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This CPD session is open to all FBDO members and associate member optometrists. Successful completion of this CPD session will provide you with a certificate of completion of one non-interactive CPD point. The multiple-choice questions (MCQs) are available online only from Monday 5 September 2022. Visit **www.abdo.org.uk**. After member login, scroll down and you will find CPD Online within your personalised dashboard. Six questions will be presented in a random order. Please ensure that your email address and GOC number are up-to-date. The pass mark is 60 per cent.

CPD CODE: C-102987

Modern management of presbyopia

PART 3: Surgical methods

By Jay Dermott D.Opt BSc (Hons) FFDO

The person choosing to make their career in the field of vision, seeking to help others by correcting its defects, realises very early on that they will be paying a lot of attention to the matter of presbyopia. In the very early part of any career, it emerges that the changes in vision that occur with time will present the lion's share of the problems that will be encountered and, simultaneously, the opportunities to apply their professional skill. Such is the inevitability of the effects of presbyopia.

AN INEVITABLE CONSEQUENCE OF LIVING?

Worldwide presbyopia numbers have exceeded one billion since 2005[1] and were estimated to have doubled to approach two billion around 2015[2]. The majority of those with uncorrected presbyopia live in a rural setting. However, if we exclusively consider what are known as the world's seven major markets, it is also a matter of demographic record (**Figure 1**) that there is an ageing population and that is not expected to change.

The median age of the United Kingdom (UK) is now in the presbyopic range[3]. These demographic figures point to a presbyopic population of more than 289 million people in the seven major markets[4] – and more than 30 million in the UK in the year 2021.

PATIENTS DEMAND CHOICE

Now that the 21st century nears maturity, we live in a society that has for decades increasingly championed choice and convenience in all aspects of life – major and minor. This creates a demand for alternatives to the correction of presbyopia. The ever-innovative

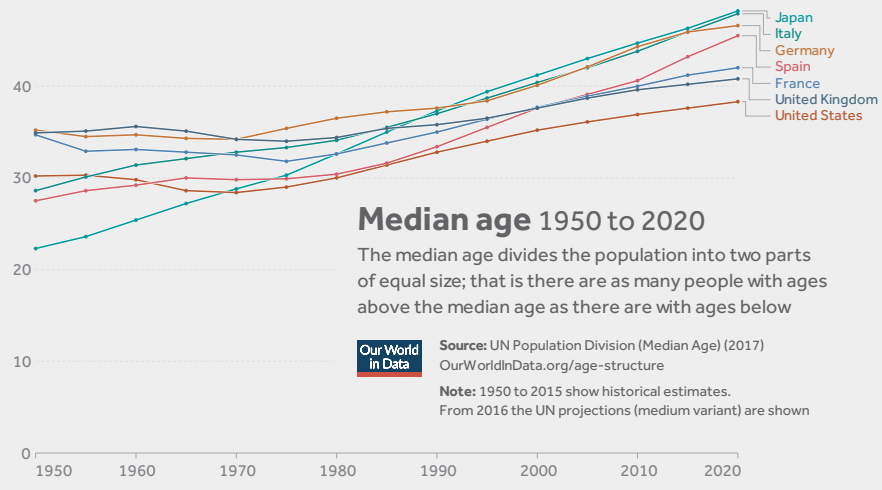

FIGURE 1: *Age demographics of the world's seven major markets*

refractive surgery sector has not been slow in producing a host of potential surgical choices to offer those seeking a better way to address the challenges of presbyopia, and now potential medical solutions are arising. Throughout this attempt to catalogue these choices, it will not escape the reader's attention that none can be called perfect.

In a vision correction utopia, a prospective patient might be able to request from their doctor an intervention that will, at a stroke, return them to the effortless dynamic clear vision at all distances they enjoyed in their youth. Such a utopia does not yet exist, however, which raises the question of managing patient expectations. That is a subject area that every optician will be very familiar with and being well-informed about what is available in presbyopia management may provide some useful assistance when faced with queries from the patient who is researching all their options.

