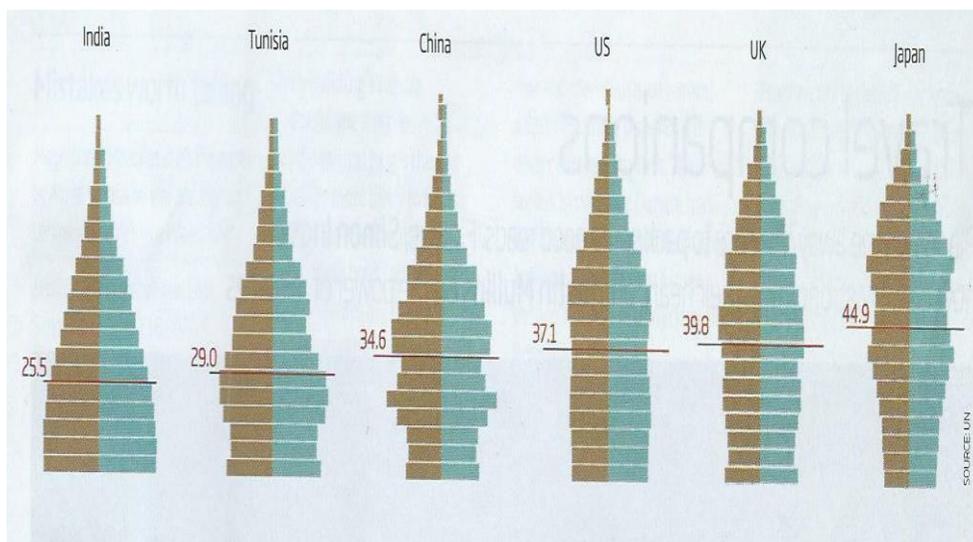


Fig1. Distribution of refractive errors in an adult European population (Williams KM, Verhoeven VJM, Cumberland P et al., Eur J Epidemiol 2015; 30: 305-315)

Due to the age-dependent loss of natural focusing ability, near additions begin to be required from the age of about 40, the required positive lens power increasing with age. For most older individuals, the maximum addition prescribed in practice rarely exceeds +3.00 D. Fig.2 shows the age distributions of the UK and some other populations. Even though some older myopes may be able carry out close work using their uncorrected vision, it is evident that there is a huge demand for presbyopic corrections, particularly in the developed world with its generally ageing population.



*Fig.2. Age distribution in 5-year bands of the population of the UK and a selection of other countries. Brown and blue bars represent females and males respectively. The numbers give the mean ages of the different populations. Presbyopic additions for close work would normally be required after the age of about 40.*

One problem for most presbyopes is the need for different corrective lens powers for distance and close work. It was realised in the 18<sup>th</sup> C that one solution to this problem was to provide both powers in the same frame, with the wearers adjusting their gaze direction so that the appropriate correcting power lay on the visual axis. This concept was pioneered in the Franklin bifocal, introduced in the 18<sup>th</sup> C, with the distance correction occupying the top half of the frame and the near correction the bottom half, and has since proliferated into a wide variety of bifocal, trifocal and varifocal (progressive) designs.

Such solutions still have their limitations, however. The position of some near tasks, e.g. above the head, may not make it easy to view them through the appropriate part of a bifocal. Further, all near tasks do not lie at the same distance, so that different add powers may be required for different activities, such as computer work, reading music, or fine needlework. Progressive designs go some way towards answering this need, but at the expense of spatial distortions and limited useful lens area for each distance.

These considerations have led to more than a century of efforts to develop spectacle lenses of adjustable power (see, e.g., reviews by Bennett, 1970; Sullivan & Fowler, 1988; Charman, 2014). For much of this time the goal was to be able to vary the lens power across the full aperture of the lens from that required for distance vision to that required for near tasks. More recently, as in the **adlens adjustables** (adlens, Oxford, UK), the concept has been successfully extended so that the lens power can be varied over a wider range, from which the both the required distance and near corrective powers can be selected according to the individual wearer's task-dependent current needs.

### 3. Adjustable-focus lenses

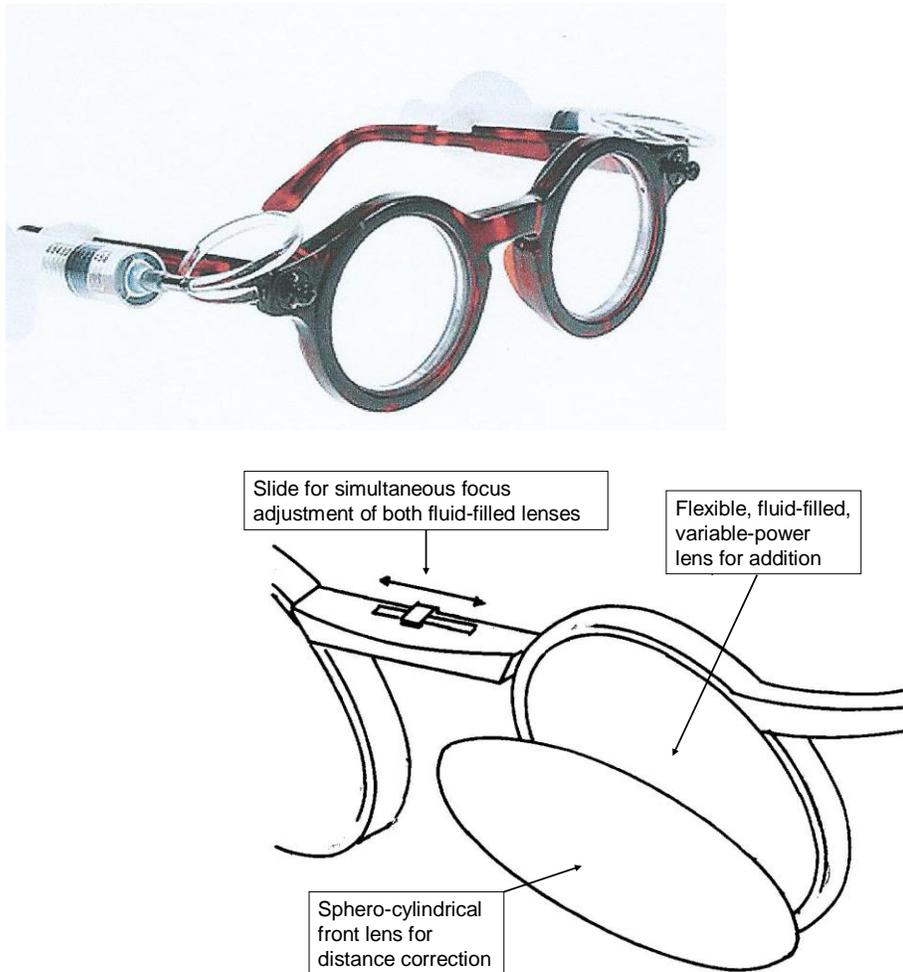
The classical way of producing lenses of variable optical focusing power, e.g. for cameras, is to use several optical components whose axial spacing can be varied. Although spectacles designed on this basis have been produced, such an approach is not well suited to these devices, due primarily to cosmetic and weight requirements. It has, however, been employed in some low-vision devices. At the present time, then, spectacle developments have been concentrated on using single lenses (or combinations in close contact) whose power can be varied either mechanically or electrically. Only spherical powers can be adjusted in current devices, any ocular astigmatism remaining uncorrected.

