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Cosmetic extended hydrogel contact lens wear: A search and review of current literature

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Abstract

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COSMETIC EXTENDED HYDROGEL CONTACT LENS WEAR: A SEARCH AND REVIEW OF CURRENT LITERATURE

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COSMETIC EXTENDED HYDROGEL CONTACT LENS WEAR: A SEARCH AND REVIEW OF CURRENT LITERATURE

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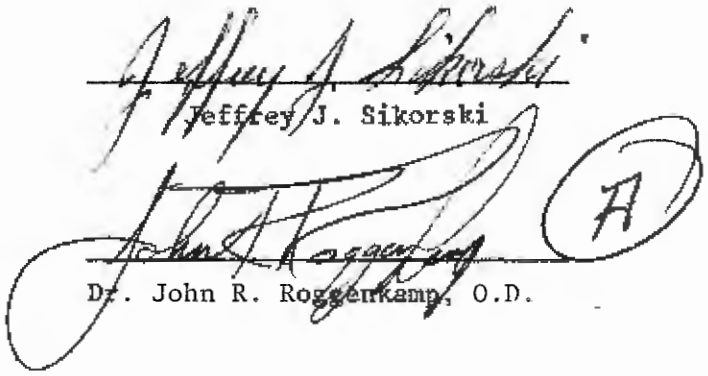

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INTRODUCTION

For almost as long as contact lenses have been a treatment for ametropia, the notion of continuous wear has been of interest to eye care practitioners. Continuous wear implies contact lens wear without removal from the time of its dispensing until replacement. Extended wear refers to day and night wear of contact lenses which are removed for cleaning and disinfecting at regular intervals. In light of recent technological advances in the field of new contact lens materials, extended wear lenses are sure to be one of the most attractive concepts. Many contact lens wearers would wish to wear their lenses for prolonged periods of time without manipulation, with optimum vision, and with minimal risk of pain or injury.

The content of the following literature search and review and summarizes current development, studies, clinical experiences and opinions in the area of cosmetic soft extended contact lens wear. Some of the information has been gathered from work done explicitly on aphakic prolonged wear, however, I feel that the results are directly applicable to cosmetic wear. Much of the published data is from work done in the United Kingdom as practitioners there have had a longer experience with the subject matter. It would appear that even with recent advances in the soft lens field, the problems accompanying extended wear remain complex.

I. AVAILABLE LENSES

There are currently only three soft lenses which have been approved by the Food and Drug Administration for extended wear purposes for cosmetic use. Those available to eye care professions in the United States may be summarized:

Hydrocurve II Lens (bufilcon, A^{55}, 55 percent water) by Hydrocurve Soft Lens, Inc. This was the first lens FDA approved for cosmetic extended wear in January 1981. The material is a hydrophilic random copolymer of 2-hydroxyethylmethacrylate, N - (1. 1-dimethyl - 3 - oxobutyl) - acrylamide, and methacrylic acid. The copolymer chains are joined by cross links of trimethylolpropane trimethylacrylate. The Hydrocurve lenses are lathe cut producing spherical anterior and posterior curves, with minimal center thickness. The posterior peripheral curve is flatter than the base curve and the anterior periphery is lenticular.

Parameters:	Diameter	Base Curve	Curve Thickness	Anterior Optic Zone
	14.0 mm	8.5 mm	0.05 to 0.07	not available
	14.5 mm	8.8 mm	0.05 to 0.07	

Posterior peripheral width is approximately 0.4 mm and 12.50 mm radius. Power range -0.25 to -12.00 D.

Chemical methods are to be employed for disinfection and thermal methods are not recommended.

Permalens (perfilcon A, 71 percent water) by Cooper Vision Inc., Optics Division. This material is a terpolymer of 2-hydroxyethylmethacrylate, N-vinyl - 2 - pyrrolidone, methacrylic acid, cross linked with ethyleneglycol dimethacrylate. The lenses are lathe cut with a monocurve posterior surface.