WHAT DO WE MEAN BY 'PRESBYOPIA'?

It is perhaps not surprising that the perfect surgical solution is not available when any review of the literature quickly reveals that there isn't even universal agreement on the exact mechanism of accommodation. Such uncertainty even extends to a good functional definition of the problem.

A modernised and refined definition of presbyopia was suggested by Wolffsohn and Davies (2019)[5] as follows: *"... presbyopia occurs when the physiologically normal age-related reduction in the eyes focusing range reaches a point, when optimally corrected for distance vision, that the clarity of vision at near is insufficient to satisfy an individual's requirements".*

This relates well to actual, real-world reasons why a prospective patient might seek correction of their presbyopia. It would seem clear that some may wish to have those requirements met without the use of spectacles or contact lenses.

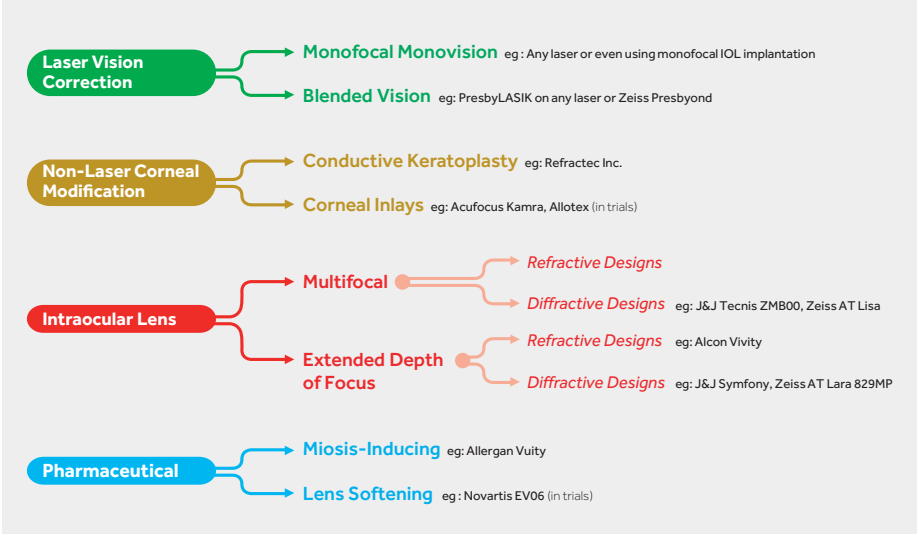

FIGURE 2: ***The presbyopia treatment refractive market***

PROBLEMS OF PROVIDING SUFFICIENT CHOICE

The correction of presbyopia by diverse surgical means involves a large and ever-growing number of options facing the prospective patient, but fundamental to all of them is the need to properly address patient requirements over a full range of vision – from far to near. It is a distinction of modern life that there are increased visual demands in the middle-near to intermediate range.

Consider the visual impact of the near-ubiquitous use of satellite navigation systems in cars, tablets, laptop computers and mobile phones. It is a difficult enough proposal to dispense a suitable spectacle or contact lens-based visual solution effective across this range of distances, but these at least have the advantage of being easily modifiable or even easy to move away from altogether.

Patients choosing surgical solutions for presbyopia must make carefully informed decisions, as modifications or even reversal of the post-operative result may not be possible – or may involve significant risks to ocular health. When the stakes are this high, patient choice becomes even more important, and the expansion of the worldwide refractive surgery market seen over the past 15 years has lent an almost bewildering complexity to what is on offer (**Figure 2**).

BLENDED VISION

An updated version of 'monovision' is the concept of blended vision. The modern world requires much attention to be placed on seeing objects in the middle or near-to-middle distance, as the optician who regularly counsels on the benefits of progressive power lenses will testify. The original ideas around monovision, with one eye purely corrected for near and the other for vision at a close working distance, have been found wanting in more recent years[6].

