Good clinical practice in orthokeratology

Pauline Cho *, Sin Wan Cheung, John Mountford, Peter White

School of Optometry, The Hong Kong Polytechnic University, Hong Kong SAR, China

Abstract

Overnight orthokeratology is becoming more and more popular especially in the Asia-Pacific region where the treatment is primarily used for myopic control in young children. Risk of complications in contact lens wear increases during overnight wear and may further increase when the treatment is used on children. The aim of this paper is to provide a comprehensive guideline for practitioners to improve their orthokeratology practice and minimize unnecessary or preventable complications.

The fundamental requirement for starting an orthokeratology practice is to have proper education in the area and to equip the practice appropriately. Overnight trial fitting is recommended to confirm the physiological response prior to commencement of the treatment. Practitioners should provide adequate information, both oral and written, to patients before and after the commencement of treatment to avoid any legal dilemmas and to improve patients’ compliance. Costs for the treatment should be transparent and provision of an emergency contact number is a must. Patients should be regularly recalled for aftercare visits and all communication with patients should be properly documented. In this paper, patient selection and the clinical procedures were discussed and a standard of practice in orthokeratology proposed.

We believe that the key to providing a safe orthokeratology practice is to continually update knowledge in the field, and to practice to the highest professional standards.

© 2007 British Contact Lens Association. Published by Elsevier Ltd. All rights reserved.

Keywords: Orthokeratology; Guidelines; Overnight wear; Standard of care

1. Introduction

Optometry is a primary care health profession, yet it has the unique dichotomy of providing a professional service as well as supplying the required optical aids at a profit. It would therefore be prudent to open this discussion with reference to the “rights” of “patients” compared to those of “customers”. In terms of the optometrist’s professional relationship with the patient, this is governed to a large degree by whether the relationship is contractual or not. With respect to orthokeratology (ortho-k), legal responsibility is usually established under tort law, whereby the practitioner’s duty of care, legal obligation, or standard of care is not necessarily dictated by a formal, written agreement between both parties, but is reflected by the common law system. Any sub-standard practice may result in a civil claim for compensation arising from professional negligence. However, some practitioners may prefer to establish a contractual relationship with their patients, in terms of services and goods provided, and this in turn would be governed by contract law [1]. In this case, the patient would appear more like a customer. Nevertheless, whatever the relationship, the legal responsibilities of the optometrist are set in law and cannot be ignored, as the law protects the patient/customer in both cases.

Overnight wear ortho-k is becoming increasingly popular for myopic reduction in many parts of the world [2]. Recent studies have shown the treatment to be effective for slowing the progress of myopia [3,4] and this is likely to increase the use of ortho-k. Modern ortho-k involves the use of RGP lenses worn on an overnight wear basis. The advantages of this modality are less lens awareness, easier adaptation, lower risk of lens loss and a faster reduction in refractive error compared to daytime wear [5]. Also, the patient benefits from the freedom of having to wear optical correction during the day which may interfere with sports and recreational activities.

The major drawback of overnight wear ortho-k is the potentially higher risk of corneal ulceration [6–10]. In many
Asian countries, where myopia has a high prevalence, ortho-k is mainly prescribed for slowing myopic progression in children, and in most cases, overnight therapy is used. The Internet is replete with unsubstantiated claims regarding the efficacy of the procedure and this, unfortunately, is the most common source of information for patients and parents interested in the treatment for their children. This can lead to unrealistic expectations and inappropriate or misleading information which can lead to unhappy patients and/or serious complications. A patient may claim compensation if the practitioner makes unsubstantiated statements which result in harm, as this may constitute negligence, or if the practitioner is unable to provide reasonable care and skill in diagnosis, advice and treatment resulting in injury to the patient [1].