Parameters:	Diameter	Base Curve	Center Thickness	Optic Zone Diameter
	13.5 mm	7.7, 8.0, 8.3 mm	0.10 to 0.24 mm	7.0 to 11.0 mm

Power range -.25 to -10.00 D. Chemical or low heat thermal disinfection systems are suitable

Sauflon PW (lidofilcon B., 79 percent water) by American Medical Optics. A copolymer of methylmethacrylate and N-vinyl - 2 - pyrrolidone, with allyl methacrylate and ethyline dimeth-acrylate as cross linking agents, this material does not contain hydroxyethylmethacrylate (HEMA) as do almost all other soft lenses. Although very recently FDA approved for cosmetic extended wear, the Sauflon PW lens is currently available in minus and low plus as custom made lenses only. Large scale production of these cosmetic lenses are due within the next several months. The aphakic extended wear lens has the following parameters:

Parameters:	Diameter	Base Curve
	14.4 mm	8.1, 8.4, 8.7 mm

The anterior and posterior surfaces are spherical, with no posterior bevel. The center thickness can only be assumed to be larger than other soft lenses due to the increased water content. The disinfection recommendations include any low heat thermal units, but chemical methods, particularly the Burton Parsons regimen, are preferred.

II. PATIENT SELECTION

A. Indications

In selecting the appropriate patient, Binder makes note of the increased risk of ocular complications with extended wear lenses compared to daily wear soft lenses, and only patients unable to remove and care for lenses on a daily basis should be considered for extended wear. Examples are: (1) elderly patients with a mental block against insertion and removal of a lens; (2) a physical handicap preventing handling of a lens such as rheumatoid arthritis, Parkinsonism, or following a cerebral vascular accident; (3) a child with monocular aphakia whose parents are unable to insert and remove the lens.[1] Coon includes the very young and geriatic patients, high ametropes, institutionalized patients, and patients with specific demands such as physicians on call, ambulance drivers, and firemen who would need instant clear vision, and patients such as mountain climbers who would find themselves in conditions where lens care is not practical.[2] This approach to extended wear was formulated prior to FDA approval, and may prove too conservative in that it fails to satisfy those patients who wish to wear lenses continuously for convenience or who may intermittently desire to wear lenses on an overnight basis.

In such cases where extended wear is not a necessity, Nesburn suggests fitting patients who have healthy eyes, are mentally alert, have clean lids, and show signs of good hygiene.[3] Screening for success would include an assessment of the tear film and secretion, lids for normal function, cornea, conjuctiva, and sclera

for excellence in appearance rather than mere adequacy. Some suggest a grading method to quantify appearances for baseline data.[7, 33] In general, similar criteria for successful daily wear of a contact lens are applied to extended wear.

B. Contraindications

Coon sums up the contraindications of extended wear:[2]

1. Reduced tear flow
2. Edema
3. Ocular allergy
4. Papillary hypertrophy of tarsal conjuctiva
5. Ocular infection
6. Unacceptable vision with contact lenses
7. Middle age hyperopia
8. Inability to remove the lens in an emergency
9. Unable to obtain proper after care
10. Uncooperative patient
11. Ill defined need of lenses
12. Poor hygiene
13. Retardation
14. Structural abnormality of the eyelids
15. Using ocular medications containing preservatives, epinephrine, or fluorescein

Shaw adds these contraindications to the fitting of extended wear lenses:[4]

1. Patients with infections or severe blepharitis.
2. Patients with inflammation, such as iritis, uveitis, or IOL problems.
3. Patients with frank corneal decompensation.
4. Patients with dry eyes (may be a relative contraindication).
5. Patients who are unwashed, unintelligent, uninformed, uncooperative, unrealistic (convenience-minded).

Phillips warns against fitting persons without a definite need, patients prone to edema, middle age hyperopes, and those who can not remove the lens in an emergency.[5] The extended wear lens is not to be regarded as an easy way out for those who are unable to handle soft lenses.

