ADJUSTABLE FOCUS EYEWEAR

WHY EXPANDED ACCESS TO NEW LENS TECHNOLOGIES IS IN THE PUBLIC INTEREST

INNOVATION

AND SOLUTION

adlens

Figure 1 Originally intended to be for temporary wear, eyeglasses were invented sometime between 1280 A.D. and 1300 A.D. in Italy

ECONOMIC IMPACT OF ACCESS TO EYEWEAR

The considerable economic impact of improving vision through the provision of eyeglasses is neatly summed up by David S Landes,[1] professor emeritus of economics and history at Harvard University, who marks the invention of eyeglasses as a key factor for bringing about economic growth in Europe during the Renaissance: the early availability of eyeglasses in the region gave the continent's economy a fundamental advantage over the rest of the world by effectively doubling the working life of skilled craftsmen.

There are numerous reports demonstrating the positive economic impact of good vision[2-4] and yet, even in the world's most developed regions, access to affordable eyeglasses remains an issue. In the UK alone it is estimated that 53.5% of those that suffer from visual impairment require nothing more than a pair of eyeglasses to restore their sight.[2] Now more than ever, emerging eyeglasses technologies have the potential to improve access to affordable vision correction, putting control of vision quality in the hands of those who understand it best: the user. An overarching question remains whether current regulation is up to the task of meeting the needs of consumers.

Over-the-counter

Adlens desires to sell adjustable focus eyewear at retail stores in the UK.

Significant evidence and years of experience (summarised below) support Adlens' mission to make adjustable focus eyewear readily available as over-the-counter (OTC) eyewear to consumers in the UK.

This new category of eyewear allows consumers to self-adjust the focus of each lens in accordance with their needs. Consumers purchase adjustable focus eyewear, which comprises a frame and plano (no power) lenses (there is no ground-in prescription), at the point of sale and then turn a dial located to the side of each lens until the desired focus is achieved. The power of each lens is typically limited to -6 to +3 dioptres.

The eyewear closely models the eye's natural dynamic behavior, enabling better vision quality and individual control. Currently, adjustable focus eyewear can be purchased for approximately the same price as a pair of high-end ready-to-wear reading eyeglasses.

Constructive cooperation

Broad access to the device, with meaningful individual control of its use, is consistent with widespread national and state efforts to engage consumers in their own health care.

Adlens is prepared to work with eye care professionals, regulators and the vision community, including ophthalmic dispensers and other retailers, to ensure that consumers understand the product, its benefits and limitations, and how it is not a substitute for prescription eyewear or a reason to postpone eye examinations.

Sale of adjustable focus eyewear, coupled with appropriate information about the product, vision and eye health can be used to promote healthy behaviors by consumers, including consumer commitment to obtaining regular eye examinations.

Benefits

Adjustable focus eyewear provides consumers with the capacity to function with improved visual acuity immediately, rather than having to wait for the fabrication and delivery of their prescription eyeglasses. 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.

As each lens can be adjusted individually, it is possible for consumers to easily manage differences in power between eyes.

The technology can be used as OTC eyewear without a prescription for instant serviceable vision correction at times when speed, flexibility in focus or both are important (e.g., when prescription eyeglasses are lost or broken, when patients face changes in the powers needed in eyeglasses due to surgery or medical treatment, or for vision needed for tasks performed at different distances).

Today, over 600,000 consumers worldwide wear adjustable focus eyewear with no reported ill effects or health and safety concerns.

Adjustable focus eyewear can be used by adults and teenagers who are not blind or partially sighted. This eyewear is not intended or designed for long-term use as it does not provide the precision vision that prescription eyeglasses do. Nonetheless, the product provides significant benefit to the wearers in many situations.

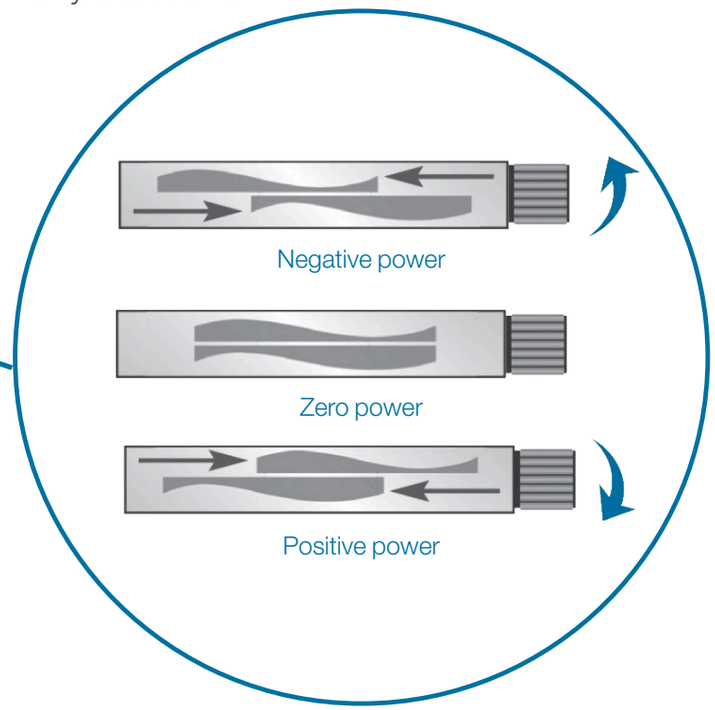


Figure 2. Each lens comprises two wave-shaped polycarbonate plates that are able to glide across one another. Turning the dials at the side of each lens moves the plates relative to one another, thereby altering the power of the lens.