#### 3.1. Mechanically-varied power

##### 3.1.1. Liquid-filled lenses

In these lenses, a liquid is contained between a rigid wall, which may include spherocylindrical and prismatic corrections, and a flexible wall. Alternatively two flexible walls may be used. The curvature of any flexible wall, and hence the power of the complete lens, can be controlled by varying the volume of liquid enclosed between the two walls. The power variation is purely spherical. This concept was successfully developed in **Adspecs** (Centre for Vision in the Developing World, Oxford, UK, Fig.3, top), intended primarily for use in countries where optometrists or similar personnel may be in short supply. The power is adjusted for each individual eye by the wearer using the pump and adjustment wheel on the side-arm of the spectacles, until vision, at distance or near as required, appears optimal. The adjustment is then disabled. **adlens Hemispheres** are similar in principle. More sophisticated was the **Superfocus** device (Superfocus LCC, Van Nuys, CA, USA, but no longer available, Fig.3, bottom), in which distance vision was corrected with conventional spherocylindrical lenses. These were closely coupled with variable power liquid-filled lenses. A single lever controlled the power of both liquid lenses, so that they had the same positive power (up to +2.5 D) and provided a variable reading correction which could be adjusted to suit the patient's needs. The later **adlens Focuss (Customfocuss)** spectacles are similar in concept, but, unlike earlier designs which used liquid lenses with circular perimeters, use liquid lenses whose

boundaries conform more to the quasi-rectangular aperture of conventional spectacle frames.



*Fig.3. Examples of liquid-filled adjustable lenses. (Top) Adspecs with removable pumps and adjustment wheels on side-arms (Bottom) Superfocus with combination of distance correction and adjustable lenses to provide a variable reading addition. The prescription lenses were held in place magnetically and could be removed and replaced if required.*

### 3.1.2. Alvarez/Lohmann lenses

Each of these lenses consists of two closely-spaced plates. In their simplest form, the thickness of each plate follows a cubic function of the distances  $x$  and  $y$  from the centre of the lenses, but the signs of the terms differ in the two plates. The lens is designed so that initially the combined thickness of the plates is constant across the surface of the

lens, giving it zero power. If, however, both plates are sheared sideways by the same distance but in opposite directions, the plate thickness varies as the square of the distance from the combined centre, creating a spherical lens. The power of this lens will be positive for one direction of movement, and negative for the other (see Fig.4, left). The range covered by the power variation can be varied by incorporating appropriate spherical power into the plates.

Although, in principle, plates allowing variation in both spherical and cylindrical powers could be produced, current variable-power spectacles are designed to vary only the spherical power. As in the case of designs with liquid-filled, variable-power lenses, a major motivation behind the earlier Alvarez spectacle designs was to help to meet needs for distance corrections in the less-developed world. Thus each spectacle lens can be adjusted individually, to meet the needs of the anisometropic wearer, rather than being adjustable as a pair, which might be more useful for near work additions. An example of such a design, the **Focusspec** (Focus-on-Vision, Eindhoven, Netherlands) is illustrated in Fig. 3 (bottom). Other versions include **Instant 20/20 adjustable glasses**, **Adlens Adjustables**, **Emergensee** and **Eyejusters** (Eyejusters 2015 Ltd, Oxford, UK, having a power range 0 to +3.00 D).



*Figure 4. (Left) The principle of the Alvarez lens (Right) The Focusspec. In this design, the lateral translation of the components of each Alvarez lens is achieved by rotating the helical gears on each side of the frame. Note the different magnifications given by the two lenses, which have been set to powers corresponding to the two ends of the available range (+0.5 and +4.5D). Spectacles with power range -1.0 to -5.0D are also available.*

*Weight is under 20 gm. It can be seen that there are the limits to the useable optical area of each lens. These vary with the power setting*

### ***3.2. Electrically-varied lenses***

All of the devices as proposed at present are based on liquid crystal (LC) technology. In purely refractive devices, application of an electric field across an LC-filled cell of either conventional lenticular or Fresnel lens form changes the refractive index of the LC and hence the power of the lens. Alternatively the lens may be made in a thinner diffractive, zone-plate form, where changes in the zonal distribution of the phase of the light as a function of the changes in the refractive index result in more light being diffracted towards the required focus. A switched near addition of this type was apparently incorporated in **emPower** spectacles (Pixeloptics, Roanoke, VA, USA), although these are not currently commercially available.

### ***3.3. Other possibilities***

These include fluid lenses in which optical power is derived from the curvature of the interface between two immiscible fluids of differing refractive index, one being conductive, the other insulating. Application of a voltage across the insulating liquid results in a change in curvature of the interface and hence of lens power. At present, however, the lens apertures are too small and the lens depths too large for ophthalmic use.

## **4. Optical and mechanical properties of current adjustable-focus spectacles**

At present only a rather limited amount has been formally published on these topics. Some further exploratory studies on two Alvarez-type devices (FocusSpecs, adlens adjustables) are described in the Appendix to this report but much more thorough work is required.

#### ***4.1. Optical characteristics***

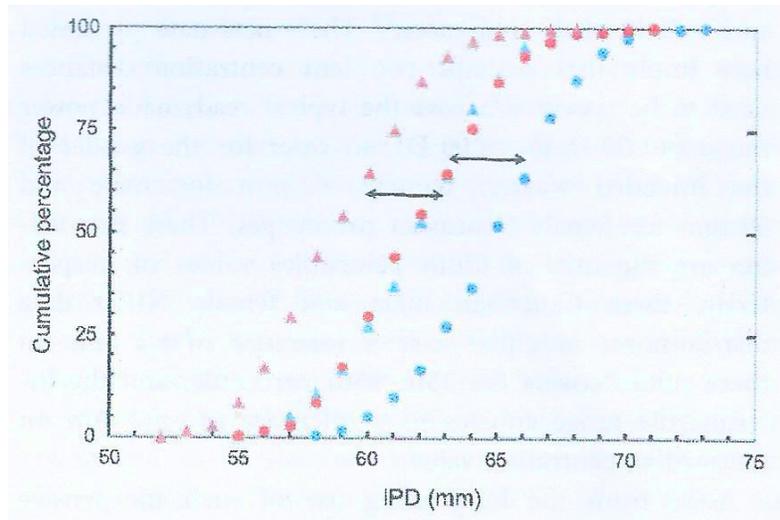
Douali & Silver (2004) suggest that the optical aberrations and off-axis performance of liquid-filled Adspec lenses are comparable to those of conventional ophthalmic lenses. Axial performance of Alvarez lenses appears to be good at most settings but there is a suggestion of markedly increasing oblique astigmatism away from the optical centre. Total lateral movement of each plate across the full power range in the Focusspec (+0.5 to +4.5 D) is about 3 mm, that in the adlens adjustable (-6.00 to +3 D) is about 6 mm. The area of variable power in both types is an ellipse with horizontal and vertical diameters of about 30 by 20 mm. The manufacture of such lenses with complex surfaces at low cost is a remarkable achievement. Ranges of powers and distances between lens centres (typically 63 mm) appear to be in accord with manufacturers' specifications.

#### ***4.2. Mechanical and adjustment characteristics***

The major complaint with the Superfocus device was liquid leakage. Current liquid lens spectacles appear to have stood up to extended useage in field trials (interestingly, most of those discontinuing wear said they did so for cosmetic reasons). The robustness of current Alvarez devices is less certain and anecdotal reports on the Web suggest that some purchasers are unhappy with this aspect. The polycarbonate lenses of the Focusspec are coated to reduce reflection and scratching. This is important, since the greater number of lens surfaces in the Alvarez design inevitably increases potential reflection problems (and introduces the further problem of how to clean the inner lens surfaces, where misting in damp atmospheres may cause particular difficulties).

