2022 Glenn A. Fry Award Lecture: Enhancing Clinical Assessment for Improved Ophthalmic Management

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Abstract

Detailed clinical assessment is critical to allow sensitive evaluation of the eye and its management. As technology advances, these assessment techniques can be adapted and refined to improve the detection of pathological changes of ocular tissue and their impact on visual function. Enhancements in optical medical devices including spectacles, contact and intraocular lenses, have allowed for a better understanding of the mechanism and amelioration of presbyopia and myopia control. Advancements in imaging technology have enabled improved quantification of the tear film and ocular surface, informing diagnosis and treatment strategies. Miniaturized electronics, large processing power and in-built sensors in smartphones and tablets capacitate more portable assessment tools for clinicians and facilitate self-monitoring, treatment compliance and aid communication with patients. This article gives an overview of how technology has been used in many areas of eye care to improve assessments and treatment, as well as providing a snapshot of some of my studies validating and utilising technology to inform better evidence-based patient management.

We live in an amazing world. In most cases, scientists have learnt that trying to mimic 'nature' is the most efficient approach to enhance human innovations. Every time we peal back a layer of biological complexity through human ingenuity, more research questions are generated and more of nature's beautiful architecture is revealed. This architecture is not fixed, but adapts with its environment. It is inconceivable to me that this is the result of a random, uncreated universe, or just one of infinite universes which just happens to be able to sustain life as we know it and in which we have the good fortune to exist. My belief in a created, structured universe is what has motivated my career to develop instrumentation and techniques to better understand the workings of the eye as it interacts with medical devices (such as contact lenses and intraocular lenses) and the changing environment (such as impacting dry eyes, ocular allergy and myopia; Figure 1). As a clinical scientist, my ultimate goal is to achieve impact by translating research into evidence-based clinical practice, by collaboration and challenge to create change (such as through consensus reports and practice surveys) for the benefit of patients, who are my inspiration for research ideas.

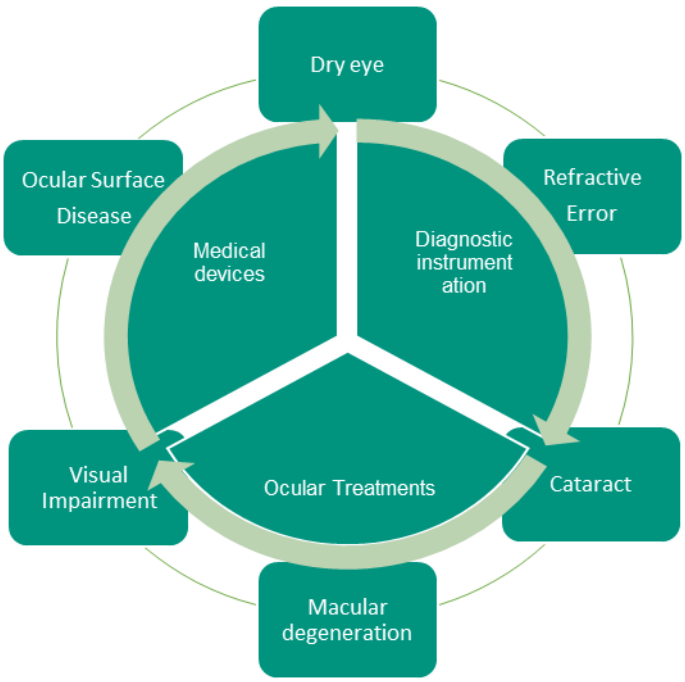

Figure 1: Summary of the research covered in this paper.

Instrumentation

It is critical for clinicians and researchers to understand the instrumentation they use in the clinic (not just how to take a measurement) and that it is optimised for its purpose.[1, 2] The same is true for measurement techniques, where repeatability and standardisation are key for successful treatment.

