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Proposed practice guidelines for continuous contact lens wear

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The introduction of silicone-containing hydrogel contact lenses (SCHCLs) for continuous wear (CW) presents practitioners with a unique challenge. To facilitate the transition, we propose a set of guidelines for the conduct of CW practice. The general concepts for the guide are derived from a range of similar codes of practice that have been produced for a range of aspects of eye care. The more general competencies required of eye care practice are assumed and are not discussed in detail. The document is based on the precept that the prescription of SCHCLs is an appropriate practice for suitably screened patients. Practitioners should acquire general and specific knowledge of information applicable to CW with SCHCLs. Support staff should be educated to handle a range of requirements specific to CW. There are no consulting room facilities required beyond those necessary for general optometric practice but we highly recommend that the CW practitioner use grading scales for anterior eye complications and a guide to corneal infiltrative conditions. More stringent examination protocols are required than for general contact lens practice, particularly in the selection of the patient. Patient management should be conducted to a medical standard of care. Documentation is critical and will involve general information about the product, an agreement, disclosure of risk factors, instructions for wear and care, recording of patient questions and answers provided, an informed consent form and detailed, accurate record keeping. A guideline such as this document cannot be positioned as a legal standard of care, but may be used in the formulation of such a standard.

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Use of continuous wear[a] (CW) with traditional[b] hydrogel materials is accompanied by a range of changes to the cornea, including widespread alteration of its physiological status, inflammatory conditions and very occasionally microbial keratitis. In many countries, this led practitioners to forego CW throughout the 1980s and 1990s in favour of safer refractive alternatives. The introduction of silicone-containing hydrogel contact lenses (SCHCLs) has renewed interest in CW. The oxygen permeability of these materials is such that corneal physiological indicators remain essentially unaltered during wear.[1] The alleviation of corneal physiological stress during closed-eye wear is a long-awaited breakthrough that now sees experts advocate careful use of this mode of wear in practice.[2] A general lack of experience with CW and the absence of explicit practice guidelines presents practitioners with a challenge in adopting this new mode of care.

a. The term extended wear has been used to describe prolonged periods of contact lens wear, including sleep overnight, for up to seven days without removal. Continuous wear has been used to describe prolonged periods of contact lens wear including sleep overnight, for more than seven, preferably 30, days without removal. Continuous wear will be used as an all-inclusive term in this document to describe all forms of prolonged periods of lens wear including sleep overnight.
b. Traditional hydrogel materials are defined as those in which oxygen permeability is logarithmically linked to the water content (the dry material is essentially impermeable to oxygen) as opposed to SCHCLs, in which the oxygen permeability decreases with increasing water content.

A comprehensive set of guidelines for CW practice has potential benefit in three major ways. First, practitioners can adopt these guidelines as a procedural checklist to provide confidence in their clinical handling of CW. Second, patients will benefit from a set of practice procedures if they result in improved safety standards. Finally, the establishment of a standard approach provides a certain amount of direction to the practitioner who will be judged against an appropriate standard of care in the event of a legal dispute.

The general concepts for this guide arise with reference to a number of documents prepared for eye care practitioners, such as the 'Competency Standards for Optometry' prepared by Kiely and Chakman,[3] the 'Clinical Practice Guidelines of the American Optometric Association',[4] the draft 'Care of the Contact Lens Patient' component of that series,[5] 'Preferred Practice Standards of Optometrists Association Australia, Victorian Division',[6] the 'Code of Practice Standards of the Victorian College of Optometry'[7] and the draft 'Code of Practice for the Supply of Contact Lenses and Contact Lens Care Products'.[8] The excellent book of Kerridge, Lowe and McPhee[9] was also used for reference to legal issues as they apply to professional practice in Australia. The specific application of these guidelines to CW contact lens practice is drawn from the authors' own experiences over a number of years with contact lens wear, including more than three years of experience with SCHCLs in a clinical practice setting, reference to books on contact lenses, in particular the book by Sweeney[10] entitled *Silicone Hydrogels: The Rebirth of Extended Wear*, advice on numerous CW studies from the MOST enterprises research ethics committee and legal studies by two of the authors (AJ and DR).