Guidelines have been established for silicone hydrogel contact lenses for continuous wear [11]. In view of the increasing popularity of overnight ortho-k, where children may be involved, there is a need to develop guidelines for this specialized treatment for the ortho-k practitioners [1]. Therefore, this paper aims to provide guidance for practitioners on the standards required for competent clinical practice in ortho-k. The authors also see the paper as a means of initiating discussion between practitioners so that a universally acceptable code of practice can be adopted internationally.

2. Clinical setup

In the early days of revived interest in ortho-k in the late 20th century, there was little or no structured education available. Practitioners had to educate themselves via trial and error, or apprenticeship with a colleague experienced in the procedure. However, ortho-k practice has since evolved rapidly with improvements in the technique, including higher Dk lens materials, advanced lens designs and corneal topography for monitoring corneal shape changes. There has also been a concomitant increase in the amount of published scientific research on the effects and limitations of the procedure, and specialized education programs developed in order to raise the standard of practice.

Practitioners who wish to undertake ortho-k practice should therefore attain the required educational standards and equip their clinic properly prior to fitting patients. This is already mandatory in the USA, where practitioners cannot access supply of lenses until they have been certified to FDA standards. The authors of this article firmly believe that pre-certification, prior to supply, should be the standard for ortho-k practice, so as to safeguard the interests of all stakeholders. To that effect, an ortho-k course, organized by the School of Optometry of The Hong Kong Polytechnic University, has been established and is running annually at the local level for practitioners in Hong Kong, providing certification for individuals who successfully complete the course.

2.1. Practitioners’ education in the fundamentals of ortho-k practice

The most important preparation prior to ortho-k practice is for practitioners to attain a comprehensive knowledge of the underlying science of the process, including the pros and cons, the risks and benefits, how to fit, assess and manage ortho-k patients, and issues relating to aftercare. Practitioners will also need to continue to update their education as new information comes to light. In fact there is a legal obligation to do so, as clarified by case law [12]. Practitioners must update their knowledge and ensure that practice does not become obsolete or outdated. This can be achieved via continuing education, including lectures, workshops, conferences, reading journals and from communication/sharing with peers. As stated in White and Cho [1], in legal terms, the practitioner would not be able to justify a lack of training for any shortcomings arising out of practice, nor argue that ignorance of a new treatment, e.g. ortho-k and its consequences, resulted in the adverse outcome. Practitioners have a legal obligation to keep pace with advancement should they decide to extend their practice to envelop ortho-k practice. What is also clear from case law, in common law jurisdictions, is that inexperience is no defense in terms of negligence claims in the civil courts [13]. Therefore, if one is not competent to practice independently, due to lack of experience, then adequate supervision is a must.

2.2. Minimum clinical instrumentation

There is of course the need to equip their practice with appropriate instruments and/trial lens set(s), apart from the basic instrumentation required for contact lens practice (slit lamp, etc.). The importance of the corneal topographer cannot be over-emphasized, and it should be considered mandatory for a practitioner to not only own one, but also to be conversant in reading and understanding the information generated by it. Topographical data is used to design the lens parameters and diagnose both the optimal and sub-optimal effects of the lens on corneal shape. It is an important tool to aid the practitioners to monitor and manage their patients properly and adequately.

The practitioner should be aware of the features of the instrument that make it suitable for ortho-k practice. These include:

1. A high degree of accuracy and repeatability.
2. Statistical analysis of repeated readings of apical radius and eccentricity or elevation.
3. Axial, tangential, and refractive power and curvature maps.
4. A “difference” or subtractive map function.
5. Pupil recognition.
6. A large area of corneal coverage with minimal interpolation.
As stated previously, the accepted standard for instrumentation for ortho-k is ownership and use of a corneal topographer.

Maldonado-Codina et al. [14] have shown that the use of a corneal topographer, to design the lens and monitor the results, is a distinct advantage. Other worthwhile equipment would include a radiuscope for checking the accuracy of the lens manufacture and a microscope for lens inspection.

