CONGRESS PAPER

GAS-PERMEABLE HARD CONTACT LENSES*

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The purpose of this paper is to discuss gas-permeable hard contact lenses. Either some presently available type of lens or some as yet undeveloped material will no doubt replace the conventional polymethylmethacrylate hard lens, and may conceivably displace a large percentage of the soft lenses currently in use. Only time will prove these prognostications but it is intended herein to review the current status of several materials now available and outline some of the problems which will demand our greatest attention with these new lenses, with particular emphasis on three-and-nine o'clock staining.

There is one gas-permeable lens which the writer believes to have been improperly labelled as a gas-permeable lens since its permeability is so low. The material is generally referred to as modified PMMA; one example of it is the BP-Flex lens.

The oxygen permeability has been shown[1,2] to be such that lenses with no tear pump in the thickness of 0.05mm or less will allow about one-half the minimum oxygen necessary to avoid clinically detectible edema.[3] Even though lenses of this material are usually made in an ultra-thin design, it is rare that thicknesses of 0.05mm exist, so the resultant oxygen transmissibility of most lenses is of little clinical significance. The material does however have improved surface wetting characteristics and the thin design does provide for reduced lens mass and some small degree of lens flexure, all of which should improve the efficiency of the tear pump. It is likely that these factors as much as the gas-permeability provide for the success of the modified PMMA lenses.

This type of lens is likely to play only a secondary role in hard lens fittings of the future in light of the advent of other more permeable materials. They may serve however to help out the patient who oscillates from day to day just at the edema detection threshold with standard PMMA lenses.

Cellulose acetate butyrate or C.A.B. lenses have received the most attention in the professional literature of all the gas-permeable hard lenses on the market. Two of the properties of this material deserve special attention — oxygen permeability and dimensional stability.

First of all, its oxygen permeability is not high but high enough that most lenses of standard thickness should prevent clinically observable corneal edema for normal daily wear. Hill[4] has shown that even without a tear pump, oxygen levels beneath the lens would reach two percent, the mid-point of the Polse and Mandell edema detection threshold range,[3] as long as the thickness is 0.10mm or less. Fatt[5] has shown that with commonly obtained tear film thicknesses and tear-mixing efficiencies, oxygen levels to satisfy the Polse/Mandell criterion are achievable with thicknesses down to at least 0.15mm. It has been stated that C.A.B. is thirty per cent more wettable than PMMA as well,[6] which would augment tear movement allowing thicknesses even greater than 0.15mm without detectible edema.

Careful inspection for central circular clouding is still imperative. Particular attention should be paid to those patients with thick lenses, tight fitting lenses, or low-riding stationary lenses since they are the most suceptible to oxygen deficiency.

Concerning the use of C.A.B. lenses during sleep, Sarver and Staroba[7] have shown that periods of lid closure with C.A.B. lenses caused excessive corneal swelling. They conclude that significantly better oxygen diffusion properties will be needed to consider wearing of C.A.B. lenses during periods of lid closure.

The news is not good about the second property of C.A.B. lenses; their ability to maintain their original base curve, sometimes referred to as their dimensional stability. Since C.A.B. lenses absorb about two per cent water, they are subject to significant changes in base curve during periods of hydration and dehydration.

Several investigators have studied these changes.[8-11] The results reported could be summarized as follows:

1. Moderate to high power minus lenses steepen within the first ten minutes of hydration, return to normal in about an hour and then stabilize just slightly flatter than the original dry state. Then after about four days of hydration, lenses over about ten diopters flatten as much as two diopters.
2. Plus lenses are relatively stable, showing less than a half diopter of flattening within the first two hours followed by a return to the original dry state reading.
3. The thinner the lenses, the greater are the variations in base curve for lenses having all other parameters equal.
4. A significant amount of uniform toric lens warpage is frequently detectable in radiuscopic measurements.
5. At other times the end-point of the radioscope measurement is uncertain because of an irregular base curve distortion.

The studies from which this information was obtained used lathed lenses. Some types of C.A.B. lenses

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are now molded. It is possible that the stresses within a molded lens are less and therefore the stability greater. It may be true that the distortion is less, but the author's clinical experience with one molded C.A.B. lens, the Danker and Wohlk lens has shown that time irregularities just cited still occur.

C.A.B. lenses therefore offer a significant physiological advantage over PMMA lenses but do have frustrating problems of lens instability which can affect vision or the fitting characteristics of the lenses.