Emotional stress has been cited as a contraindication due

to its presumed effect on tear and metabolic rate changes.[32] Diabetes mellitis slows down the body's healing processes, and should also be considered as a negative for extended wear. The systemic considerations would include conditions such as thyroid malfunction, blood dyscrasia, and hormonal imbalances. Medications utilized by the patient such as diuretics, antihistamines, and birth control pills must be reviewed, and considered as a possible disqualification due to their possible drying effects of the corneal surface.[7] The environmental and working conditions of the patient as well as his individual habits should be analyzed for incompatibility with extended wear such as a dry or polluted environment.[7]

III. FITTING CONSIDERATIONS

In general, the fitting characteristics of extended wear lenses are essentially the same as lenses designed for daily wear. A fit as flat as possible, maintaining patient comfort, will have the minimum effect on tear exchange and will flush out cellular debris and products of corneal metabolism. Movement of one-and-one-half mm with the blink in the straight ahead position, and two mm in an upward gaze is optimal. One of the primary reasons for starting with a flat fit is that during the first few weeks of wear the lenses tend to become slightly steeper.[1] The lens must be centered on the visual axis to permit good vision and fit concentrically on the sclera one to two mm from the limbus. The relationship of the lens edge to the conjuctiva should be evaluated with a slit lamp to look for correct alignment, edge

lift off, impingement on the limbus, or elevation by the lower lid margin, and to be sure there is no impingement of the lens on the conjuctival vessels.

Major differences in the fitting of an extended wear lens involve either selection of the lens material, which is usually higher in water content, or selection of thinner and/or flatter fitting lenses. It is not necessary to have many base curves available with the ultra-thin (minus) lenses as these lenses tend to readily shape to the cornea.[28]

deCarle describes a fairly high success rate using the Permalens suggested fitting technique. He fits the Permalens on the average 0.70 mm steeper than "K" for myopes and on the average, 0.30 mm steeper for hyperopes. This is unusual in that it is a rather tight fit in comparison to current hydrogel fitting philosophy. Since the Permalens has a high amount of oxygen permeability, he felt no need for it to move, and aimed for practically no movement which would cause less irritation with blinking.[6]

Based on the Best-Fit Band Theory study by Touch and Clark five criteria of best fit for optimizing the fitting performance of Softlens contact lenses evolve, and appear applicable to other lenses for extended wear:[18]

1. Good centration--no more than 0.5 mm decentration in primary position of gaze to insure full corneal coverage.
2. Acceptable movement--post blink motion of 0.5 mm or less; lag on upward gaze 0.5 mm or less.
3. Crisp retinoscopic reflex--unchanging crisp quality of reflex following blinking as a streak is rotated from meridian to meridian.
4. Overrefraction to a clear endpoint--find best acuity achieved with gradual line-by-line improvement from initial refractive blurring; no supplemental power.

5. Stable visual acuity--vision perceived as nonfluctuating by the patient.

IV. PRACTITIONER FOLLOW-UP

Certainly, the frequency of follow-up after successful fitting depends on the patient, his problem, and his previous history of successful extended wear. Phillips recommends a full test when the lenses are inserted, an examination at the end of the first day, the following morning, a week later, and every three months thereafter.[5]

Farkas et. al. advocates beginning with a daily wearing schedule serving three functions:[7]

1. The patient is given the opportunity to gain experience in handling the lens.
2. The cornea is afforded a more gradual adaptation to a diminished oxygen supply along with a slightly increased lacrimation factor.
3. The practitioner has an opportunity to evaluate lens acceptance at a moderate wearing level, minimizing risk.

This daily schedule can be as short as two days or as long as several months, as long as the eye demonstrates tolerance of the lens for at least a full day's wear. In cases where immediate extended wear is necessary, a lens can be inserted early in the day and evaluated the same day after prolonged wear. It is desirable in all cases to perform a full evaluation the following morning after sleeping with the lens in place. Ocular and visual appearances at this stage will usually dictate the frequency of subsequent evaluations.[7]