Although future designs might overcome this, the “one-size-fits-all” nature of current over-the-counter frames means that fits may be poor, resulting in the optical centres lying several mm away from the pupil centres of the individual patient. Even if the bridge fit gives the correct height for the optical centres of the lenses, the distance between these centres is constant (e.g. 61 mm in the Focusspec, 63 mm in the adspec adjustables). In practice the range of interpupillary distance (IPD) among wearers is quite large (about 52 to 73 mm, Pointer, 2012, see Fig.5): near and far values differ by about 3 mm because of

the convergence required for near vision. Since correcting powers may be quite high, the mismatch between IPD and optical centre distance may introduce disturbing prisms, as acknowledged in the “White Paper”. For example, for an optical centre distance of 63 mm, a woman with a near IPD of 57 mm and a refraction of +3D will experience roughly 1 Δ of base-out prism in each eye, a value which may not be tolerable (du Toit et al., 2007; Pointer, 2012). Some adaptation to induced prism is possible: du Toit et al. (2007) found that most of their young adult subjects could comfortably tolerate total unwanted induced prism powers of  $\leq 0.5$  prism dioptres vertical or  $\leq 1.0$  D base-in or base-out horizontal but that higher prism powers caused discomfort during prolonged wear.



*Fig.5. Cumulative plots of the distribution of interpupillary distance at near (triangles) and far (circles) for females (red) and males (blue). Arrows show a 3 mm horizontal separation. After Pointer, 2012).*

Adjustment of lens powers is usually achieved by rotation of some form of screw, although in some cases a lever has been used. In the case of the two Alvarez models examined, about 2.5 turns of the adjustment screw of the Focusspec produced a 4D power change and 5 complete rotations of that of the adlens adjustable produced a 9 D change. Assuming that a setting accuracy of 0.25 D is required, this corresponds to screw rotations of about 60 and 50 degrees in the two cases. These are quite large angular rotations so that, from the purely mechanical point of view, no great dexterity is required when adjusting the lens power.

Weights of current Alvarez spectacles are low (about 20 gm). While some devices (e.g. Focusspecs) have a fixed bridge geometry, others (e.g. adspecs adjustables) have a slightly flexible bridge, allowing a better individual fit to be achieved.

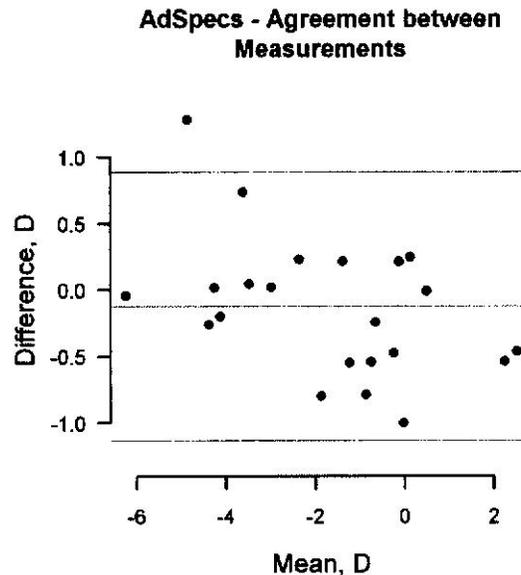
### ***4.3. Precision and accuracy of power settings***

Ideally the power selected by the wearer, e.g. for best distance vision, should be reproducible each time the adjustment is made and this constant value should duplicate that found after a full refractive examination. In practice, settings will vary, due both to imperfections in the spectacles and to the wearer's difficulties when carrying out the setting task (e.g. lack of consistency in their judgment of clarity, the ambiguities caused by ocular depth-of-focus and varying accommodation in younger wearers etc). Although some frame designs (e.g. Focusspecs) incorporate a setting scale, this may be difficult to read unless an appropriate correction is worn. With the Focusspec it appears that factors such as backlash in the adjustment screws lead to limited reliability in the setting (repeated focimeter readings of 12 settings to nominally the same power on the scale were found to give a standard deviation of around 0.25 D, as compared with 0.06 D for a fixed lens of similar power). It is, then, still necessary to refine the lens power by visual observation when changing viewing distance.

Repeated monocular settings of adlens adjustables by a hyperopic presbyope, experienced in visual observations, to give optimal visual clarity at distance suggest that such power settings can have a standard deviation (SD) as low as 0.20 D, with a mean value very close to that found clinically: with a less experienced subject the SD was 0.40 D, although the mean again corresponded well with the clinical refraction. What values of precision (reliability) and accuracy (validity) are typically found in the power settings of the general population?

Some helpful information can be found in several studies of self-refraction using liquid-filled Adspecks. A test-retest comparison by Smith et al. (2010) produced the results shown in Fig. 6. It can be seen that, although the mean of the differences between the two

measurements made by the 22 Boston college students was close to zero, in several case the differences approached 1 D. The standard deviation of the differences was about 0.5 D. Thus self-selected settings of corrective power by some individuals are somewhat variable.

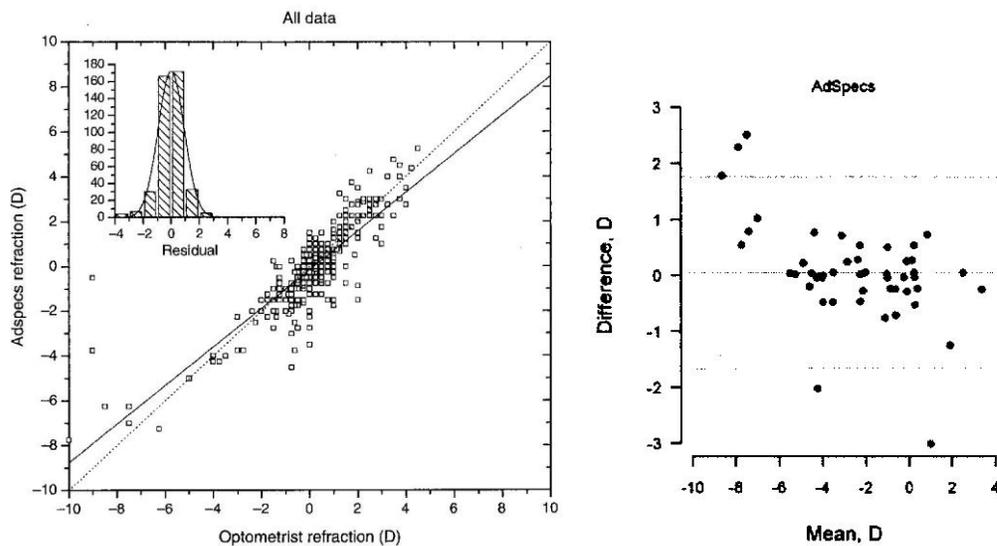


*Fig.6. Difference between two consecutive measurements of the required distance correction obtained using Adspecs as a function of their mean. The central horizontal line gives the mean of all the data, the upper and lower lines represent 1.95 standard deviations of the data.*

It must be borne in mind, however, that the reliability of all refractive techniques is limited. For example, the standard deviation of repeated measurements of best sphere by subjective refraction is typically about 0.3D (Perrigin et al., 1982; Rosenfield & Chiu, 1995; Bullimore & Adams, 1998) so that the reliability of the self-adjustment results is only a little worse.

