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EST. 1939 VOLUME 78 NUMBER 4

CLINICAL RESEARCH

Case study: Use of contact lenses to manage complications following combined corneal cross-linking and topography-guided photorefractive keratectomy for pellucid marginal degeneration

CANADIAN ASSOCIATION OF OPTOMETRISTS
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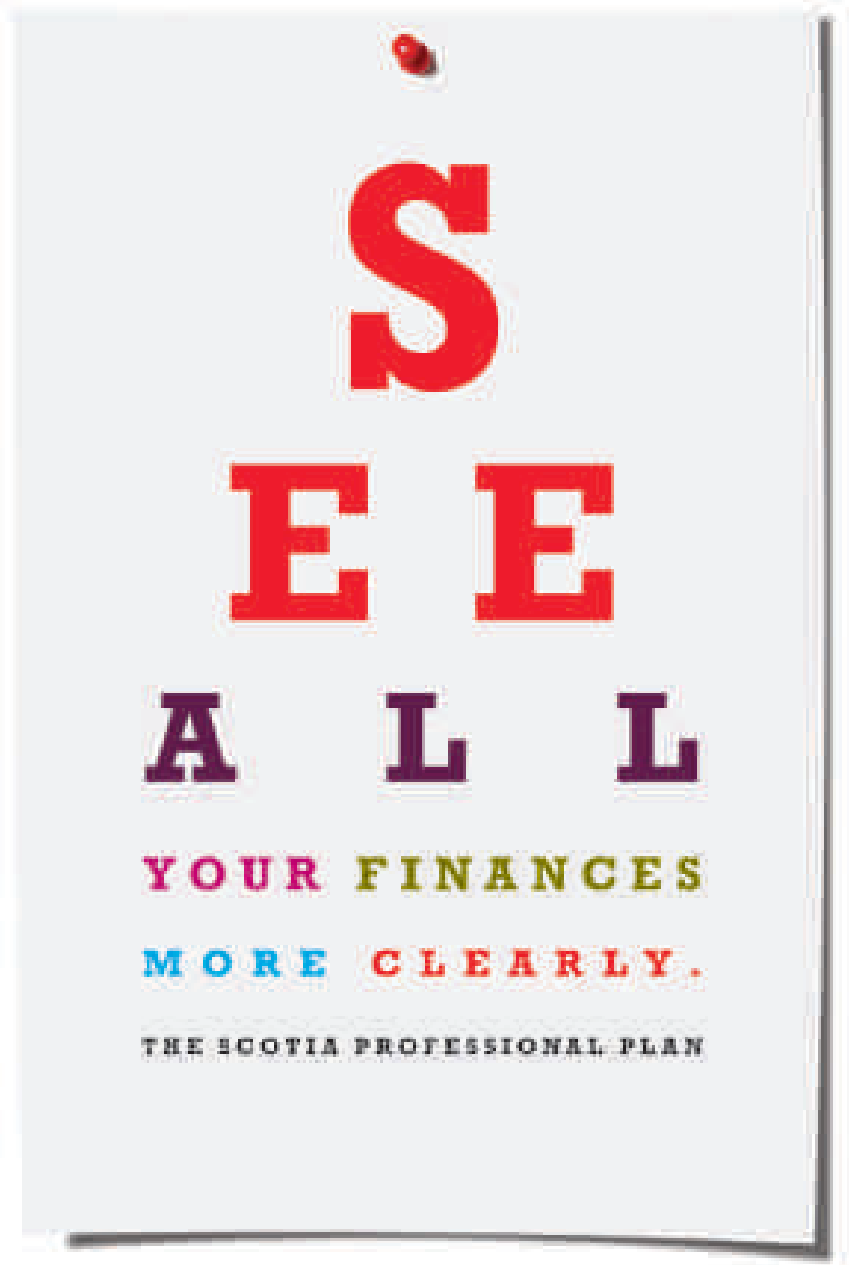

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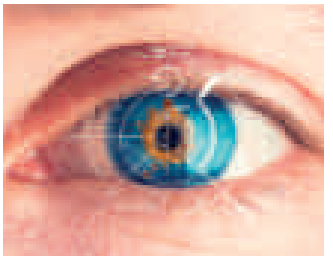

On the Cover

Management of the symptomatic ocular sequelae with specialty soft toric contact lenses designed for irregular corneae corneas assists a patient's visual rehabilitation.

B. Ralph Chou, MSc, OD, FAAO
Editor-in-Chief

Shortly after writing my editorial for the previous issue, I was contacted by reporters for CTV News and the *Toronto Star*, who were collaborating on a report about "predatory publishers". A predatory publisher is one that prints or distributes fake or unvetted studies, often for a significant fee, and takes advantage of inexperienced scholars and scientists who are desperately looking to publish their work. They asked my opinion and how this journal was dealing with its predatory publisher.

Some readers may recall that the story broke in late September, broadcast on CTV News and followed by a more detailed story in the *Toronto Star*.[1] This publication was mentioned because our former publisher was one of the two Canadian publishing houses purchased by OMICS Group of Hyderabad, India. In all, 16 Canadian health sciences publications were affected by the OMICS purchase. A follow-up story appeared in *The National Post* in late November and confirmed the worst fears about how a predatory publisher puts fake research online, complete with typographical errors and nonsensical text.[2]

Fortunately, when the warning signs of the new ownership's changes at our former publisher appeared, the CAO management was able to terminate our publishing contract and engage another independent, reputable publisher. After a few weeks of reorganizing our publication and reviewing procedures, we are back on track. Manuscripts that were in the review process when our former publisher's managing editor suddenly vanished in late summer have been recovered and sent out for review. Our publication schedule for 2017 is set, and articles that had been accepted for publication, but not yet scheduled have also been recovered and put in the schedule.

I look forward to our upcoming CAO Congress in Ottawa that coincides with the celebration of Canada150 and another exciting year for *CJO*RCO* and our profession. ●

1. Oved MC, Favaro A, St. Philip E. Canadian medical journals hijacked for junk science. https://www.thestar.com/news/world/2016/09/29/canadian-medical-journals-hijacked-for-junk-science.html#pt0-827114. Accessed 30 November 2016.
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B. Ralph Chou, MSc, OD, FAAO
Rédacteur en chef

Peu de temps après avoir rédigé l'éditorial du numéro précédent, j'ai été contacté par des journalistes de CTV News et du *Toronto Star* qui travaillaient ensemble dans le cadre d'un reportage sur les « éditeurs prédateurs ». Un éditeur prédateur est une maison d'édition qui publie ou diffuse de fausses études ou des recherches non vérifiées — souvent à fort prix — et qui tire avantage de chercheurs et de scientifiques inexpérimentés cherchant désespérément à publier leur travail. Ils m'ont demandé ce que je pensais du phénomène et voulaient savoir comment notre revue gérait les relations avec son éditeur prédateur.

Certains lecteurs se souviendront peut-être que l'affaire a éclaté fin septembre sur CTV News avant d'être reprise plus en détail dans le *Toronto Star*[1]. Le nom de notre publication a été mentionné parce que notre ancien éditeur était l'une des deux maisons d'édition canadiennes rachetées par le groupe OMICS d'Hyderabad, en Inde. Le rachat par OMICS a touché en tout 16 publications scientifiques canadiennes sur la santé. *The National Post* s'est ensuite emparé de l'affaire fin novembre et a confirmé les pires craintes sur la publication par des éditeurs prédateurs de fausses études en ligne truffées de coquilles et d'inepties[2].

Heureusement, lorsque les signes avant-coureurs du changement de propriétaire sont apparus chez notre ancien éditeur, la direction de l'ACO a été en mesure de mettre fin à notre contrat et d'engager un autre éditeur indépendant reconnu. Après quelques semaines passées à réorganiser nos procédures de publication et de vérification, nous sommes de nouveau en piste. Les manuscrits qui en étaient au stade de la vérification lorsque l'éditeur en chef de notre ancienne maison d'édition a soudainement disparu à la fin de l'été ont été retrouvés et ont été soumis à la vérification. Notre calendrier de publication pour 2017 est prêt, et les articles qui avaient été acceptés mais dont la date de publication n'avait pas encore été déterminée ont également été récupérés et ajoutés au calendrier.

Il me tarde de participer à notre prochain congrès de l'ACO à Ottawa, qui se tiendra en même temps que les célébrations du 150e anniversaire du Canada et qui marquera le début d'une nouvelle année plein de promesses pour le *CJO*RCO* et pour notre profession. ●

1. Oved M.C., Favaro A., St. Philip E., Canadian medical journals hijacked for junk science. https://www.thestar.com/news/world/2016/09/29/canadian-medical-journals-hijacked-for-junk-science.html#pt0-827114. Consulté le 30 novembre 2016.
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The '20/20/20 Rule' – When Good Intentions and Axiomatic Habit Displace Best Practices

Charles Boulet, BSc, BEd, OD
Practicing Family and Developmental Optometry
Public and Professional Educator

Abstract

PURPOSE

Optometrists often proffer the '20/20/20 Rule' as advice for clients who experience nearpoint visual strain, or who are subjected to prolonged exposure to nearpoint devices. The 'rule' is offered in the patient's best interests: To help alleviate asthenopia and visual stress from nearpoint strain, and to reduce the risk of onset or the progression of myopia and associated ocular disease. Best intentions aside, there is a paucity of clinical and scientific support for the rule. On the other hand, modern optical tools and methods, and vision rehabilitation practices are known to be helpful in addressing mild to severe binocular vision disorders, to promote comfort, and to slow the progression of myopia. While offering trite advice to address potentially serious concerns might appear to be helpful, its continued use could well be displacing other more appropriate management strategies. This paper addresses some concerns regarding the promulgation of this well-meaning, but misguided, advice.

KEY WORDS:

20/20/20 Rule, myopia, myopigenesis, myopiagenesis, computer vision syndrome, asthenopia

Optometrists are generally regarded as experts in the field of vision and visual function from the perspectives of both ocular and visual neurological health. This expertise extends well beyond simple visual acuity ('20/20 eyesight') and healthy eyes, and includes elements such as binocularity, visuomotor skills and accuracy, phoric posture, comitancy, visual processing-based skills, visual spatial awareness and manipulation, and other features. This broader view of vision permits the diagnosis and treatment of a variety of difficult and often debilitating visual functional deficits that impact comfort, health, and the ability to conduct normal daily activities, such as reading and the use of computers.

Most clinicians are familiar with the 20/20/20 Rule (The Rule) as a therapeutic and palliative guide for patients experiencing the effects of Computer Vision Syndrome (CVS), or for helping to prevent its onset. The Rule can be stated as follows: "Every 20 minutes, take a 20 second break and focus your eyes on something at least 20 feet away".[1] These instructions are routinely offered by optometrists and ophthalmologists, and are now repeated on the Internet through a variety of sources (any search engine can provide several examples). Despite this advice being commonly found in optometric clinical sources, including websites of optometric associations, it has very little evidentiary support and its therapeutic benefits are unclear.

At first glance, there is nothing inherently incorrect or harmful in repeating The Rule as clinical guidance, and this advice is generally given with good intent. Also, looking outward at a distance while reading, every 20 minutes for 20 seconds, surely does no harm. Thus, this recommendation would not be expected to be harmful. Still, there are a few significant problems with this cursory approach to treating vision dysfunction, including a potential for missed opportunities for more appropriate care and, notably, the possibility of giving patients a negative perception of doctors resulting from the latter's offer of non-science-based advice. This paper focuses on these problems with The Rule.

Computer Vision Syndrome

Computer Vision Syndrome (CVS), which The Rule is often intended to alleviate or prevent, is not a new construct in vision science and rehabilitation. Gowrisankaran and Sheedy reviewed CVS in a paper that covered 65 years of research[2], which effectively includes the time when humans began spending long hours in front of computers. They described CVS as "a collection of symptoms related to prolonged work at a computer display."[2] Klamm and Tarnow offered a parallel review of the literature from a medical-surgical perspective[3] that provides some guidance on the management of CVS that is more detailed even than that offered by The Rule. The American Optometric Association also offers more detailed guidance in the management of CVS.[4]

CVS is often described as "a collection of symptoms related to prolonged work at a computer display."[2]

CVS is not a single unified pathology, but rather a relatively poorly understood constellation of patient concerns combined with mostly predictable patterns of optometric findings such as disturbed vergence, accommodation, fixation disparity, and ocular disease related to exposure.[5] The adequate assessment of CVS, and nearpoint concerns in general, requires attention to detail and sufficient expertise to identify these obstacles to visual function and possible ocular or neurological disease. Treatment should proceed logically based on history, findings, the visual and lifestyle demands of the patient, and the ease of access to Optometric Vision Therapy services if required. The Rule cannot be considered OVT.