Assessment of Functional Vision, Eye Focus / Accommodation

Visual acuity is a well-established metric of visual function,[3] but while the measurement procedure is well defined for distance,[4] clinical measurement parameters for intermediate and near distances have been more variable. The logMAR spacing of letters and lines to unify the visual demand at all levels of acuity should be adopted,[5] but there is a choice whether the chart is more functional using words of defined length and difficulty [6-8] or capital letters to standardized with distance acuity measurement.[9] The more physical method of measuring visual acuity at a range of distances used in the past [10-12] is often impractical owing to the need to control angular image size and luminance. Rather than discrete distances, the accommodative demand can be altered with lenses,[13, 14] and we have shown that optimally these should be presented in a randomised order [15, 16] in 0.5D steps [17] and correcting for image minification/magnification,[16] to plot a defocus (or through focus) curve to map the expected acuity of an individual over the functional range of distances from far to near. The subjective range of focus has be extracted from the resulting acuity defocus chart by various absolute and relative approaches,[16] but we have proposed reporting the area under the curve in discrete distance ranges, to ensure more standardised comparisons can be made.[18]

When I started my PhD, we used an already discontinued open-field (to minimise instrument myopia)[19, 20] autorefractor, the Canon R-1,[21] to measure objective accommodation (changes in eye focus) by subtracting the refractive error on distance viewing from that when observing a high contrast target at near. The opportunity arose on moving back to the UK to validate a new open-field commercial autorefractor [21-26] and later to build the first truly open-field aberrometer [27] to further this research. Originally it was proposed that accommodation might be underestimated if the target was closer than an individuals' subjective range of clear focus [28], however we have since shown that

individuals are able to sustain their maximum accommodation even if the accommodative demand of the target is greater than this and as a result, appears blurred [29]. The accommodative system is remarkably robust to fatigue [30] and we have demonstrated that much of the accommodative range can be utilised even for prolonged demanding tasks,[31] although there is a lag of accommodation [32] with no more accommodation exerted under normal circumstances than needed to keep the target clear.[33]

The dynamics of accommodation can also be measured dynamically and we were able to adapt commercial autorefractors [23, 34-39] and subsequently our open-field aberrometer [27] for this purpose; with these techniques we were able to show ciliary muscle driven 'accommodative' restoration in early accommodating intraocular lenses designs, although this was of low magnitude and was only maintained for a limited time due to fibrosis post cataract surgery,[40-42] with some lenses extending the range of clear focus mainly through aberration changes.[43] Ex-vivo, these novel accommodating intraocular lens prototypes can be tested and refined through attaching them to mechanical lens stretchers [44-46] with us recently developing a synthetic lens capsule they can be 'implanted' in.[47, 48]

High contrast, static visual acuity is an important safety metric,[49] but is not a good predictor of functional vision.[50] Most near tasks involve an element of reading,[51] which is perceived as being critical to communication and commerce in modern societies.[52] Reading speed is fairly consistent until the critical text size is reached, after which it rapidly slows until the near acuity threshold.[50, 53] As a consequence, an acuity reserve has been shown to be needed to optimise reading performance.[54-56] Reading speed charts were originally paper based,[57-59] with an individual manually timed reading aloud paragraphs of text, and then the times had to be time-consumingly plotted to extract the 'reading speed' metrics.[60] Working with engineering colleagues we digitised this process on a tablet (Figure 2) [61] which allowed us to use the onboard sensors for the additional benefit of working distance and gaze monitoring, blink analysis, voice recording to allow for incorrect syllable detection and immediate data analysis.[62] We used a similar digital device clinical test approach

(Figure 2) to assess the adverse effects of presbyopia corrections in the form of multifocal optics. Conventional contrast sensitivity tests measure contrast detection at one spatial frequency [63], or spatial frequency at two to nine contrasts [64, 65] it is now possible to display the contrast sensitivity function as a sine wave grating with varying contrast (Y-axis) and spatial frequency (X-axis) as Robson and Campbell originally portrayed [66] on a tablet screen, with the user tracing their finger where they can see the tops of the maxima (Figure 2) which we utilised to create and validate an app to generate a complete contract sensitivity function in under a minute;[67] this is despite a study suggesting that the generated curve was not accurate, but instead of tracing the curve, they fitted their own simulation of the sinusoidal function with only 4 points.[68] Likewise, glare is traditionally assessed through basic reporting,[69, 70] a questionnaire,[71, 72] assessing its impact on an acuity/contrast task (Figure 2)[73-75] or by getting an individual to sketch the extent to which a bright light appears to scatter.[76-78] however, we developed a more objective approach where the glare profile of an individual can be plotted as the area obscured by a glare source, by moving targets out from behind it in multiple directions, with the patient reporting the position (eccentricity) when it can first be reliably detected (Figure 2).[79-81]