PRINCIPLES

Although this document is primarily directed towards the provision of CW contact lenses in Australian optometric practice, eye care practitioners worldwide will find these guidelines to be relevant to their contact lens fitting procedures and management of patients. The focus on the profession of optometry lies in the fact that the vast majority of prescriptions in Australia for contact lenses are provided by optometrists. Eye care practitioners, other than optometrists, who are providing CW lenses should also be encouraged to adhere to these guidelines.

Competency in the more general aspects of optometry is assumed as a prerequisite for beginning CW practice. To this end, it is expected that a practitioner conducting CW practice has adequate knowledge, skill, accreditation and experience in general optometric and daily wear contact lens practice, the standards of which are provided in the sources listed above and are taught in various optometry schools around the world. The broad areas of practice incorporated in the above-mentioned documents include, but are not limited to, the following: minimum standard of premises in terms of appearance and cleanliness, access to standard consulting room equipment and competency with diagnostic procedures, general optometric treatment, counselling patients and referring where appropriate, record management and review procedures. The practitioner shall adhere to the general precepts of professionalism and maintenance of professional education. No further mention of these basic competencies will be made in this document but all will be assumed to be the minimum standard on which the guidelines for CW are constructed.

These proposed guidelines have been written based on the premise that the prescription of CW contact lenses is appropriate for individuals meeting criteria as outlined below. Continuous wear with traditional hydrogel materials, where parameters of SCHCLs overlap, is considered to be inappropriate and the guide provided here is directed specifically to the use of SCHCLs. The details provided apply, in particular, to correction of refractive errors for cosmetic and functional purposes. Specialist contact lens practice, including CW correction for therapeutic purposes and provision of CW with traditional hydrogel materials, requires competencies and skills additional to those given in these guidelines.

The guidelines are intended to represent a reasonable mode of practice, balancing the best interests of public safety with the benefits that CW may offer. We have aimed for the middle ground: setting the standard too high might make adherence unachievable for most optometrists, thereby running the risk of low compliance levels or restricting of the opportunity for patients to access CW. Setting the standard too low might put public safety at risk. With this guide we have aimed to approximate a reasonable standard of care for CW that a court might determine. These guidelines also recognise the patients' right to make an informed choice about their care. The pricing of services and goods is not considered within the scope of this article, as the general precepts of professional care as described above apply to this topic.

KNOWLEDGE AND SKILL

A minimum level of knowledge is requisite for operating a CW practice. For most experienced practitioners, this will require an extension of previously held knowledge through continuing professional education. Some of this knowledge will fall into the category of general science, representing a body of information that has no immediate practical implication but enables a professional to care and manage a patient in a complex scenario. For example, the practitioner should have an enhanced knowledge of the physiology of the eye, the biochemistry of the tears, general principles of microbiology and the anatomy of the anterior eye and lids. A background of education in the general principles of CW is assumed, including complications and management of CW with traditional hydrogel materials. This includes, *inter alia*, knowledge, understanding and skill in interpretation of the items listed in Table 1.

The use of SCHCLs requires knowledge and understanding of the features of these lenses including, *inter alia*, their composition, oxygen permeability, water content, surface characteristics, mechanical prop-