The practitioner's examination in follow-up include careful assessment of the external eye, lens fit and appearance, blinking pattern, lens deposits and intraocular pressure.[3] The

existence of corneal edema, corneal staining, giant papillary conjuctivitis, corneal infiltrates, and neovascularization must be ruled out, as these complications should dictate cessation of extended wear. Patients should be instructed about the importance of removing the lens and seeking attention if they develop discomfort, pain, redness, or decreased vision.[3]

The question of how often lenses should be removed for either physiological normalization or cleaning reasons depends on variables involving both the patient and lens type. Two basic philosophies emerge. The first is that lenses are removed at regular intervals from one week to three months. The second philosophy is to simply leave the lenses in place for several months at a time, and remove them only when necessary.[3]

With extended wear, the question of practitioner time availability is of uppermost importance. Dr. Brian Holden in Australia pointed out that he has estimated that three hundred successful extended wear patients would completely occupy a practitioner's time ad-infinitum.[5]

V. PATIENT INVOLVEMENT

Always implied in successful extended wear is a high degree of patient control. The extended wear prospect should know from the onset that this type of correction is not a universal remedy for his ocular needs free of any care, worry, upkeep, or danger. Patients should be taught insertion, removal, and cleaning. They should also be instructed to remove the lens in an emergency. Often when these criteria are presented to the convenience minded candidate, the desire for extended wear vanishes.[32]

VI. LENS PROBLEMS

The problems with the extended wear of lenses in patients with lens problems that do not affect the ultimate prognosis for vision are lens dislocation, lens loss, or lens deposits.[8]

1. Lens loss and dislocation: Studies cite a major cause of lens replacement is due to dislocation and loss from rubbing of the eyelids following a forceful blink. Another cause of lens loss is emotional tearing. Lost lenses may result from lens ejection during sleep in patients who sleep with their lids partially open.[8, 12]

2. Discoloration: Ophthalmic drops, notably those containing epinephrine or fluorescein can produce lens staining.[9]

3. Lens deposits: Non-organic precipitation are typically calcium salts forming centrally located punctate spots. This deposition can be a significant factor in the spoilation of hydrophilic contact lenses.[10] It is likely that the lacrimal fluid is a major source of the calcium.[11] Organic lens debris are protein and lipoid deposits. Regular removal and cleaning of the lenses is remedial, however once protein is tenaciously deposited on the lens, there is an effective loss of clarity, and a change in the base curve of the lens.[12] Fungal invasion is reported, but somewhat rare.[12]

In addition to the above lens problems, physical deformities and damage to lenses include chipping, cracking, splitting, and changes in rigidity. This has been reported to produce scleral perforation.[13]

VII. COMPLICATIONS

Associated with soft contact lens wear are the following complications:[14]

I. Lens Related

A. Initial lens application hypoxia

B. Chronic hypoxia induced problems

1. Compromised epithelium
2. Stromal edema
3. Neovascularization

C. Lens fitting problems

II. Patient Related

A. Infectious conjuctivitis, red eyes, corneal ulcers

B. Unsuspected glaucoma

III. Lens and Patient Related

A. Giant papillary conjuctivitis

B. Corneal opacification

C. Miscellaneous

Disturbances to corneal integrity include edema, pannus, epithelial microvesicles, corneal ulceration, and non-ulcerative keratitis.[15]

The degree of corneal edema may be mild enough so as not to result in an interruption of lens wear, or can be as serious a complication as acute keratopathy. The latter is a serious complication with edema present from endothelium to epithelium. Wrinkles form in Descemet's membrane and the epithelium is raised in vesicles. There is marked circumcorneal injection, extensive swelling of both upper and lower lids, and some flare and cells in the anterior chamber. The patient with acute

keratopathy is often prostrate with pain.[16] Changes in the endothelial mosaic clarity and endothelial "blebs" along with stria have been observed during early stages of continuous wear.[15]

Pannus and corneal vascularization is often seen in patients who have worn lenses for six months or more. Usually the vascular invasion is slow and limited to the anterior stroma or subepithelial regions.[16] The likely etiology may be prolonged hypoxia of the peripheral cornea due to lens thickness.