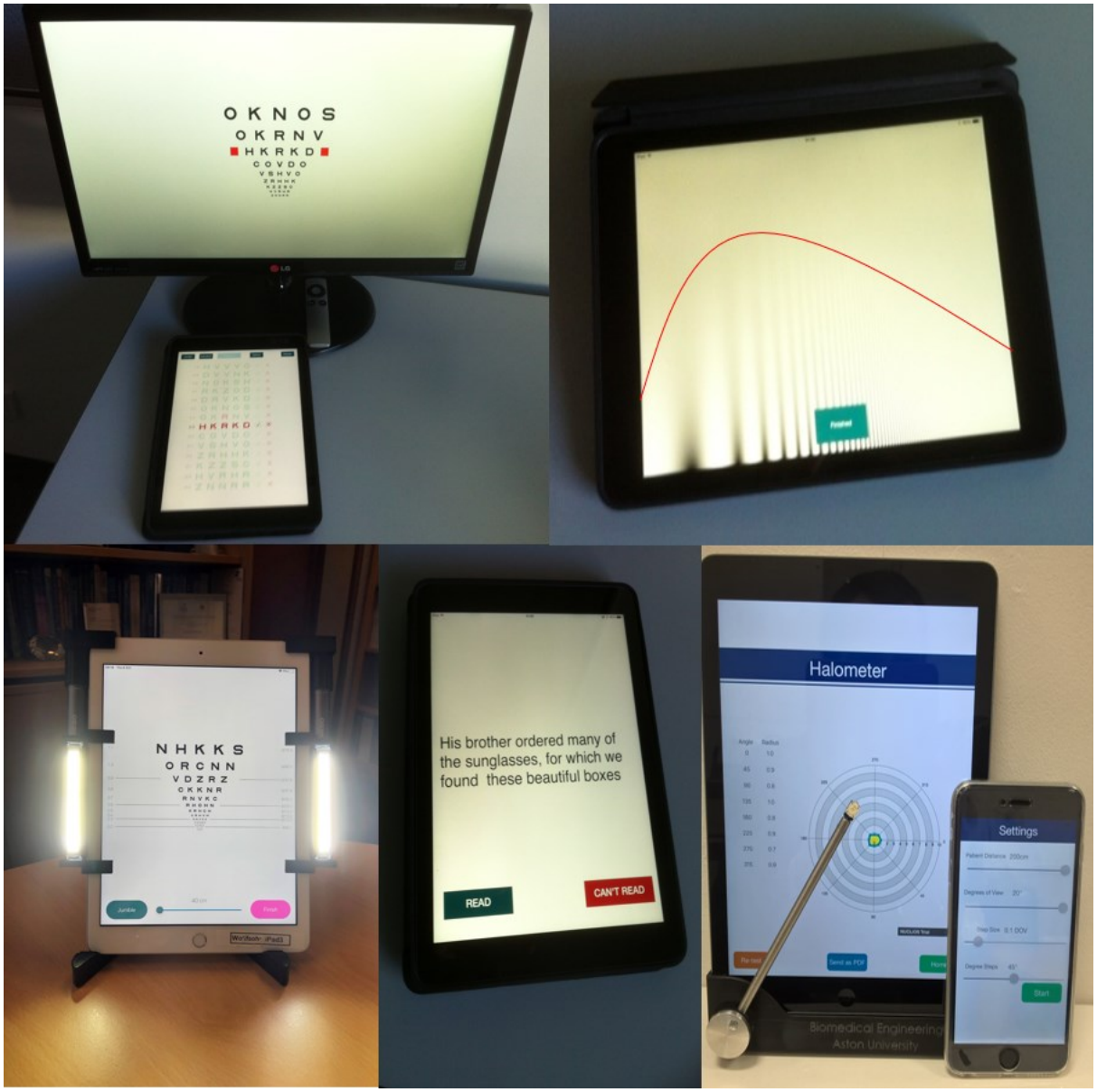

Figure 2: Tablet based visual function assessment applications.

