Section on Cornea and Contact Lenses
Information for Eyecare Practitioners
CONTINUOUS AND EXTENDED WEAR CONTACT LENSES
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Introduction

The vast majority of contact lenses are worn on a daily basis and lenses are removed at the end of each day before sleeping. This modality does not, however, offer the ultimate convenience sought after by many wearers. Lenses have to be inserted and removed each day and, unless they are daily disposables, they require daily cleaning and disinfection procedures. The prospect of day and night lens wear without the need for daily handling and maintenance has, therefore, been appealing to contact lens wearers since their very inception. Day and night lens wear first became a reality more than twenty five years ago but its popularity and success has been particularly turbulent over this time.

What is meant by "Extended Wear"?

Extended wear (EW) typically refers to wearing contact lenses, both during the day and while sleeping for periods of up to six nights and seven days consecutively. The majority of soft lenses worn on an EW basis are "disposable", and are usually inserted once only and removed and discarded after one week of wear.

What is meant by "Continuous Wear"?

Continuous wear (CW) refers to wearing contact lenses both during the day and while sleeping for periods of up to thirty days and nights consecutively. Initially this modality was used primarily for therapeutic cases[1] but when CW with conventional hydrogel lenses started to be prescribed more widely, the high incidence of reported complications resulted in the Food and Drug Administration (FDA) rescinding approval for wearing periods of greater than seven days and six nights in 1989. The CW modality has more recently regained popularity following the introduction of highly oxygen permeable silicone hydrogel lens materials and the FDA approved the use of silicone hydrogel contact lenses for CW and the term "continuous wear" has now become synonymous with the use of some of these materials.

How are EW and CW different from Orthokeratology/Corneal Reshaping?

EW and CW differ from orthokeratology/corneal reshaping in that the lenses are worn both day and night as compared with primarily being worn overnight for corneal reshaping. Please see the separate position paper on orthokeratology/corneal reshaping for more details.

What is required of contact lenses for EW and CW?

Contact lenses for EW and CW must be able to provide sufficient oxygen to maintain corneal integrity, normal metabolism and to aid in defense against infection. Contact lenses act as a potential barrier to oxygen transport even when the eyes are open to the atmosphere. Under closed eye conditions, oxygen is only available from the blood vessels inside the eyelid, and from within the eye itself. This significantly reduced availability necessitates even higher oxygen transmissibility

properties for lenses which are worn on an EW or CW basis. Oxygen transmissibility is determined by both the lens material permeability (Dk) and the lens thickness (t). The units of Dk are 10-11 (cm2/sec)(mlO2/ml x mmHg) or "barrer" and the units of oxygen transmissibility are 10-9 (cm/sec)(mlO2/ml x mmHg). Conventional hydrogel materials rely on their water component to transport the oxygen through their bulk but this is severely limiting since water is not very effective at transporting oxygen. Silicone hydrogels and rigid gas permeable (GP) materials transport oxygen through their polymer phases which can be much more effective. Consequently highly oxygen transmissible lenses can be manufactured using these materials which are more appropriate for overnight lens wear.

The amount of oxygen required by an individual's cornea during closed eye conditions varies considerably. The cornea normally swells by about 3% during overnight eyelid closure with no contact lens in place [2]. The most widely cited figure for the minimum acceptable oxygen transmissibility (Dk/t) of contact lenses for overnight wear is 87 x 10-9 [3]. More recently, a level of 125 x 10-9 units has been reported as a requirement to prevent stromal anoxia during closed-eye conditions [4]. The debate as to the exact minimum value required has continued vociferously[2], but there is general agreement that the levels significantly exceed those offered by conventional hydrogel lenses. Many of the silicone hydrogel lenses currently available meet these requirements but not all are approved for overnight wear. It is also important to emphasize that these Dk/t values are "averages" and patients exhibit widely different corneal metabolic requirements.

What are the indications for EW and CW?

There are a number of reasons for considering a day and night wearing modality. In addition to those patients simply desiring convenience, a group of obvious candidates for EW and CW are patients with high refractive errors who may be vulnerable as a consequence of their unaided visual performance. These patients could benefit enormously from being able to see clearly at all times, particularly when waking unexpectedly during the night. Other prospective patients include those who have an active lifestyle or occupation in which spectacle wear is hazardous or impractical but who may require visual correction at all times of the day and night. This could include members of the emergency workforce working on shifts or with unpredictable hours and schedules. There may also be situations where hygiene is a concern and patients are unable to disinfect or handle their contact lenses each day in a sanitary manner because of location, for example military personnel and outdoor enthusiasts. EW or CW may also be used for a number of therapeutic and bandage applications to aid in pain management and / or healing. In addition, certain binocular vision abnormalities can be managed with EW or CW where continuous visual correction can aid the development of visual function in an otherwise amblyopic eye.