Blended vision has a variety of explanations varying from a simple micro-monovision, using a 'low add' in the near eye such as +0.75, to an active manipulation of higher order aberrations to control image imperfections, such as spherical aberration in order to bring about optical effects which are positive for the patient, such as enhanced near or middle-distance vision. **Figure 3** illustrates the idea of separating visual space into eight zones varying from very close to infinity and then applying treatment 'bracketing' a group of five zones for each eye, giving enhanced intermediate function in the 'gold' zone where the brackets overlap.

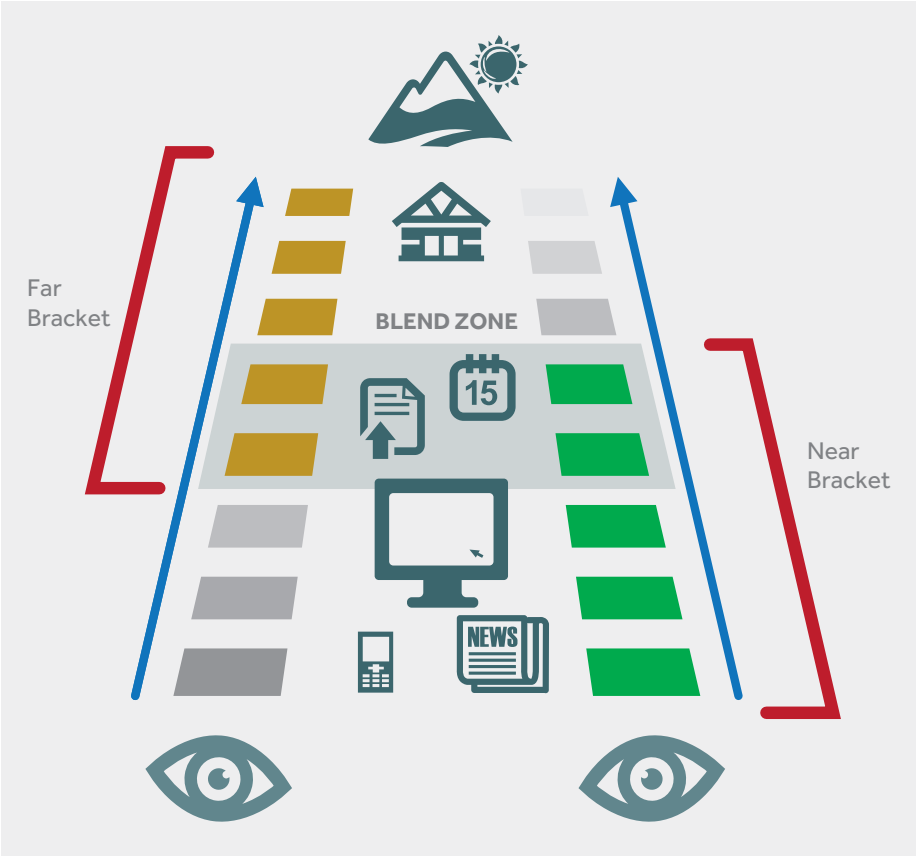

FIGURE 3: *Zonal separation of visual space*

Whilst this is not suitable for all patients, and certainly requires some pre-operative contact lens simulation before surgical intervention, authors report excellent outcomes[6,7] whether blended vision is achieved by laser or intraocular lens (IOL) means.

LASER VISION CORRECTION IN PRESBYOPIA

Laser-based methods of surgical correction of presbyopia centre around either the traditional monovision or more recent multifocal laser ablation or blended vision methods. It is possible for any laser surgeon to select monofocal treatment targets, as with contact lenses, to produce a regular monovision result.

PresbyLASIK is a corneal refractive technique in which either a central or peripheral annular zone for near is ablated in the manner of either a centre-distance or centre-near multifocal contact lens correction. Such treatment is reported to work well if combined with micro-monovision in the non-dominant eye[6].