Myopia Management

The Rule might be given as advice to minimize the risk of myopic progression, or even to prevent the onset of myopia. A generalized version of the theory would suggest that the stress of working at close distances causes sufficient accommodative and vergence strain to lead to an adaptation towards structural myopia. This 'near-environment stimulus' hypothesis of myopigenesis is difficult to substantiate given current understanding and research. The distinction between structural myopia, where myopia is a result of excess axial length for the refractive power of the anterior segment, and what may be called nearwork-induced transient myopia (NITM), a transient condition precipitated by the stress of visual work at near proximity, is central to this discussion.

While recent research suggests that there is a trend towards an esotropic posture with the extended use of small handheld devices,[6] there is no compelling evidence that the use of such devices initiates or accelerates structural myopia, which is the greater concern given it is irreversible, non-transient, and a potential risk to sight and ocular health. Lougheed wrote that "despite ongoing attempts to tie these close behaviours to the onset of nearsightedness, or myopia, researchers have not come up with convincing results."[7] There is little doubt that prolonged nearpoint activity can, at least in some cases, lead to accommodative hysteresis (AH) and NITM, which is a clinical entity distinct from structural myopia which can often be addressed using conservative means, such as low add powers suitable to the task. The cause of NITM and the types and benefits of treatment depend on many factors, including vergence ranges and facility, accommodative range and facility, working distance, monocular and binocular refractive status, duration and nature of the visual task, ambient lighting, neurological health, and so forth.[8,9] Unless there is significant pathology present, such as mTBI/TBI, one should expect NITM patients to respond well to vision therapy and appropriate lenses, or simply lenses.

Recent studies have shown that genetics and exposure to appropriate environmental illumination are much more likely to play a role in the onset and progression of structural myopia[10-12] than the extent and nature of near tasking. For example, Lougheed wrote that "a rapidly growing body of research on certain populations in East Asia is yielding strong evidence linking diminishing levels of exposure to outdoor light with a prevalence of myopia that is approaching epidemic proportions."[7] The notion that myopia arises from nearpoint strain disregards the physiological fact that hyperopes experience much greater nearpoint visual strain than do myopes, but they neither exhibit a commensurate progression towards myopia, nor do they gain the relative benefits for near work provided by it.

Research also supports the notion that, while we cannot prevent structural myopia, we can modulate some aspects of myopic progression[13-21] and the extent of NITM. In the case of accommodative hysteresis and NITM, in practice, The Rule at best will offer only brief symptomatic relief and such patients would require more in-depth assessment and treatment than the axiom provides. For a significantly hyperopic or astigmatic patient, or in cases of convergence insufficiency, or mild traumatic brain injury (mTBI), The Rule will offer little, if any, relief for the discomfort associated with nearpoint tasking, nor will it advance the patient's need to thrive.

Poor reading skills and poor academic achievement can be attributed in part to higher degrees of hyperopia, and in some studies better reading skills have been associated with emmetropia or myopia, or strong visuomotor skills[22-25]. While there is much concern regarding the progression of myopia worldwide, myopia has also generally been associated with higher academic achievement. The Rule can be expected to have little impact on these structural refractive states or their resulting effects on learning and academic outcomes.

Management of CVS and Nearpoint Strain

Birnbaum's excellent book on the diagnosis and management of binocular vision disorders and nearpoint stress[5] has become an important reference in visual rehabilitation. While it was written at about the time when desktop computers were only starting to become commonplace in homes and offices, many of the diagnostic and treatment principles apply equally well today, but perhaps with more gravity given our deepening relationships with and dependence upon more modern, near environment devices.

When a patient struggles with near-environment tasks, the clinician should take this as a sign to begin a more in-depth investigation by considering possible medical causes and impediments to visual function. For the purposes of this paper, we assume that no medical issues are contributing to the patient's discomfort. Furthermore, a full discussion of all possible elements of CVS and nearpoint strain, and the nature of mTBI, is beyond the scope of this review. To address CVS, a much more active and broader intervention is required than The Rule implies. The signs and symptoms of CVS may be grouped as follows:[2]

- Internal ocular symptoms (strain and ache)
- External ocular symptoms (dryness, irritation, burning, formation of pingueculae/pterygia, keratitis, conjunctivitis)
- Visual symptoms (blur or unsteady focus, double vision)
- Musculoskeletal symptoms (neck and shoulder pain, facial/cranial muscular tension)

The major factors associated with CVS can be classified as follows:

1. Environmental Factors: Improper lighting, display position, size and viewing distance, and exposure of the ocular surface tissue.
2. Factors relating to the user's visual functional profile and functional status vis-à-vis visual tasking demands. These might include inadequate compensation of refractive state for the task at hand given age and health, inadequately compensated anisometropia, unaddressed oculomotor disorders or problems with posture for the task, such as high phoria or strabismus, uncompensated diplopia, tear film abnormalities, and visual health abnormalities (i.e., field loss, nerve conduction concerns).

The proper management of nearpoint strain and CVS requires sufficient care to address the patient's concerns globally, and this requires a more elaborate response that may be obscured when a clinician offers a vague recommendation such as 'take a break every 20 minutes'.

The 20/20/20 Rule and Refractive Status

Unmanaged refractive needs are a common cause of nearpoint strain, and are therefore worthy of brief comment. Even within this narrow domain, there are several distinct reasons why a patient might exhibit signs and symptoms of CVS, and where The Rule would have little or no impact. For example, a 3D myope would not be expected to experience the same relief by gazing in the distance as would a 3D hyperope given the differences in relative accommodative effort at both near and far. The aniseikonic patient might not receive any relief at any distance or for any duration, unless the aniseikonia was appropriately managed, such as through aniseikonic optical solutions.

Similarly, patients with significant astigmatism (greater than 1.00D) will often feel chronic aesthenopia at all gaze distances, depending on the visual demand and environment, and this can be exacerbated during reading, especially in the case of compound hyperopic astigmatism. An emmetrope with accommodative hysteresis or dysfunction might also find that The Rule has little to no effect on their chronic concerns, depending on the cause of the AH.

These few examples are only offered to consider how even refractive concerns render The Rule ineffectual. Dismissing these as a simple need to 'take a break' is a disservice to the client and a potential liability risk in those cases where the near point strain is related to current pathology.

Current Support for the 20/20/20 Rule

As recently as November 27, 2016, a search of PubMed for '20/20/20 Rule' returned no results related to management of CVS, myopia, or NITM. Google Scholar also returned no results for this 'Rule' (same date). In a general Google search for '20/20/20 Rule', although several blog posts were identified, none provided any supporting evidence (at least within the first few dozen relevant listings). One could reasonably conclude that, given the apparent lack of supporting literature, no formal research has ever been conducted on The Rule, which now appears to have evolved to a simple meme with no supporting evidence in either clinical or pure science.

If we had sufficient clinical rationale, efficacy, or anecdotal evidence to support The Rule, perhaps we could be justified in offering this 'good advice', despite a lack of research evidence. The rationale behind offering The Rule as advice appears to be 'if you are experiencing aesthenopia, remove the offending stimulus' or 'look away from your nearpoint device occasionally to prevent nearsightedness'. Even if we accept this reasoning as valid, we must then assume that, in all cases, having the patient direct their gaze at a distance of 20 feet, at intervals of 20 minutes, and for a period of 20 seconds would be most comfortable. This is one case where the patient would be better off not following their doctor's advice and instead respect their own sense of how much reading they can tolerate comfortably.

Additionally, in the light of objective scrutiny, it is clinically unreasonable to assume that the same prescription of a 20-second break every 20 minutes while reading should somehow apply to all patients, especially given the many diverse reasons why patients struggle with nearpoint visual strain. While such a break might offer brief relief, an honest clinician should not be satisfied with such a superficial understanding of the patient's condition.

DISCUSSION

The 20/20/20 Rule is a quaint axiom that cleverly alludes to 20/20 visual acuity. However, the desire for a crafty turn of phrase might be the tail wagging the dog in this case, where we fit the condition to meet the needs of the treatment. It is difficult to find references to the origins of The Rule itself, but it appears to have been derived from the notion of 20/20 acuity. Clinically, it could have just as easily been derived from the metric measure of acuity, but a '6/6/6 Rule' may not have had the same broad acceptance.

Patients listen to their doctor's advice and consider it valuable by default: Understandably, patients should believe that what their doctor says is true. When treatment options for CVS, NITM, mTBI, or myopigenesis are summarized with a clever axiom, the patient is at risk of being confused with unnecessary words where chair time could otherwise be put to better, more clinically productive use. Analogously, when a clinician offers aspirin to a patient with a fever to minimally, and transiently, affect the patient's temperature, the clinician must follow through and determine why the fever is present in the first place. At the very least, the clinician should develop a plan to monitor and treat the fever with a more evolved clinical approach than ASA QHS RTC PRN. This situation is similar to the case with CVS, myopia management, mTBI, and binocular vision disorders generally: Patients deserve better and doctors should work to raise the standard of care for their patients, and this includes referrals to specialized optometric clinics where OVT rehabilitation services are provided.

In some cases, The Rule might be offered as general guidance for so-called visual hygiene to render reading more comfortable and to prevent the onset of visual functional problems. Regarding the first count, competent readers with either no or negligible visual functional concerns can read for extended periods without breaks or concerns. Chronometric management of reading 'risks' will at best almost certainly interfere with the flow of the task, and possibly create a problem where none exists. Regarding the second point, there is no indication that reading leads to visual functional problems, aside from chronic accommodative hysteresis and/or NITM in some cases.

The CVS patient is affected by the incongruity of their visual functional status and their present visual tasking. A clinician can often address these concerns through thoughtful prescribing and a broad knowledge of available lens technologies. This might include a consideration of multifocal lenses, modified progressive addition lens options such as near PALs, the avoidance of bifocals, and a consideration of isophoric and iseikonic lens designs for anisometropia of 1.0D or more in any meridian (see for example ShawLens.com). Clinically, trial lenses should be used routinely in the prescribing process, and thoughtful prescribing should include consideration of the use of specialty lens designs such as Shaw aniseikonic/anisophoric 'balanced' lenses, and modern progressive addition near-tasking lenses, or lenses with low add power. If the patient is uncomfortable while reading, a detailed optometric assessment and selection of an optimised lens can be a suitable solution for part-time or full-time wear. When lenses alone cannot satisfy the client's needs, visual rehabilitative therapies should be considered.

Reading at near distance and use of near devices such as tablets and phones will not likely alter the structural refractive status[7,26] or lead to ocular disease, as has been suggested and promulgated in the media.[27] With respect to interventions to stop the progression of myopia, Aller stated that "(a)ll of the methods described have been shown to varying degrees to be effective in slowing myopia progression. As they cannot reliably stop progression, prevent onset, or cause true regression of myopia, these methods are limited to reducing the rate of change.".[26]

Vision rehabilitation through Optometric Vision Therapy (OVT) is often the most important therapeutic element in successful longterm treatment for embedded visual strain. Unfortunately, despite research that supports OVT's preferred role in the management of convergence insufficiency, for example,[28-30] OVT is only infrequently discussed in medical and optometric practice as a possible remedy. The simpler solution to advise patients to 'take a break from reading every now and then', paradoxically admits that there is a problem, but then offers no solution and only weak palliation. In other cases, patients are referred to additional medical diagnostics, imaging, and treatment which fail to address visual functional concerns. Best client-centred prac-

tice would then dictate that time spent advising patients about The Rule could be, and rather should be spent assisting them in locating visual rehabilitative services, pursuing orthoptic solutions to reduce discomfort and improve function, or in advancing medical diagnostics to rule out ocular pathology or pathology of the visual nervous system.