What are the risks associated with EW and CW?

EW and CW can result in both inflammatory and infectious complications. Inflammation and infection are characterized by the presence of infiltrates, which are collections of polymorphonuclear leucocytes released from the limbal blood vessels. While most cases of corneal infiltrates are primarily inflammatory in nature, some cases may be infectious. These cases of infection, or microbial keratitis (MK) are very serious and require immediate treatment with appropriate antimicrobial agents to result in a favorable final outcome. Prognosis for most patients is good, particularly if treatment or referral occurs early in the disease process, but it does depend upon the causative organism and in many cases a scar will remain. The generally accepted figure for

annualized incidence of MK in conventional hydrogel daily wear patients is 4 per 10,000 wearers [5,6]. This risk increases by approximately five times with EW [5-7] to an annualized incidence of 20 per 10,000 wearers.

The corneal infections observed with overnight wear in the 1980s [8] were presumed to occur primarily as a result of poor hygiene and compliance. It was hoped that by using lenses on a disposable basis, in which the lenses were inserted once only and then discarded upon removal, the reported infection rates with overnight wear would decrease. Unfortunately disposability was found to have no impact on the rate of infection with EW of conventional hydrogel materials [5] and the rate of ulcerative keratitis associated with EW of disposable lenses was found to be exactly the same as had been reported with conventionally replaced hydrogel lenses when worn overnight[7]. When silicone hydrogel lenses were introduced to the market there was a similar hope that the rate of corneal infections associated with their overnight wear would decrease as a result of the increased oxygen available to the cornea. Recent studies now indicate however that the risk level is similar regardless of lens material [9,10]. The one exception is for GP materials where the risk does appear to be the lowest, but to date there are no published rates for infection subsequent to overnight wear with the new generation of high Dk/t GP lenses.

The incidence of infiltrates has also been reported to be higher when contact lenses are worn overnight [11]. The per wearer annualized incidence for symptomatic corneal infiltrates of any severity with CW of silicone hydrogel lenses has been reported to be 2.5% in a recent post market surveillance study [12]. It is not entirely clear whether silicone hydrogel materials have had an effect on the rate of inflammation with overnight wear. A recently published meta-analysis of inflammatory complications with overnight wear in conventional and silicone hydrogel lens wearers found approximately twice the risk of inflammation with silicone hydrogels compared with conventional lenses [13]. However, as the majority of conventional lenses were worn on an EW basis (up to 6 consecutive nights) and the silicone hydrogel lenses were worn on a CW basis (up to 30 consecutive nights), it is unclear whether the difference can be attributed to the material or to the number of consecutive nights of lens wear.

Are some individuals at greater risk than others?

There are a number of individuals who are associated with a higher risk of infection and inflammation with EW and CW contact lens wear. These include those individuals who are new to the overnight modality, have a higher refractive error (≥ 5.00D), males, and both young (≤ 25 years) and older (> 50 years) wearers [14,15]. In addition to the increased risk associated with the overnight wearing modality, a number of actions or behaviors have also been associated with greater risk including swimming without goggles (or not disinfecting lenses after swimming in them), use while on vacation, inappropriate hand washing, poor hygiene, internet purchase and smoking [14,15].

How can the risks associated with EW and CW be reduced?

The risks associated with EW and CW can be reduced to some degree. A careful examination by the prescribing doctor, with the purpose of determining whether a patient's eyes are suitable for the use of contact lenses for EW or CW is considered to be an important preventive step. This individualized approach in determining the best lenses and wearing schedule for each patient based

upon their demographic and refractive profile is essential. In all cases the relevant risk factors should be assessed and patients counseled appropriately.

All patients should be advised that they should NEVER sleep in an uncomfortable lens or when they have a painful or red eye. EW and CW patients should check their eyes prior to sleep to ensure that they look "good", feel "good" and that they can see well [16]. If they are at all concerned they should remove the lenses and contact their practitioner. In addition, patients may be more prone to experiencing adverse events when they are physically unwell and should be advised to remove their EW or CW lenses during these times.

When are EW and CW the right option?

Overnight wear of contact lenses is certainly not for everyone, but the modality does offer many advantages over daily wear. When discussing the opportunity for EW or CW with patients it is important to provide a carefully balanced argument. Patients will appreciate learning about the potential disadvantages, as well as being informed of the positive aspects. Comprehensive follow-up examinations are crucial for patient success with overnight lens wear. While newer GP and silicone hydrogel materials appear to have solved hypoxia problems for the majority of patients choosing to wear lenses overnight, some patients will experience complications and the prescribing doctor must be equipped to manage these complications when they occur. Even though newer materials are a significant improvement over older generation materials, further modifications to lens designs and surfaces are vital to the continuing success of overnight wear modalities.