Another solution, which uses a proprietary treatment design plan on a specific laser, is Zeiss Presbyond, which seeks to modify spherical aberration to the benefit of the patient[7]. The manufacturers emphasise that the advantage of this treatment is that it is customised to the aberration profile of the individual eye, meaning that the 'blend zone' concept encountered in **Figure 3** is bespoke-designed, and customised to the needs of the patient.

Studies report good visual and satisfaction outcomes with the treatment, at levels equivalent to those found with other surgical corrections[8] – but however admirable the technology, any laser correction of presbyopia will always be time-limited to some extent.

Blended vision provides a solution for most near visual tasks for most people most of the time, but it is usual that one or two instances eventually emerge (small print in poor light, for instance) where a spectacle correction may make things more comfortable.

When addressing a question of the lens with a corneal answer, treatment will inevitably become less effective over time as presbyopia increases and the patient must be counselled to expect a decreased effect over time. Much depends on individual tasks and circumstances, however, but the fundamental aim should always be to under-promise and over-deliver.

CONDUCTIVE KERATOPLASTY

It would be amiss to leave the topic of corneal surgical treatments for presbyopia without at least mentioning some lesser-known arrivals in the market. The concept of radio frequency (RF) energy to shrink collagen – and thereby alter the corneal shape in the non-dominant eye[9] – was attempted in the early 2000s with varying degrees of success. Problems ranged from the temporary or unpredictable nature of the treatment to difficulty seeking patient understanding.

To be a candidate, the patient had to be close to emmetropic in both eyes, but also be willing to compromise good distance vision in the non-dominant eye permanently in favour of near correction, which did not always make counselling these patients straightforward.

INLAYS

In a very similar vein, corneal curvature can be adjusted in a non-dominant eye using an inlay placed in the cornea under a LASIK-like flap (**Figure 4**, *courtesy of ReVision Optics*). This results in a more convex corneal aspect bringing about a blended vision-like result. It is fair to say that visual results with corneal inlays such as the Raindrop (now withdrawn from the market) and Kamra have been good [10,11], but the biocompatibility of the materials has produced issues leading to unacceptable numbers of explantations[12].

The good news for the future is that clinical trials are advanced in a new inlay[13]

CORNEAL INLAY

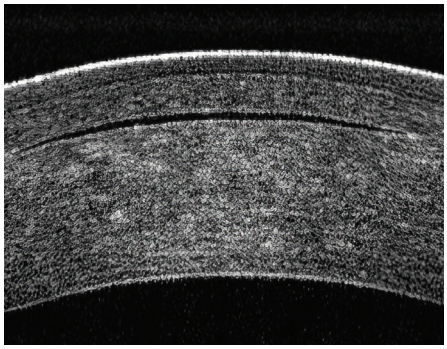

FIGURE 4: *Anterior eye OCT showing a corneal inlay (Raindrop) in situ*

which uses a lenticule of donor human corneal tissue to construct the inlay. More results and longer follow-up are required, but it suggests an approach that potentially addresses the biocompatibility issue with inlay surgery.

INTRAOCULAR LENSES (IOLS)

The phenomenon of refractive lens exchange, essentially lens replacement for refractive reasons rather than cataract, became popular in the early 2000s with the arrival on the market of new technology IOLs, designed to give visual comfort and use innovation to address presbyopia. Some of these IOLs have since become obsolete, but the modern IOL market is filled with newer designs[14-16] that have proven track records in providing patient satisfaction.

Essential similarities exist between the spectacle and contact lens world of presbyopia correction and the surgical one; the relevant options remain monovision or multifocal. Presbyopia-correcting IOLs produce their effect by either refractive or diffractive means. In doing so, they produce a trade-off between providing clear vision across all relevant distances and regulating the induced aberrations with resultant loss of visual quality and contrast sensitivity. Managing this trade-off is where the need for compromise is called for.