- Presenting history and suitability of a patient to enter CW
- Characteristics, cause, significance, risk factors, strategies for prevention, presentation, differential diagnosis and management of various effects of CW contact lenses on the eye, namely:
    - Short-term physiological effects including, *inter alia*, striae and folds, corneal oedema, endothelial blebs and corneal staining
    - Long-term physiological effects including, *inter alia*, microcysts, vascularisation, endothelial changes, infiltrates, staining and tarsal conjunctival changes
- Symptomatic problems including, *inter alia*, complaints such as discomfort and lens dryness
- Complications including, *inter alia*, contact lens induced acute red eye (CLARE), contact lens related peripheral ulcers (CLPUS), corneal abrasions, superior arcuate epithelial lesions (SEALS) and contact lens induced papillary conjunctivitis (CLPC)
- Adverse effects, covering the spectrum of infective keratitis
- Applications of systems used in the care and maintenance of contact lenses
- Use of clinical equipment and interpretation of findings with such equipment
- Assessment of the suitability of a patient to sign an informed consent and follow instructions

Table 1. Areas in which practitioners fitting CW lenses should have knowledge, understanding and skill in interpretation

- Answering basic questions on CW
- Knowing when to seek advice from the practitioner in response to questions on CW
- The assignment of appropriate examination timing and duration
- An appreciation of the importance of timing and attendance for the after-care schedule
- Following up patients who do not attend for after-care appointments
- Documenting the attempts to contact non-compliant patients
- Understanding how to be conservative with a patient's health
- Advising on the appropriate maintenance of CW materials, such as cleaning and use of appropriate solutions and lubricating drops
- The differentiation of emergency situations from those that require a routine appointment
- Being able to take appropriate action in the case of an emergency situation
- Understanding the wearing and replacement schedules and the bases for these schedules
- Monitoring of the appointment scheduling and follow-up
- Monitoring of lens replacement

Table 2. Areas in which office staff in CW practices should be educated

erties and fitting characteristics. The practitioner should also understand the differences between SCHCLs and alternate contact lens materials, and between different SCHCLs on the market. The practitioner should attend continuing education courses regularly and read the literature on new developments concerning SCHCLs, to remain current with changes in the field. The practitioner should also have knowledge, understanding and skill in interpretation of the characteristics, cause, significance, risk factors, strategies for prevention, presentation, differential diagnosis and management of various signs observed primarily with CW of SCHCLs lenses, such as the appearance of mucin balls, inter alia.

OFFICE PROCEDURES

The legal principle of vicarious liability applies to the practice of optometry. This means that any actions or advice given by people acting on behalf of the optometrist are attributable to the optometrist. This applies both to components of the examination, which might be legitimately delegated or to casual enquiries to a receptionist. To meet this responsibility, the optometrist should ensure that office staff are educated to deal with situations relating to CW, which may include, *inter alia*, those items outlined in Table 2.

Procedures should be in place to enable timely dealing with complications and adverse reactions. Practitioners are advised to use a mobile telephone or a 24-hour pager service. An answering machine is not considered an adequate substitute for this purpose because of the potential delay in receiving the alert to a potential problem. Arrangements may be made for rotation of on-call practitioners within or between practices. A hospital outpatient facility should be identified and details of the contact lenses and care provided to the patients to present in the case of an emergency. Where the attending practitioner is based in a remote area and does not have immediate access to medical treatment, more stringent criteria should be applied before fitting CW.

CONSULTING ROOM FACILITIES

There is no requirement for additional consulting room equipment above that used in the conduct of a standard optometric examination and daily wear contact lens practice. The following items are considered essential.

1. A slitlamp biomicroscope with a minimum magnification of or about 16x and adequate resolution to decipher the endothelial mosaic.
2. An instrument for assessing the curvature and optical quality of the cornea, such as a keratometer or corneal topographer.

We also highly recommend that the practitioner make use of:

1. A set of grading scales such as those

provided by the CCLRU[11] or Efron[12] to be used in the assessment of ocular health. They are beneficial in quantifying clinical observations, the severity of a condition, its progression or regression.

2. The CCLRU/LVPEI Guide to Corneal Infiltrative Conditions[13] to aid in the differential diagnosis and management of such conditions.