A significant concern related to such cursory treatment of CVS and nearpoint visual strain lies in the fact that the pathology is multi-factorial and requires a much more in-depth assessment of vision than what is provided by the Modified Clinical Technique (MCT), for example.[31] The Rule has no diagnostic value. In 'Visual Impediments to Learning', the author offers supplemental commentary on the sensitivity of the MCT to visual functional concerns[32] and a more robust approach to visual assessment. The MCT is a coarse net and lets pass many visual functional concerns; if the source of the CVS and nearpoint strain is not uncovered, further investigations are indicated through a more elaborate optometric visual functional assessment. For example, Quaid and Simpson showed that vergence facility (which is rarely even tested in routine optometric care) is highly predictive of reading problems when combined with symptom questionnaires regarding reading speed and overall reading skills (as determined objectively using the Visagraph infrared tracking device).[22] If the 20/20/20 Rule is offered to manage learning concerns, CVS, visual strain, or myopia, this should be taken as an indication that further clinical investigations are required to uncover more clinically relevant and suitable solutions.

As human visual needs and habits evolve, optometrists will play an increasingly important role in the management of visual function, comfort, and development. Identification, assessment, and treatment of CVS, accommodative hysteresis, and myopic progression require attention to detail and knowledge of what is clinically helpful, and what is not. Patients rely on doctors to offer salient advice and pay for advice that is evidence-based and not simply a placebo or a redirection to a protocol that will have only minimal, if any, impact, and which is decidedly without scientific foundation.

In the final analysis, given the paucity of reasons to recommend The Rule, one wonders why it is still offered as professional advice. There is no foundation for this guidance clinically, so perhaps the clinician is simply inclined to "offer something rather than nothing". Since we cannot say why The Rule would help and since it distracts from pursuing clinically meaningful solutions, this practice should be questioned. In this sense, doing 'something' in this case may actually worsen the problem because the opportunity to provide more helpful solutions may be lost when the patient concludes that there is nothing else to be done.

CONCLUSION

The 20/20/20 Rule is a popular optometric axiom that has made its way into popular culture partly, perhaps mostly, due to its promotion by the profession of Optometry. It is intended to promote greater comfort while reading, i.e., to reduce the symptoms of CVS, to abate accommodative hysteresis and NITM, and to prevent myopia or to slow myopic progression. While The Rule's clinical impact for patients can at best be described as marginal, it will have, in the most extreme cases, no more impact than that of aspirin on a bad fever. The clinician's role is to diagnose and treat the ill patient; in this case, the patient suffering from nearpoint visual strain, mTBI, or myopic progression. These issues may be addressed through optics, optometric vision rehabilitation, or medical intervention.

The Rule alone will not satisfy troubled patients. It is not based on any definable clinical science, nor does it offer any preventive value for healthy and strong readers. Therefore, it should not be given as professional advice per se. Because it provides such limited benefit to the patient, the time taken to explain The Rule is a missed opportunity for advancing further diagnostics, or for exploring more elaborate options for treatment and palliation. While best practice would include some instruction to the patient to take occasional breaks from reading, the value of doing so should not be overstated, nor should the clinician include the erroneous suggestion that this could prevent the onset of structural myopia and associated ocular disease.

Optometrists and ophthalmologists need to consider the potential problems with public and professional perceptions when they offer trite and unproven advice to resolve complex issues. A greater concern is that pithy advice such as The Rule detracts from and marginalizes the proven benefits of Optometric Vision Therapy, such as the level one evidence presented in the Convergence Insufficiency Treatment Trial,[30] and it also diminishes the clinical value of a more comprehensive assessment of binocular visual function, which would lead to a more nuanced and valuable clinical result for the patient. ●

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Case study: Use of contact lenses to manage complications following combined corneal cross-linking and topography-guided photorefractive keratectomy for pellucid marginal degeneration

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Abstract

This case report describes two significant long-term complications experienced by a patient following treatment for pellucid marginal degeneration (PMD). Two years after undergoing a combination of topography-guided photorefractive keratectomy (T-PRK) and corneal collagen cross-linking (CXL) procedures, the patient continued to experience glare and dryness associated with persistent stromal haze and dry eye. These procedures resulted in dissatisfaction with the final outcome, which led the patient to seek contact lens correction. Management of the symptomatic ocular sequelae with specialty soft toric contact lenses designed for irregular corneas supported her visual rehabilitation.

KEY WORDS:
topography-guided photorefractive keratectomy (T-PRK), corneal collagen cross-linking (CXL), Pellucid Marginal Degeneration (PMD), stromal haze, dry eye

Pellucid marginal degeneration (PMD) is a progressive non-inflammatory ectatic disorder involving the inferior peripheral region of the cornea.[1–3] In this disorder, thinning occurs in a crescent shape extending from the 4 o'clock to 8 o'clock position in the peripheral cornea. While the amount of irregular astigmatism depends on the severity of the condition, the vision distortion secondary to PMD is typically asymptomatic in the early stages because the area of thinning does not involve the visual axis. For this reason, corneal topography is the gold standard for diagnosis of this condition.3 The current standard of practice in the management of PMD includes spectacles, contact lenses and surgical interventions, such as lamellar or penetrating keratoplasty.1,[4,5] Recently, simultaneous topography-guided photorefractive keratectomy (T-PRK) and corneal collagen cross-linking (CXL) procedures have been used to manage PMD and other causes of keratoectasia with the aim of slowing the progression, minimizing corneal irregularity, and reducing the need for a corneal transplant. [6–10]

T-PRK involves ablation of the corneal stromal tissue by an excimer laser with customization based on wavefront aberrometry, tomography, and topography.[11–13] By flattening the corneal apex or elevated and steepened tissue adjacent to ectatic areas, this procedure normalizes the cornea by reducing the astigmatism and irregularity of the corneal surface.[6,11,13] CXL uses the photosensitization of riboflavin with ultraviolet A (UVA) light to induce the polymerization of collagen fibers in the anterior 200 to 300 microns of the corneal stroma.[14–18] CXL effectively increases the corneal rigidity and the biomechanical strength by three-fold.[8,17,19] CXL also results in simultaneous flattening of the steepest area and steepening of adjacent areas around the cone, which decreases corneal asymmetry and spherical aberration.[19] The combination of these procedures, with CXL performed immediately after T-PRK, is beneficial in the management of corneal ectasia.[8–10] It has been demonstrated that the operating time can be reduced if these procedures are performed simultaneously.[20] This also allows for riboflavin to reach and induce collagen cross-linking in the deeper layers of stromal tissue.[20] It minimizes the potential for superficial stromal scarring resulting from PRK by diminishing fibroblast activity after the eradication of keratocytes.[6] Reversing the order of these two procedures would result in either the removal of stiffened cross-linked corneal tissue or a reduction in the ablation rate of cross-linked tissue with altered biomechanical properties, neither of which would be beneficial.[8,10,20]

The effectiveness of simultaneous T-PRK and CXL in halting the progression of ectasia over a limited period of time and improving uncorrected and best-corrected visual acuities for PMD has been well documented.[8,10] However, little information is available regarding the complications from these procedures. This case report describes two such complications (permanent corneal stromal haze and dry eye) and their management.

CASE REPORT

A 41-year-old Caucasian female presented at the University of Waterloo School of Optometry and Vision Science Contact Lens Clinic for a consultation regarding specialty contact lens options. Her chief visual concerns included significant light sensitivity and glare, both of which were severe enough to have impacted her daily activities. Her ocular history was significant for bilateral PMD that had been diagnosed five years previously at a refractive surgery consultation appointment in 2010. Shortly after her diagnosis, she underwent simultaneous T-PRK and CXL in both eyes. The patient attributed her debilitating visual symptoms and dry eye to these procedures. Overall, her general heath was unremarkable other than the occasional migraine. A previous medical examination had ruled out Sjogren's syndrome. Her current medications included cyclosporine (Restasis®), duloxetine (Cymbalta®), lorazepam, and zopiclone (Imovane®).

Other significant ocular and contact lens history included prior experience with gas permeable and disposable soft lenses, with little success primarily due to her severe symptoms of dryness, which eventually led to contact lens intolerance. She had previously been prescribed a series of standard dry eye managements, including lid hygiene and hot compresses, frequent application of artificial tears with and without lipid components, a one-month course of topical loteprednol, a two-year course of topical cyclosporine A and bilateral inferior punctal occlusion. None of these prior therapies had restored the patient's visual comfort to a level that allowed her to perform daily functions.

Upon ocular examination, refraction was -0.75/-2.50 x 148($6/9^{-2}$) in her right eye and -0.25/-2.25 x 057 ($6/9^{+2}$) in her left eye. All entrance tests were unremarkable. Her pupils were equal in size at approximately 8.0mm under scotopic conditions and 5.0mm under photopic conditions.

Biomicroscopic examination of the anterior segment revealed central stromal haze in both eyes with significant confluent staining of the epithelium of the inferior cornea, which was graded at 2+. Bilateral central stro-

mal haze was also observed using an anterior segment optical coherence tomography (OCT) imaging system (Visante™, Zeiss, Jena, Germany) (Figure 1A shows the right eye and Figure 1B shows the left eye). Furthermore, the demarcation line as a result of the CXL procedure could be observed and the corneal haze extended through the anterior and posterior stroma. Mild to moderate meibomian gland dysfunction was noted in both eyes. Tear breakup times (TBUT) were 4 seconds and 5 seconds in the right and left eyes, respectively. A phenol red thread test (PRTT) gave results of 22mm in the right eye and 18mm in the left eye, which ruled out aqueous-deficient dry eye.

Figure 1A

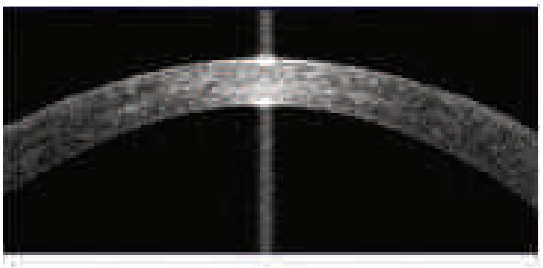


Figure 1B

Corneal topographies obtained with a Pentacam™ system (Oculus, Wetzlar, Germany) revealed simulated keratometry values of 38.4D@168°/ 40.0D in the right eye and 38.8D@67.5°/ 39.6D in the left eye (Figure 2).

Figure 2A

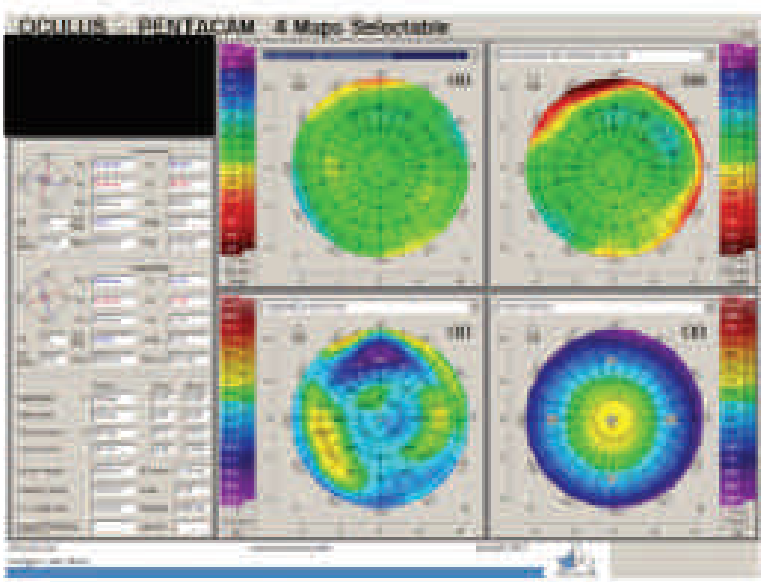
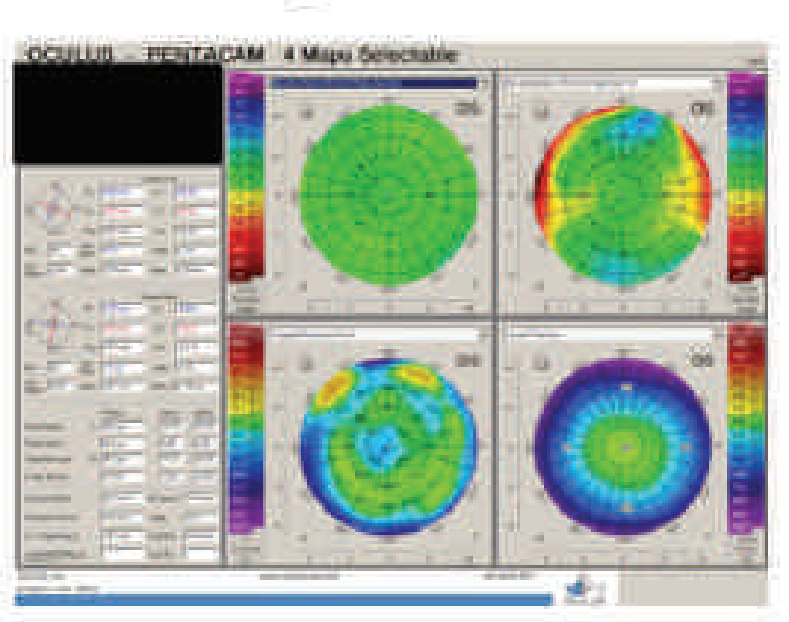


Figure 2B



According to her prior medical records at the refractive surgery consultation, her baseline simulated keratometry readings were 43.00D@097°/ 45.00 in the right eye and 45.00D@015°/ 46.00 in the left eye. Pachymetry results revealed a thinnest-point reading of 564µm in the right eye and a thinnest-point reading ranging from 247 µm to 555µm with large variability across multiple scans in the left eye. Mild-to-moderate meibomian gland dysfunction without corneal abnormalities was noted on an anterior segment health check.