A very promising group of gas-permeable lenses is the silicon-PMMA combination type. Lenses such as the Boston lens from PCL, the Polycon lens from Syntex, and the Minicon 0_2 (PHCL) lens from N & N fall within this category. These would appear to be the best hard lenses currently available. They offer a permeability superior to the C.A.B. lens and far better dimensional stability.

A review of the differences between these three similar lenses is in order, beginning with the Boston lens from PCL. Its primary advantage over the other two is that the fitter has freedom to specify lens parameters. Virtually any former hard lens fitting design or any new design which the gas-permeable lens allows can be employed. The exception would be lenses modelled after the Korb technique which are very thin, high-riding lenses. It is claimed that the fragility of the plastic will not safely allow center thicknesses less than that of standard PMMA thickness, which is too thick for the Korb design.

One weakness of the Boston lens, then, is the requirement that the lenses be at least standard PMMA thickness. We have begun to order for problem cases lenses about thirty per cent thinner and using lenticular design where appropriate to see if lens thickness can safely be reduced. To date the damage rate has not been remarkable, which would suggest that fears of lens fragility may be largely unfounded. Dr. Jack Morgan of Kingston compared the rate of lens damage for two groups of patients using Boston lenses.[12] One group had never worn hard lenses before, the other had previously worn PMMA lenses. He found twice the incidence of damaged lenses in the group of previous wearers.

Other characteristics of the Boston lens and its manufacture worth noting are:

1. Stability of the material showing no more base curve distortion than PMMA lenses.
2. Good quality assurance. Measurable lens parameters seldom exceed tolerances.
3. Similar fitting characteristics to PMMA lenses of the same parameters.

The Polycon lens manufactured by Syntex Ophthalmics is another silicon-PMMA lens which will be available in Canada very soon.

Polycon lenses have less oxygen permeability than the Boston lens material.[13,14] The permeability constant or DK value has been reported between 4.2 and 5.0 x 10-11 ml 0_2 cm^2/sec. ml mm Hg for the Polycon lens[13,14] and 7.4 x 10-11 ml 0_2 cm^2/ sec. ml mm Hg for the Boston lens.[15] The permeability constant is a figure describing the oxygen permeability of a material and can be stated without reference to a specific lens thickness. Equivalent oxygen percentage of a lens is a description of oxygen levels more frequently used but it must be stated relative to a specific lens thickness. The two values are related and the equivalent oxygen percentage can be calculated from the permeability constant.[16]

Syntex claims to be able to make the lens thinner than the Boston lens while retaining a strength equivalent to PMMA lenses of the same thickness. The thickness of a Polycon lens for example would be 0.08mm for a -4.50 diopter lens and 0.15mm for a plano lens. The difference in the thickness between it and the thicker but more permeable Boston lens would allow for a similar equivalent oxygen percentage available to the cornea. What one loses in permeability with the Polycon lens, one gains in the shorter distance the oxygen has to travel through the thinner Polycon material. Both lenses would have about a five per cent equivalent oxygen percentage for the -4.50 diopter lens just mentioned.

By way of comparison, the C.A.B. lens has an oxygen permeability reported[5] between 3 and 5 x 10^{-11} ml 0_2 cm^2/sec ml mm Hg and thicknesses similar to those of the Boston lens. The oxygen transmissibility (permeability/thickness) of the C.A.B.lens should therefore be about one-half that of the Boston lens and the similar Polycon lens.

Syntex have chosen to adopt, presumably for economic reasons a one-size-fits-all philosophy, much like that of some of the soft lens manufacturers. The size is to be 9.5mm with an 8.4mm optic zone and a standard series of peripheral curves. The laboratory's philosophy that practitioners will have to find eyes to fit their lens parameters rather than the converse is one which should be rejected by the professions.

It is for this reason that the author's experience with the third lens in this category, the N & N Menicon O^2 lens is limited. It too is a one-size lens, this time 9.2mm diameter/8.0mm optic zone for non-aphakic lenses. Its thickness lies about half way between that of the Boston and of the Polycon lens. Published permeability data in the literature from N & N rates it as slightly higher than that of the Polycon lens[17]. Taking into consideration the thickness differences of the three silicon-PMMA lenses, they should all provide nearly equal oxygen levels to the cornea.

Correspondence with practitioners who have used the N & N lens extensively indicates impressive results, similar to those published for the Polycon lens[18] and those of the author for the Boston lens. This would support the hypotheses that all three lenses would provide similar oxygen levels and certainly sufficient oxygen levels for most patients.