The big questions

Health care regulators and eye care practitioners generally raise the following questions about the impact of making adjustable eyewear widely available:

1. Is there potential for harm or injury to a consumer who self-adjusts the lenses in adjustable focus eyewear poorly?
2. Can people use adjustable focus eyewear reliably and accurately?
3. Is it safe to use adjustable focus eyewear?
4. Will consumers who have access to adjustable focus eyewear choose to avoid eye examinations, leading to eye health problems resulting from undiagnosed conditions or diseases?

We address each of these questions in turn.

Potential harm to the consumer?

There is no evidence that any long-term damage to vision or health occurs from using eyeglasses with refractive powers that do not provide the sharpest focus for a particular task. Consumers routinely use OTC reading eyeglasses or out-of-date prescription eyeglasses when engaged in activities where best corrected visual acuity would be obtained by using eyeglasses with different powers.

Regulators understand that consumers are not harmed by wearing eyewear that improves the user's vision but does not achieve perfect acuity. Almost all eyecare professionals will permit duplication of existing prescription eyewear for as long as the wearer chooses to have new eyewear made to match old. By not requiring further examination, there is implicit acknowledgment that there is no harm in wearing eyewear that is not the precise power needed to completely correct a vision deficiency. Similarly, in the UK, OTC reading eyeglasses may be sold to all over the age of 16 years who are not registered blind or partially sighted. There is no evidence that this widespread use has resulted in any discernible harm to consumers.

Consumers are also protected from harm from imprecise eyewear because wearers have an immediate solution should they experience any discomfort or perceived reduction in acuity – they simply remove the eyewear. This solution also exists for the adjustable focus lenses. With adjustable lenses, though, wearers have an additional solution – they can readjust the lens until their visual acuity is improved and discomfort, if it exists, disappears.

We've been 'self adjusting' lenses for centuries

Precedent for 'self adjustment' of lenses

A small but important part of the routine eye examination conducted by optometrists the world over is the 'refraction': that is, the process of determining the power of the lens required to provide the customer with optimal vision correction. There are a number of ways of conducting the refraction process but the most common by far is known as 'subjective refraction'. Most eyewear users will be familiar with this procedure as it is the part of an eye examination during which the optometrist presents a series of lenses before their eyes and asks, "Which is better? Lens one or lens two?" The result of this forced-choice process depends entirely on the patient's ability to determine which combination of lenses provides optimal vision.

Indeed, in a sense, the optometrist is acting merely as a facilitator of the refraction process...changing lenses upon request of the customer.

It should therefore come as no surprise that people, when provided with the right tools (of which adjustable focus eyewear is an example), are extremely capable of refracting themselves.

Clinical findings

The results of studies[5-9] on the accuracy of adjustable focus eyewear published in the British Medical Journal, Ophthalmology and Optometry and Vision Science are detailed in Table 1 below. In all cases at least 80% of those who used adjustable focus eyewear to correct their vision were able to achieve the "gold standard" of 6/6 vision and in the largest studies, 99% were able to achieve the legally mandated limit for driving (approximately 6/12).[10]

Furthermore, no study found a statistically significant difference between the power selected by the user and the power determined by an ophthalmologist. This technology is both easy to use and accurate.

Region	Sample	Age (yrs)	Finding	6/12 (%)
Urban PRC[5]	554	12–17	85% achieved ≥6/7.5	99.3%
Rural PRC[6]	648	12–18	97% achieved ≥6/7.5	99.2%
Urban USA[7]	350	12–18	88% achieved ≥6/6	Not reported
Urban USA[8]	100	19-28	88% achieved ≥6/6	Not reported
Rural Africa[9]	213	18–60	87% achieved ≥6/9	Not reported

Table 1. Summary of visual outcomes from clinical research involving the use of adjustable focus eyewear.

Safety on our roads

There are few activities for which the risk of poor vision is so startlingly manifest as driving. A study on the prevalence of illegal motor driving among adults in the US[11] revealed that 4% of drivers aged 65 years or older with vision below legal limits persisted in driving a car.

Similar results have been reported in the UK. Road crashes caused by poor vision are estimated to cause 2,900 casualties and cost £33 million in the UK each year.[12] At present, many drivers use eyeglasses with out-of-date prescriptions or, more worryingly, need eyeglasses for driving but do not have them.

This year a survey of 1,000 drivers conducted by Brake found that 25% of drivers had not had a sight test in the last two years.[12] Further, 12% had not visited an optometrist for five years or more: for 3% it had been more than a decade since they had a sight test and 4% (the equivalent of more than 1.5 million drivers in the UK) had never had their eyes examined.