We concluded that the patient exhibited visual symptoms secondary to corneal haze as a result of having undergone T-PRK and CXL, as well as evaporative dry eye symptoms that worsened following the procedure. After extensive discussions with the patient on management options, we decided that she might benefit from specialty contact lenses. The initial specialty contact lens option considered for this patient was scleral lenses. In anticipation of easier adaptation, we chose a scleral lens with a smaller overall diameter and a thinner center thickness. According to the Rose K2 XL™ (Blanchard Laboratories, Sherbrooke, Quebec) fitting guide21, we selected the following diagnostic lenses:

OD: Rose K2 XL / 8.00/ 14.6/ plano/ Standard periphery

OS: Rose K2 XL / 8.10/ 14.6/ plano/ Standard periphery

The lenses were applied and a settling time of 30min was allowed. The lens fitting characteristics were then examined. Both lenses demonstrated excessive clearance centrally and minimal clearance limbally. The lenses were well-centered and provided good coverage. Mild edge lift was noted in both eyes at 3 and 9 o'clock . The patient also reported mild-moderate lens awareness in both eyes. The fit of the lenses was deemed to be too steep centrally. Based on the assessment and over-refraction of the trial lenses, we placed a final order with the following parameters:

OD: Rose K2 XL / 8.00/ 14.8/ -4.00/ Decreased edge lift #1

OS: Rose K2 XL / 8.30/ 14.8/ -2.75/ Decreased edge lift #1

Follow-up #1
At the lens delivery appointment, the fit of the lenses was deemed appropriate, with adequate central clearance. The patient continued to report mild-moderate lens awareness. She was counselled that initial lens awareness is appropriate for a novice scleral lens wearer, and informed to slowly increase wear time to ease the adaptation process, beginning with two to three hours daily until her next follow-up appointment. She was also instructed how to properly insert and remove the scleral lenses along with proper handling techniques. The lenses were dispensed to the patient along with a starter kit of Daily Boston Simplus ® solution (Bausch and Lomb, Rochester, NY).

Follow-up #2
At the two-week follow-up appointment, lens assessment using a biomicroscope confirmed that the lenses were well centered with an appropriate apical clearance of approximately 75 microns in accordance with the Rose K2 XL fitting manual.21 Mild, but tolerable, compression in the limbal zone was noted superiorly and inferiorly in both eyes. The spherocylindrical over-refraction was +1.00-2.00x105 (6/7.5) in the right eye and +0.25-1.00x090 (6/7.5^{-3}) in the left eye. However, while the patient reported a reduction in her symptoms of dryness with lens wear, she was dissatisfied with the general comfort of the contact lenses, and noted greater lens awareness in the left eye compared to the right eye. Ultimately, we concluded that the patient should discontinue the use of scleral lenses due to inadequate comfort and poor adaptation to this type of lens.

The patient was refitted with Kerasoft® IC (Bausch + Lomb), a custom soft keratoconic lens design, as an alternative for the management of her visual symptoms. We ordered lenses with the following parameters:

OD: Kerasoft® IC / 8.20/ 14.5/ -0.50 -0.75 x 052 / Flat #1 periphery

OS: Kerasoft® IC / 8.60/ 14.5/ -1.25 -1.00 x 075/ Standard periphery

Follow-up #3
At the two-week follow-up appointment for the Kerasoft® IC lenses, the patient was quite content and reported a subjective improvement in the quality of her vision with lens wear and no eye fatigue. She reported good overall comfort with the lenses. However, she was only able to wear her lenses for two hours per day, after which her vision became foggy. She was using Biotrue™ multipurpose solution (Bausch + Lomb) to clean and store the lenses on a nightly basis. The patient achieved visual acuities of 6/7.5 in the right eye and 6/9+ in the left eye with no significant improvement in vision with a spherical over-refraction. In a lens assessment, both lenses were observed to be well centered with adequate movement on primary gaze and upgaze. The rotation was stable at 5 degrees counter-clockwise in the right eye and 12 degrees counter-clockwise in the left eye. A moderate amount of lipid deposits was found on her lenses. At the end of the appointment, we decided that she should continue with her lenses with no changes in the parameters, but to switch her care system to Peroxiclear™ (Bausch + Lomb). Complete Blink and Clean™ eye drops (Abbott Medical Optics, Abbott Park, IL) were recommended as needed during contact lens wear.

Follow-up #4
The patient reported good results with Kerasoft® IC lenses. Her wear time had increased to seven hours per day for three to four days per week with the change in her care system and the use of Complete Blink and Clean™ eye drops (Abbott Medical Optics) four times daily. The patient continued to experience subjective glare with the lenses, likely as a result of her large pupil size in photopic and scotopic conditions and the significant corneal haze secondary to the simultaneous T-PRK and CXL procedures. The custom soft keratoconic lenses successfully restored her functional vision for normal daily activities. She will be followed-up quarterly.

DISCUSSION

Pellucid marginal degeneration (PMD) is a progressive non-inflammatory keratoectasia resulting in inferior corneal thinning and irregular astigmatism.[1–3] The use of gas permeable corneal and scleral contact lenses can correct the irregular astigmatism that is induced as the condition progresses and the cornea thins. It has been shown that simultaneous T-PRK and CXL can increase the effectiveness of CXL by allowing better penetration of the riboflavin solution used with CXL, due to the absence of Bowman's layer and a partially ablated stroma.[20] The use of simultaneous procedures may also reduce the sub-epithelial haze that commonly follows PRK.[6] The combined T-PRK and CXL technique can be an effective option for the management of PMD and can improve the prognosis by reducing the amount and irregularity of the corneal astigmatism. However, little

information is available regarding complications and patient satisfaction following the procedure. This case study presented a 41-year-old female patient who exhibited clinically significant permanent corneal haze and dry eye symptoms after undergoing combined T-PRK and CXL.

Permanent corneal haze following CXL is defined as a stromal opacity that persists for more than six months post-CXL, and has been documented in 5% to 8.6% of cases.[22,23] The corneal opacity that follows CXL typically spans the anterior 300 microns of stroma and can be differentiated from the sequelae post-PRK because the latter is sub-epithelial and much shallower.[15,18,24,25] Furthermore, this long-term CXL complication is differentiated from the transient lacunar honeycomb-like central opacity that occurs within the anterior 300 microns of the corneal stroma present in all eyes at 1-month post-CXL.[26,27] The presence of a transient haze, which only extends throughout the depth of the corneal stroma affected by CXL, is an expected indication of a successful CXL procedure. With the use of topical preservative-free steroid therapy, which is typically prescribed for 1 to 3 months postoperatively, the decrease in corneal transparency subsides over 6 months to 1 year following CXL, and coincides with the completion of keratocyte repopulation.[22,27] On the other hand, a permanent stromal haze reflects changes in crystalline proteins and lamellar interconnections induced by the interaction of riboflavin and ultraviolet A radiation.[28,29] While this steroid-resistant haze has not been shown to cause any reduction in high-contrast visual acuity, it may increase the backscatter of light that is internally reflected within the cornea.[22,29–31] Thus, it may have led to the degradation of visual quality and the debilitating symptoms of glare and visual distortion due to these aberrations experienced by the patient in this case. Raiskup et al. noted a higher risk of permanent stromal haze following CXL in cases of severe keratoectasia with steeper pre-operative keratometric values.[23] These cases likely presented with intrinsic stromal anomalies associated with keratoectasia, such as micro-striae and hyper-activated keratocyte nuclei in the stromal tissue, and with the presence of Vogt's striae prior to the CXL procedure.[23]

Regarding possible treatments, no studies to date have investigated the potential benefits of reducing the post-CXL stromal haze with the use of mitomycin C, an anti-proliferative agent that has been shown to reduce the risk of post-PRK corneal haze.[32] However, the use of mitomycin C in patients with keratoectasia may be potentially contra-indicated due to the cytotoxic properties of mitomycin C, and the role it plays in inducing keratocyte apoptosis may increase the risk of accelerating further corneal thinning.

Our patient exhibited significant corneal haze that spanned the full stromal thickness in both eyes, as demonstrated in the anterior segment OCT scans in Figure 1. The scans also demonstrate a demarcation line through the stroma that signifies the extent of anterior stroma that had been affected by CXL.[15,18,25-27,30,33] This presentation of stromal opacity that extends into the posterior stroma is atypical of post-CXL stromal haze. Güell et al. reported posterior stromal haze developing 5 months after simultaneous T-PRK and CXL in a 22-year-old patient with forme fruste keratoconus.[34] In another case series, linear hyper-reflective structures were noted in 13 of 28 eyes that had undergone simultaneous T-PRK and CXL for the management of keratoconus.35 However, the authors did not find any correlation between the prevalence of posterior stromal haze and the patient's preoperative corneal thickness or ablation depth.

Dryness after kerato-refractive surgery is one of the primary causes of patient post-operative dissatisfaction.[36] Interruption of the neural feedback system due to a reduction in corneal sensitivity has been proposed to be the primary cause of dry eye after kerato-refractive surgery.[37,38] In the case of combined T-PRK and CXL, the epithelium is removed using either topical alcohol, mechanical scraping, a rotating brush, or a laser, followed by irradiation of the anterior 300 microns of stromal tissue with UVA.[20,39,40] This procedure leads to disruption of the sub-epithelial and anterior-mid stromal nerve plexus, resulting in transiently reduced lacrimal gland production within the first six months post-operatively.[29,38,39] Regeneration of the sub-epithelial plexus from the surrounding non-irritated area begins at the end of the first month, while extension of the deeper stromal nerve plexus into the anterior stroma can be observed as early as the second to third month.[29] With the use of confocal microscopy, studies have confirmed that the number of nerve fibres is essentially restored to preoperative baseline values by six months after the procedure, but the interconnections between neural fibres continue to increase up until two years after the procedure.[29,41] Corneal sensitivity returns to its preoperative baseline within one year after the procedure, and basic tear secretion and tear film stability should be restored concurrently. [29,42,43]

In this patient, PRTT of greater than 15mm was measured in both eyes along with a decreased TBUT, which suggested the presence of other factors that may have contributed to the signs and symptoms of dryness. Firstly, the cornea takes on an oblate topography after undergoing kerato-refractive surgery. The irregularity of the corneal surface, as confirmed by the presence of an oblique corneal cylinder, may act as an obstacle for the even distribution of the tear

film with blinking. Secondly, the discrepancy between reported symptoms and signs of dryness can be explained by an altered excitability in regenerated nerves caused by the induced inflammatory process after corneal nerve injury.[44] Thirdly, the long-term use of antidepressant and antianxiety medications has been known to have an anti-cholinergic effect, which results in decreased aqueous production and dry eye symptoms.[45,46] Finally, a natural decrease in goblet cell population with age can contribute to a compromised mucin layer that results in the instability of the tear film.[39,47]

In this case study, a 41-year-old patient underwent simultaneous T-PRK and CXL shortly after a diagnosis of PMD. For a patient who was visually asymptomatic prior to her diagnosis, her quality of life is arguably decreased post-operatively due to her debilitating symptoms of glare, light sensitivity, and dryness. Bilateral and permanent post-CXL corneal haze and the resultant increase in internal reflectivity (light scatter) within the stromal tissue are responsible for her visual symptoms. These symptoms are likely exacerbated by her larger-than-average scotopic and photopic pupil sizes of 8mm and 5mm, respectively. The T-PRK and CXL procedures exacerbated her dry eye symptoms; she was already at high risk given her age, a pre-operative history of meibomian gland dysfunction and the use of an oral contraceptive, and her current use of antidepressant and anti-anxiety medications. While this patient is now being successfully managed with specialty soft toric lenses for her irregular cornea, careful screening pre-operatively, while paying special attention to pupil size and ocular history, may help identify patients who are at higher risk of developing undesirable outcomes.