2.3. Trial lens sets

Various manufacturers supply trial lens sets so that the practitioner can assess the corneal response to the lens prior to proceeding fully with a course of treatment. Undoubtedly, more than one common practice may exist among different practitioners with different pros and cons. In the case of trial lens sets, practitioners may choose to have a partial or full set. Where some practitioners may choose not to use any trial set, but to send patient data to the laboratory or to directly order lenses via lens fitting software, the first lens ordered for the patient will serve as the trial lens and will be kept by the patient if the ortho-k results are good. It is essential that all trial lenses are made from the highest Dk material available, as low Dk material will not be suitable for overnight trials. Maldonado-Codina et al. [14] have shown that the use of trial lenses instead of empirical prescribing can lead to a reduction in the number of lenses required as well as the resultant saving in chair time.

Trial lenses can be stored either wet or dry. If stored dry, the lenses should be carefully cleaned with a recognized RGP cleaning agent, rinsed with saline and then dried prior to placement in the holder. The lens holder or case should also be cleaned regularly. If stored wet, the same rules apply, but care must be taken to replace the storage solution at regular intervals, and to check the lens container for biofilm build-up. Lenses should also be checked regularly for scratches (slit lamp microscope) and warpage (radiuscope).

2.4. Trial fitting

What is the adequate settling time for trial ortho-k fitting? There are variations among practitioners. Some practitioners do not keep trial lenses and order the first trial lenses by sending relevant ocular or lens data (either the K readings or the suggested lens parameters by lens fitting software) to the laboratory. After the lenses are received, ortho-k treatment for the patient commences with the very first pair of lenses tried. For empirical fitting, usually the only corneal data supplied to the laboratory are the K readings and it is reported that empirical lens fitting will not lead to a high first-fit success rate [14]. Also, the effects of the lens on the cornea with respect to physiological response are unknown prior to the commencement of the treatment, that is, a patient may start on a course of treatment when it is inappropriate.

Some practitioners allow a couple of hours of settling time, e.g. the patient is fitted with a pair of trial lenses and asked to wear them for a specified period in the daytime and then return for evaluation to determine if the lenses are acceptable. When the patient returns, lens fitting (fluorescein pattern and lens movement) is evaluated, and corneal topographical changes are determined. The prescription lens design is then determined from the results. Others allow the patient to take the trial lenses home to wear overnight and to return early the next morning to determine the lens fitting and corneal topographical change. The results from this are then used to determine whether further trials are required to optimize the results or whether the final lens parameters can be calculated and the lenses ordered. This method is the most scientifically valid for the following reasons:

1. Significant change in lens fit can occur as short as 10 min of lens wear, that is, the validity of the observation of the second trial lens can be affected by the changes induced by the first trial lens [15].
2. A short (1–4 h) open eye trial wear period may give clues on refractive and visual response but cannot give the same outcome as a full overnight trial of 8 h [15].
3. Overnight ortho-k involves closed eye wear of the lenses and not open-eye wear, where the effects of lid forces and blinking can have an effect on lens centration.
4. Closed-eye trial would determine ocular response to overnight ortho-k.

Therefore, overnight trial is the preferred standard of lens fitting. It is the only valid means of determining the centration of the lens and the physiological suitability for the treatment.

2.5. Appropriate charges for ortho-k treatment

Ortho-k requires practitioners to be diligent and vigilant. Regular and frequent aftercare to monitor corneal changes is essential. This is particularly important if children are involved. It is therefore necessary for practitioners to take the increased chair time into account when deciding on the appropriate professional fee level. Fees charged for ortho-k practice vary from one practice to the next. The important issue here is that the fee structure is transparent and that any patient agreeing to undergo a course of treatment using ortho-k lenses is fully aware of the short- and long-term costs of the treatment. There must be no hidden costs or misrepresentation, as this could impact negatively on the validity of the patient’s consent or, if applicable, on the nature of the contract for services provided. There is a legal responsibility to communicate sufficiently with patients so that they are able to make informed decisions. Any information which could potentially influence the patient’s decision to undergo or forego a treatment or examination should be disclosed. One’s duty to disclose also includes a thorough and accurate representation of the costs. In the
Australian case of Rogers vs Whittaker [16], the judgment determined that:

“There is a fundamental difference between, on the one hand, diagnosis and treatment and, on the other hand, the provision of advice or information to the patient . . . Because the choice to be made calls for a decision by the patient on information known to the medical practitioner but not to the patient, it would be illogical to hold that the amount of information to be provided by the medical practitioner can be determined from the perspective of the practitioner alone or, for that matter, of the medical profession.” [17]

The same rules apply to the optometry profession and patients must be duly informed about costs. How this information is disclosed may vary, as some practitioners may choose to offer a package price, including the first pair of lenses that fit satisfactorily and a year of aftercare consultations, whereas others may choose to charge their patient per pair of lenses used, and a separate charge for aftercare. Provided the costs are transparent, and the patient is aware of these, then there should be no legal dilemma. Ortho-k patients will continue to require regular and frequent aftercare for as long as they continue to use ortho-k lenses and patients should be made aware of this from the outset.

2.6. Information and consent forms

In contact lens wear, ortho-k is not daily wear, nor is it extended wear. However, it does involve overnight wear and, though the risks involved in ortho-k are not fully understood, it can be argued that it is expected to increase the risk over daily wear contact lenses [18]. Although the Dk/t of lens material used is high, it is still below the amount estimated by Harvitt and Bonanno [19] to deliver adequate oxygen to the cornea to avoid hypoxia under closed eye conditions. It is therefore important for prudent practitioners to provide adequate information to the patients before (Information sheets and Consent forms) and after commencing the treatment (Education materials and advice).

2.6.1. Information sheets

In the case of children, before the patients and their parents join the treatment, information about the treatment, the pros and cons of ortho-k, potential and foreseeable risks associated with ortho-k lens wear, and the alternatives available, should be given. Table 1 is an example of written advice on the pros and cons of ortho-k lens wear. The information should not only point out the practitioner’s duty of care to the patient and the charging system but also the patient’s responsibilities with respect to lens care, maintenance and aftercare visits. An example of an information sheet is shown in Fig. 1. Most importantly, the patient must be given a ‘cooling–off’ period where they are encouraged to think about the information they have been given, and have the ability to seek clarification [1]. Only then should the treatment commence.

2.6.2. Consent forms

Consent forms are important but are frequently overlooked or underused. An example of a consent form is shown in Fig. 2. The practitioners should also be clear about the legal age of children who may sign the consent form. Children of 16 years of age have reached the age of majority in terms of setting their own health care course, as determined by section 8 of the Family law Reform Act 1969 in England and Wales, and hence may legally consent to treatment or examination without the parent/guardian being informed. For children/minors below the age of 16 years, the parents should normally be involved in the decision-making process and decisions will be made in the child’s best interests after assessing the potential risks and benefits. The same age criteria apply in Australia. It is prudent to involve both the child and parent in the decision-making process at the consent stage prior to ortho-k treatment, especially with respect to mature minors, i.e.

| Table 1 |
| Example of written advice on the pros and cons of ortho-k lens wear |