Several studies using Adspecs give information on the accuracy of self-adjusting refractions as compared with clinical estimates. In the study by Douali and Silver (2004), discrepancies between the Adspec setting and the clinical best-sphere measurement ranged up several dioptres, the standard deviation of the differences being about 0.8 D (Fig.7 left). The agreement improved somewhat when results for wearers with

astigmatism were excluded. In the study by Smith et al. (2010) the mean difference between the refractive estimates was close to zero, although its standard deviation was about 1 D (Fig.7 right). He et al. (2011) found no significant difference between the overall results of self-refraction and cycloplegic subjective refraction in urban Chinese children aged between 12 and 17 years but the standard deviation of the differences was about 0.7 D. The results of Zhang et al (2011) for rural Chinese aged 12-18 years were very similar: non-cycloplegic self-refraction correlated well with cycloplegic subjective refraction (mean difference close to about 0.1 D, standard deviation about 0.4 D). Although these results vary somewhat, due to perhaps to the differences between the subjects and exact procedures used, they suggest that self-adjustment yields reasonably accurate corrections, as judged against the results of subjective refraction for most individuals. Interestingly, there is no indication of any marked accommodation during the self-adjustment process with young individuals. Nevertheless, a minority, particularly among high myopes, are wrongly corrected by more than 1D (see Fig.7).



*Fig.7. (Left) Agreement between AdSpec and clinical estimates of best sphere corrections for 213 individuals aged 18 to 60 years from South Africa, Ghana, Malawi and Nepal. The inset shows a histogram of the differences (after Douali & Silver, 2004). (Right) The difference between AdSpec and clinical refractions in 50 Boston college students, as a function of their mean (after Smith et al, 2010). Note that in both studies major differences are found for a minority of individuals, particularly among high myopes.*

Overall, self-selection of correcting power yields good levels of agreement with clinical subjective findings for a high proportion of eyes. Moreover, Appleton (1971) found that the provision of spectacle prescriptions in 0.50D intervals, rather than the customary 0.25 D, was acceptable to most patients, implying a reasonable degree of tolerance to small errors in prescription. Nevertheless self-selection leads to a significant subset of individual eyes being poorly corrected (e.g. Fig.7), particularly among higher myopes and astigmats.

#### ***4.4 Visual acuity achieved with self-adjustment***

The largely satisfactory quality of the refractive results is supported by corresponding measurements of visual acuity. As shown in Table 1, a high percentage of self-corrected subjects in the studies cited could achieve good levels of acuity (meeting typical vision requirements for driving) with their self-selected correction. Only slightly better results were obtained with corrections based on clinical subjective refractions, which presumably included cylindrical corrections for any astigmatism.

*Table 1. Visual acuity results after correction by self-adjustment and by clinical refractive procedures. Levels of acuity may not be comparable in the different studies, due to the use of different chart designs (tumbling Es or letters).*

| Study                  | Subjects     | Level of VA         | % achieving this VA by self-refraction (Adspec) | % achieving this after clinical subjective refraction |
|------------------------|--------------|---------------------|---|---|
| Douali & Silver (2004) | Adults       | ≥6/9 (better eye)   | 87  | -   |
| Smith et al (2010)     | Young adults | ≥6/6 (Monocular?)   | 88  | 98  |
| He et al. (2011)       | 12-17 years  | ≥6/7.5 (better eye) | 92  | 100   |
| Zhang et al (2011)     | 12-18 years  | ≥6/7.5 (better eye) | 97  | 99  |

The impact of the lack of astigmatic correction was explored in a recent large-scale study in which patients were divided into two groups which received either fully-customised spectacles with full correction of individual spherical and cylindrical errors for each eye or a “ready made” correction in which both the lenses were spherical with power equal to that of the spherical equivalent in the eye with the smaller refractive error. In both groups frames were properly fitted. Overall visual outcomes and patient satisfaction in the two groups were broadly similar, although both were a little better with the customised correction. Importantly, however, visual outcomes and patient satisfaction were markedly lower for the subset of patients who had astigmatism  $\geq 2.00$  DC and wore a ready-made correction rather than a custom correction (Brady et al., 2012). Visual acuity in the presence of ocular astigmatism depends upon the latter’s magnitude and axis direction, together with the nature of the chart used but some representative figures are given in Table 2.

*Table 2. Dioptres of astigmatism and spherical ametropia required to degrade monocular acuity to different levels. Note that that the dioptric astigmatism required is larger than that of the spherical error (after Duke-Elder & Abrams, 1970, p.289).*

| Visual acuity                  | 6/9  | 6/12 | 6/15 | 6/21 | 6/30 | 6/45 | 6/75 |
|--------------------------------|------|------|------|------|------|------|------|
| Astigmatism<br>axis horizontal | 1.00 | 1.50 | 2.00 | 2.50 | 3.00 | 4.00 | 5.50 |
| Astigmatism<br>axis oblique    | 0.75 | 1.00 | 1.50 | 1.75 | 2.25 | 2.75 | 4.25 |
| Spher. myopia<br>or hyperopia  | 0.50 | 0.75 | 1.00 | 1.25 | 1.50 | 2.00 | 3.00 |

What has not been explored is the quality of binocular vision given, particularly when only a single frame size and design is available. It might be conjectured that many of those who find the spectacles uncomfortable to wear are experiencing stress due to adverse prismatic effects of the type described in section 4.2, caused by a mismatch

between their interpupillary distance and the separation of the optical centres of the spectacle lenses.

#### ***4.5. Potential risks and hazards of errors in setting the required spectacle power***

No studies have yet been made to determine whether vulnerable groups (e.g. children, people with learning disabilities, older people or people suffering from dementia) experience difficulty with adjustable-power spectacles. Teenagers appear to have no problems in making accurate power adjustments (He et al., 2011; Zhang et al. 2011) but this might not be the case with younger children. It is usually considered that at-risk children have completed their myopia development by the early teenage years but arguments continue as to whether this development might be influenced in younger children by any correction worn, so that caution should in any case be exercised with this group. While healthy older people should have no problem in making the necessary adjustments, obvious problems might exist for those with hand tremor or similar conditions. One important consideration with the elderly is that wear of spectacles of inappropriate power or with distortions may lead to an enhanced probability of falls (Elliott, 2014), although there appear to be no strong reason why these risks should be higher with adjustable-focus spectacles than with conventional spectacles. It might be anticipated that those with learning difficulties or dementia would be better served by fixed-focus spectacles, since they may not be aware that their variable power spectacles are inappropriately adjusted. Assessment of the vision of those with developmental problems is normally a challenging task, involving considerable professional skills (Saunders, 2009).

On the whole, however, the conclusion reached in a different context by Europe Economics in their recent report to the GOC (Europe Economics, 2013) also seems sensible in relation to adjustable focus spectacles:

*“The harm caused by incorrect prescriptions is unlikely to be severe in adults, but is generally more significant in children, where the result can be visual problems not being corrected, leading to long-term visual and developmental complications. (This is) Partly*

*due to (problems) being more likely to be noticed and corrected in adults than in children and vulnerable adults.”*

## **5. Current legislation on the sale of optical appliances**

In essence, the provisions of the Opticians Act 1989, Part 4 allow the sale of:

- (i) Any optical appliance or zero powered contact lens, if the sale is made under the supervision of a registered medical practitioner, a registered optometrist or a registered dispensing optician, or to a prescription less than 2 years old which has been given by a registered medical practitioner or registered optometrist.
- (ii) “Ready readers” with two single-vision lenses of the same positive spherical power not exceeding 4.00 D, provided that the buyer has attained the age of 16.