TECHNICALITIES

The emphasis of this article will not be on the more technical aspects of how the IOLs work. Such treatment of the subject is already readily provided in the literature[17], but a simplified summary of the science involved serves to illustrate the similarities between optometric and surgical solutions.

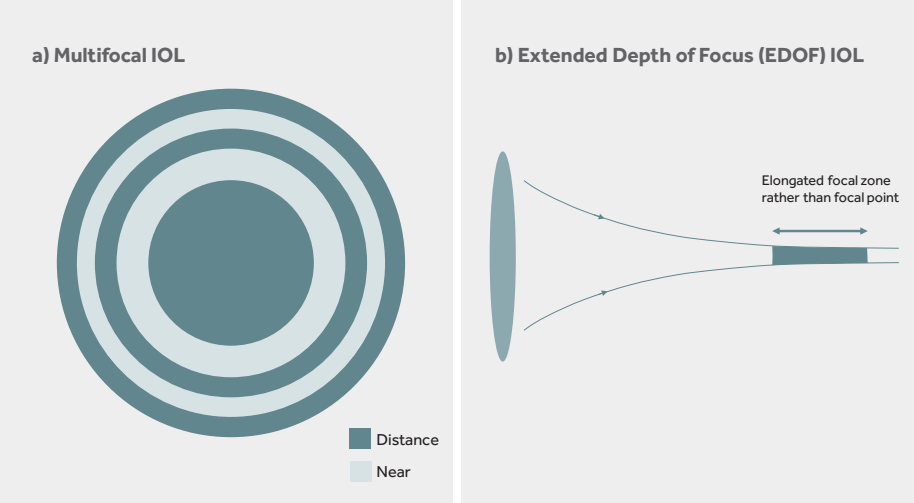

FIGURE 5: ***Principles designs for presbyopia management IOLs***

Figure 5 shows us that presbyopia IOLs work in either a true multifocal way, providing two, three or even four foci and presenting them to the eye, or by controlling lens aberration to sufficiently extend depth of focus to provide clarity over a useful range of working distances.

Multifocal designs (MFIOLs) work by a principle of presenting simultaneous images to the eye, requiring the brain to make a choice between them according to whatever the object of regard is at that time. Producing this effect by refractive means has been associated with noticeable visual side effects like glare, haloes and starburst effects (collectively known as dysphotopsia, illustrated in **Figure 6**) and less patient satisfaction[18]. This has led to the development of lenses producing the same effect using diffractive optics.

A diffractive design lens can be considered as a base monofocal or toric 'carrier' lens, onto which is placed a diffractive zone plate consisting of tiny steps or echelettes. The height of these steps is of the order of the wavelength of visible light and so can produce a number of foci according to the orders of diffraction (**Figure 7**).

This is optimised for wavelengths around the peak of the v-lambda curve at 550-570 nanometers, but fortunately any chromatic aberrations induced by the diffractive zone is opposite in nature to those produced by the base carrier lens, leading to an achromatic doublet-like effect, reducing the aberrative impact.

The concept of optical power doesn't correlate directly to the diffractive design, but it suffices to say that a higher add effect is provided by using more, narrower steps in the zone plate and a lower add with fewer but wider zones.

The downside of diffractive designs is there is only so much light to go round between the foci so, if 60 per cent of light distributes to the distance focus, that leaves only 40 per cent for intermediate and near tasks and that does not even include light energy lost from the main foci. Emphasising in pre-op counselling