<table>
<thead>
<tr>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>In successful overnight wear, good vision can usually be maintained throughout the day after lens removal.</td>
<td>Ortho-k is NOT a CURE for myopia. The treatment effect will wear off gradually after stopping lens wear.</td>
</tr>
<tr>
<td>Night therapy brings convenience to those who do sports or who do not like to wear conventional contact lenses or spectacles during the day.</td>
<td>Ortho-k lenses require more time to fit compared to conventional contact lenses. Aftercare consultations are more frequent to ensure effective and safe treatment.</td>
</tr>
<tr>
<td>Our recent research has shown the treatment to be effective in slowing myopic progression in children.</td>
<td>Due to changes in ocular environment under close eye condition, the risk of complication is relatively higher than day wear regime.</td>
</tr>
<tr>
<td>On average, ortho-k can usually reduce myopia of 4.00D within two weeks. However, individual variation does exist.</td>
<td>Some contact lens-related problems, such as solution sensitivity, infection or corneal epithelial trauma may occur, though the risk of complication is very dependent on compliance.</td>
</tr>
<tr>
<td>Complications associated with conventional contact lens wear, such as dryness and irritation from dust can be avoided.</td>
<td>Non-compliance or poor compliance can result in significant corneal abrasion, red eye and discomfort. Corneal ulceration may result if the condition is not detected earlier or left untreated.</td>
</tr>
<tr>
<td>The treatment is reversible and can be stopped anytime. The eyes will soon resume their normal condition thereafter.</td>
<td>Treatment effect may vary and is patient dependent. Some patients may not be able to achieve the desired effect.</td>
</tr>
<tr>
<td></td>
<td>During the course of treatment, temporary spectacles may be needed.</td>
</tr>
</tbody>
</table>
Orthokeratology

Orthokeratology (Ortho-k) is an option for vision correction for myopes by altering the corneal shape. It only "treats" myopia but does not 'cure' myopia. It is only a temporary measure and the effect will be reversed if you stop wearing your ortho-k lenses.

The treatment time is dependent on the individual. This treatment includes a number of scheduled and unscheduled visits. Unscheduled visits are usually necessary if there are any unexpected problems. Missing or turning up late for any of the scheduled follow-up appointments will delay the treatment. The number of lenses required for this treatment is patient dependent.

You need to return for regular (frequent) follow-up visits, and to strictly follow the instructions given by your optometrist during the treatment period. This is extremely important, as failure to comply may lead to complications, and in severe cases you may need to stop the planned treatment with no refund.

Common lens complications include:
- Mild lens binding on awakening (you will be taught how to dislodge a bound lens safely and easily)
- Mild (superficial) corneal staining (which will normally heal after a few hours)
- Solution allergy (you will be switched to another care system)
- Fluctuating vision on certain days after myopia reduction (this could happen if your lenses did not centre properly when you wore them the night before)

All these complications will be kept to a minimum if you follow instructions properly.

During the treatment, before complete myopic reduction, you may be required to temporarily wear spectacles/disposable contact lenses to correct remaining Rx during the day time to aid vision. When the treatment is completed, you will need to continue to wear the final pair of lenses to maintain the myopic reduction effect. Regular after-care visits (3-6 monthly) are still necessary to ensure the health of your eyes.

It is important that you come for these regular check-ups even if you do not have any complaints.

Payment of the treatment for the first year is $___________ and will be made in _______ installments over the first _______ months. The payment includes the preliminary and fitting consultations, the lenses and _______ number of aftercare in the first year. The cost of replacement lenses will be $_______. If you are required to stop this treatment due to undesirable ocular responses (e.g. unacceptable degree of complications in spite of clinical actions, or poor eye response to this treatment), there will be no refund of the installment paid. You may stop the treatment anytime without any commitment on the balance. If you decided to stop the treatment, two complementary eye examinations will be provided to ensure recovery of the shape of your cornea. You would need to return all the ortho-k lenses prescribed before, as using these lenses without proper instructions and monitoring may lead to complications.

Please note that severe complications in contact lens wear without early detection or intervention include corneal infection and possible vision loss.

Fig. 1. Example of information sheet.
Practitioners should therefore consider avoiding the prescription of suction holders and teach children how to remove their lenses by blinking or manipulation with their fingers.

Leaflets or handouts on how to remove a bound lens properly, how to use the suction holder safely, and how to care for the lens and lens accessories would be useful for distribution to the patients or their parents/guardians. It is not advisable to try to incorporate all necessary information, including those previously mentioned, in the consent form. It is advisable to have them in separate handouts for distribution to patients for reference.