Similarly, all three lens types should prove invaluable in refitting those long-term hard lens wearers whose corneas have become distorted from years of full-time wear such that spectacle refraction is nearly impossible. Frequently in these cases a low-grade corneal edema exists as well, leading to edematous corneal formations.[19]

Kame has recently published a study of 26 patients with edematous corneal formations.[13] Historically this type of patient has been treated by removal of lenses for several weeks which allows for a disappearance of the edematous corneal formations. Kame has found that refitting these patients with Polycon lenses allows for as rapid and as complete a remission from the edematous corneal formation as totally abstaining from the lenses.

The major benefit to the patient of course is the avoidance of the period of inadequate vision with outdated spectacles before proper spectacles or contact lenses can be prescribed. Similar remissions should occur with any of the silicon-PMMA lenses.

As a result of the development of the oxygen-permeable hard lens there should be a resurgence of interest in hard lens designs and fitting techniques. A new-found freedom from the constraints of oxygen needs will allow closer attention to resolving other physiological and optical problems. Although fitters will have to be ever-watchful for the presence of corneal edema in highly sensitive patients, the physiological problem likely to surface as the most troublesome will be what is known as juxtalimbal staining, three-and-nine o'clock staining, or limbal exposure keratitis.

In its most innocuous form it presents as transient mild punctate staining in the lateral peripheral portions of the cornea, those portions not covered by the contact lens. In other cases the punctuate epithelial disruptions coalesce to form larger areas easily visible without flourescein staining. In yet other cases, the staining extends around the entire lower limbal area. Even in the milder forms of three-nine staining, the conjunctival blood vessels adjacent to the corneal disturbance become engorged causing an unisightly red eye. Often this is the presenting complaint rather than discomfort. In more severe cases, non-staining grey sub-epithelial plaques form at the limbus. In the worst cases, such a severe epithelial disturbance occurs that there develops a reduction in corneal thickness in the juxta-limbal area. It is thought that this localized thinning is similar in origin to dellen, a rare pathologic thinning of the cornea caused by a localized discontinuity of the pre-corneal tear film.[20]

Three-and-nine o'clock staining is not a rare complication of hard lens wear. Varying degrees of this phenomenon occur persistently in as many as twenty-five per cent of all hard lens wearers.[21]

There have been several theories proposed to explain the existence of this form of staining. Unfortunately no one feels that oxygen deficiency is the cause, so one would deduce that gas-permeable lenses should do nothing to prevent or reduce three-nine staining. Our experience with the various types of gas-permeable lenses would support this deduction. We have found what seems to be greater numbers of cases of three-nine staining but this may only be a false impression because of the greater numbers of patients able to have their corneal oxygen needs satisfied and wear lenses long enough to manifest the staining.

Several theories have been proposed to explain three-nine staining. What follows is a review of the scientific support for each where it exists, and suggestions for treatment which follow from each theory.

The first is the theory that pressure from the lens edge, peripheral curve, or secondary curve are irritating the tissue. Presumably cases of with-the-rule corneal toricity would be worst since greater pressure from lens bearing would be applied to the flatter horizontal corneal meridian. This does seem unlikely since those portions of the cornea which stain are peripheral to the points of lens contact. Nothing could be located in the literature which supports what would seem at first glance to be a logical theory.

Others have postulated that contact lens wearers secrete an excess of lacrimal fluid, thereby creating a dilution of the elements of the tears responsible for maintaining epithelial integrity.[22] This theory too seems to suffer from a lack of scientific support.

Before commenting on the remaining three theories it would be useful to review briefly the composition of the pre-corneal tear film, its secretion by the various glands, and its distribution, by the eyelids.

The tear film is generally considered to have three layers. The thin oily outermost layer consists mostly of lipids secreted by the Meibomian glands and the glands of Zeis and Moll. Almost the entire seven micron thickness of the tear film is formed by the next layer, the aqueous layer, which is secreted by the main and accessory lacrimal glands. The innermost mucus layer is an extremely thin semi-solid mucin coating of the epithelium. Its shape under high magnification parallels the microvillous morphology of the superficial epithelium. Its origin is primarily the goblet cells of the palpebral conjunctiva.

It has been proven that this innermost layer of the tears is the one critical to corneal surface wetting and tear film stability. Lemp *et al*[23] published in 1970 results of an experiment using rabbit corneas and solutions matching as closely as possible human tears. He was able to remove the mucus layer from corneas. In this state, the cornea proved to be unwettable by the tear solutions. By smearing a mucus film lightly over the surface of the corneas, they became completely wetted with a drop of tear solution.