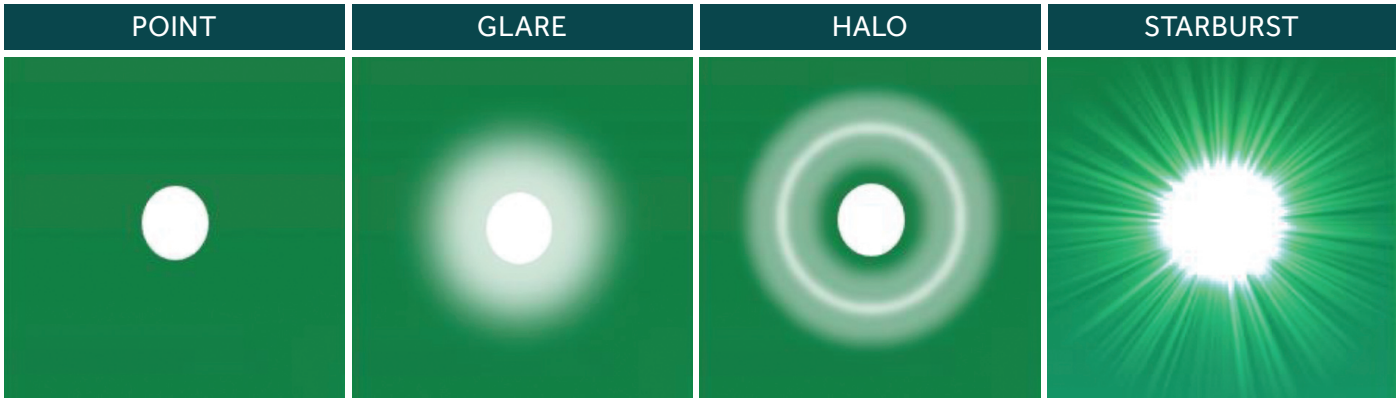

FIGURE 6: ***Unwanted glare produced by some IOL designs can result in visual discomfort (dysphotopsia) particularly haloes (derived from spherical aberration) and starbursts (derived from coma) around light sources***