While it has been possible to improve the sensitivity, reliability and clinical application of a range of traditional and newer visual metrics, these do not fully capture the patient experience. Patient reported outcome measures take input from multiple patients with the disease of interest and clinical experts, applying statistical optimization (such as Rasch analysis) to develop,[82] but allow quality of life in conditions to be assessed. We have been involved in developing quality of life questionnaires for macular degeneration,[83, 84] visual impairment [85-90] and presbyopia.[91-93] With time

we have had to develop some further to remain relevant to changing lifestyles and impact of social media,[94, 95] especially the ubiquitous digital environment.[96, 97] We have demonstrated they are influenced by whether they are self-completed or the questions are posed to them, so this needs to remain the same if scores are to be compared over time or across patients / treatments.[98] Traditional patient reported outcome measures only assess one trait, by design, so do not account for the patient experience of the management of their condition. Hence patient reported experience measures [99, 100] and item-banks [101] are needed in future to better monitor the impact of ocular disease and management approaches.

Enhancing Residual Vision in the Visually Impaired

Visual impairment from ocular disease is generally un-correctable, so low vision rehabilitation focuses on making the best use of the remaining vision [102-105] such as through the use of coloured lenses,[106-108] optical magnifiers [109, 110] (including optimised page illumination)[111] and electronic vision enhancement systems (EVES)[112-114] which we and other research groups have evaluated. We developed the terminology EVES to better describe the use of technology that has emerged in instrumentation for those with low vision than the traditionally used Closed Circuit Television (CCTV) terminology. EVES can allow real-time digital enhancement of text [115] and we have demonstrated it benefit in television [116] or even real-world viewing through a head-mounted helmet [117-119]. Clinicians need to balance the desire for greater magnification,[120] with the compromise of a smaller field-of view and an increasing scanning requirement.[121]

Monitoring Ocular Physiology

Subjective grading scales vastly improved practitioner attempts to describe clinical features such as ocular redness,[122, 123] which are impacted by changes in ocular physiology such as with disease

severity or product toxicity.[124] Research by us and other research groups have demonstrated that clinicians use both the area and redness of the vessels to make their clinic judgement of severity.[125, 126] However, we have shown that anterior eye grading scales are not comparable or that linear,[127] breaking a continuous physiological variable into a limited number of discrete steps;[128] while it was initially advocated that 0.1 increments would increase the sensitivity of grading,[129] we found 0.5 increments within the usual 4 to 5 point scale seems to be the best that can be differentiated by clinicians [130]. With digital imaging, we have extracted and objectively quantified features associated with ocular physiology such as redness [126, 131] and transparency,[132] from images of sufficient resolution / compression format,[133] improving sensitivity and repeatability of assessment.[134] These can be translated back to typical clinical scale grades to aid clinical interpretation.[131] Others have applied similar techniques to staining [135-137] and gland drop-out.[138, 139]

Tear film biomarkers have been linked to systemic as well as ocular disease.[140-142] Hence the possibility of non-invasive extraction of tear film biomarkers that can be analysed in a clinical setting (point of care) using 'lab-on-a-chip' technology is an attractive proposition that we and others have utilised.[143-146] The sampling of tears is still a challenge with capillary tube,[147] sponge,[148] Schirmer strip [147, 149] and eye wash [150, 151] techniques, each having their own profile of lipid and protein capture. Even within a technique such as using a Schirmer strip, we have shown there is significant variability between brands.[149]

The slit lamp biomicroscope consists of magnifying binoculars and a conjugate illumination system that can be varied in spectral transmission, height and width.[2, 152, 153] Together with its stabilisation of the patient on a chin and head rest and adjustable three-directional stage, it has become a core instrument for the examination of both the anterior and posterior eye. Fluorescein dye is widely used to assess corneal compromise and damage,[154, 155] but with careful tuning of the blue illumination (with a peak at 495nm, not Cobalt infused glass with its peak around 450nm!) and yellow observation filter (with a sharp cut-off at 500nm), we demonstrated the image is much

enhanced.[156] Specific instruments have been developed from the early corneal topographers using light to enhance anterior eye images, with Placido discs [157] to view the stability of the tear film over time,[158] cool white light to visualise the lipid layer through interferometry,[159] blue light to excite fluorescein dye molecules to assess corneal damage [156] and infrared light to perform meibography, [160] although our research has identified these instruments are not always initially optimised.[161]