If a person's prescription eyewear or contact lenses are damaged or lost, they have no choice but to refrain from driving (or drive illegally) while they wait for new prescription eyewear to be fabricated.

A new solution

If adjustable focus eyewear is widely available, drivers might try them and thereby appreciate that their vision requires correction. Even if they did not visit an optician, it would be safer for all road users if such drivers used adjustable focus eyeglasses rather drive with no vision correction whatsoever.

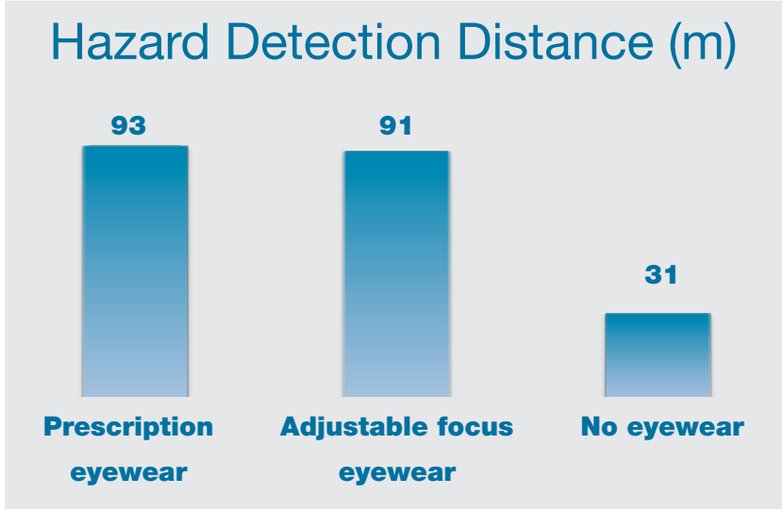


Figure 3. Summary of visual outcomes from clinical research involving the use of adjustable focus eyewear

A vision for safer roads

This assertion is supported by research from the University of Michigan Transportation Research Institute (UMTRI). UMTRI has been the forerunner of road safety research since 1965, with a multi-million dollar budget for identifying and solving issues related to safety on the road. A recent, and as yet on-going, study[13] utilises adjustable focus eyewear to shed light on the importance of proper vision in reacting to hazards while driving.

Early results indicate that there is no statistically significant difference in the distance at which road hazards (including pedestrians) and road signs are detected while wearing prescription eyeglasses and adjustable focus eyewear during driving. Both prescription eyeglasses and adjustable focus eyewear were found to offer a significant advantage over wearing no corrective eyewear at all (figure 3). This research indicates that adjustable focus eyewear can offer a temporary solution to the vision correction needs of drivers, restoring visual performance behind the wheel and leading to greater safety on our roads.

Impact of adjustable focus eyewear on the frequency of eye examinations

There is no evidence to suggest that consumers will get fewer eye examinations if they have access to adjustable focus eyewear.

To think otherwise implies that consumers will not take responsibility for their eye health unless forced by law to get eye examinations when their visual acuities change.

In fact, evidence exists that demonstrates that the rate of eye examinations was not reduced when OTC readers were made available. It is logical to assume that the introduction of adjustable focus eyewear would have the same result.

This issue was dismissed decades ago when OTC reading eyeglasses were introduced in the eyewear market. Regulators saw the wisdom of allowing wide access to magnifying eyeglasses to correct presbyopia. As people age, it becomes increasingly difficult to focus on details of objects and typeface near viewers, thereby diminishing their abilities to read and perform other close tasks. Today, magnifying eyeglasses that improve near vision are available without a prescription throughout both the US and the UK.

A few states in the US decided, like the UK, to require that OTC readers be sold with an affirmative statement that consumers who used these reading eyeglasses should still get regular eye examinations, e.g., New York, Massachusetts. There have been no reports to suggest that the frequency of eye examinations in these states differs from that in states that do not have disclosure requirements.

Moreover, while the cost of selling reading eyeglasses is higher to traditional retailers in parts of the world that require such disclosures (because of signage and point-of-sale materials requirements), there is no data to suggest that these disclosure requirements have had any impact on reducing access to OTC reading eyeglasses. Of course, people within these regions need not only buy reading eyeglasses in stores that comply with the disclosure requirements: they are free to buy through the Internet and within other jurisdictions.

The issue of consumers' not obtaining eye examinations has also been raised in the context of Internet sales of eyeglasses in the US. Data from the Vision Council of America[14,15] indicates that Internet sales of eyeglasses has had no impact on the frequency of eye examinations in the US. In fact, the number of adult eye examinations in the US annually continues to increase, at the same time that online purchase of prescription eyeglasses and contact lenses is growing. Similar trends have been reported in the UK.

While the need for and frequency for regular 'well-eye' examinations is still the subject of some discussion on the part of some professional and industry groups, most countries in the world do not have laws establishing eyeglass prescription expiration dates. Therefore, a consumer in these parts of the world can obtain prescription eyeglasses based on an old prescription, with no legislative or regulatory emphasis on obtaining eye examinations at any particular time.

This is further evidence that regulators understand that consumers are not benefitted from reducing access to eyewear in order to coerce some otherwise reluctant patients to get eye examinations.