## **6. The adlens “White Paper”**

This proposes (adlens, 2014) that, in addition to (ii) above, over-the-counter sale of spectacles with adjustable-focus lenses should be permitted. With self-adjustment of power by the wearer to yield optimal clarity of vision, these would allow instant correction of spherical refractive errors for distance vision and adjustment of powers to optimise visual performance for near tasks at different distances.

The Paper argues that legislation drafted in an era of fixed-power spectacles should not be applied “*beyond the purposes for which it was enacted*” and that unrestricted availability of adjustable focus eyewear “*is consistent with widespread national and state efforts to engage consumers in their own health care*”.

It is suggested that “*This eyewear is not intended or designed for long-term use as it does not provide the precision vision that prescription eyeglasses do.*” On the other hand “*The eyewear also permits consumers to use the same pair of eyeglasses for different situations*

– a person who needs higher magnification for reading or close work can change the power and use the same pair of eyeglasses for computer work, for instance, and for a multitude of other tasks”. This appears to imply that it is envisaged that the purchaser of these spectacles might normally hope to be able to use these spectacles for both distance and near tasks for a reasonable span of time, insofar as their optical and mechanical properties are adequate. Anecdotal reviews on the Web suggest that this is indeed the expectation of most purchasers, although many feel that the cosmetic appearance of the spectacles limits them to short-term wear. However, as progressively more improved designs become available, cosmetic appearance is likely to become less of a limitation.

The “White Paper” notes:

- (i) Any residual spherical errors, due to incorrect self-selection of spherical power by the wearer, or uncorrected astigmatic errors, do not cause long-term damage to the wearer.
- (ii) Subjective selection by the patient has always formed part of subjective refraction routines conducted by refractionists and trials show good agreement between self-selected correcting powers and those found by professional examiners.
- (iii) The easy availability of adjustable spectacles might encourage those drivers whose refractive errors are not corrected or who use obsolete prescriptions to improve their vision on the road by wearing and correctly adjusting, the variable-power spectacles
- (iv) Legislation to allow the sale of ready-readers has had no impact on the annual number of eye examinations. This has, in fact steadily increased in the following decades. Nevertheless the importance of encouraging the public to have regular eye examinations is stressed
- (v) Although it is conceded that current adjustable spectacles do not correct ocular astigmatism, only a small proportion of the population has a high level of cylindrical error (e.g. only 5% have 2 DC or more) and their vision would still be improved by the elimination of spherical error by adjustable spectacles.

- (vi) Although the distance between the optical centres of the lenses is fixed, prismatic effects due to the distance or near interpupillary distance of the wearer differing from this fixed distance are unlikely to cause problems.
- (vii) The devices are well suited to the needs of presbyopes, and those whose refraction may be fluctuating, e.g. after cataract surgery or while diabetes is being brought under control.

Broadly speaking, the evidence already discussed supports (i), (ii), (v), (vi) and (vii) in most, although not all, cases. (iii) is a conjecture, which may or may not be true in practice. Although, as (iv) suggest, it is true that the number of eye examinations has increased since ready-readers were introduced, it remains possible that a still greater increase might have occurred in the absence of their introduction, fuelled perhaps by an ageing population, greater awareness of the importance of vision and so on. Some further factors relevant to any change in the regulations are discussed below.

## **7. Discussion**

### ***7.1. Implications of proposed change in regulations***

The central issues in the Adlens proposal are whether the sale of adjustable focus spectacles – which permit self-selection – should be permitted and whether this would have any adverse effects on the public’s health and safety. Is it desirable to change the law so that individuals can self-select what they believe to be the optimal power of spherical correcting lens for each eye for distance and near vision, without the intervention of any professionally-qualified individual?

It is important to recognise that adjustable-focus spectacles are only one of many ways in which self-selection of an optical correction might be carried out. In the case of such spectacles, self-selection of the optimal power is achieved after purchase by suitable adjustment of the lens powers when the device is worn. However, the principle would appear to be the same if, e.g., the purchaser looked into a black box and adjusted lenses to achieve optimal distance or near vision and then purchased ready-made fixed-focus

spherical-lens spectacles to match the derived specifications. The same “self-selection” principle would also apply if, as in the past, individuals selected from a display offering a choice of fixed-focus spectacles with equal right and left lens powers, capable of covering the range of more common ametropias, and checked the vision achieved by observation of a suitable chart. Smith et al. (2010) found that a self-selection method of this type which they termed “predetermined lens refraction” led to better values of corrected visual acuity than did self-adjusted Adspecs. Self-selected fixed-focus spectacles would, of course, lack the adaptability to different working distances given by adjustable-focus devices but might well be preferred by some users who found the need for adjustment irritating.

In my opinion, then, if over-the-counter sale of variable-focus spectacles with a wide range of correcting powers extending beyond 0 to +4D was permitted, with the intention that they should be adjusted to correct individual distance and near vision, such sale would also need to be permitted for fixed-focus appliances having the same correcting purpose.

### ***7.2. Adjustable focus lenses as distance corrections: ametropia and ocular pathology***

Here the uncorrected individual is aware that distance vision is blurred and selects a lens power that appears to make distant objects as clear as possible. As already noted, apart from the limitations set by a lack of cylindrical and prismatic corrections, the available evidence suggests that the self-selection process usually gives a satisfactory level of visual acuity. However, the obvious problems are that in some cases peak acuity after adjustment may not match normal standards and that marked changes in refraction may be undetected. In the context of normal eye examinations these would be important cues to developing ocular problems. It was, presumably, considerations of this type that led to the retention of the requirement for a prescription when the regulations regarding “ready-readers” were revised during the 1980s.

In this respect, it can reasonably be argued that, whereas the onset of presbyopia is a normal part of the ageing process, affecting all individuals, marked distance refractive

error is a defect of sight which only affects a subset of the population and needs to be considered differently.

Is there any evidence that those having marked refractive error might be more susceptible to the development of pathology than emmetropes having little or no refractive error? It has, in fact, long been well known that myopia, particularly at higher levels, is associated with a variety of pathological complications (e.g. Saw et al., 2005). Importantly, however, it is now recognised that risks of retinal and other pathologies are higher for all myopes, with the risks steadily increasing with the magnitude of the myopia (Flitcroft, 2012). As examples, Table 2 gives the odds ratios (essentially the relative chance of the condition occurring in myopes in comparison with non-myopes) and their 95% confidence limits for myopic maculopathy and retinal detachment. It can be seen that even relatively low myopes are at much higher risk than are non-myopes. Flitcroft (2012) makes the important additional point that, although the odds ratios for lower myopes may be smaller than those for higher myopes, there are many more of the former, so that they may contribute a comparable number of cases of sight-threatening pathology and hence a similar health burden for the country. Hyperopia may also be associated with higher risks for some conditions (Flitcroft, 2012).