Impact of Technological Advances in the Optics and Properties of Ophthalmic Medical Devices

Many ophthalmic medical devices have been developed to overcome refractive errors, with more complex optics applied to the amelioration of presbyopia,[162, 163] which our seminal position paper defined as "when the physiologically normal age-related reduction in the eyes focusing range reaches a point, when optimally corrected for distance vision, that the clarity and comfort of vision at near is insufficient to satisfy an individual's requirements".[164] They can be implanted (such as intraocular lenses)[165] or applied to the ocular surface (such as contact lenses)[163] and need to have minimal impact on the physiology of the eye.

Our advancements in the understanding of contact lenses, particularly to reduce the drop out [166] linked with prior ocular surface disease,[167-170] have included better evaluation of lens fit,[171-177] the emergence of silicone hydrogel materials [178-183] along with their impact on ocular surface temperature [184, 185] and corneal oxygen consumption,[186] lubricating solution delivery [187-189] and nano-thickness surface coatings (to change surface lubricity while maintaining lens material bulk properties).[190, 191] Our translational research on soft contact lens fit evaluation has led to a simplified recording method where centration/coverage, movement on blink on up-gaze, lag on horizontal gaze and push-up recovery speed are graded on a three point scale[174] to inform clinical decision making,[172] which has been adopted by the International Association of Contact lens Educators (IACLE). We have also provided similar practical guidance on rigid corneal lens evaluation.[175, 192]

Advances in instrumentation have allowed us to better understand of how soft contact lenses drape over the cornea and sclera (which if more of a tangent than previously thought),[193-197] the shape profile of contact lenses [198] and the impact of lens design on its centration and mobility.[173, 199, 200] We developed a technique to compensate for image distortion due to the optics of the eye,[201] which had previously been overlooked, leading to the incorrect observation [202] that soft contact lenses significantly indent (build up) the corneal epithelium.[199, 203]

For contact lens wearers, we have shown toric surfaces can improve the visual function of astigmats [204-208] and multifocal optics can assist in ameliorating presbyopia,[50, 183, 209] although it is challenging to predict the benefits of different designs for an individual patient, as we and others have shown.[210, 211] We demonstrated multifocal contact lens use is often one of a number of correction options used by an individual for different life environments,[212] in a similar way as to them not restricting themselves to one set of clothes or pain of shoes for all occasions. Daily disposable soft contact lenses can also be a useful barrier for airborne antigens in our controlled environment,[213] similar to that found in lens wearer. [214] In addition, we have evaluated their ultraviolet radiation filtation,[215-217] protecting the crystalline lens from a loss of flexibility.[218] Scleral lenses can stabilise a protective fluid layer on the ocular surface [219] and we have revealed they have little impact on corneal physiology in daily wear if the lens Dk/t is at least 125.[220-222]

I have played a mentoring role to support academics in the British and Irish, University and Colleges Committee of Contact lens Educators (BUCCLE) to review the evidence-base for key areas of clinical contact lens practice [124, 223] and conducted studies to address gaps such as the adaptation time required after fitting neophytes [224, 225] (which has now been replicated by another group) [226] and optimising the grading of ocular physiology.[130] To consolidate the increasing evidence-base in contact lenses, I brought together experts in the field to create the Contact Lens Evidence-based Academic Reports (CLEAR), published in 2023; this was an initiative to support clinicians in performing evidence-based practice to the benefit of their patients, to identify gaps in the literature

for researchers to tackle and to identify opportunities for industry to innovate [227-233]. These advocate for changes to commonly used, but unhelpful, terminology such as: referring to 'corneal rigid lenses' rather than rigid gas permeable (which would include scleral lenses)[234] or gas permeable (which described all modern) contact lenses;[228] avoiding the overlap between continuous and extended wear definitions [235, 236] by using 'planned' or 'sporadic' 'overnight wear' which fit better with the risk of complications;[237] and replacing eponym terms (named after an individual) with the Federative Committee for Anatomical Terminology [238] recommended 'anterior limiting lamellar' rather than Bowman's layer and 'posterior limiting lamellar' to replace Descemet's membrane.[239]