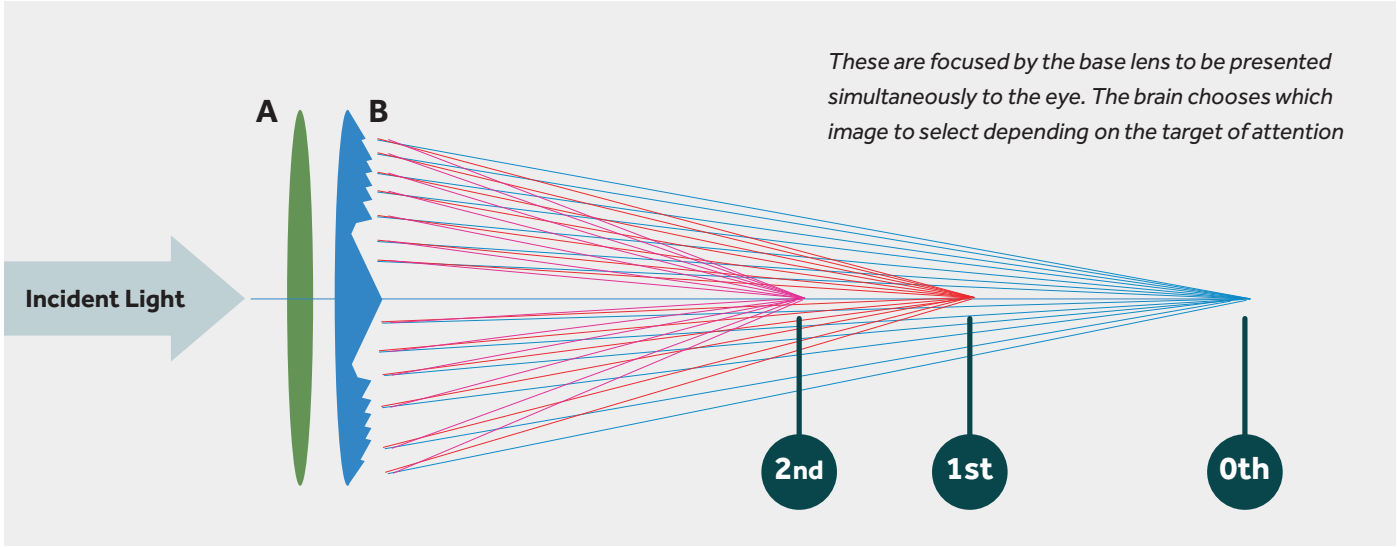

FIGURE 7: ***A schematic representation used to illustrate the principle of a diffractive multifocal IOL. A diffractive IOL produces foci using a zone of echelettes (B) mounted on a base carrier monofocal lens (A), separating light into wave trains of different orders of diffraction, each designed to produce images by constructive interference at different angular separations; 0th order for distance, 1st for intermediate and 2nd for near.***

the importance of use of good light for near tasks is essential for diffractive IOL patients[18].

Monochromatic aberration control can be used to benefit the patient. Optical aberration can be very useful to a lens designer and can be used to produce an extended depth of focus (EDOF). IOLs seek to manipulate the spherical aberration induced by the mechanism of action of the IOL to produce a larger range of useful vision, allowing near vision by virtue of increased negative spherical aberration which produces an extended focal range (**Figure 5b**). These EDOF lenses have been associated with less dysphotopsia than multifocal IOLs, although it is unclear whether these lenses achieve their effect by actually elongating Sturm's conoid[19].

MANAGING THE DOWNSIDES BY MIXING AND MATCHING

Each lens type has its attendant disadvantages. It could be viewed that there is not really any such thing as a poor lens design, only wrong lens choices. It is necessary to carefully counsel potential patients to more confidently match the best lens for their visual needs. Compromise features highly in this because lives feature a wide range of activity and the best solution for the patient's computer use in their profession might not be the best fit for use elsewhere. Undoubtedly, along with lens sophistication comes greater dysphotopsia, and designs with less reported visual discomfort bring less spectacle independence.

One emerging surgical philosophy that appears to address this compromise is a 'mix and match' approach, whereby the surgeon implants an EDOF design in one eye and a MFIOL (usually a trifocal) in the other.

Recent studies[16,19] have specifically examined quality of vision and patient-reported outcomes of such patients, one reporting that 98 per cent of patients had clear distance vision, with 88 per cent never or rarely requiring reading spectacles. In all, there was a statistically significant increase in their quality of vision as scored on an accredited questionnaire for both day and night tasks, and 91 per cent declared that their expectations of surgery were fulfilled or more than fulfilled.

LIGHT-ADJUSTABLE LENS

A presbyopia correction worthy of special note is the Light-Adjustable Lens (RxSight, Aliso Viejo, Ca, USA) which is a novel concept that received US Food & Drug Administration (FDA) approval in 2017[20] and represents an interesting approach that could offer a potential solution for the phenomenon of 'refractive surprise'.

Despite the best efforts in standardisation in pre-operative biometry, surgical technique and lens selection calculation formulae (often involving artificial intelligence examining huge data samples), unpredicted residual prescription after surgery is still a problem[21] and is not welcome in a demanding refractive surgery market.

The IOL is made of a material that responds to UV illumination in such a way as to change surface shape in a predictable manner[22]. The lens is implanted in the normal way, and then in three to five post-operative sessions, controlled exposure to UV light is used to change the lens geometry to bring about power change found during the refraction.

In between these sessions, the patient must wear complete UV protection to prevent unwanted shape change. It is even possible to try different power combinations including aiming for blended vision before a final UV exposure at a particular wavelength causes irreversible 'lock-in' of the lens shape and the final result.

PHARMACOLOGY

There must have been so many patients through the years who have asked optometrists or opticians if there was a 'magic pill' that would rid them of the scourge of presbyopia. Such an approach has apparent advantages over surgical methods, being minimally invasive as well as easy to reverse. The answer has always been in the negative of course – but this could possibly be about to change.

Pharmacological approaches take the approach of either inducing miosis or by boosting the accommodative effect by softening the lens. It bears mention that the target market older patients are likely to develop lenticular opacities in this central and paracentral range, which poses a potential query over the desirability of planned prolonged miosis if this occurs.