Epithelial microvesicles (microepithelial cysts) occur in a significant number of patients after four or more weeks of wear. Generally the number of vesicles is small, but can increase in number, coalesce, and form a paracentral annulus after several months of continuous wear. The microvesicles seem to begin near the basement layer of the epithelium and move forward with time, eventually breaking through the surface of the epithelium, and only then show staining. They may be collections of disorganized cellular growth or pockets of cellular debris and may be related to constant lens pressure bearing areas on the cornea.[15]

Corneal ulceration has been reported with subsequent development of hypopyon and dense scarring. No particular microorganisms were cultured from this eye or the contact lens in this report.[15]

The "red eye" reaction can be caused by one or a combination of non-ulcerative keratitis, conjuctivitis, and/or keratoconjunctivitis. The observation of debris trapped beneath the contact lens when the patient first presents symptoms of a red eye suggest the etiology of the condition may be an accummulation of

toxins on or beneath the lens. The most offending organism is keratoconjuctivitis is staphylococcus aureus.[16] Numerous other potential pathogens have been recovered in cultures of material collected from soft contact lens wearers.[17]

VIII. OXYGEN DEMANDS OF THE CORNEA

The normal intact cornea is maintained in a state of detergescence or relative dehydration in order to maintain its tranparency.[19] Oxygen is necessary for this process. Without sufficient oxygen, normal corneal metabolism is interrupted, altering the corneal hydration mechanism and resulting in the imbibing of water into the cornea. Most conventional hard and soft contact lenses create at least small amounts of corneal edema even when fitted ideally, and it can be argued that small amounts of edema are physiologically tolerable. For instance, the normal corneal swells to three to four percent during overnight sleep with no apparent long term effects.[20] The extended wear contact lens will act as a barrier to oxygen, especially under the conditions of the closed eyelid environment. Studies in the changes in corneal thickness due to extended lens wear show estimates ranging from an increase of nine percent during sleep[11] to no significant evidence of corneal swelling when topical solutions are not applied.[22]

Polse and Mandell[23] have quantitifed the critical oxygen tension necessary at the corneal surface to be 11 to 19 mm Hg to eliminate or prevent corneal swelling. Uniacke et. al.[24] defined the minimum oxygen level needed to maintain corneal

energy stores (glycogen) at about 35 mm Hg. Weissman and Fazio have shown that oxygen flux entering the cornea should begin to decrease in humans from its normal level (6 to 7 micro 1. O_2/sq cm hr) at about 20 mm Hg oxygen tension at the corneal surface. They have proposed this as another measure describing the point at which corneal metabolism is first compromised. Using this flux to determine a minimum transmissibility necessary to maintain total corneal health, Weissman found that not one of the FDA approved lenses for cosmetic extended wear would meet the criteria established for total corneal health under closed-eye conditions.[25, 26]

During sleep, the available oxygen to the cornea is roughly one-third the amount available during the open eye situation. Moreover, during sleep the eye's surface temperature rises, theoretically creating the need for even more oxygen to maintain its normal metabolism. Besides corneal swelling, pH changes occur probably due to build up of the carbon dioxide which is trapped beneath the lens and eyelid. And pH changes can alter lens parameters which, in turn, may cause a lens to tighten. In addition, osmotic changes in the tears may bring more water into the cornea, which adds to the edema problem.[7]

Obviously some corneal thickness increase is tolerated. Perhaps the fact that our eyes are open two-thirds of the day allows those who wear lenses under extended conditions to recover from the anoxia caused by the one-third of the time when the eye is closed over the lens.

IV. SUCCESS RATES

In the field of extended contact lens wear "success" is an elusive concept. Its definition and application vary from one investigator to another. The utilization of the lens also has a bearing on its "success". For example, Nesburn and Binder report success rates of 70 to 80 percent. In one study, Binder evaluated patients fitted with lenses for therapeutic purposes and for the correction of aphakia. A case was considered successful simply if the medical problem improved, or if the lens was fitted to improve vision and the vision improved. From this high, success rates in the literature drop to as low as 17.5 percent.[3, 8, 27]

Rubens requirements for extended wear include the maintenance of a physiological norm and tolerance to the presence of a foreign body. The ideal lens should be smooth and comfortable, not affected by temperature, pH or toricity, not liable to surface contamination, and not liable to deteriorate with time. All of these criteria are rarely met.[28]

Hodd defines a successful patient as one who has the following characteristics:[29]

1. Can wear the lens continuously with no discomfort.
2. Can see within one line of the spectacle acuity.
3. Has stable vision.