2.6.4. Communication with patients

It would not be professional to simply distribute instructions/advice or forms for patients to read by themselves. A diligent practitioner needs to go through the forms/instructions/advice to ensure that the patient has understood the content and to allow the patient the opportunity to ask questions. Again, this can reflect on the validity of the consent, as patients must be informed in terms they may readily understand and having time to digest the contents of documentary information is an important consideration. As mentioned earlier, it is important that patients are clear about the pros and cons of ortho-k, and the
alternatives afforded to them. Practitioners should not allow
potential refusal of treatment to stand in the way of properly
informing patients, as patients must be able to make informed
decisions. Well-informed patients are more likely to comply
and are less likely to encounter problems. The important thing
is for practitioners to establish good rapport with their
patients. Having gone through the forms and handouts with
the patients, it is also important that the practitioners
document these actions in the patient’s file, or such
documentation may be indicated by a clause in the consent
form. This will minimize the chance of practitioners
forgetting to provide any set of instructions to the patients
and also be protective in civil cases when the practitioner and
patient disagree over the information provided. The need to
document has been clearly stated in Chester vs Afshar [23], a
case where there was a conflict of recollection between the
parties about what exactly the patient had been told. In this
case the defendant practitioner had made no notes about the
information provided and failed to convince the trial judge
that he had provided sufficient information. This typifies the
need to keep detailed contemporaneous notes on the patient’s
record of information received, especially about risks of
treatment. Disclosure of risks, pros and cons, and limitations
of ortho-k practice may be in written, verbal or video format.
All formats may be appropriate or reasonable, depending on
the circumstances at the time, and provided that the patient
understands what is being communicated. However, the
patient must be afforded the opportunity to ask questions and
to seek clarification on unclear issues. Therefore, face-to-face
appointments or telephone discussions, at least, should be
arranged to provide the patient the opportunity to do this.

Apart from oral and written advice and instructions, on-site
demonstration on how to care for the lenses is also important.
The importance of compliance cannot be over-emphasized
[24], and showing relevant examples of good compliance in
the office would be a good start. Special emphasis should be
placed on the care of lens accessories, particularly the lens
case and lens suction holder (if prescribed), as these items
have been identified to be the most frequently and severely
contaminated items in ortho-k [21,22]. Reviewing cleaning
and disinfecting procedures for lenses and accessories at
every aftercare visit would be prudent and essential as it has
been shown that most patients forget after a while. To ensure
that patients replace their lens case and suction holder
regularly, practitioners may consider getting patients to bring
these items back in exchange for new ones, as it has also been
shown that patients tend to forget to replace them [21,22].
Patients should also be reminded not to store accessories in
bathrooms or toilets. The standard of practice should therefore
consist of written and verbal communication with the patient
of the relevant risks and benefits of the procedure and the costs
associated with it, both initial and long-term.

Since ortho-k lenses are worn at night, it is important for
practitioners to provide a telephone number for their patients
in case of emergency. The telephone number may be written
or typed on a card which the patient can access easily, and
should not be buried in one of the information or instruction
handouts.

2.7. Consultation forms

As mentioned earlier, it is important for practitioners to be
meticulous in the documentation of the management of ortho-
k patients [23]. To minimize inadequate record-keeping, the
conventional contact lens record forms may be modified to
include checklists of essential assessments for each type of
consultation for ortho-k patients. An example of this is
presented in Appendix A (aftercare form). These checklists
will also serve as evidence of appropriate management and
care in case of a lawsuit. Should a legal case arise, it would be
the practitioner’s word against the patient’s, and any such
documentation (including consent form and information
handouts) would have greater credence and would lend
weight to the practitioner’s case.

The standard of care would therefore require specific and
comprehensive consultation documentation.