The American Academy of Optometry's position on EW and CW

The American Academy of Optometry neither condones nor condemns the overnight wear of contact lenses. It is in the best interest of prospective lens wearers for the added risks and benefits associated with overnight wear to be made known prior to selecting a modality. It is important that appropriate hygiene, lens handling, lens care, wearing schedule, and information on the appropriate action in the case of an adverse event be given to patients prior to the dispensing of all contact lenses, but particularly for lenses prescribed for the purpose of EW and CW. Even if lenses are "approved" for up to six or thirty consecutive nights wear, a flexible wearing schedule may be recommended dependent on individual circumstances.

Given the increased risks associated with extended wear, removal of contact lenses prior to sleeping is advisable for the vast majority of wearers. Greater safety is probably still an achievable goal for the contact lens industry, and it should be pursued. Unfortunately human nature dictates that strict adherence to stringent practices is unlikely. Therefore, systems and products must have safety profiles that allow for deviation from perfect practice by prescriber and wearer.

References

1. de Carle J. Extended wear lenses gaining ground. Contact Lens Forum 1979;4:31-41.

2. Fonn D, Bruce AS. A review of the Holden-Mertz criteria for critical oxygen transmission. Eye Contact Lens. 2005 Nov;31(6):247-51.

3. Holden BA, Mertz GW. Critical oxygen levels to avoid corneal edema for daily and extended wear contact lenses. Invest Ophthalmol Vis Sci 1984;25:1161-1167.

4. Harvitt DM, Bonanno JA. Re-evaluation of the oxygen diffusion model for predicting minimum contact lens Dk/t values needed to avoid corneal anoxia. Optom Vis Sci 1999;76:712-719.

5. Cheng KH, Leung SL, Hoekman HW, Beekhuis WH, Mulder PG, Geerards AJ, Kijlstra A. Incidence of contact-lens-associated microbial keratitis and its related morbidity. Lancet 1999;354:181-185.

6. Poggio EC, Glynn RJ, Schein OD, Seddon JM, Shannon MJ, Scardino VA, Kenyon KR. The incidence of ulcerative keratitis among users of daily-wear and extended-wear soft contact lenses. N Engl J Med 1989;321:779-783.

7. Schein OD, Glynn RJ, Poggio EC, Seddon JM, Kenyon KR. The relative risk of ulcerative keratitis among users of daily-wear and extended-wear soft contact lenses. A case-control study. Microbial Keratitis Study Group. N Engl J Med 1989;321:773-778.

8. Weissman BA, Mondino BJ, Pettit TH, Hofbauer JD. Corneal ulcers associated with extended-wear soft contact lenses. Am J Ophthalmol 1984;97:476-481.

9. Morgan PB, Efron N, Hill EA, Raynor MK, Whiting MA, Tullo AB. Incidence of keratitis of varying severity among contact lens wearers.

10. Schein OD, McNally JJ, Katz J, Chalmers RL, Tielsch JM, Alfonso E, Bullimore M, O'Day D, Shovlin J. The incidence of microbial keratitis among wearers of a 30-day silicone hydrogel extended-wear contact lens.

11. Cutter GR, Chalmers RL, Roseman M. The clinical presentation, prevalence, and risk factors of focal corneal infiltrates in soft contact lens wearers. CLAO J 1996;22:30-37.

12. Chalmers RL, McNally JJ, Schein OD, Katz J, Tielsch JM, Alfonso E, Bullimore M, O'Day D, Shovlin J. Risk factors for corneal infiltrates with continuous wear of contact lenses. Optom Vis Sci 2007;84:573-579.

13. Szczotka-Flynn L, Diaz M. Risk of corneal inflammatory events with silicone hydrogel and low dk hydrogel extended contact lens wear: a meta-analysis. Optom Vis Sci 2007;84:247-256.

14. Stapleton F, Keay L, Jalbert I, Cole N. The epidemiology of contact lens related infiltrates. Optom Vis Sci 2007;84:257-272.

15. Morgan PB, Efron N, Brennan NA, Hill EA, Raynor MK, Tullo AB. Risk factors for the development of corneal infiltrative events associated with contact lens wear. Invest Ophthalmol Vis Sci 2005;46:3136-3143.

16. Yamane S, Paragina S. Patient education. In Bennett ES, Weissman BA, editors. *Clinical Contact Lens Practice*. Philadelphia: Lippincott, 1991:59-1 to 59-9.

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