At the same time, there is evidence that eye examination frequency is increased by efforts to educate consumers about the importance of obtaining comprehensive eye examinations at regular intervals. For the most notable, see the:

- National Eye Health Education Program
- Think About Your Eyes campaign
- EyeSmart campaign

It is worth noting that none of these education efforts attempt to coerce patients into getting eye examinations by withholding prescriptions or denying access to OTC products.

Rather, government agencies and professional associations all seem to accept that the preferred and appropriate way to persuade the public to get regular eye examinations is through education and information. This approach would be enhanced and supported by distribution of information about eye health and the importance of eye examinations with the sale and display of adjustable focus eyewear.

Educational programs are in place that emphasise the importance of regular eye examinations even when the patient is asymptomatic; these are having a positive impact on awareness and intent to obtain an eye examination.

Adlens supports encouraging the public to obtain regular eye examinations as part of their necessary health care.

The myth: OTC eyeglass sales discourage people from having regular eye examinations.

The facts: It may be hard to imagine today but prior to 1989 it was illegal for anyone other than an optician to sell reading eyeglasses in both New York State and the United Kingdom. The UK's Opticians Act 1958 limited the sale of all eyeglasses to opticians. Enforcement of the Act had, by the early 1980s, so restricted competition for the sale of eyeglasses in the UK that there arose a great public outcry against the exorbitant prices charged for eyeglasses by opticians. The problem arose from the entanglement of two very different activities: the necessary and important business of the care and maintenance of the health of the eyes, and the rather separate business of selling eyeglasses.[16]

One of the first arguments against OTC sale of eyeglasses was that such sale would act as a disincentive for people to have regular eye examinations. The Office of Fair Trading, which had studied this issue and published a report[17] in 1982, found that only 2% of those who bought eyeglasses without a prescription would avoid regular eye examinations. Clearly, the public has long since been able to differentiate the need for careful examination of eyes from the marketing of vision.

Furthermore, we now have the benefit of over 30 years worth of empirical data to refute the argument that the sale of eyeglasses without a prescription leads to a reduction in the number of eye examinations conducted each year. Did the introduction of ready-made-reading eyeglasses lead to a reduction in the number of eye examinations? For that matter, has the now fairly widespread Internet availability of prescription eyeglasses and contact lenses led to a reduction in eye examination rates in the UK (or anywhere in the world)? The answer is an emphatic no. Figure 4 draws on data published in the annual reports of the Federation of Ophthalmic Dispensing Opticians[18-49] and by various market research agencies.[50, 51]

The introduction of reading eyeglasses and the online sale of eyewear has not caused a reduction in the annual eye examination rates in the UK.

The single largest reduction in eye examinations rates in England in the past 30 years is attributable to the introduction of fees for eye examinations in 1988.[52]

Conversely, the single largest increase in eye examination rates in Scotland (well over 200%) is attributable to the fact that fees for eye examinations were scrapped in 2006.[53]