2.8. Properly educate supporting staff

It is important that supporting staff should be educated to
handle ortho-k queries. It is vital that staff have an accurate
understanding of what is involved in ortho-k. They should
not make over-zealous statements nor should they provide
misleading or negative comments. It would be advisable to
draft a list of frequently asked questions and the appropriate
answers.

The supporting staff should also be educated properly to
handle emergency calls.

If they are involved with insertion and removal, it is
important to keep a check on them, e.g. regular reviews
(unannounced of course) may be necessary to ensure a
quality service. They should also be educated on the
importance of compliance and proper care procedures.

Some practitioners will save the chair time by allowing
the supporting staff to teach the lens handling techniques. In
that case, the supporting staff should be properly trained by
the practitioners prior to handling a case. They should also
be educated and familiar with all the information to be
delivered to the patients. It is advisable that after the patients
can successfully handle the lenses, practitioners should
confirm their competency before dismissing the patients.

3. Clinical pearls in ortho-k practice

Some simple clinical pearls that can act as a guide to ‘best
practice’ in ortho-k are listed below.

3.1. Select patients carefully

In ortho-k practice, as in routine cases, it is prudent to
select patients carefully. Practitioners are well advised to
avoid patients with unrealistic expectations and, where children are involved, avoid taking on child patients whose parents cannot commit time and effort in monitoring lens usage and care, or bring their children in for aftercare consultations.

At what age should children be fitted? This question is frequently asked by both practitioners and parents. There is no norm. Some practitioners do not fit children, some practitioners fit children over 7 years old, and some practitioners fit children as young as 5 years old [25]. The decision is basically up to the practitioners. The important issues are that (1) parents are clearly and properly informed and are supportive, not coerced and/or misled, and (2) the practitioners fit the children because they see the need and are prepared to take diligent and vigilant care of the children. In cases where the child refuses to undergo the treatment, but the parents are keen, it would be prudent to forego the treatment, as there is an increased risk that the child will not be compliant, hence increasing their exposure to risk. Furthermore, coercion from the parent or practitioner to persuade the child to undergo the ortho-k treatment would also violate the criteria for voluntary consent and hence vitiate the consent.

Also, the child’s medical history MUST be taken into account. Does the child suffer from any general medical condition where their immune system may be compromised? Is the child taking any medication that may interfere with their ability to safely wear contact lenses (e.g. Roaccutane), or do they suffer from any chronic general or mental health issue? What is the standard of living of the patient, and how far away from help are they if a problem arises? What is their general environment like? Children have immaturely developed immune systems, so the practitioner must be careful in assessing the challenge to that system that the overnight wear of contact lenses would invoke.

Children/minors are a particularly vulnerable group of patients who may lack capacity to consent to treatment, so it is vital that advice provided for parents/guardians is clear and detailed so that they can safeguard the interests of their children/wards. The parent/guardian must accept the responsibility to help minimize the risks associated with the treatment and be able to note early warning signs of problems which may arise. They must also be able to take appropriate action whenever necessary, but can only do so if properly informed by the practitioner.

3.2. Information and consent form + verbal advice

As mentioned earlier, it is important that the patient is adequately informed, and given a chance to ask questions about the treatment on a regular basis. Failure to do so may expose the practitioner to accusations of breach of duty and carelessness, which may constitute negligence if the patient suffers harm. Ortho-k patients will undertake a treatment with known and foreseeable risks, so the practitioner has a duty to provide reasonable aftercare, which includes regular monitoring of the patient’s progress and updates on information to ensure that the best interests of the patient are assured. Consequently, it is highly advisable that patients are provided with an emergency contact number, especially as lens wear usually takes place after normal office hours.

3.3. Delivery

Patients (or parents if child cannot handle this procedure) should be taught how to insert and remove lenses, and should not be allowed to leave with the lenses until they have shown that they can perform these tasks properly. They should be taught to remove their lenses by the standard technique, with the procedures being the same as for RGP lenses. However, in view of the significant problem with lens binding, it might be prudent to advise removal of lenses after instillation of a drop of lubricant.