EXAMINATION PROTOCOLS AND PROCEDURES

The practitioner should be familiar with and competent in the operation of all clinical equipment and interpretation of findings from such equipment. In particular, the practitioner should be skilled in slitlamp biomicroscopy; for example, the practitioner should be capable of observing and assessing epithelial microcysts and the corneal endothelium.

Practitioners should ensure that they have the necessary information available, either provided by a competent colleague or obtained first-hand by examination, to determine the suitability of a patient for CW. This will include, *inter alia*:

1. Details from a general ocular examination conducted no more than 12 months prior to lens fitting.
2. Details from an initial contact lens examination conducted no more than 12 months prior to continuous lens wear fitting. It is assumed that the information obtained from the examination will include aspects of a general first visit for a contact lens wearer who is to undertake daily wear of contact lenses.

In addition, the suitability of a patient to be fitted with CW contact lenses should be based on assessment of a number of features including, *inter alia*, those items outlined in Table 3.

Patients should be selected for CW conservatively and the principles of informed consent should be applied meticulously for the marginal patient. Wearing schedules should be selected to suit the individual and a 30-day removal schedule should not be assumed to be the best option for all. The practitioner should allow adequate time for education and discussion with the

- Ocular health—as a guide to a patient's suitability to enter CW. A pre-fitting lens health reference table is provided in Sweeney[14]
- Demographic and lifestyle features, which may impact on the success of CW
- The competency of a patient to sign an informed consent form and to follow instructions for the use of the lenses and action to take in the case of an emergency
- The fit of the lens on the eye. Criteria for acceptable fit should be more stringent than those used for daily wear of contact lenses, in terms of good centration and movement and absence of lens edge lift
- The appearance of the lens on the eye in terms of wettability
- Vision achieved with the lenses

Table 3 . Features to consider before a patient commences CW

- Assessment of the wearing history and related factors since the last examination
- Measurement of vision
- Gross external examination
- Slitlamp biomicroscopic examination of the contact lenses on the eye and assessment of fit, centration, wettability, movement and deposits
- Slitlamp biomicroscopic examination of the eye with lenses removed for the purpose of assessing ocular health, both with white light and with cobalt blue light using a wratten filter and fluorescein instillation. Lid eversion is also an important feature of this examination.

Table 4. Essential aspects of the after-care schedule

- A description of the product and its regulatory status
- A statement to the effect that the patient has a duty to advise the practitioner of any reasons that may invalidate his or her ability to consent to the agreement
- A list of the complications and adverse effects that may occur with CW, their symptoms, management and potential outcomes. In particular, the agreement should disclose that the chances of suffering an infectious corneal ulcer with CW is estimated to be 20 in every 10,000 people wearing CW per year, of which approximately one in 10 suffer significant vision loss.[15,16] However, it should be noted that these figures are specific for CW of traditional hydrogel materials.
- A statement to the effect that it has not been demonstrated that wearing SCHCLs eliminates such complications and adverse effects. Although some research suggests adverse events may be reduced,[17,18] epidemiological evidence to support that premise does not exist at the time of writing.
- A description of the mechanisms by which the risk of a complication or adverse outcome is minimised, and the importance of compliance with the following points to achieve this risk minimisation:
    - The after-care schedule
    - The prescribed wearing schedule
    - The prescribed lens replacement schedule
    - Care and maintenance procedures of the lenses
    - Steps to follow when given symptoms arise
- Options other than CW
- The practitioner undertaking (see Table 6)
- The responsibilities that the patient agrees to bear (see Table 7)

Table 5. Essential points of the practitioner-patient agreement for CW

- Explanation of what the lens is and does
- Full disclosure of possible complications and risks
- Availability and access to care and advice
- Advice on emergency procedures including contact numbers in case of an emergency
- Advice on whom to contact if a dispute arises from the agreement or the conduct of the practitioner
- Commitment to:
    - Advise appropriately on the suitability of the patient to wear CW
    - Provide care to the best ability of the practitioner
    - Provide details of other options for refractive correction
- Freedom to discontinue wear without prejudice
- Willingness to respond to all questions
- Willingness to provide the patient with all appropriate documentation