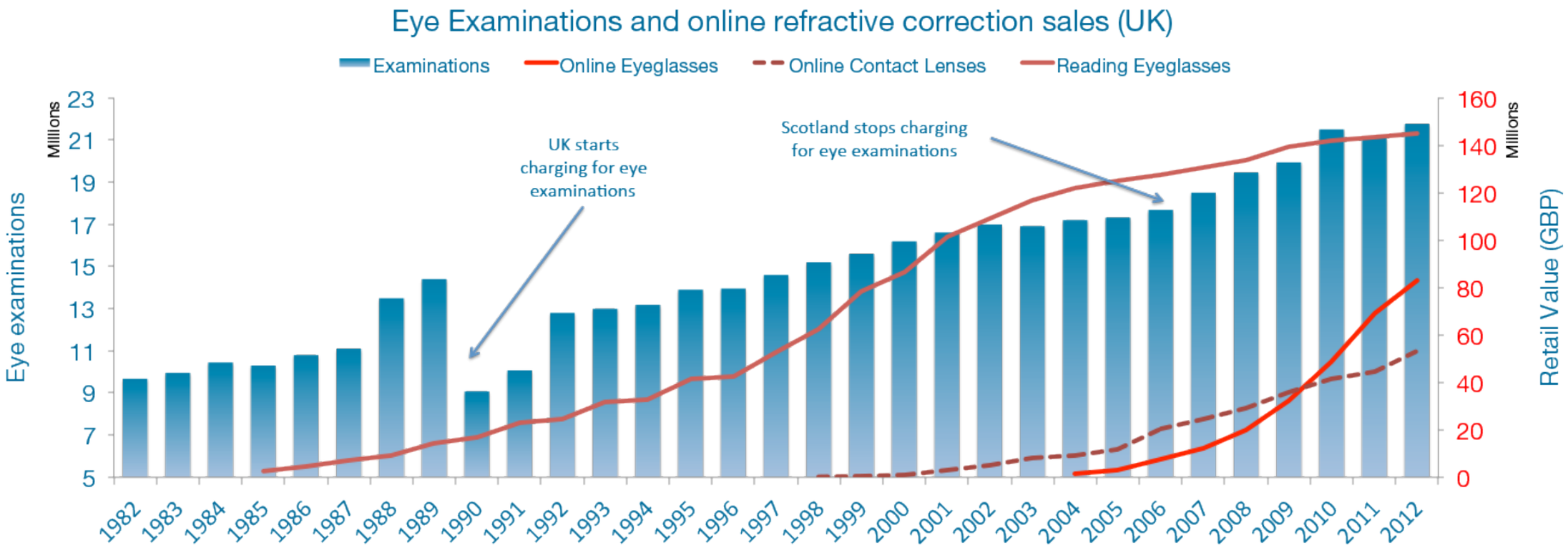


Figure 4. The introduction and sale of OTC and online vision correction products has had no discernible impact on the number of eye examinations conducted each year in the UK over the past 30 years.

Thirty years of experience

Adjustable focus eyewear does not correct astigmatism. Is this an issue?

The answer to this question is “yes” for those who sell premium eyewear at premium prices, but “no” for those who are asking if the lack of astigmatic correction in adjustable focus eyewear can cause harm to either the wearer or others.

Consumers who spend hundreds of dollars on eyewear expect that their lenses correct astigmatism accurately. Nevertheless, a recent study[54] on the impact of astigmatism on vision has shown that astigmatism of less than 0.50D has almost no effect on vision quality.

Astigmatism of 1.00D or more is quite noticeable but, in the UK, only 23% of the population has astigmatism of 1.00D or more in both eyes (figure 5).[55,56] Vision degrades quite severely on account of 2.00D of astigmatism (5% of population) but even these individuals would find substantial benefit from the sort of vision improvement offered by adjustable focus eyewear.

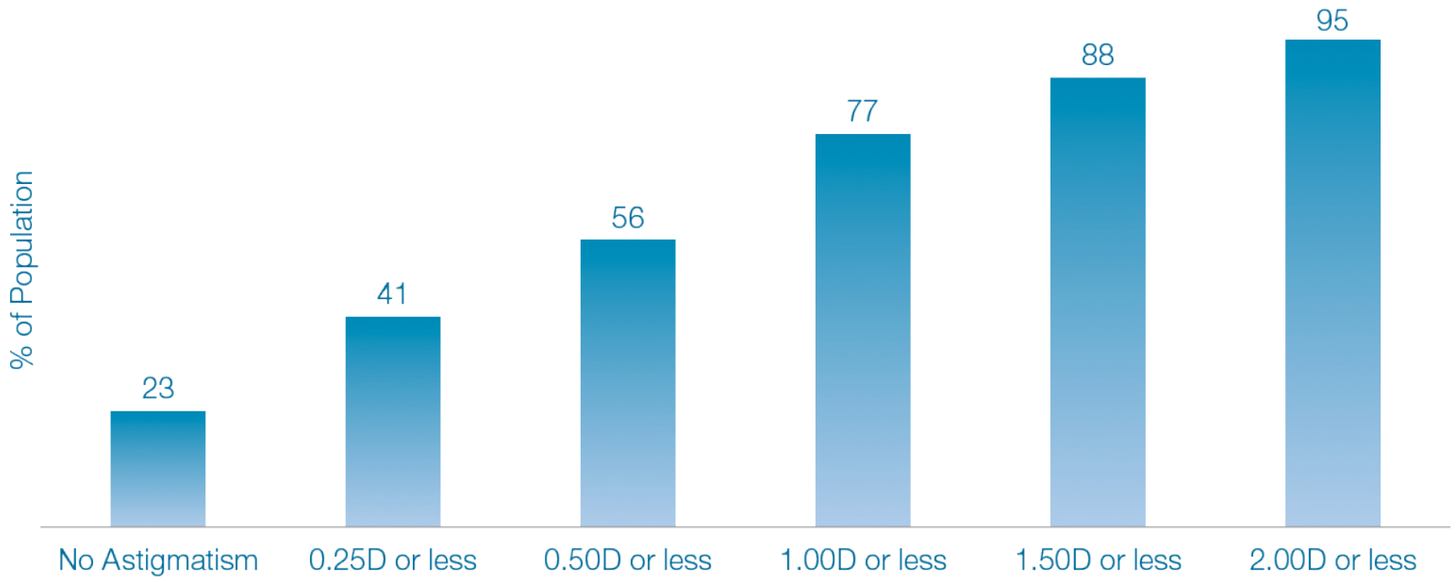


Figure 5. Astigmatism in Western Europe. Only 5% of the population has 2.00D of astigmatism or more.

A vision of astigmatism

Figure 6 illustrates what persons with 5.00D of myopia (near-sightedness) and 2.00D of astigmatism will see when looking at distant objects (image at far left). If these individuals were to use adjustable focus eyewear, then they would experience substantial improvements in vision (image at middle) despite the fact that the eyewear is not designed to correct for astigmatism. The image on the far right is illustrative of the sort of visual clarity achievable through correcting the astigmatism completely using fixed-lens prescription eyewear.