We have reported how intraocular lenses have developed rapidly over the past two decades [240, 241] with our research identifying improvements in toric lens stability [242-246] (and improving on the objective assessment of lens rotation and centration) [247] and evaluating more advanced multifocal optics [248] such as segmented,[80, 249] trifocal [69, 81] and those that aim to simulate true 'accommodating'.[40-43]

Myopia Control

Early research exploring the increase in myopia globally was focused on the impact of near vision on the oculomotor system, [250-252] such as our research on near work-induced transient myopia [253, 254] and changes in autonomic stimulation.[33, 255, 256] However, since the advent of treatments which can reduce the amount of myopia a child will develop (i.e. myopia control rather than management), [257-259] unlike approaches such as undercorrection,[260, 261] we have charted a growing concern amongst practitioners across the globe and uptake of myopia control treatments.[262-266] Advances in biometers, such as the ones we have validated, [267, 268] have allowed eye growth to be more sensitively tracked and longitudinal data on untreated children [269-272] is being used in our app to allow practitioners to share a child's eye growth curve prediction to be shared with their parents along with tracking real world data on myopic control appliances and approaches (Figure 3). Through

being appointed the International Myopia Institute Chief Scientific officer, white papers have been published on a range of key aspects of evidence-based myopia understanding such as best practice for designing clinical trials,[273] the role of binocular vision,[274] public health initiatives,[275, 276] clinical guidelines [277, 278] and digests updating previous white papers.[279-281]

Figure 3: Myopia prediction and monitoring app for practitioners and MyDryEye symptom monitoring and treatment tracking app for patient examples.

Technology Driven Enhancements in Ocular Surface Disease Diagnosis and Treatment

The Tear Film and Ocular Surface Society defined dry eye as "a multifactorial disease of the ocular surface characterized by a loss of homeostasis of the tear film, and accompanied by ocular symptoms, in which tear film instability and hyperosmolarity, ocular surface inflammation and damage, and neurosensory abnormalities play etiological roles".[282] It is a disease of both symptoms and signs, so it is a subset of ocular surface disease. It was acknowledged as a disease, rather than a condition, due to its impact on individuals lives, impacting quality of life, livelihoods [283-285] and mental health.[286-288] Its prevalence has been reported to vary widely across different populations,[289] but some of the variation is likely due to the previous lack of an accepted diagnostic criteria. A number of symptomology questionnaires have been developed to 'diagnose' dry eye,[290] but each of them has limitations in how they were designed and evaluated compared to current standards.[291, 292] By refining the most common questionnaire, the Ocular Surface Disease Index (OSDI) with its 12 items, allowed us to reduce it to six of its original questions, without losing sensitivity and specify, while reducing the response burden.[293]

Placido disc topographers have been converted from static image capture to video outputs,[161, 294] allowing the stability of the tear film (which is the where the change in refractive index occurs to give the mire reflection) to be assessed [295] as well as to apply software tools such as to quantify the tear meniscus height [296-298] or to assess meibomian gland drop-out.[138, 139] In addition, blue (to assess fluorescein staining)[156] and infrared (to allow visualisation of the meibomian glands after lid everting) [299] light modes are usually available.[300] Apps are being developed to allow some of these measures (such as symptomology,[301] functional dynamic visual acuity [302] and tear meniscus height imaging)[303] to be conducted on widely available smartphones; this is an area where more technological innovation is expected in the near future, including the use of artificial intelligence to quantify physiological change.[139, 304] For example, we developed a simple digital test that can be presented on a smartphone (Figure 3), in which individuals simply reported how many seconds after

a blink their eyes felt uncomfortable, in combination with a standard questionnaire, achieved a 71% sensitivity and 90% specificity of a full TFOS DEWS II diagnosis of dry eye disease.[305]

Risk factors of dry eye disease are fairly consistent across the world including female sex, menopause, limited sleep, digital device use and contact lens wear.[289, 306-311] Most worrying is the increase in ocular surface disease in children,[312, 313] such as our finding of a correlation between digital screen time and meibomian gland loss [314]. Digital eye strain (symptoms resulting from digital device use) is common across a range of ages [315, 316] and a recent TFOS Lifestyle report that I chaired [317] consolidated the evidence on risk factors, the mechanism (largely driven by the reduction in complete blinking) and management (with omega-3 supplementation being the only approach with strong evidence of a beneficial effect). Optimisation of the ocular surface, binocular vision and refractive error correction are all key to reducing digital eye strain, and there is growing evidence for the importance of regular breaks (such as advocated by the 20/20/20 rule which now has some evidence behind from us and another research group,[318, 319] but this advice might not yet be optimised)[320] and blink exercises.[321]