CONCLUSION

Simultaneous T-PRK and CXL can effectively improve corrected and uncorrected visual acuities while slowing the progression of PMD and other keratoectasiae.[8,10] This combination may effectively delay the need for more invasive management such as penetrating keratoplasty and implantation of intrastromal ring segments.[17] This case report reviewed two significant long-term complications after these procedures (glare associated with persistent stromal haze and chronic dryness), which resulted in the patient's dissatisfaction with the outcome. A more careful consideration of inclusion criteria for these procedures may ultimately increase the relative benefits of slowing the progression of PMD while decreasing the relative risks of complications. ●

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Étude de cas : Utilisation de lentilles de contact pour la prise en charge des complications suite à une intervention combinant réticulation cornéenne et kératectomie photoréfractive guidée par topographie pour la dégénérescence pellucide marginale

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Résumé

Ce cas décrit deux complications à long terme importantes rencontrées par une patiente après le traitement de la dégénérescence pellucide marginale (DPM). Deux ans après avoir subi une kératectomie photoréfractive guidée par topographie (T-PRK) combinée à une procédure de réticulation du collagène cornéen (CXL), la patiente continuait à éprouver des éblouissements et une sécheresse associés à une opacité stromale persistante et à un œil sec. Ces procédures ont causé une insatisfaction avec le résultat final, ce qui a conduit la patiente à utiliser des lentilles de contact pour corriger sa vision. La prise en charge des séquelles oculaires symptomatiques avec des lentilles de contact toriques souples spécialement conçues pour les cornées irrégulières a favorisé sa rééducation visuelle.

MOTS CLÉS :
Kératectomie photoréfractive guidée par topographie (T-PRK), réticulation du collagène cornéen (CXL), dégénérescence pellucide marginale (DPM), opacité stromale, œil sec

La dégénérescence pellucide marginale (DPM) est une pathologie ectasique non inflammatoire progressive impliquant la région périphérique inférieure de la cornée[1–3]. Dans cette affection, un amincissement en forme de croissant s'étendant des positions 4 heures à 8 heures se produit dans la cornée périphérique. Alors que le degré d'astigmatisme irrégulier dépend de la gravité de la maladie, la distorsion visuelle secondaire à la DPM est généralement asymptomatique dans les premiers stades, car la zone d'amincissement n'implique pas l'axe visuel. C'est pourquoi la topographie cornéenne est la méthode diagnostique de référence pour cette affection[3]. La pratique courante dans la prise en charge des DPM comprend des lunettes, des lentilles de contact et des interventions chirurgicales telles que la kératoplastie lamellaire ou pénétrante[1,4,5]. Récemment, une kératectomie photoréfractive guidée par topographie simultanée (T-PRK) et des procédures de réticulation du collagène cornéen (CXL) ont été utilisées pour traiter la DPM et d'autres causes de kératectasie dans le but de ralentir la progression de la maladie, de minimiser l'irrégularité cornéenne et de réduire la nécessité d'une transplantation cornéenne[6–10].

La T-PRK implique une ablation du tissu stromal cornéen « sur mesure » au laser Excimer guidé par l'aberrométrie du front d'onde, la tomographie et la topographie[11–13]. En aplatissant l'apex cornéen ou le tissu élevé et raidi adjacent aux zones ectasiques, cette procédure normalise la cornée en réduisant l'astigmatisme et l'irrégularité de la surface de la cornée[6,11,13]. Le CXL utilise l'effet photosensibilisant de la riboflavine et les rayons ultraviolets A (UVA) pour induire la polymérisation des fibres de collagène dans les 200 à 300 microns antérieurs du stroma cornéen[14–18]. Le CXL augmente efficacement la rigidité cornéenne et la force biomécanique par trois fois[8,17,19]. Il entraîne également un aplatissement simultané de la zone la plus abrupte et une accentuation de la courbure des zones adjacentes autour du cône, ce qui diminue l'asymétrie cornéenne et l'aberration sphérique[19]. La combinaison de ces procédures, le CXL étant réalisé immédiatement après la T-PRK, est bénéfique dans la gestion de l'ectasie cornéenne[8 10]. Il a été démontré que le temps d'intervention peut être réduit si ces procédures sont effectuées simultanément[20]. Ceci permet également à la riboflavine d'atteindre les couches profondes du tissu stromal et d'y induire la réticulation du collagène[20]. De plus, ceci minimise le risque de cicatrices stromales superficielles résultant de la PRK en diminuant l'activité des fibroblastes après l'ablation des kératocytes6. L'inversion de l'ordre dans lequel les procédures sont effectuées aboutirait soit à l'élimination du tissu cornéen réticulé durci, soit à une réduction du taux d'ablation des tissus réticulés possédant des propriétés biomécaniques modifiées, aucun de ces résultats n'étant bénéfique[8,10,20].

L'efficacité de la T-PRK et du CXL effectués simultanément pour suspendre temporairement la progression de l'ectasie et améliorer les acuités visuelles non corrigées et corrigées dans les cas de DPM a été bien documentée[8,10]. Cependant, il y a peu d'information disponible en ce qui concerne les complications qui peuvent survenir suite à ces procédures. Ce rapport de cas décrit deux de ces complications (opacité permanente du stroma cornéen et œil sec) et leur prise en charge.

RAPPORT DE CAS

Une femme de 41 ans de race blanche s'est présentée à la clinique de lentilles cornéennes de l'École d'optométrie et de sciences de la vision de l'Université de Waterloo pour une consultation sur les lentilles de contact spécialisées. Ses principales préoccupations visuelles comprenaient une sensibilité à la lumière et un problème d'éblouissement importants, qui étaient tous deux suffisamment graves pour avoir une incidence sur ses activités quotidiennes. D'après les renseignements qui figuraient à son dossier oculaire, une DPM bilatérale avait été diagnostiquée cinq ans auparavant lors d'un rendez-vous de consultation en vue d'une chirurgie réfractive, en 2010. Peu après le diagnostic, elle a subi une intervention combinant une T-PRK suivie d'un CXL dans les deux yeux. La patiente attribue ses symptômes visuels débilitants et son problème d'œil sec à ces procédures. Dans l'ensemble, sa santé générale était bonne, exception faite de migraines occasionnelles. Un examen médical antérieur avait exclu le syndrome de Sjögren. Les médicaments qu'elle prenait au moment de la consultation comprenaient la cyclosporine (Restasis®), la duloxétine (Cymbalta®), le Lorazépam et la zopiclone (Imovane®).

Ses antécédents médicaux oculaires comptaient une expérience antérieure avec des lentilles souples jetables perméables au gaz qui n'avait pas été couronnée de succès, principalement en raison de ses symptômes sévères de sécheresse, qui ont finalement conduit à une intolérance aux lentilles de contact. On lui avait déjà prescrit une série de traitements standard pour les yeux secs, dont les soins d'hygiène de la paupière et les compresses chaudes, l'application fréquente de larmes artificielles avec et sans composants lipidiques, un traitement d'un mois de lotéprednol topique, deux ans de cyclosporine A topique et une occlusion du méat inférieur bilatérale. Aucune de ces thérapies antérieures n'avait rétabli le confort visuel de la patiente à un niveau qui lui permettait d'exercer ses activités quotidiennes.

Au cours de l'examen oculaire, la réfraction était de -0,75/-2,50 x 148 (6/9^{-2}) pour l'œil droit et -0,25/-2,25 X 057 (6/9^{+2}) pour l'œil gauche. Toutes les analyses de départ étaient normales. Ses pupilles étaient de taille égale à environ 8,0 mm dans des conditions scotopiques et 5,0 mm dans des conditions photopiques.

L'examen du segment antérieur au biomicroscope a révélé une opacité stromale centrale dans les deux yeux, avec une prise fluo significative de l'épithélium de la cornée inférieure, classé à 2+. On a également observé une opacité stromale centrale bilatérale à l'aide d'un système d'imagerie par tomographie à cohérence optique (OCT) du segment antérieur (Visante™, Zeiss, Jena, Allemagne) (la figure 1A montre l'œil droit et la figure 1B montre l'œil gauche). En outre, la ligne de démarcation résultant de la procédure CXL pouvait être observée et l'opacité cornéenne s'étendait à travers le stroma antérieur et postérieur. Un dysfonctionnement léger à modéré de la glande de Meibomian a été observé dans les deux yeux. Le Tear break-up time (TBUT) était de 4 secondes pour l'œil droit et de 5 secondes pour l'œil gauche. Un test du fil de coton au phénol rouge (phenol red thread test, PRTT) a donné des résultats de 22 mm dans l'œil droit et de 18 mm dans l'œil gauche, ce qui a exclu l'œil sec avec insuffisance lacrymale.

Figure 1A

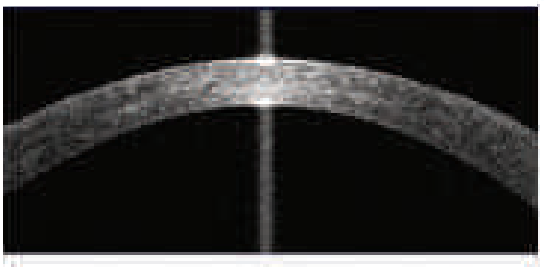


Figure 1B

Les topographies cornéennes obtenues avec un système Pentacam™ (Oculus, Wetzlar, Allemagne) ont révélé des valeurs de kératométrie simulées de 38,4D@16,8 °/40,0D dans l'œil droit et de 38,8D@67,5°/39,6D dans l'œil gauche (figure 2).

Figure 2A

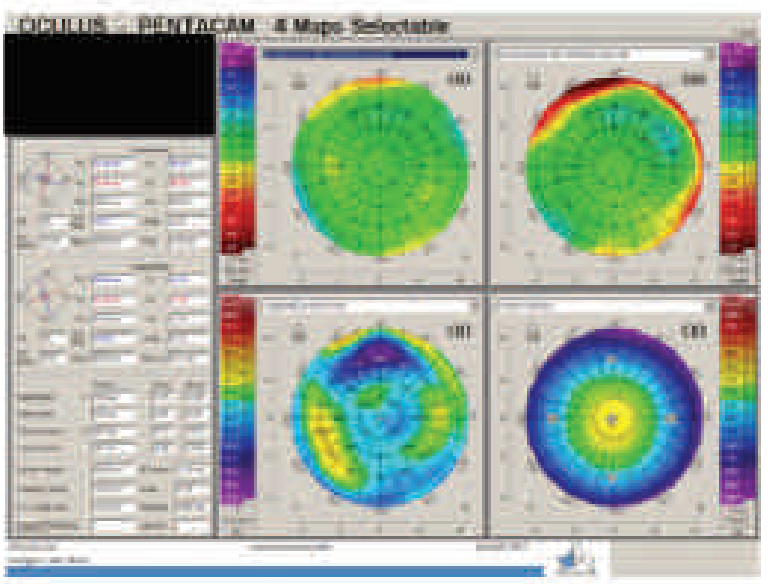
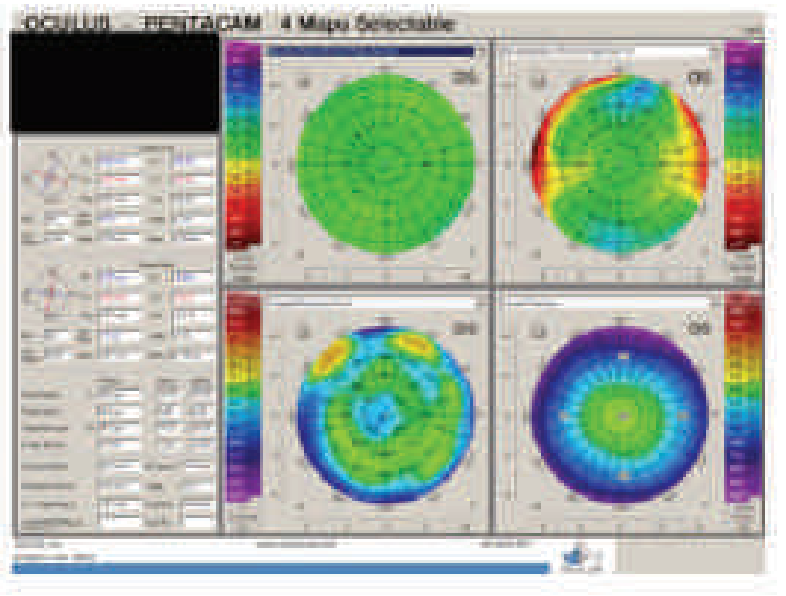


Figure 2B



D'après les renseignements consignés dans son dossier médical au moment de la chirurgie réfractive, ses lectures kératométriques simulées de base étaient de 43,00D@097°/45,00 dans l'œil droit et de 45,00D@015°/46,00 dans l'œil gauche. La pachymétrie mesurée au point le plus mince était de 564 µm dans l'œil droit et allait de 247 µm à 555 µm dans l'œil gauche avec une grande variabilité entre les mesures. Un dysfonctionnement léger à modéré de la glande de Meibomian sans anomalies cornéennes a été noté lors d'un examen du segment antérieur.