Adjusting the spherical power of the lens can allow an astigmatic wearer to see more clearly than without the device, despite the absence of a specific correction for astigmatism.

There is no harm to the wearer and there is enhanced ability to perform tasks when astigmatic persons use adjustable focus eyewear.

In fact, many patients with mild to moderate astigmatism wear prescription eyewear (particularly contact lenses) without cylinder, using spherical equivalent corrections.

5 D Myopia, 2 D astigmatism | Sphere-only correction | Full prescription

Figure 6. Vision quality for a 5.00D myope with 2.00D of astigmatism without vision correction (left). Wearing adjustable focus eyewear without correcting astigmatism (middle). Wearing fixed-lens prescription eyewear that corrects astigmatism (right).

Prismatic effect

Users of adjustable focus eyewear are able to adjust the power of each lens. They are not, however, able to adjust the location of each lens in front of the eye. Many believe that it is necessary to ensure that eyewear is made or adjusted so that the centre of each lens is correctly aligned with the centre of each pupil. While this may be true for progressive lenses (sometimes referred to as no-line bifocal lenses) or lenses with very high powers, the same cannot be said for the lenses found in adjustable focus eyewear.

Figure 7 shows the prismatic effect*, that is, the extent to which lenses force a person's eyes to converge or diverge, produced by adjustable focus eyewear when worn by people in the UK. Up to 3 prism dioptres can be tolerated without significant discomfort. Clearly, the placement of the lenses in adjustable focus eyewear gives sufficient alignment for the vast majority of customers.

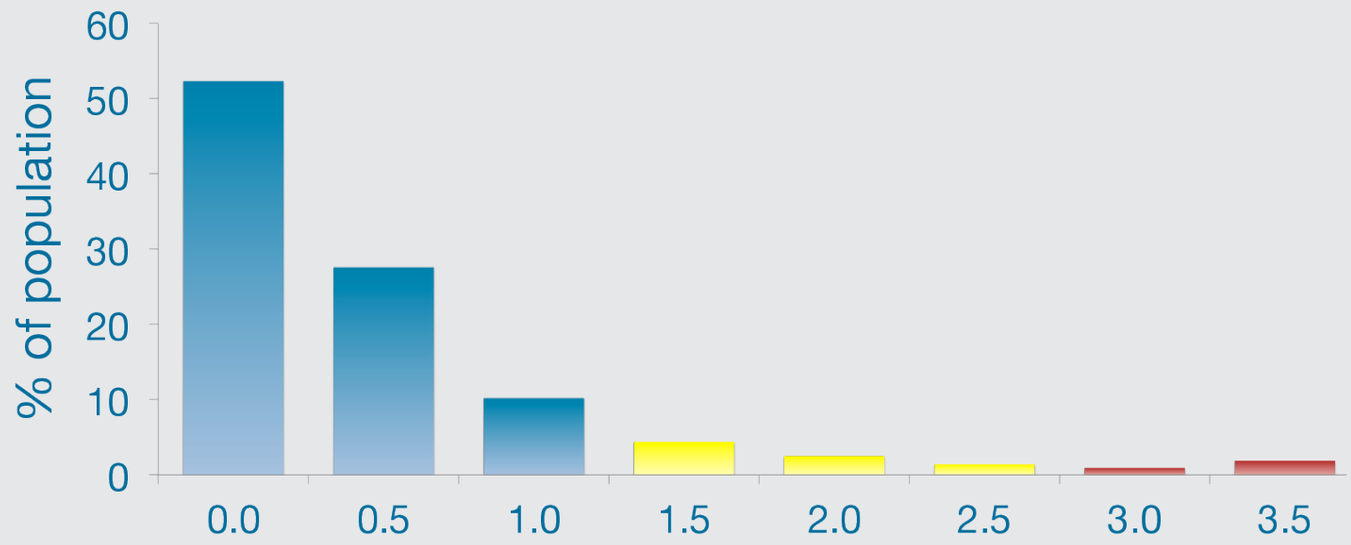


Figure 7. Prismatic effect* experienced by population when wearing adjustable focus eyewear. Nine out of ten users will experience little to no discomfort when wearing adjustable focus eyewear on account of the location of the lenses in front of the eyes.

* Prismatic effect is a measure of the extent to which lenses force the eyes to rotate inward or outward. If the prismatic effect is very large then the eyes will not be able to fixate an object and double vision will occur. One prism dioptre can be tolerated without discomfort and up to 3 prism dioptres can be tolerated without significant discomfort. This statistical analysis of prismatic effect is based on data from population-based studies of refractive error and interpupillary distance in the UK. The optical centration distance of adjustable focus eyewear is 63mm.

40 years and over

Adults and teenagers over the age of 16 who are not blind or partially sighted will be able to use adjustable focus eyewear to enhance their vision to a greater or lesser extent depending on their refractive error. Those over the age of 40 years find this eyewear particularly useful for tasks that involve near or intermediate vision (e.g. reading or computer screen use). Adlens recommends that adjustable focus eyewear not be used by children under the age of 8 years unless under close supervision by an optometrist or physician.