While dry eye disease is still subclassified into evaporative and aqueous deficiency components, there is much variability as to how these are defined in a research setting, our research findings suggest that there are probably more subtypes within this multifactorial disease.[322] We have shown that examination of the meibomian glands can inform the likely improvements with eyelid debridement and warm compresses.[323] Consistent lid eversion with a robust technique (as we have evaluated)[324] is critical to meibography, with some papers reporting regeneration of the glands [325] which seems unlikely over the short time periods and with the interventions reported.

Artificial tears are the mainstay of dry eye disease management.[326-329] In a longitudinal study designed to provide an evidence-based guide to the use of artificial tears for those with dry eye disease, we found symptoms will improve within a month in those they benefit (approximately two-thirds of those in the trial), with signs taking up to 6 months to be impacted from four times a day

prescribed usage.[330] Hence the importance of ongoing use of artificial tears should be emphasised, but if there is no improvement in symptoms by a month of compliant use, another approach should be tried. Those that have the evaporative dry eye subtype gain more benefit from artificial tears including lipids, as we have found previously.[330, 331] Lipid sprays are effective despite being sprayed on the closed eyelid, rather than directly onto the ocular surface,[332] although this does depend on the formulation.[333] These finding provide the evidence which informs our current management of patients with dry eye disease (Figure 4). Tear film biomarkers [334-336] and advanced corneal imaging [337] to personalise dry eye disease management and point-of-care devices to quantify them [143, 144, 338, 339] are an area of active research by our group and others.

Other simple treatments for dry eye disease include warming the meibomian glands. Microwave heated compresses work well [340, 341] and are better than the traditionally advocated water warmed flannels [342, 343] as they maintain the required temperature [344] of around 40°C [345]; however, there is still scope to refine the treatment protocol and to assess whether mechanical in-office [346-348] or portable devices we have evaluated [349] outperform simple approaches. We have shown that the meibomian glands do need to be more than 10% of their original length to have potential of expressing meibum.[323] More information is also needed on the benefits of wet versus dry heat [350, 351] and whether this is based on an individual's ocular surface biomarkers. In the TFOS DEWS II management report, we identified there are few dry eye treatment direct comparator trials, rather new treatments are evaluated against a placebo.[329] Hence, before this is available, we conducted a survey of eyecare practitioner practice across the globe identifying how they currently use treatments based on dry eye disease severity and subtype;[352] this should allow practitioners to benchmark their practice as well as identifying those comparisons that need research evidence.

Using our now widely accepted TFOS Dry Eye Workshop II criteria [290] of symptoms (OSDI score of ≥13 or DEQ-5 score of ≥6) and at least one homeostasis marker (non-invasive breakup time <10s; tear film hyperosmolarity defined either by the highest osmolarity value of ≥308mOsm/l among eyes or

an interocular osmolarity difference of >8mOsm/l; or ocular surface damage defined either by >5 corneal staining spots, >9 conjunctival staining spots, or a LWE staining of ≥2mm length and ≥25% width), we found the prevalence of dry eye to be 32% in a demographically representative population in the United Kingdom [307], 58% in a Mediterranean population [306] and it have been reported as 18% across Asia.[353]

Ocular allergy is also common and affects the ocular surface.[354] There is much overlap with dry eye disease [355] and while we have confirmed it is conventional to apply pharmaceutical treatments,[356, 357] we demonstrated that non-pharmaceutical artificial tear and cold compress approaches can be equally effective in acute disease symptomology.[358] While contact lenses were considered a contraindication, the use of daily disposables have been found to protect the ocular surface and reduce symptomology [213, 214] and there is now a drug delivering contact lens system for a combined antihistamine and mast cell stabiliser.[359]