Nous avons conclu que le patient présentait des symptômes visuels secondaires à l'opacité cornéenne survenue suite à la T-PRK et au CXL, ainsi qu'aux symptômes de kératoconjonctivite sèche qui se sont aggravés après la procédure. Suite à des discussions approfondies sur les options de prise en charge avec la patiente, nous avons décidé qu'elle pourrait bénéficier de lentilles de contact spécialisées. Les premières lentilles de contact spécialisées prises en considération pour cette patiente étaient des lentilles sclérales. Pour faciliter l'adaptation, nous avons choisi une lentille sclérale avec un diamètre global plus petit et une épaisseur centrale plus mince. Selon le guide d'ajustement Rose K2 XL™[21] (Blanchard Laboratories, Sherbrooke, Québec), nous avons sélectionné les lentilles diagnostiques suivantes :

OD : Rose K2 XL/8,00/14,6/plan/Périphérie standard

OS : Rose K2 XL/8,10/14,6/plan/Périphérie standard

Les lentilles ont été appliquées, avec un temps de stabilisation de 30 minutes. Leurs caractéristiques d'ajustement ont ensuite été examinées. Les deux lentilles ont démontré un dégagement apical excessif et un dégagement minimal du limbe. Les lentilles sont bien centrées et offrent une bonne couverture. Une légère élévation du bord a été notée dans les deux yeux à 3 et 9 heures. La patiente a également signalé une sensation de corps étranger due à la lentille de légère à modérée chez les deux yeux. L'ajustement des lentilles était jugé trop cambré au centre. Sur la base de l'évaluation et de la surréfraction des lentilles d'essai, nous avons placé une commande finale avec les paramètres suivants :

OD : Rose K2 XL/8,00/14,8/-4,00/Diminution de l'élévation du bord n° 1

OS : Rose K2 XL/8,30/14,8/-2,75/Diminution de l'élévation du bord n° 1

Première visite de suivi
Au rendez-vous de délivrance des lentilles, l'ajustement des lentilles a été jugé approprié, avec un dégagement apical adéquat. La patiente a continué de signaler une sensation de corps étranger légère à modérée. Elle a été avisée que cette sensation initiale de lentille est normale pour un porteur de lentille sclérale novice, et on lui a recommandé d'augmenter lentement le temps de port pour faciliter le processus d'adaptation, en commençant par deux à trois heures par jour jusqu'à son prochain rendez-vous de suivi. On lui a également expliqué comment insérer et enlever les lentilles sclérales correctement avec des techniques de manipulation appropriées. Les lentilles ont été délivrées à la patiente avec une trousse de départ de la solution Daily Boston Simplus ® (Bausch et Lomb, Rochester, NY).

Deuxième visite de suivi
Au cours de la visite de suivi de deux semaines, l'évaluation des lentilles à l'aide d'un biomicroscope a confirmé que les lentilles étaient bien centrées avec un dégagement apical approprié d'environ 75 microns, conformément au manuel d'ajustement Rose K2 XL[21]. Une compression légère, mais tolérable du limbe a été notée dans la région supérieure et inférieure des deux yeux. La surréfraction sphérocylindrique était de +1,00-2,00x105 (6/7,5) dans l'œil droit et de +0,25-1,00x090 (6/7,5^{-3}) dans l'œil gauche. Cependant, bien que la patiente ait signalé une réduction de ses symptômes de sécheresse avec le port des lentilles, elle était insatisfaite du confort général des lentilles de contact et notait que la sensation de corps étranger due à la présence de la lentille était plus forte dans l'œil gauche que dans l'œil droit. En fin de compte, nous avons conclu que la patiente devrait cesser l'utilisation de lentilles sclérales en raison d'un confort insuffisant et d'une mauvaise adaptation à ce type de lentille.

La procédure d'ajustement a été répétée avec des Kerasoft® IC (Bausch + Lomb), une lentille kératocônique souple « sur mesure », comme alternative pour la gestion de ses symptômes visuels. Nous avons commandé des lentilles avec les paramètres suivants :

OD : Kerasoft® IC/8,20/14,5/-0,50 -0,75 x 052/Périphérie aplatie n° 1

OS : Kerasoft® IC/8,60/14,5/-1,25 -1,00 x 075/Périphérie standard

Troisième visite de suivi
Lors du rendez-vous de suivi de deux semaines pour les verres Kerasoft® IC, la patiente s'est montrée satisfaite et a rapporté une amélioration subjective de la qualité de sa vision sans fatigue oculaire avec le port des lentilles. Elle a déclaré un bon confort général avec les lentilles. Cependant, elle ne pouvait porter ses lentilles que deux heures par jour, après quoi sa vision devenait voilée. Elle utilisait la solution polyvalente Biotrue™ (Bausch + Lomb) pour nettoyer et entreposer les lentilles chaque soir. La patiente a obtenu des acuités visuelles de 6/7,5 dans l'œil droit et 6/9 + dans l'œil gauche sans amélioration significative de la vision avec une surréfraction sphérique. Dans une évaluation des lentilles, les deux lentilles étaient bien centrées avec un mouvement adéquat pour le regard fixe primaire ou le regard vers le haut. La rotation était stable à 5 degrés dans le sens inverse des aiguilles d'une montre dans l'œil droit et à 12 degrés dans le sens inverse des aiguilles d'une montre dans l'œil gauche. Une quantité modérée de dépôts lipidiques a été trouvée sur ses lentilles. À la fin du rendez-vous, nous avons décidé de continuer avec ces lentilles sans changer les paramètres, mais de passer de son système de soins à Peroxiclear™ (Bausch + Lomb). Des gouttes oculaires Blink et Clean™ complètes (Abbott Medical Optics, Abbott Park, IL) ont été recommandées au besoin pendant le port des lentilles de contact.

Quatrième visite de suivi
La patiente a signalé de bons résultats avec les verres Kerasoft® IC. Son temps d'utilisation était passé à sept heures par jour, trois à quatre jours par semaine avec le changement de son système de soins et l'utilisation de gouttes pour les yeux Complete Blink and Clean™ (Abbott Medical Optics) quatre fois par jour. La patiente a continué à éprouver un éblouissement subjectif avec les lentilles, probablement en raison de la grande taille de ses pupilles en conditions photopique et scotopique et de l'opacité cornéenne importante survenue suite aux procédures de T-PRK et de CXL simultanées. Les lentilles kératocôniques souples personnalisées ont rétabli avec succès sa vision fonctionnelle pour les activités quotidiennes normales. Elle sera suivie tous les trois mois.

DISCUSSION

La dégénérescence pellucide marginale (DPM) est une kératectasie non inflammatoire progressive qui cause un amincissement de la région inférieure de la cornée et un astigmatisme irrégulier[1–3]. L'utilisation de lentilles de contact sclérocornéennes perméables aux gaz peut corriger l'astigmatisme irrégulier qui est induit à mesure que la maladie progresse et que la cornée s'amincit. Il a été démontré que la T-PRK et le CXL simultanés peuvent augmenter l'efficacité du CXL

en permettant une meilleure pénétration de la solution de riboflavine utilisée avec le CXL, en raison de l'absence de la couche de Bowman et de la résection partielle du stroma[20]. Des procédures simultanées peuvent aussi réduire l'opacité sous-épithéliale qui suit généralement la PRK[6]. La technique combinant la T-PRK et le CXL peut être une option efficace pour la prise en charge de la DPM et peut améliorer le pronostic en réduisant le degré et l'irrégularité de l'astigmatisme cornéen. Cependant, il y a peu d'information sur les complications et la satisfaction des patients après l'intervention. Cette étude de cas a présenté une patiente âgée de 41 ans qui présentait une opacité cornéenne permanente cliniquement significative et des symptômes de sécheresse oculaire après avoir subi une T-PRK et un CXL combinés.

L'opacité cornéenne permanente suite au CXL est définie comme une opacité stromale qui persiste pendant plus de six mois après le CXL et a été documentée dans 5 % à 8,6 % des cas[22,23]. L'opacité cornéenne qui suit un CXL s'étend généralement à travers les 300 microns antérieurs du stroma et peut être différenciée des séquelles de la PRK parce que celles ci sont sous-épithéliales et beaucoup moins profondes[15,18,24,25]. Par ailleurs, cette complication à long terme du CXL est différente de l'opacité centrale lacunaire transitoire de type nid d'abeilles qui se produit dans les 300 microns antérieurs du stroma cornéen, présente dans tous les yeux à 1 mois après le CXL[26,27]. La présence d'une opacité transitoire, qui ne s'étend qu'à travers la profondeur du stroma cornéen affecté par le CXL est un signe que la procédure de CXL est réussie. Avec l'utilisation d'un traitement stéroïdien topique sans conservateur, qui est généralement prescrit pendant 1 à 3 mois suite à l'intervention, la perte de transparence de la cornée diminue sur une période de 6 mois à 1 an après le CXL, ce qui coïncide avec l'achèvement du repeuplement kératocytaire[22,27]. D'autre part, une opacité stromale permanente reflète les changements dans les protéines cristallines et les interconnexions lamellaires induits par l'interaction de la riboflavine et des rayons ultraviolets A[28,29]. Bien qu'il n'ait pas été montré que cette opacité résistante aux stéroïdes entraîne une réduction de l'acuité visuelle à fort contraste, elle peut augmenter la rétrodiffusion de la lumière qui est réfléchie à l'intérieur de la cornée[22,29–31]. Il est donc possible qu'elle ait conduit à la dégradation de la qualité visuelle et aux symptômes débilitants d'éblouissement et de distorsion visuelle dus à ces aberrations qu'a ressentis la patiente dans ce cas. Raiskup et coll. ont noté un risque plus élevé d'opacité stromale permanente après la CXL dans les cas de kératectasie sévère avec des valeurs kératométriques préopératoires plus élevées[23]. Ces cas présentaient probablement des anomalies stromales intrinsèques associées aux kératectasies telles que des microstries et des noyaux de kératocytes hyperactivés dans le tissu stromal, et la présence de stries de Vogt avant la procédure de CXL[23].

En ce qui concerne les traitements possibles, il n'y a eu aucune étude à ce jour sur les avantages potentiels de la mitomycine C, un agent antiprolifératif dont on a montré qu'il réduit le risque d'opacité cornéenne suite à une PRK, sur la réduction de l'opacité stromale qui survient après un CXL32. L'utilisation de la mitomycine C chez les patients atteints de kératectasie peut être potentiellement contre-indiquée en raison des propriétés cytotoxiques de la mitomycine C et le rôle qu'elle joue dans l'induction de l'apoptose des kératocytes peut augmenter le risque d'accélérer l'amincissement cornéen.