*Table 2. Odds ratios for myopic maculopathy and retinal detachment in different myopic groups.*

| Myopic refractive error (D) | Condition          | Odds ratio | 95% Confidence limits |
|-----------------------------|--------------------|------------|-----------------------|
| -1.00 to -2.99              | Myopic maculopathy | 2.2        | 0.5 to 9.9            |
| -3.00 to -4.99              |                    | 9.7        | 2.8 to 36             |
| -5.00 to -6.99              |                    | 41         | 13 to 124             |
| -7.00 to -8.99              |                    | 127        | 34 to 472             |
| ≤-9.00                      |                    | 349        | 121 to 1000           |
|                             |                    |            |                       |
| -0.75 to -2.75              | Retinal detachment | 3.1        | 2.6 to 3.8            |
| -3.00 to -5.75              |                    | 9.1        | 7.5 to 10.8           |

|                 |  |      |              |
|-----------------|--|------|--------------|
| -6.00 to -8.75  |  | 21.5 | 17.3 to 26.7 |
| -9.00 to -14.75 |  | 44.2 | 34.2 to 57.2 |
| ≤-15.00         |  | 88.2 | 56.1 to 139  |

In general terms, then, if self-selection of spectacles to correct distance vision were to discourage the purchaser from having a full eye examination, although all individuals would be at risk of suffering from undetected pathology, the dangers would be higher in myopes, particularly higher myopes. This might suggest that self-selection should be confined to the correction of only low myopic errors, emmetropic or hyperopic errors. The current adlens adjustables have a power range of -6 to +3 D, while the some Focusspecs cover the range -1 to -5 D, i.e. both devices might be bought by at-risk myopes.

It should be noted that those adjustable-focus appliances that combine a fixed spherocylindrical prescription for distance vision with a variable-power near addition (e.g. Superfocus, adlens Focuss) are premium products (cost around \$1000) in which the determination of the distance correction and frame fitting are carried out by professional personnel. Presumably sales of these would be governed by current legislation on prescription appliances.

### ***7.3. Readymade reading spectacles***

Although there do not appear to be any systematic studies on the background of those who purchase readymade reading spectacles which meet the requirements of present regulations, it seems likely that the majority is composed of individuals who have adequate unaided distance vision (emmetropes and low ametropes, particularly hyperopes) but find themselves experiencing problems with near vision due to presbyopia. It is possible that some pre-presbyopic hyperopes also find them useful. Evidently the worry is that many of these users of over-the-counter devices, finding that they can attain reasonable distance and near vision, will avoid formal eye examinations, with the possibility that detection of vision-threatening incipient abnormal ocular conditions will be delayed. . I know of no study which attempts to determine whether

those purchasing ready readers are more or less likely to have regular eye examinations than the rest of the population, or whether they constitute a disproportionately large fraction of patients needing ophthalmological treatment;. Information on these points is needed. The finding that total annual numbers of eye examinations have increased, rather than decreased, since legislation was changed to allow the sale of such spectacles (used in the Adlens White Paper to refute the “myth” that over-the-counter eyeglass sales discourage people from having regular eye examinations), may simply reflect changes in the absolute numbers and age distribution of the population: it does rule out the existence of individuals who rely entirely on over-the-counter devices and never undergo a full eye examination. Had no ready-readers been available, the increase in eye examinations might have been even greater.

It could be argued that, since the prevalence of many common pathological conditions (e.g. glaucoma, cataract, age-related macular degeneration) tends to increase with age, any failure to undergo regular eye examinations is likely to present more serious risks in older individuals. These are, of course, the prime customers for over-the-counter reading spectacles. As an example, Fig.8 plots the overall prevalence of age-related macular degeneration as a function of age, as found in several studies in different parts of the world (Hyman, 1991). Clearly the probability that the condition is present increases rapidly after the age of about 60. Anything that discourages older people from having regular eye examinations therefore increases the chance that early signs of the development of pathology will be missed.

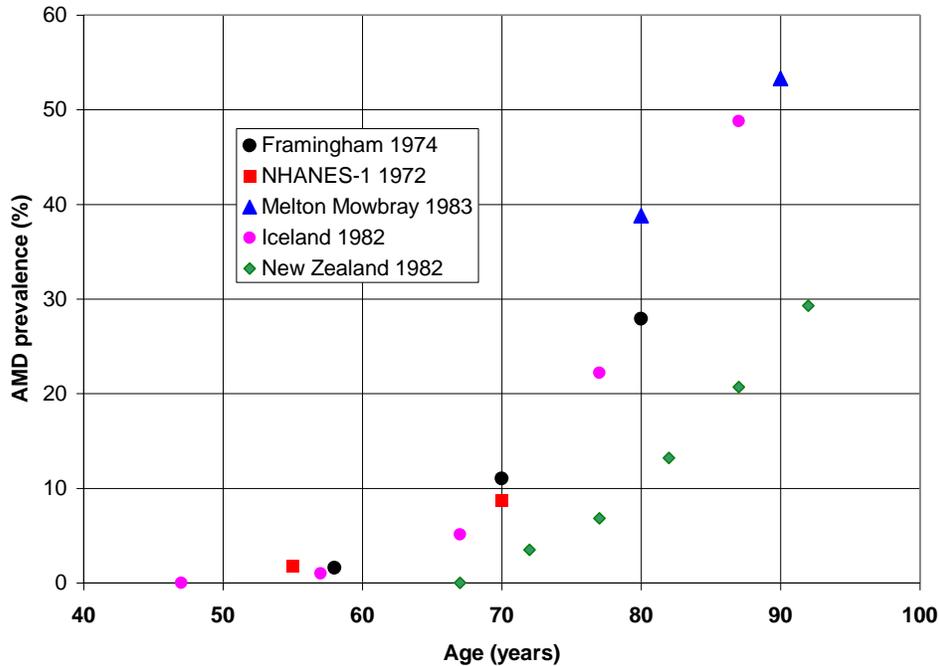


Fig.8. Prevalence of age-related macular degeneration as a function of age. Based on data from various parts of the world, as collated by Hyman (1991)

In spite of the above concerns, current regulations allow the over-the-counter sale of spectacles with equal pairs of positive lenses of power up to +4.00 D. Powers are self-selected by the purchaser. It could reasonably be argued that adjustable spectacles with a power range 0 to +4.00 D would give similar optical effects if the powers changes in the two lenses were ganged together, rather than being independent, although independent adjustment has the advantage of allowing correction of small anisometric errors in near-emmetropes. Many purchasers of current fixed-focus ready readers buy more than one pair, with powers suitable for tasks with different working distances. Adjustable spectacles, such as Eyejusters (range 0 to +3.00 D) would obviously offer a better solution to the problem of varying working distances.

#### 7.4. Other considerations

During this discussion we have assumed that the optical and mechanical properties of the devices meet accepted contemporary standards and that they match the specifications given by the manufacturer. In practice, experience with readymade reading spectacles

suggests that these assumptions are not always justified (e.g. Elliott et al., 2012). An issue which deserves to be re-emphasised is the fit of the spectacles. As noted earlier, readymade spectacle frames are often made to a “one size fits all” design. While it is often acknowledged that the associated horizontal distance between the optical centres of the lenses does not match the interpupillary distance of the wearer, (which varies with the convergence required for near work), an inappropriate bridge design and frame fit may place the optical centres at the wrong height, or allow the frame to be tilted, introducing inappropriate prism effects. However, much the same criticisms could obviously be levelled at over-the counter “ready reader” frames.

Spectacles with independent adjustments of the two eyes meet, in principle, the needs of anisometropes, although problems could arise in cases where the lenses are adjusted so that the powers are unequal, whether or not this is intentional. The resultant differences in spectacle magnification might introduce aniseikonic symptoms and differential prism effects, particularly in the vertical meridian which may cause stress to the wearer. The “White Paper” points out, however, that those experiencing visual discomfort can be expected to discontinue wear of the correction.