Fluctuating vision after cataract surgery

There is a particularly novel use for adjustable focus eyewear that no fixed-lens eyewear can offer: the ability to manage fluctuating vision. There are nearly 1,000 cataract surgeries performed each day in the UK.[57] Almost all of these patients will experience fluctuating vision for several weeks after surgery while the cornea heals. Eyecare professionals are unlikely to prescribe corrective eyeglasses during the period in which vision fluctuates as prescription eyeglasses are unlikely to work once their vision has stabilised. Patients are usually told that they must make do without eyeglasses (or with old outdated eyeglasses) until such time as their vision settles. Adjustable focus eyewear can be used as a temporary, non-prescription pair of eyeglasses to offer relief to cataract patients who are suffering from fluctuating vision. Furthermore, as each lens can be adjusted individually it is possible for patients to easily manage differences in power between eyes as their vision changes.

Fluctuating vision during diabetes

The same argument may be applied to those who are developing diabetes or who are trying new medications to bring their diabetes under control. Fluctuating vision is one of the first signs of uncontrolled diabetes and in the UK almost 700 people are diagnosed with diabetes each day.[58] Adjustable focus eyewear is best used during the period in which diabetics are trying to establish control of their blood glucose levels under the supervision of a medical advisor. It is important to emphasise to patients that adjustable eyewear is a temporary solution to enhance their quality of life and that fluctuating vision and the underlying metabolic causes thereof should always be managed in the context of wider medical supervision.

Cost and Access

Currently, each time a prescription spectacle wearer's visual acuity changes, even if in only one eye, the wearer needs to schedule an appointment and visit the eye doctor to make changes to the prescription. According to the data available from the Federation of Ophthalmic and Dispensing Opticians[49] and various market research organisations[51] the average cost of a visit to an optometrist is £140 nationwide. This cost includes the examination and any eyewear purchased including eyeglass or contact lenses and frames.

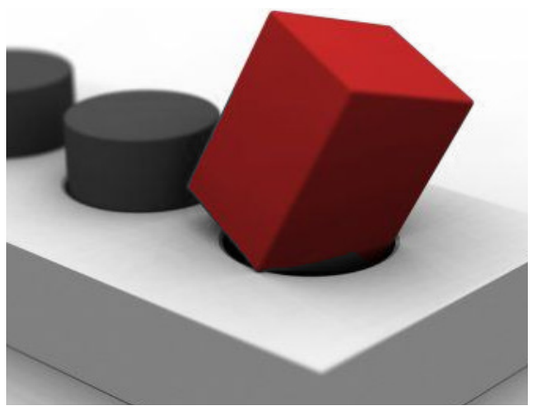
For senior citizens whose visual acuity may change several times in one year, the costs of repeated eye examinations can be prohibitive. For those in nursing homes or assisted living facilities, their abilities to get to the doctor are limited. In all of these situations, consumers who have immediate access to adjustable focus lenses can make the necessary adjustments themselves as a stop-gap measure.

An estimated 13% of prescription eyeglass purchasers need to return to the optometrist or the optician to exchange their newly purchased eyeglasses for a different pair, due to a needed adjustment in the eye doctor's prescription or the optician's placement of the prescription lenses in the frame. Again, access to adjustable focus eyewear provides an interim solution until such time as the visit can be arranged or the new lenses can be delivered.

For consumers who can afford only one pair of prescription eyeglasses, adjustable focus eyewear offers a low cost alternative to buying a second pair of prescription eyeglasses for situations when different powers are needed, particularly for close focus needed for using mobile devices and computers, or for reading books. Purchasing adjustable focus eyewear (priced around £30) can result in substantial consumer savings while providing improved vision, particularly when compared to the cost of purchasing additional prescription eyeglasses.

Adjustable Focus Eyewear as a Medical Device

The Medicines and Healthcare Products Regulatory Agency (MHRA) has classified eyeglass frames, sunglasses, prescription spectacle lenses and non-prescription reading eyeglasses as Class I Medical Devices. Adjustable focus eyewear is included in this classification. Class I devices are deemed to be low risk and are therefore subject to the least regulatory controls. For example, dental floss, toothbrushes and cotton swabs are classified as Class I medical devices. As such, the use of adjustable focus eyewear has been deemed not to pose a significant health or safety risk to consumers. Adlens and its products are registered with the MHRA and the products all meet and exceed the safety and lens impact resistance tests required by ISO standards.

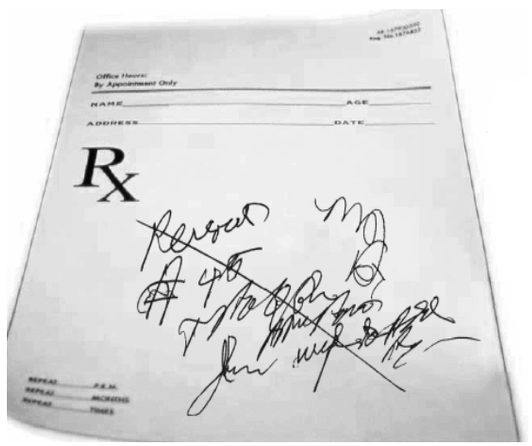


Square peg, round hole

Applying existing UK regulation to Adlens' adjustable focus eyewear is like fitting a square peg into a round hole. The laws clearly did not intend to and do not specifically address adjustable focus eyewear.