Notre patiente a présenté une opacité cornéenne importante à travers toute l'épaisseur du stroma dans les deux yeux, comme montré dans les lectures d'OCT du segment antérieur à la figure 1. Les lectures montrent également une ligne de démarcation à travers le stroma qui indique l'étendue du stroma antérieur affecté par le CXL[15,18,25 27,30,33]. Cette présentation de l'opacité stromale qui s'étend dans le stroma postérieur est atypique de l'opacité stromale qui apparaît après la procédure de CXL. Güell et coll. ont rapporté le développement d'une opacité stromale postérieure 5 mois après une intervention de T-PRK et de CXL simultanés chez un patient de 22 ans avec un kératocône fruste[34]. Dans une autre série de cas, des structures linéaires hyperréfléchissantes ont été observées dans 13 des 28 yeux qui avaient subi une T-PRK et un CXL simultanés pour la prise en charge du kératocône[35]. Cependant, les auteurs n'ont trouvé aucune corrélation entre la prévalence de l'opacité stromale postérieure et l'épaisseur préopératoire de la cornée du patient ou la profondeur de l'ablation.

La sécheresse qui survient après une intervention kératoréfractive est l'une des principales causes de l'insatisfaction des patients suite à l'intervention[36]. L'interruption du système de rétroaction neurale due à une réduction de la sensibilité cornéenne a été proposée comme principale cause de l'œil sec après une intervention kératoréfractive[37,38]. Dans le cas de procédures de T-PRK et de CXL combinées, on élimine l'épithélium en utilisant de l'alcool topique, un grattage mécanique, une brosse rotative ou un laser, suivi d'une irradiation des 300 microns antérieurs du tissu stromal avec des UVA[20,39,40]. Cette procédure entraîne la rupture du plexus nerveux sous-épithélial et antérieur-médian du stroma, ce qui entraîne une diminution transitoire de la production des glandes lacrymales dans les six premiers mois qui suivent l'intervention[29,38,39]. La régénération du plexus sous-épithélial à partir de la zone non irritée environnante commence à la fin du premier mois, tandis que l'extension du plexus nerveux stromal plus profond dans le stroma antérieur peut être observée dès le deuxième ou le troisième mois[29]. Des études par microscopie confocale ont confirmé que le nombre de fibres nerveuses est essentiellement rétabli aux valeurs de base préopératoires six mois après la procédure, alors que le nombre d'interconnexions entre les fibres neurales continue à augmenter jusqu'à deux ans après la procé-

dure[29,41]. La sensibilité cornéenne retourne à sa ligne de base préopératoire dans l'année qui suit la procédure, et la sécrétion de larme de base et la stabilité du film lacrymal sont habituellement restaurées simultanément[29,42,43].

Chez cette patiente, on a mesuré une PRTT supérieure à 15 mm dans les deux yeux avec un TBUT réduit, ce qui suggère la présence d'autres facteurs pouvant avoir contribué aux signes et symptômes de sécheresse. Tout d'abord, la cornée prend une topographie oblate après une chirurgie kératoréfractive. L'irrégularité de la surface de la cornée, confirmée par la présence d'un cylindre cornéen oblique, peut constituer un obstacle à la répartition régulière du film lacrymal lors du clignement de l'œil. Deuxièmement, l'écart entre les symptômes signalés et les signes de sécheresse peut s'expliquer par une excitabilité altérée dans les nerfs régénérés causée par le processus inflammatoire induit après une lésion du nerf cornéen[44]. Troisièmement, on sait que l'utilisation à long terme d'anxiolytiques a un effet anti-cholinergique qui entraîne une diminution de la production aqueuse et des symptômes d'œil sec[45,46]. Enfin, la diminution naturelle de la population de cellules caliciformes avec l'âge peut contribuer à compromettre la couche de mucine, ce qui se traduit par l'instabilité du film lacrymal[39,47].

Dans cette étude de cas, une patiente de 41 ans a subi une intervention combinant une T-PRK et un CXL peu de temps après un diagnostic de DPM. Si l'on prend en considération le fait que la patiente était visuellement asymptomatique avant son diagnostic, sa qualité de vie a sans doute diminué après l'opération en raison de ses symptômes débilitants d'éblouissement, de sensibilité à la lumière et de sécheresse. L'opacité cornéenne bilatérale et permanente qui s'est développée suite au CXL et l'augmentation de la réflectivité interne (diffusion de la lumière) dans le tissu stromal qui en a résulté sont responsables de ses symptômes visuels. Ces symptômes sont probablement exacerbés par ses pupilles plus grandes que la moyenne, soit environ 8,0 mm dans des conditions scotopiques et 5,0 mm dans des conditions photopiques. Les procédures de T-PRK et de CXL ont exacerbé ses symptômes de sécheresse oculaire; elle était déjà à haut risque en raison de son âge, d'une histoire préopératoire de dysfonctionnement de la glande de Meibomian, de l'utilisation d'un contraceptif oral, et de son utilisation actuelle de médicaments antidépresseurs et anxiolytiques. Bien que cette patiente soit maintenant prise en charge avec des lentilles toriques spécialisées pour sa cornée irrégulière, un dépistage préopératoire soigneux accordant une attention particulière à la taille des pupilles et aux antécédents médicaux oculaires peut aider à identifier les patients qui sont plus à risque de développer des résultats indésirables.

CONCLUSIONS

La T-PRK et le CXL simultanés peuvent améliorer efficacement les acuités visuelles corrigées et non corrigées tout en ralentissant la progression de la DPM et d'autres kératectasies[8,10]. Cette combinaison de procédures peut retarder efficacement la nécessité d'une prise en charge plus invasive comme la kératoplastie pénétrante et l'implantation de segments annulaires intrastromiques[17]. Ce rapport de cas a examiné deux complications à long terme importantes qui surviennent suite à ces procédures (éblouissement associé à l'opacité stromale persistante et sécheresse chronique), qui ont entraîné l'insatisfaction de la patiente avec le résultat. Un examen plus attentif des critères d'admissibilité pour ces procédures pourrait accroître les avantages relatifs du ralentissement de la progression de la DPM tout en diminuant les risques relatifs de complications. ●

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Does My Patient Understand What I Am About to Do? A Brief Overview of the Law on Informed Consent

This article was prepared and written by the BMS Group Healthcare Professionals Insurance Alliance legal team at Gowling WLG (Canada) LLP (Gowlings). CAO members who participate in the professional liability insurance program are eligible for 30 minutes of pro bono and inclusive professional liability claims defence services from Gowlings, one of Canada's largest and most highly recognized legal firms in the areas of medical defence and professional liability.

"Had I known this could have happened, I would never have agreed to the procedure."

Lawyers who defend healthcare professionals have heard this phrase from plaintiffs on countless occasions. In medico-legal actions, allegations that a plaintiff did not provide their informed consent to a procedure that ultimately caused or contributed to his/her injuries are common.

As healthcare providers, optometrists have a legal duty to obtain consent from their patients prior to any treatment. Failure to obtain consent to treatment from a patient exposes you to a potential civil claim and/or proceedings before your provincial regulator.

For consent to treatment to be considered valid, it must be "informed" consent. The patient must have been given an adequate explanation regarding the nature of the proposed investigation or treatment and its anticipated outcome, as well as the significant risks involved and any available alternatives. The information provided must be sufficient to enable the patient to reach an informed decision.

While there are general principles that underlie the doctrine of informed consent, each provincial regulatory body has its own policy guidelines and/or practice directions on informed consent. Additionally, some provinces have imposed a statutory obligation to obtain informed consent (e.g., the Health Care Consent Act in Ontario, and the Health Care Consent and Facilities Admission Act in British Columbia). Finally, in addition to any practice directions or statutory responsibilities, there is a common law duty to obtain informed consent to treatment. As a result, the information in this article is rather general in nature. It is strongly recommended that you contact your provincial regulator if you have any specific questions about the requirements in the jurisdiction where your practice is located.

In Canada, for patient consent to be valid, the following criteria must be satisfied:

1. The patient must have the capacity to consent to treatment.
2. The patient must receive a proper disclosure of information from the caregiver.
3. The authorization should be specific to the procedure to be performed.
4. The patient should have the opportunity to
   a. ask questions, and
   b. receive understandable answers.
5. The authorization obtained should be free of undue influence and coercion.
6. The authorization obtained should be free of any misrepresentation of material information.

1. The patient must have the capacity to consent to treatment

Consent can only be valid if the person providing it has the capacity to do so. The question of legal competency typically arises in situations where the patient is under the age of 18 or may have some type of mental illness. However, these factors alone should not determine competency (i.e., someone under the age of 18 or who has a cognitive deficit can provide valid consent to treatment).

When determining capacity, you must be confident that the person consenting to treatment can appreciate the nature and consequences of the consent discussion. If you have any doubt, seek consent from the parent, guardian, or substitute decision-maker. If there is any question as to whether the patient may not appreciate the nature and consequences of the consent discussion due to a language barrier, ensure that someone who can provide translation is present.

2. The patient must receive a proper disclosure of information from the caregiver

Your patient must understand the nature of the treatment and why it is being proposed. The patient must be advised of the risks associated with the treatment. A question typically arises regarding the extent to which you have to advise the patient of risks. In Canada, you are required to advise a patient about attendant, material and special risks. Attendant risks are those that are more common. Material risks are those that are less common, but serious should they occur. Material risks can differ between patients, so you should take into account your patient's particular health and condition when considering what risks are material. Finally, specific risks include those that are possible with respect to the specific patient.

In Canada, the test for determining whether the patient provided their informed consent is whether an average reasonable person, in the same position as the patient, would have consented to the treatment knowing the attendant, material and special risks.

In addition to the above disclosure, the patient should be advised of the treatment's potential impact on their lifestyle, and any economic considerations associated with receiving or refusing the proposed treatment. The patient must be provided information regarding any alternative treatments available and the risks and benefits of each. Finally, the patient needs to be informed as to the risks of refusing treatment.

3. The authorization should be specific to the procedure to be performed

The consent that a patient provides must relate to the specific treatment/procedure that you are proposing or recommending.

You do not have to obtain a patient's consent for every single step of a treatment plan. However, a blanket consent form, such as that typically signed by the patient at admission to a clinic or private practice, is not sufficient. If the method of treatment that you are proposing for a patient consists of a course of treatment over a period of time, it is not necessary for you to obtain a separate consent for each stage of the treatment. However, the entire course of treatment should be discussed with the patient.

If other individuals will be helping to treat the patient (i.e., students, optometric assistants, etc.), then you must ensure that the patient is advised of the fact that others will be involved in providing treatment and that the patient's consent authorizes their involvement.

4. The patient should have the opportunity to ask questions and receive understandable answers

The discussion regarding consent to treatment should not be a one-way monologue. Ideally, you should have a conversation with the patient during which they can ask questions and you can provide the information necessary to answer those questions.

5. The authorization obtained should be free of undue influence and coercion

You must ensure that your patient does not feel pressured or obligated to proceed with the proposed treatment. Not only should you ensure that the patient does not feel pressured to proceed by a third party, you must also ensure that you as the caregiver are not advocating the treatment plan or procedure in such a way that the patient feels they have no choice but to proceed.

6. The authorization obtained should be free of any misrepresentation of material information

While you are free to provide the patient with your opinion as to the best course of action, you should be as objec-

tive as possible when presenting the information to the patient. You must provide accurate and impartial information on all treatment alternatives.

DOCUMENTING THE CONSENT DISCUSSION

It is essential that you document the consent discussion that you have with your patient. While you may have a standard practice regarding the discussion you have with a patient prior to undertaking treatment, this does not eliminate the requirement to document your discussion. Ideally, you would discuss the proposed treatment plan with the patient, document the discussion, and then have the patient sign-off on the treatment plan. However, at a minimum, you must document the fact that you spoke to the patient, identified the treatment plan/procedure, advised them of the risks and benefits, and informed them of any alternatives. You should also note any questions that the patient had and whether the patient provided their consent.

In a medico-legal action where informed consent is an issue, the patient may claim that you did not provide them with all of the necessary information to make an informed decision. If you have documented your discussion, it should help to support your argument that you did provide all of the necessary information. A lack of documentation regarding a consent discussion increases the chances that a court or regulatory body will conclude that you did not provide the patient with the necessary information.