The leading edge of the upper lid has been shown to be the applicator of ocular mucus.[20] The tarsal border is the only part of the upper lid to apply any pressure to the corneal surface during the blink. It applies a force across the globe which is greatest at the apex of the cornea and least at the limbus. Quite possibly then, a difference across the cornea exists in the quality or quantity of ocular mucus laid down.

The downward movement of the upper lid with each blink is coincident with an upward reflex rotation of the eyeball. This movement is known as Bell's Phenomenon.

When the eyelids open, a uniform three-layered tear film forms almost instantly on the normal cornea. This tear film remains stable for a period of time which has come to be termed tear breakup time — the interval between a complete blink and the first randomly distributed dry spot. Some of the lipid from the superficial layer of the tears migrates through the aqueous layer, contaminates the inner mucus layer, and leads to the formation of a corneal dry spot. Epithelial damage can result if this dry spot is not immediately rewetted. Tear breakup time is the best method of measuring the stability of the tear film and is an indirect measurement of the quality and/or quantity of the mucus layer of the tear film.

This brief review of tear physiology will serve as background for the remaining three theories of three-nine staining.

The first might be called the lacrimal deficiency theory. It is postulated that some people have either reduced mucus secretion or have a type of mucus inadequate for guaranteeing tear film stability and this leads eventually to three-nine staining.

Lemp, Dohlman and Holly[24] have shown by conjunctival biopsies of five patients with exaggerated dry eye problems either an absence of, or a severe reduction in, the numbers of conjunctival goblet cells. Interestingly, these patients all had normal aqueous tear volumes. Although not yet proven, it is conceivable that other patients have only a minor reduction of goblet cell count or goblet cell production which only becomes clinically apparent under situations such as breakup time testing or wearing hard contact lenses. These findings suggest that we should perform BUT tests on prospective contact lens patients to rule out gross mucin deficiencies. No studies appear to have been done correlating BUT with three-nine staining, although this would seem to be an obvious study to test the hypotheses that mucin deficiency is the cause of three-nine staining.

Some recent work by Korb and Herman[25] with sequential staining of the cornea offers hope as a predictor of poor contact lens candidates as well. By staining the tear film at five minute intervals with fluorescein, they found forty-two per cent of people showing corneal staining, most of them only after repeated instillations of dye. This could be another technique for assessing the effectiveness of the tear film in keeping the cornea wet which may relate to the three-nine staining problem.

The next two theories of three-nine staining postulate deficiencies not in the production of mucus but in its distribution by the eyelids.

The first is that the contact lens inhibits the completeness or the frequency of the blink. A study of six patients published in 1969 by Sarver, Nelson & Polse[26] supports this theory. Of six hard lens wearing subjects, five had varying degrees of three-nine staining in both eyes. They were asked to wear one contact lens only for four hours, during which time the blinking pattern was monitored. All five with three-nine staining continued to demonstrate the staining in the eye with the contact lens. However, three of the five showed staining of the contralateral cornea as well. These three had unusually low blink frequencies or blink amplitudes as well. The study demonstrates that blinking is at least one of the factors responsible for three-nine staining. A similar study by Korb and Exford[27] the next year also implicated the blinking mechanism in three-nine staining.

The final theory is the "bridging theory". It is felt by many investigators that the thickness of the contact lens causes lid-globe congruity to be poor in the area adjacent to the lens. This results in a poorly distributed mucus layer in the juxta-limbal areas, leading to local instability of the tear film. Dry spots appear and damage is done to the epithelial cells through evaporation.

As reported, the application of mucin in the limbal area is likely to be naturally the least complete. If the application of mucin is further weakened by the thickness of the contact lens edge, then it seems reasonable that this area should suffer some tear film instability.

Personal observations have supported the statement often appearing in the literature that three-nine staining is more frequent and severe in highly myopic hard lens patients. Presumably the extra edge thickness of these lenses causes the greatest lid gap and poorest mucus layer rejuvenation in lateral juxta-limbal areas.

Scientific evidence seems to support the last three of these theories; that is, that three-nine staining can be caused by a deficiency in secretion by the goblet cells, or by a deficiency in spreading of this mucus layer by an inadequate blink pattern or by a bridging effect of the upper lid by the lens.

Attempts at remediation should therefore be first directed towards the detection of these deficiencies. Assessment of the adequacy of mucus production can be estimated by doing tear breakup time tests and to some extent by single or sequential staining of the cornea with fluorescein. Mucus deficiency would be expected in certain inflammatory conditions of the conjunctiva which reduce the goblet cell population, such as avitaminosis A, ocular pemphigoid, and Stevens-Johnson disease. If medication is being taken which reduces mucus membrane secretion, there is also a potential problem with dry eyes.