Finally there is the question (implicit in many parts of the Adlens paper, e.g. pages 9, 17) of whether the present regulations represent an unreasonable restriction in freedom of trade and consumer choice. At present, relief of blurred distance vision caused by simple refractive error can only be obtained through a qualified practitioner. It is, perhaps, curious that, in contrast, in cases where an individual experiences some general medical symptoms, she/he can freely choose to purchase numerous drug or herbal remedies, or to consult various non-medical practitioners, from herbalists to reflexologists, in search of relief of the symptoms, although it might be sensible to consult a medical practitioner. Presumably it is accepted that the individual bears the responsibility for her/his own choice, even though the dangers of, e.g., excessive, unsupervised, aspirin consumption are well known. Apart from the question of cost and worries about the cosmetic aspects of spectacle wear, many individuals dislike having their eyes examined, citing stress from such concerns as going into a dark room, the close approach of the examiner during ophthalmoscopy, airpuff tonometry, the possibility use of drops and dilation, and worries

about wrongly answering puzzling questions as to whether things look clearer or not (Shickle et al. 2014a, b). It may be that some of these individuals would receive at least partial help from easier access to over-the-counter corrections which, if not ideal, offer real benefits. However, education on the benefits of regular eye examinations remains vitally important and it is likely that some of those purchasing variable focus spectacles might feel that, since they could see reasonably clearly, there was no need further action regarding their vision.

## **8. Summary**

- (i) The regulatory paper produced by Adlens Ltd, together with associated material published elsewhere, provides good evidence that self-adjustment of the power of correcting spectacle lenses leads to results which approximate closely to clinically-found values and yield good levels of acuity in most wearers, with the possible exception of high myopes where errors in excess of 1 D appear to be common (see Fig.7). However, a major concern remains that that unrestricted over-the-counter sale of such devices might discourage purchasers from having a full eye examination, resulting in the delayed detection of ocular pathology. Potential risks may be higher among myopes (see section 7.2).
- (ii) Self-correction is unsuitable for some potential users (e.g. children, people with learning disabilities, older people or people suffering from dementia)
- (iii) The risks associated with over-the-counter sales of adjustable-focus spectacles having a wide range of positive and negative powers lenses within which a distance correction is self-selected by the wearer are the same as those for over-the-counter sale of self-selected fixed-focus spectacles with lenses within a similar range of powers. Current legislation bans over-the-counter sale of fixed-focus optical appliances and requires that these should be made to prescriptions produced by eye care professionals after a full eye examination, on the basis that this helps to protect public health. The regulatory paper does not produce any evidence to contradict this view and, as a result, fails to make the case that public health and safety would not be adversely affected by a

change in the law to allow for the over-the-counter sale of all types of adjustable-focus spectacles.

- (iv) In the spirit of the present regulations, there would appear to be no fundamental reason why adjustable “reading” spectacles with pairs of lenses with positive power variable within the range 0 to +4.00 D should not be made available as an alternative to currently-permitted over-the-counter devices having pairs of fixed power lenses within the same range. The availability of independent adjustment of the two lens powers within this range would be helpful to anisometropes.
- (v) Variable-power hybrid spectacles, in which sphero-cylindrical lenses made to a prescription for distance vision produced by a professional examiner are coupled to adjustable-focus near additions would appear to meet existing regulations regarding powered appliances.
- (vi) It would be helpful to have up-to-date information on the extent to which those already purchasing readymade reading spectacles have regular eye examinations in comparison with the rest of the population. Using known prevalence rates for pathology as a function of such factors as age, sex and refractive state, it would then be possible to begin to make some quantitative estimates of the possible adverse effects of changing current regulations for over-the-counter sale of appliances.

W.N.Charman, PhD, DSc, 1<sup>st</sup> October 2015

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## **10. Appendix: Exploratory assessment of some optical properties of Focusspec and adlens Adjustables variable-focus spectacles**

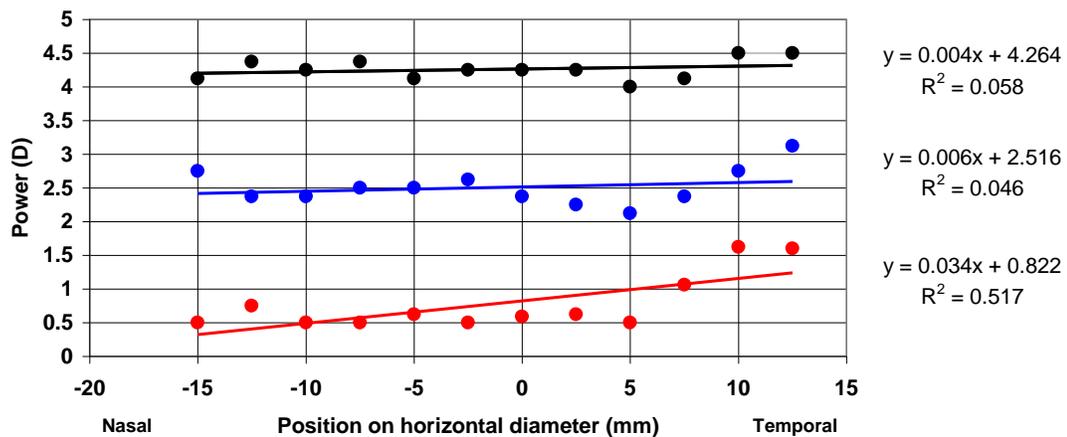
For the spectacles to be useful, it would be hoped that, at any fixed level of lens adjustment, the power of the Alvarez lenses would be constant across most of the lens aperture. The optical centre of the lens would be expected to remain the same whatever the adjusted lens power: this can be assessed by observing the prismatic effects across the lens, which should follow the Prentice rule (Prism power = Spectacle power x decentration in cm).

A manual focimeter with a 4 mm aperture was used to measure the variation in power and prism across the lenses.

### **Focusspecs**

These are specifically designed as spectacles for use in third-world countries, to be used in situations where no professional aid is available. The model examined was an early version in which the side-arms were rather flimsy. Improvements in frame design have since been made by the manufacturer. The useful area of each lens appears to be elliptical with horizontal and vertical diameters of about 30 and 25 mm, although the horizontal diameter varies by a few mm with the power setting since the individual Alvarez elements are sheared with respect to one another.

The range of power adjustment is nominally +0.5 to +4.5 D. Fig.A1 shows the variation in best-sphere power across a horizontal diameter of the lens for three power settings across the available range.



*Fig.A.1 Variation of best-sphere power across the horizontal diameter of the left lens of a Focusspec, with power set at low medium and high levels (approximately +0.50, +2.50 and +4.25D). The origin for position is slightly displaced from the optical centre of the lens, which lies at about -2.5 mm (see Fig.2). The formulae give regression line fits to the data.*

It can be seen that the power is, as desired, generally constant across the central area of each lens for each power setting but that, for the lowest power setting, the power in the temporal region tends to become too positive. In general, however, the region of constant power is large enough to allow a reasonable field of clear vision to be explored by suitable eye movements.

The corresponding prismatic effects are shown in Fig.2. The prismatic effects are those expected from Prentice rule. With position specified in mm, the regression-line slopes would be expected to be about 0.05, 0.25 and 0.43  $\Delta/\text{mm}$ , in comparison with the observed values of 0.06, 0.24 and 0.40  $\Delta/\text{mm}$ . Any discrepancies are those to be expected from the accuracy of the measurements. The absence of any marked non-linearities in the data is important, since their presence would indicate the existence of spatial distortions in the imagery produced by the lens. The optical centre appears to remain stable at about -2.5 mm as the lens power is altered.