Currently[23] there is one eyedrop treatment that is licensed by the FDA for presbyopia and available in the US with another in advanced clinical trials and others in the pipeline, although in the UK nothing has to date been approved by the National Institute for Health and Care Excellence (NICE).

Simulating the approach of the EDOF IOL lenses, pilocarpine hydrochloride 1.25 per cent is licensed as monotherapy (just one active pharmacological agent) by the FDA[24] for the correction of presbyopia under the trade name of Vuity. It does so by constricting the pupil to increase depth of field and thereby correct for near vision by reducing image blur with a pinhole effect.

On the downside, miosis is temporary though and treatment is to both eyes, leading to concurrent loss of vision in low light including night driving. Frontal headaches due to muscular spasm have also occurred. Reported results show an improvement of three lines of near visual acuity or more after three hours in 31 per cent of participants in the FDA trial, as opposed to eight per cent in the control group, with one in three participants achieving 20/40 unaided near visual acuity (equivalent to N6 on a regular reading chart). However, these modest gains contrast with the short duration of the effect over which best near vision performance was achieved, decreasing to 18.4 per cent after six hours.

Other approaches that combine several pharmaceutical agents including carbachol and brimonidine to produce miosis are still in clinical trials[25].

Lens softening approaches seek to reverse the lens stiffening occurring with age by breaking the disulfide bonds using lipoic acid and choline ester chloride within the material of the crystalline lens matrix.

To date, only modest gains in near vision ability have been demonstrated against placebo in clinical trials[26] and there has been little investigation of the real potential gains from this treatment modality, namely such softening of the lens in the over-55 age group necessary to reinvigorate the lens to pre-presbyopic levels of performance, which would surely be the major target.

More studies in peer-reviewed academic journals, including monocular and combination treatments with longer follow-up time, are really required before definitive conclusions on pharmacological treatment can be reached.

IN CONCLUSION

The area of presbyopia holds much promise for any successful therapy and to date, despite many and varied approaches, there is no single stand-out front runner in the field from the medical and surgical perspective. In order to rise to prominence, the treatment would have to give high quality vision across all distances, reliably and permanently, or at least with a long duration. There would have to be negligible side effects, closely mimicking the ease of vision enjoyed in youth.

Each treatment described here fulfils that criterion to at least some extent and has a following amongst surgeons and satisfied patients alike. It is fair to say that there is nothing that suggests that non-surgical solutions will be overtaken for the presbyopic patient because no medical or surgical treatment yet offers the ease of use combined with freedom from side effects of spectacles or contact lenses.

Despite that somewhat stark fact, patients continue to present themselves for treatment, willing to accept and compromise a less-than-perfect visual outcome for the ease that a non-lens-based approach will bring. It falls to those counselling prospective patients to use their knowledge and experience to match each patient with the treatment best suited to their needs. The delivery of such advice often starts with an optometrist or an optician and often at the patient's routine eyecare appointment, so maintaining a current awareness of the presbyopic refractive market is essential.

Also, refractive surgeons in Europe and the US are currently debating a new protocol with IOL manufacturers in an attempt to simplify the nomenclature surrounding lens performance. The suggestion is that descriptions (only) of range of focus, mechanism of action and magnitude of dysphotopsia to be expected are to be used[27]. Time will tell whether or not this new initiative will lead to better treatment selection and thereby better patient satisfaction.

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LEARNING OUTCOMES FOR THIS CPD ARTICLE

DOMAIN: Communication

1.3: *Communicate effectively with patients about surgical methods for the management of presbyopia, to assist them in making informed decisions about their care.*

2.1: *Provide information to patients about surgical solutions for the management of presbyopia using language and communication approaches that is appropriate to the individual.*

DOMAIN: Clinical Practice

5.3: *Understand what surgical solutions are currently available for patients for the management of their presbyopia .*

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