If one is faced with a mucin-deficient eye, then the best advice is probably to forget contact lenses. As a last resort, one may wish to try artificial tears. Burton Parsons' Adsorbotear has been shown to have the greatest retention time,[28] but to date nothing has been formulated to match the conjunctival mucin in its ability to adsorb to the cornea and create a hydrophilic surface.

In cases where blinking seems to be inappropriate, one must determine if some aspect of lens fit is inhibiting the blink. For example, sometimes a small interpalpebral lens leads to an incomplete blink and a low-riding lens. When the excursion of the upper lid is only to the top edge of the lens, desiccation of the lower three-nine o'clock peripheral cornea is inevitable.

Modifications to the lens to make it more comfortable, such as blending and polishing of the secondary and peripheral curves, removing lens scratches, and optimum finishing of the lens edge will encourage complete blinking by improving lens comfort. As a general rule, small interpalpebral lenses are the most likely to cause peripheral corneal staining because of their inhibition of blinking. Often remaking the lens to a larger type high-riding lens is needed.[29]

Korb[30] has described the normal blink as one in which only the smaller palpebral fibres of the orbicularis oculi muscle contract. In an abnormal blink the larger orbital portion of the muscle contracts as well. Bell's Phenomenon occurs with the normal blink but disappears in the abnormal blink when the sphincter action of the orbital portion of the muscle appears. This inappropriate action often appears during adaptation to contact lenses, causing an inhibition of Bell's Phenomenon. It is Bell's Phenomenon which Korb feels is essential to maximize lens movement on the eye during the blink and to provide for adequate re-wetting of the corneal surface. He has outlined a blinking training procedure[28] for new contact lens patients which teaches them to blink naturally with a foreign body on the eye. He instructs the patients to touch the orbital rim at the outer canthus while blinking. If any inward tugging is felt, then the wrong muscles are being used and Bell's Phenomenon is not operating optimally.

Cases in which bridging seems to be taking place present the biggest challenge to the hard lens fitter. The objective of lens design is to make the lens edge as thin as possible.

The best hard lens design with thinness of the lens as a primary component is the Korb technique.[30] With this system the lens is fitted flatter than the flattest corneal meridian, is made extremely thin, and has peripheral and edge contours that encourage the upper lid to catch the edge of the lens and hold it in a high-riding position.

The design of the Polycon lens is a modification of the Korb technique. As a result, it should lead to a lower incidence of three-nine staining than the C.A.B. or Boston lenses.

Since C.A.B. and Boston lenses apparently cannot be made as thin as Korb would suggest, the other modifications that can be employed in an attempt to reduce three-nine staining would include:

— ordering the minimum allowable center thickness
— ordering lenticularization of high minus lenses and thick plus lenses
— the use of some minus carrier to lenticular lenses to encourage a high-riding lens
— going larger with the lens so that more of the peripheral cornea is covered. This offers less corneal area to suffer the effects of evaporation.
— a technique once employed by the author for a patient with persistent staining and injection was to fit a plano-T Bausch and Lomb Soflens between the eye and the offending Boston lens. Corneal edema became apparent at ten hours of wear but the injection and staining disappeared. The patient, if pressed to wear the lenses longer, would simply take out the soft lens and wear the hard lens alone for a few hours. Removal of the soft lens would allow recovery from the edema and the hard lens alone would not be worn long enough to create the peripheral staining problem.

These are some of the suggestions to relieve what may become the most difficult problem to solve for gas-permeable hard lens wearers.

Other hard lens problems, particularly refractive ones, can be attacked much more vigorously with gas-permeable lenses than with the PMMA lenses. The limitations imposed upon lens parameters by corneal oxygen demands will be relaxed. Thus larger lens diameters and optical zones can be prescribed for those suffering flare, thicker prism ballast front surface toric lenses can be prescribed to compensate for residual astigmatism, back surface toric lenses, or combination front surface/back surface toric lenses can be fitted to the highly toric cornea, vertical prism so often omitted from contact lens correction can be included, and presbyopic correction lenses can be provided when they become available.

Correction of these optical problems will always be a challenge but given the freedom of design which gas-permeable lenses will allow, practitioners will be able to provide contact lens correction for an ever-expanding population. Further challenges in keeping abreast of the advances in materials, lens designs, and diagnostic techniques will make this an exciting field for many years.

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