When the laws were enacted, there was no eyewear technology that allowed consumers to improve their vision by self-adjusting the power of Plano lenses. The laws address the issues associated with the only eyewear then available – indeed, the only form of eyewear available since the 12th century - eyeglasses with prescriptions that are permanently ground in and fixed in the lenses, and ready-to-wear reading glasses.

UK law currently provides two main possibilities for selling appliances designed to correct, remedy or relieve a defect of sight:



Prescription or supervision

1. The sale of optical appliances must be supervised by a registered medical practitioner, a registered optometrist or a registered dispensing optician. However restricting sales of adjustable focus eyewear in this way does not make sense because the wearer is free to adjust the focus of this eyewear themselves at any time; or

2. Optical appliances can be sold without supervision (subject to certain exceptions and limitations) provided the optical appliance is in accordance with the customer's written prescription. However, as adjustable focus eyewear is adjustable by the customer, the requirement that the optical appliance be in accordance with the customers written prescription again simply does not make any sense.

No special fitting

Indeed, many of the constraints associated with dispensing fixed-power lenses do not apply to adjustable focus lenses. There is no need for any of the delineated providers to be present at the point of sale (optometrists, ophthalmologists, opticians). Without the need for a written prescription, the only role a provider would fill would be to assess the suitability of the lenses to correct vision and to fit the eyewear.

The former is adequately addressed by the consumer, who is in the best position to know when the eyewear is properly focused by making the necessary adjustments for the different situations. The latter is addressed by the fact that no professional "fitting" is required since there is no need for centration of the lenses and the frame's temple arms and nosepads are flexible and adjustable.

No substitute

Clearly, consumers who try the new technology are discerning and can easily determine whether adjustable focus eyewear improves their vision adequately on a temporary basis. Adlens is not attempting to encourage consumers to use this eyewear as a substitute for prescription eyeglasses, as our proposed change to the Opticians Act 1989 makes abundantly clear. Indeed, given the consumer information available in advertisements, at the point-of-sale and on the Internet, it is unlikely that consumers will think that the product is a substitute for prescription eyewear.

The UK law governing sales of optical appliances in the UK was not written with adjustable focus eyewear in mind. It needs to be updated so it permits consumers to purchase adjustable focus eyewear from a variety of outlets, but with appropriate safeguards to address any real public health and safety concerns.

Current regulation inconsistent with public's health, safety and welfare concerns

In light of the technological advancement adjustable focus eyewear presents, we believe that limiting its distribution is inconsistent with the desire to enact a positive impact on the public's health safety and welfare. Regulation of the sales of eyewear for vision correction is intended to protect the public from significant and discernible harm that could result when consumers purchase and wear fixed-power lenses with ground in prescriptions; the law should be interpreted and enforced in a manner that achieves its goal and not be applied beyond the purposes for which it was enacted.

Absent evidence of public harm or safety concerns or other rational justifications, extending the law to limit the distribution and availability of adjustable focus eyewear would merely result in restraining the sale of a useful and safe product to consumers and excluding would-be competitors. Rather, ensuring access to the product with appropriate consumer information will enhance the public's health, safety and welfare.

World-wide, over 600,000 consumers have purchased adjustable lenses. Consumers are benefiting from the use of the eyewear as spare pairs when they lose or misplace their prescription eyeglasses, engage in tasks or situations that require multiple viewing distances, at night when their tired eyes would benefit from adjustment of the lens' powers, or as they await the delivery of their new prescription eyeglasses. Notably, the governments of Japan and Rwanda have purchased the eyewear as part of their disaster readiness programs; the US military's United States Africa Command (AFRICOM) and European Command (EUCOM) use adjustable eyewear to assist civilians in their humanitarian assistance medical initiatives.

Conclusion

Adjustable focus eyewear can benefit a variety of groups. Senior citizens, whose vision can change more frequently as they age and who may face fixed or reduced incomes with retirement, may have the most to gain. Cataract patients need eyeglasses on a temporary basis post-surgery and their investment in a pair of costly prescription eyeglasses that they will use for only a short time is unnecessary. Diabetics must deal with fluctuating vision as blood sugar changes. Patients with low vision may need added magnification as macular degeneration or other conditions progress.

Finally, it is generally accepted that the introduction of innovative products in an industry can result in increased competition and lower prices. Both of these results would benefit the pocketbooks of consumers while improving their eye health by increasing access to eye care products.

Banning the sale of adjustable focus eyewear by applying laws not intended to address the product is misplaced. Such anti-competitive conduct would benefit existing sellers of corrective eyeglasses, while denying consumers an affordable product that is safe, results in cost-savings and is used world-wide. Expanding access to adjustable focus eyewear will facilitate competition and so ensure convenience and low prices, with appropriate safeguards to address any real public health and safety concerns. We respectfully request that regulators and legislators work with Adlens to ensure that consumers can purchase adjustable focus eyewear from a variety of outlets.

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