His reasons for failure:

1. General discomfort.
2. Lenses fall out or are displaced.
3. Poor or variable visual acuity.
4. Conjuctival injection.
5. Corneal edema.
6. Acute red eye reactions.
7. Patient complaint of lens being too visible.

8. Lenses greased up.
9. Lenses with white spots.
10. Using permanent medication.
11. Corneal problems, ulcers infiltration, and dry staining.

Hodd contends that appropriate patient selection can reduce the failure rate from 60 to 30 percent. He contends that those cases successful beyond six months remain successful. Maskell in his work found 61 percent discontinued extended wear after successfully adapting to the lenses for four or more months. His "success" rate was reported as 1 out of 3 for 150 cases.[30]

X. COST

In the United Kingdom fees charged by the practitioner to cover the fitting, supply, and one year's after care of the lenses is roughly one-and-one-half times the cost of daily wear lenses.[30, 32] This increase, of course, is to cover the additional practitioner's time and additional skill and responsibility involved plus the fact that more lenses will be used over the first twelve months. Permalens has produced data to show the relatively small increase in cost in an attempt to convince the patient (via the practitioner) that he would not lose too much financially by having extended wear lenses. That manufacturer estimates an average weekly cost over two years for extended wear lenses to be $3.77. For daily wear lenses $2.90 is the weekly cost.[32]

According to Cavanagh, et. al., an average patient in Georgia could expect to pay $550.00 for initial fitting and 60 to 90 days follow up care. An additional three or four office visits during the first year would be added. Replacement

costs for the two lenses the first year and thereafter should be between $100.00 to $200.00 per year. Over a 10 to 20 year period, replacement costs could thus reach the $4,000.00 range.[31]

XI. THE FUTURE

Maskell conducted an extended poll in the United Kingdom and found the responses indicated that fewer extended wear lenses were being fitted in 1980 at the time of the poll than were being fitted 18 months prior.[30] A majority of the respondents, however, felt that the use of extended wear lenses will increase. Many clinicians expressed concern over the long term effects on the eye and on the general well being of the patient. Other concerns were that: the risk/benefit ratio of extended wear lenses is not in the patient's favor; not only are they time consuming to fit and costly to maintain, they require the practitioner to be constantly available to respond to a patient's plea for help; visual acuity isn't always good; availability of the lenses is poor; lens reproduction is poor; and public demand is lower than was anticipated. It is interesting to find that although extended wear for cosmetic reasons was initiated and nurtured primarily in the United Kingdom, it would appear that no more than 25 to 50 United Kingdom practitioners out of 9,000 are engaged in fitting a reasonable number of extended wear lenses.[30]

Phillips gives the following predictions:[32]

1. Increased use of extended wear lenses in hospitals.
2. More care in selecting suitable patients.

3. More emphasis on "extended wear" rather than "permanent wear" coupled with greater use of cleaners for both in situ and normal use.
4. Development of lenses suitable for use as both daily and extended wear.
5. Dual development of better cleaners and disposable or easily replaceable lenses.
6. Slow increase in the use of extended wear lenses in cosmetic cases. Numbers increasing more rapidly during the 1980's as the problems are solved.

As the eye care profession in the United States moves into an era of extended wear lenses, the big questions it must ask itself are:

Just how much of an advantage is extended wear to the typical cosmetic case compared to the risks at this time?

Does the profession have enough time to fit all cosmetic contact lens patients with extended wear lenses?

The practical clinical success of extended wear contact lenses in some cases can not be denied, but for many patients extended wear still may be a goal for the future and not a present reality. From the standpoint of practical conveniences, increased use should still be the goal of the profession.

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