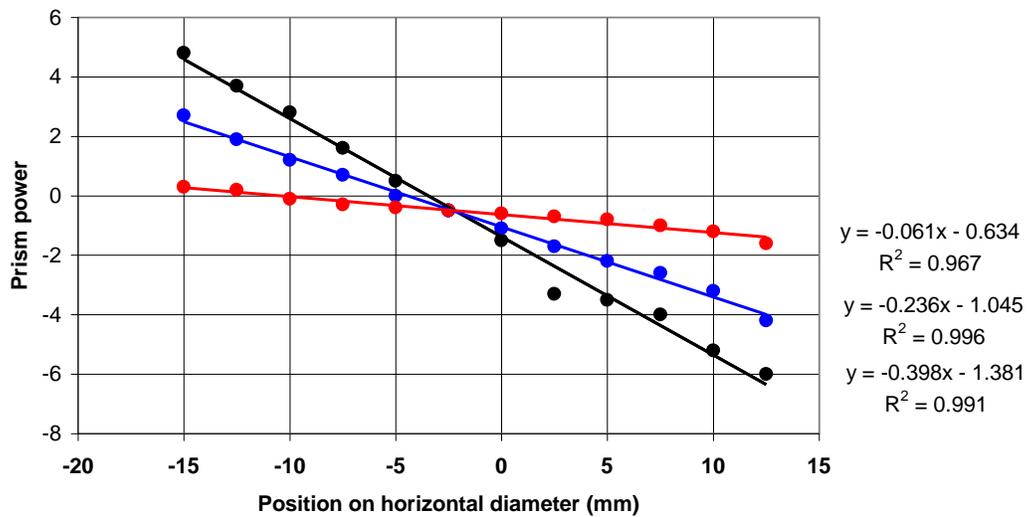


Fig.A2 Base-in/base-out prismatic effects across the horizontal diameter of a Focusspec lens for the same power settings as in Fig.A1. The origin of the distances was selected as being close to the optical centre.

**adlens adjustables**

Here the useful lens aperture appears an ellipse with a horizontal diameter of about 35 mm and a vertical diameter of about 25 mm. The measured variation in mean spherical power across a horizontal diameter is shown in Fig.A3. Again, power appears to be adequately stable across the horizontal aperture for the 3 selected power settings within the available spherical range of +3 to -6D.

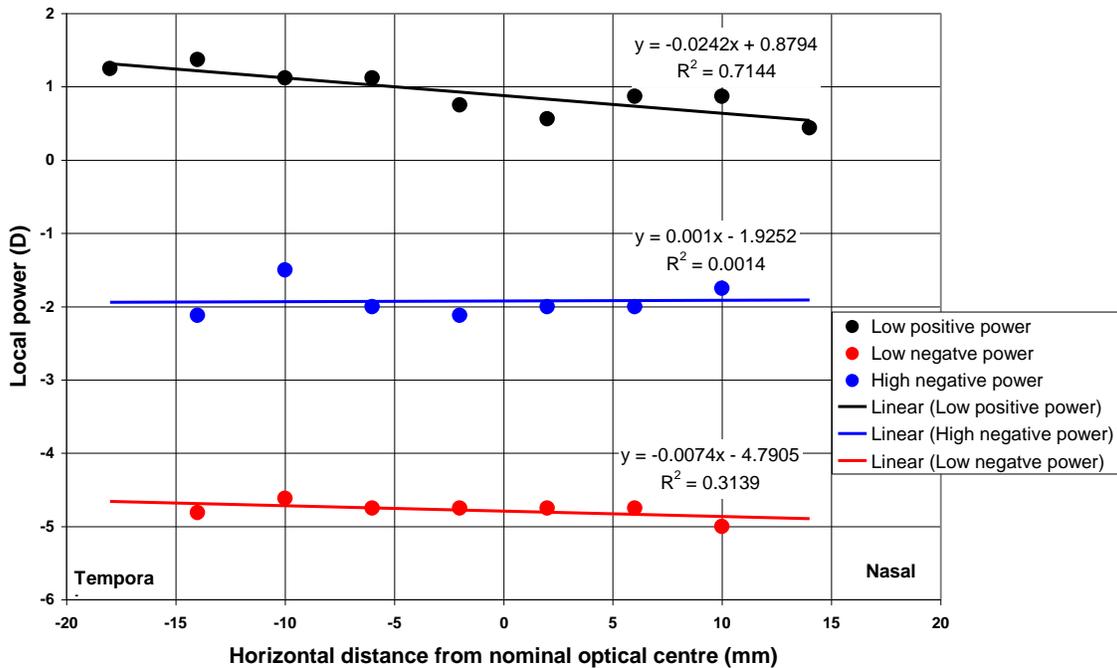


Fig.A3. Variation in spherical power across a horizontal diameter of an adlens adjustable lens at 3 power settings

The corresponding horizontal prism measurements are shown in Fig.A4. The three lines cross at a reasonably consistent optical centre, implying that this is unaffected by the power changes. The observed slopes of the regression lines (0.11, -0.16, -0.42 Δ/mm) are again comparable to those expected on the basis of Prentice rule (0.09, -0.19 and -0.48 Δ/mm).

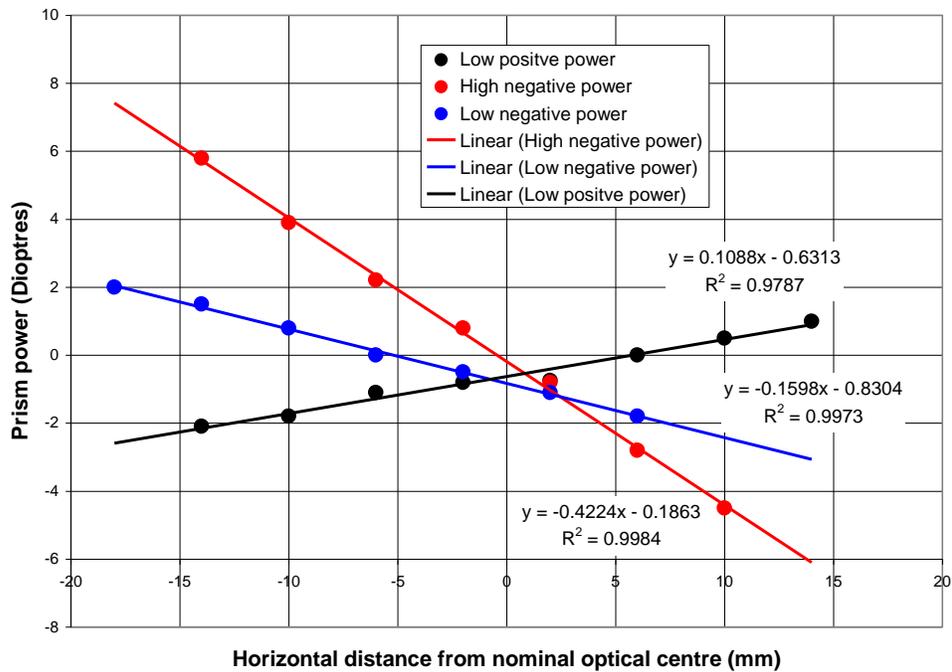


Fig.A4. Base-in/base-out prismatic effects across the horizontal diameter of an adlens adjustable lens under the same conditions as in Fig. A3.

## Summary

The optical qualities of the Alvarez lenses in the two varieties of variable-focus spectacles appear to be basically satisfactory. Further measurements will explore the oblique astigmatism of the lenses and will use interferometry to examine their optical quality in more detail.