Table 6. Essential details of the practitioner undertaking

- The choice to wear CW
- Disclosure of all information that may be relevant to the success in CW
- Seeking advice from other sources re CW and the agreement—professionals, family, friends et cetera.
- Asking questions of relevance to CW
- Attending for after-care or visits scheduled outside the usual after-care routine
- Following instructions for wear and replacement
- Adherence to instructions for the care of lenses
- Following instructions in case of adverse reaction

Table 7. Responsibilities the patient agrees to bear

- Wearing and cleaning schedule
- Lens replacement schedule
- Care and maintenance of the lenses
- Care of the lens case
- Instructions on use of comfort drops
- Vigilance with regard to solution expiry date
- How to check lenses in the eyes on a daily basis
- Follow-up visit schedule
- Key features of urgent problems and how to distinguish them from less urgent issues
- When to refrain from wearing or sleeping in lenses
- Steps to take in the event of a problem

Table 8. Instructions for patients adopting CW

patient to ensure that all appropriate aspects of CW are understood.

Close monitoring of ocular health during CW is essential. An after-care schedule should be tailored for the individual. Recommended timing for after-care following lens delivery is at day one, one week, one month, three months, six months and then at intervals of not more than six months.

Usually, when a patient has been wearing lenses in CW, after-care will consist of at least the items outlined in Table 4.

This routine may vary depending on circumstances and additional components should be added depending on signs and symptoms recorded during the course of the examination.

The ongoing suitability of a patient to continue in CW should be based on assessment of the signs and symptoms of the patient. A useful reference table to success in CW is provided in the Sweeney[14] book. Management should be based on addressing patient concerns and any signs arising from the examination. In particular, the management of complications should be performed to a medical standard of care. The practitioner should identify the need for referral in appropriate circumstances, such as when the patient's management requirements are outside the bounds of competency of the practitioner or there are other reasons in which the patient's interests are best served by referral, and facilitate arrangements for the attendance. Where a complication has potentially sight-threatening implications, management of the conditions should be instituted immediately.

PATIENT ADVICE, INSTRUCTION AND DOCUMENTATION

The practitioner is responsible for informing, advising, educating and counselling the patient regarding CW and its suitability for the individual. Results of initial and follow-up examinations and implications for the patient should be communicated in a manner that is easy to understand. It is highly unlikely that circumstances will arise in which withholding of information is appropriate. Items that may need to be commu-

nicated include, *inter alia*, the following.

1. Relationship between examination findings and symptoms reported.
2. Discovery of signs that may be of relevance to the patient's eye health.
3. Reinforcement of safety protocols and procedures.
4. Recommendation for management as necessary.
5. Explanation of alternative management options and disadvantages of such options compared to the recommended course.
6. Recommendation for further examination if warranted.

The prescription and supply of CW contact lenses entails a unique risk among optometric services, so it is important to have a range of documentation encompassing the pertinent aspects of CW. Brennan and Coles[14] provide a sample set of documentation in which they outline the general principles surrounding the construction of such information.

General information

To help the patient make an informed choice about using contact lenses in CW, the practitioner should make information available to the patient about the following.

1. The lens material, its advantages over previous materials, known effects of CW on ocular health, complications of CW, risk factors for adverse events, the cost of the lenses and the cost of care.
2. Options other than CW, such as daily disposable lenses, two- or four-weekly disposable lenses worn in daily-wear mode, frequent replacement lenses, rigid gas permeable lenses for both daily and CW, spectacles and refractive surgery. The comparative advantages of these modalities should be provided to the patient.

This material may be in written form with the practitioner ensuring that any questions the patient might have are answered fully prior to dispensing CW lenses.