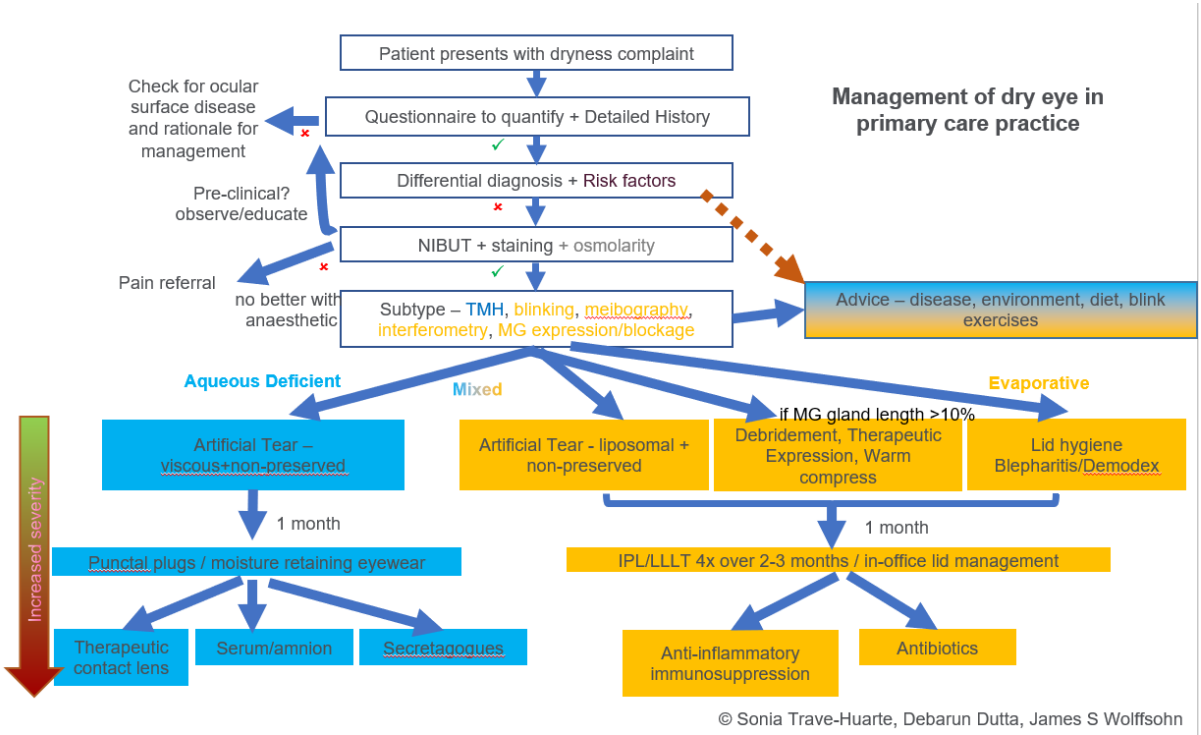

Figure 4: TFOS compliance diagnosis and management algorithm built on current research evidence. NIBUT = non-invasive tear breakup time; TMH = tear meniscus height; MG = meibomian gland; IPL = intense pulsed light therapy; LLLT = low level light therapy.

Conclusions

While technology is driving many of the lifestyle changes that are driving the myopia epidemic and increase in dry eye disease, for example, it also can be utilised to allow more sensitive and detailed evaluation of the eye and its management. Assessment of visual function and eye focus has been improved though modern techniques and instrumentation. Mobile technology can aid practitioners in capturing data and communicating with patients. It can also be used by patients to monitor their condition, to aid compliance with prescribed medication and to even enhance their visual input. Advancements in optical medical devices including spectacle, contact and intraocular lenses, have allowed for a better understanding of the mechanism, and management of presbyopia and myopia control. Enhancements in imaging technology have enabled improved quantitative and qualitative assessment of the tear film and ocular surface, informing diagnosis and treatment strategies. Optometrists play a key role in translating research to inform their clinical practice, adopting relevant technology to enhance their clinical assessment of their patients to allow sensitive and detailed evaluation of the eye and its management.

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Conflict of Interest Disclosures

I am a co-founder of Eyoto, Aston Vision Sciences and Wolffsohn Research companies.

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Conceptualization: JSW; Funding Acquisition: JSW; Investigation: JSW; Writing – Original Draft: JSW; Writing – Review & Editing: JSW.

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