In conclusion, by incorporating a comprehensive informed consent policy into the standard procedures for your practice, you can reduce your exposure to liability and provide your patients with the information to which they are both legally and ethically entitled.

Please note that this commentary is not legal advice, and should not be relied upon as such. If you have any questions regarding informed consent as it relates to your practice, please contact the Canadian Association of Optometrists (CAO) and/or your provincial regulator. ●

Mon patient comprend-il ce que je m'apprête à faire? Bref survol de la loi sur le consentement éclairé

Cet article a été préparé et rédigé par l'équipe juridique de la Healthcare Professionals Insurance Alliance du BMS Group chez Gowling WLG (Canada) LLP (Gowlings). Les membres de l'ACO qui participent au programme d'assurance responsabilité civile et professionnelle ont droit à 30 minutes de services pro bono et inclusifs de Gowlings en cas de poursuite pour responsabilité professionnelle. Gowlings est l'un des cabinets juridiques les plus importants et les mieux cotés au Canada dans les domaines de la défense médicale et de la responsabilité professionnelle.

« Si j'avais su que cela pouvait m'arriver, je n'aurais jamais consenti à l'opération. »

Les avocats des professionnels de la santé ont entendu ce commentaire d'innombrables fois. Dans les affaires médico-légales, les patients allèguent souvent qu'ils n'ont pas donné leur consentement éclairé à une intervention qui a fini par leur causer des lésions ou y a contribué.

En tant que fournisseurs de soins de santé, les optométristes ont l'obligation juridique d'obtenir le consentement de leur patient avant chaque traitement. Si vous n'obtenez pas le consentement au traitement, vous vous exposez à une poursuite civile et/ou à une convocation devant l'organisme de réglementation de votre province.

Pour être valide, le consentement au traitement doit être un traitement « éclairé ». Le patient doit avoir reçu une explication raisonnable de la nature de l'investigation ou du traitement proposé et du résultat à prévoir, ainsi que des risques importants auxquels il s'expose et des solutions de rechange possibles. L'information fournie doit être suffisante pour permettre au patient de prendre une décision éclairée.

En plus des principes généraux qui sous-tendent la doctrine du consentement éclairé, l'organisme de réglementation de chaque province a ses propres politiques et/ou directives de pratique en matière de consentement éclairé. En outre, certaines provinces ont imposé l'obligation statutaire d'obtenir le consentement éclairé (p. ex., la Loi sur le consentement aux soins de santé en Ontario et la Loi sur le consentement aux soins de santé et l'admission dans les services de santé en Colombie-Britannique). Enfin, en plus des directives sur la pratique ou des responsabilités statutaires, la common law oblige à obtenir le consentement éclairé au traitement. L'information présentée ici est donc de nature plutôt générale. Il est vivement recommandé de communiquer avec l'organisme de réglementation de votre province si vous avez des questions précises au sujet des exigences applicables du secteur de compétence où vous exercez.

Au Canada, pour être valide, le consentement du patient doit satisfaire aux critères suivants :

1. Le patient doit avoir la capacité de consentir au traitement.
2. Le fournisseur de soins doit faire une divulgation appropriée de l'information au patient.
3. L'autorisation doit viser l'intervention spécifique à pratiquer.
4. Le patient devrait avoir la possibilité de :
   a. poser des questions,
   b. recevoir des réponses claires pour lui.
5. L'autorisation obtenue doit être libre de toute influence indue et de toute coercition.
6. L'autorisation obtenue doit être libre de toute présentation erronée de l'information importante.

1. Le patient doit avoir la capacité de consentir au traitement

Un consentement n'est valide que si la personne qui le donne a la capacité de le faire. La question de la compétence légale se pose typiquement lorsque le patient n'a pas 18 ans ou peut souffrir d'une maladie mentale quelconque. Cependant, ces facteurs ne devraient pas déterminer à eux seuls la compétence (c. à d. une personne qui n'a pas 18 ans ou qui a un déficit cognitif peut donner un consentement valide au traitement).

Pour évaluer la capacité, vous devez avoir confiance que la personne consentant au traitement peut comprendre la nature et les conséquences de la discussion sur le consentement. En cas de doute, demandez le consentement du père ou de la mère, du tuteur ou du décideur substitut. S'il est possible que le patient ne comprenne pas la nature et les conséquences de la discussion sur le consentement à cause d'un problème de langue, faites venir quelqu'un pour traduire.

2. Le fournisseur de soins doit faire une divulgation appropriée de l'information au patient

Votre patient doit comprendre la nature du traitement et la raison pour laquelle vous le lui proposez. Vous devez informer le patient des risques associés au traitement. Il y a une question typique au sujet de la mesure dans laquelle le patient doit connaître les risques. Au Canada, vous êtes tenu de mettre le patient au courant des risques inhérents, importants et spécifiques. Les risques inhérents sont les plus communs. Les risques importants sont ceux qui sont moins communs, mais graves s'ils surviennent. Les risques importants peuvent différer d'un patient à l'autre, si bien que vous devez tenir compte de l'état de santé et de la condition de votre patient dans la détermination des risques qui sont importants. Enfin, les risques spécifiques comprennent ceux qui sont possibles pour le patient particulier.

Au Canada, pour déterminer si le patient a donné son consentement éclairé, il faut voir si une personne raisonnable moyenne, se trouvant dans la même situation que le patient, aurait consenti au traitement si elle avait connu les risques inhérents, importants et spécifiques.

En plus de la divulgation qui précède, il faut informer le patient des conséquences possibles du traitement sur son mode de vie, et des considérations économiques associées à la réception ou au refus du traitement proposé. Il faut informer le patient des autres traitements possibles et des risques et avantages de chacun. Enfin, il faut l'informer des risques que comporte un refus de traitement.

3. L'autorisation doit viser l'intervention spécifique à pratiquer

Le consentement que donne le patient doit viser le traitement/l'intervention spécifique que vous proposez ou recommandez.

Il n'est pas nécessaire d'obtenir le consentement du patient à chaque étape du plan de traitement. Cependant, le formulaire de consentement général, comme celui que le patient doit typiquement signer au moment de son admission dans une clinique ou un bureau privé, ne suffit pas. Si la méthode de traitement que vous proposez pour un patient consiste en une série de traitements échelonnés dans le temps, il n'est pas nécessaire d'obtenir un consentement pour chaque étape du traitement. Cependant, il faut discuter de l'ensemble du traitement avec le patient.

Si d'autres personnes participent au traitement (p. ex., un étudiant, un assistant optométrique, etc.), alors vous devez bien informer le patient du fait que d'autres personnes interviendront au traitement et obtenir le consentement du patient à leur intervention.

4. Le patient devrait avoir la possibilité de poser des questions et de recevoir des réponses claires pour lui

La discussion concernant le consentement ne doit pas être monologue. Idéalement, vous devriez avoir une conversation où le patient pourra poser des questions et vous pourrez donner l'information nécessaire en réponse à ces questions.

5. L'autorisation obtenue doit être libre de toute influence indue et de toute coercition

Vous devez bien vérifier que votre patient ne se sent pas contraint ni obligé d'aller de l'avant avec le traitement proposé. Non seulement vous devez vérifier que le patient ne subit pas de pressions d'un tiers, mais encore vous devez veiller, en tant que fournisseur des soins, à ne pas préconiser le plan de traitement ou l'intervention de telle manière que le patient estimerait ne pas avoir d'autre choix que de l'accepter.

6. L'autorisation obtenue doit être libre de toute présentation erronée de l'information importante

Vous êtes libre de donner au patient votre opinion sur la meilleure ligne de conduite à suivre, mais vous devez être aussi objectif que possible dans la présentation de l'information au patient. Vous devez donner une information exacte et impartiale sur tous les traitements possibles.

DOCUMENTATION DE LA DISCUSSION SUR LE CONSENTEMENT

Il est essentiel de documenter la discussion que vous avez avec votre patient au sujet du consentement. Vous avez peut être une pratique type au sujet de la discussion que vous avez avec vos patients avant d'entreprendre un traitement, mais cela ne remplace pas la nécessité de documenter votre discussion. Idéalement, vous devriez discuter du plan de traitement proposé avec le patient, documenter la discussion, puis faire signer le plan de traitement par le patient. Cependant, au minimum, vous devez documenter le fait que vous avez parlé au patient, lui avez expliqué le plan de traitement ou l'intervention et en avez exposé les risques et les avantages, et l'avez informé des autres solutions possibles. Vous devez aussi noter les questions que le patient avait à poser en précisant si le patient a donné son consentement.

Dans une affaire médico-légale, où le consentement éclairé fait partie du contentieux, le patient peut soutenir que vous ne lui avez pas donné toute l'information nécessaire pour prendre une décision éclairée. Si vous avez documenté votre discussion, cela devrait faciliter la preuve que vous avez effectivement donné toute l'information nécessaire. L'absence de documentation concernant une discussion éclairée augmente les chances que le tribunal ou l'organisme de réglementation arrive à la conclusion que vous n'avez pas donné l'information nécessaire au patient.

En conclusion, en intégrant une politique détaillée de consentement éclairé dans les procédures normales de votre pratique, vous pouvez diminuer votre responsabilité et donner à vos patients l'information à laquelle la loi et l'éthique leur donnent droit.

Prière de noter que ce commentaire n'est pas un avis juridique, et qu'il ne faut pas l'utiliser comme tel. Si vous avez des questions au sujet du consentement éclairé dans votre pratique, communiquez avec l'Association canadienne des optométristes (ACO) et/ou l'organisme de réglementation de votre province. ●

Tips To Minimize Workplace Negativity

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Negativity in the workplace can be detrimental to patient retention, not to mention your pocketbook. It only takes one negative experience for a patient to decide to try another eye doctor or optical store. There are a lot of choices out there for eyewear and eye care, so you have to ensure that you minimize any issues regarding negative behavior by your staff.

Negativity typically manifests as one or two employees with attitude or authority issues. They don't like being told what to do, they don't like the way things work or they just don't like much, period. They are generally negative in all regards, and they don't stop complaining. These employees are like weeds that will keep spreading if not pulled. Not only can these malcontents affect your customers, your great employees may also eventually leave if you don't address negativity issues in your workplace. A McKinsey study concluded that 59% of employees would be "delighted" if managers dealt with problem employees. In reality, however, only 7% of employees believe that their companies are actually doing a good job in this regard.

Here are 5 Tips to Minimize Negativity:

1. Don't Let Negativity Slide

Negativity grows and becomes an issue in a practice because it is often ignored. If you don't address a negative or abusive attitude in an employee, other employees are going to take offense and may quit. You don't need a turnover problem on top of a negativity issue. Address the problem head-on and as soon as possible. Any delay can cause the problem to escalate.

2. Set the Standard for Positivity

Leaders set the tone, so set a tone of positivity. A positive attitude at all times should be a non-negotiable standard of practice at your office. Everyone can have an off day, but a series of consistently bad days during which an employee exhibits a bad mood may be an indication of their overall attitude and demeanor. People rarely change, so what you see is likely what you're going to get. Find ways to uncover whether people are positive or negative during the initial hiring interview so that you'll begin with the right people in the first place initially.

3. Treat Everyone the Same

Hold everyone to the same standards and expectations. Everyone in the office is expected to be happy, friendly and positive during all transactions with patients and colleagues. Don't condone negativity in any way. If you do so once, your problem employees may look for an opening to be negative again.

4. Respond to Employee Concerns

As a leader, it is not always possible for you to see and hear everything. One option to address this limitation is to create an open-door policy so your staff will feel comfortable coming to you for any situation. If any of your employees are acting negative or abusive, your staff should feel safe telling you what is going on. If they do confide in you, it is imperative that you take action in some way. By not responding, you may create an entirely different set of issues and challenges. Let the employee who reported the problem know what you plan to do and when.

5. Involve Staff in Office Policy-Making

Involving staff in the development of office policies and guidelines helps set expectations for how they should present themselves at the office. If they have been involved in creating an office policy handbook that outlines how a positive attitude and demeanor are expected at all times, they are more likely to help promulgate this behavior. At the very least, your staff will know that a standard has been set, and if you have to address any problems, they can't say they were unaware of the office policies.

Final thoughts — If you present a positive attitude at all times and don't accept anything less from your employees, you are already well on the way to building a positive, supportive work environment. ●

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