Patient-practitioner agreement/ disclosure

An agreement between the patient and the practitioner, in the form of an official statement, should be provided. Such a statement should provide a full disclosure of all factors that may be relevant to the patient's ability to make an informed choice about the use of CW contact lenses. This document should include, *inter alia*, the points listed in Table 5. It should also disclose the undertaking that the practitioner makes to the patient, providing such details as outlined in Table 6, and the responsibilities that the patient agrees to bear, including those items listed in Table 7.

This information should be provided in terms that the layperson can understand.

Instructions for wear and care

These instructions should be provided in written form to ensure that comprehensive advice is given and that the responsibilities of the patient are clear. Points to include, *inter alia*, are outlined in Table 8.

There is a risk that a defective product might be made available to the patient and it is important to explain to the patient that the nature of frequent replacement lenses prevents all lenses from being inspected and verified by the practitioner. The patient should be instructed to examine the lens prior to wear and about those symptoms that may indicate a defect in the product.

Question and answer sheet

All relevant questions that the patient asks regarding the provision of CW lenses and the answers provided should be documented. We recommend having a blank sheet of paper attached to the remainder of the documentation to formalise this process.

Informed consent form

The informed consent form formalises the relationship between the patient and practitioner. The purpose of this form is to demonstrate that the patient has been provided with the appropriate information to make an informed choice and is willing to undertake CW with the collateral risks. It is signed by the patient, the practitioner and a witness. Brennan and Coles[14] suggested a sample document.

Record keeping

Each encounter with the CW patient should be documented, even if it is simply a telephone call to ask a simple question. For examinations, documentation of the presenting history, content of the examination and management advice is a critical feature of all professional services provided by optometrists and this tenet is imperative for CW practice. Non-compliance with any components of the wear, replacement, care and after-care schedule should be clearly recorded.

DISCUSSION

The development of guidelines for the conduct of CW practice may seem out of context when it is considered that guidelines have not been specified for many other components of eye care and optometry in Australia. For example, daily wear of contact lenses has been the most frequent cause for litigation being brought against optometrists. However, of the routine parts of optometric practice, the provision of CW contact lenses is fraught with the most danger, and has globally resulted in the greatest number of large-scale legal actions.[19] Therefore, we consider that it is more important to establish guidelines for CW practice than it is for some of the other components of optometry. The introduction of a new genre of CW materials also makes these guidelines timely. The American Optometric Association is producing codes of practice for a variety of different aspects of optometry and it is likely that such codes will continue to be developed, both in and outside the United States. As the profession of optometry develops, further refinement of aspects of this proposed guideline is likely.

The relationship between a set of practice guidelines and a legal obligation is obtuse. It is not possible to provide a comprehensive pre-emptive standard of care for legal purposes. Establishment of a reasonable standard of care is a matter for a court to decide after the event, depending on the circumstances of a given case.[9] In part, this is likely to be based on the opinions of a representative group

of practitioners. As such, the guidelines provided here could be used in the development of an appropriate standard of care for a given scenario, but this document should not be taken as a definitive statement in this regard. Classé[19] reports the following as the major sources of legal action in contact lens care: failure to manage corneal infection, inappropriate patient selection, inadequate training of the patient, improper wear schedules, improper management of other contact lens related complications and inadequate monitoring of corneal health. Classé[19] has also listed the major ways to minimise litigation and we have attempted to incorporate these precepts into the guidelines.[19]

Some practitioners may see the establishment of practice guidelines as a defensive approach to the provision of care. Some may perceive it as cynical to practise primarily in a fashion designed to minimise the risk of litigation. Others may claim that the documentation of guidelines will add to the number of lawsuits by providing a checklist against which an individual might be assessed. Still others will object to the development of codes of practice on the grounds that they infringe on the decision-making base of professionalism. In the end, this article is produced in an attempt to provide some guidance to the optometrist who is unsure of the requirements for setting up CW practice and as a document that may add to the provision of consistently good service to the community.

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