Parents and patients should be given the name of a proper anti-bacterial hand wash that they can procure from the pharmacy, and advised about the absolute importance of hand washing prior to lens insertion and removal. Written instructions are also essential. The patient should also be directed to the location of the closest emergency eye centre should it be needed.

The use of a suction holder to aid insertion and removal should be avoided to prevent dependency on the suction holder. It has also been reported [21,22] that patients tend to forget about proper care of accessories, and a suction holder is one of the most heavily contaminated items in contact lens wear. However, if for whatever reason, it has to be prescribed, careful instructions, written and oral, should be given to ensure proper use and care of this accessory.

Other advice, applicable to general contact lens wear, about abnormal and normal symptoms that may occur should be given, and the schedule of aftercare explained (see Section 3.4). The wearing schedule will be determined for each individual in the following visits. It has been reported that some patients only need to wear the lenses every second night, but this cannot be used as a general rule, so the optimal wearing schedule must be determined for the individual patient. Some practitioners ask patients to stop wearing the lenses during the weekend so as to rest but there is no scientific evidence to support this argument. Oedema/ staining problems, if any, will not be resolved by asking a patient to rest one night during the week.

3.4. Schedule of aftercare (standard of ortho-k practice)

Unlike conventional contact lens wear, an aftercare schedule for ortho-k patients is more intensive especially during the first year, and it is essential that patients, particularly children, return for the scheduled aftercare to minimize complications and to enhance compliance. We recommend the schedule presented in Table 2. As discussed earlier, since overnight wear is involved, it is important that the patient returns early the next morning, after the first overnight lens wear, to check for any signs of oedema.
Table 2
Recommended standard of practice in orthokeratology

**Orthokeratology
Standard of Practice**

The practice must be equipped with a corneal topographer and a slitlamp biomicroscope (40X), and the practitioner must be competent with the use of these instruments to monitor corneal changes after orthokeratology treatment.

**Preliminary consultation**
As in conventional Contact Lens Practice plus the following:
- Use of informed consent form** which should include a phone number for the patient to contact practitioner after office hours in case of emergency.
  **children should not be coerced into the treatment (eg. in cases where parents are keen, but the children refuse to wear the lenses)
- Patient must have pre-fit corneal topography.

**Delivery consultation**
As in conventional Contact Lens Practice plus the following:
- Instruction on proper use and care of lens suction holder (if appropriate)
- Instruction on the use of ocular lubricant on awakening before lens removal
- Instruction on how to loosen and remove a bound lens

**Aftercare consultations**
As in conventional Contact Lens Practice plus the following:
- **First early in the morning aftercare consultation**
  - after *first overnight lens* wear, within 2 hours after awakening with lenses on (however, lenses should be removed immediately if there is any abnormal sign or symptom)
    - this visit is necessary for every pair of new lenses delivered
    - check
      - for lens binding, lens centration and fluorescein pattern
      - unaided visual acuity
      - refraction
      - corneal health (*specifically check for corneal edema and central corneal staining*)
      - corneal topography
    - lens condition
      - to decide if the patient is suitable to continue orthokeratology lens wear based on the above examination results
- **Subsequent aftercare consultation** (if no problems in first aftercare visit)
  - 7 days, 14 days, 1 month and then 3 monthly after commencing lens wear for the 1st year (subsequently 6 monthly visit)
  - can be any time of the day, but MORNING visits, within 2 hours of awakening, should occur (with or without lenses depending on the outcome of the first morning aftercare) on at least every third visit in the 1st year (maybe once a year thereafter).
  - After about 3 months of successful lens wear, check regression (ie. morning + late afternoon evaluation) to determine the wearing schedule most appropriate/suitable for the patient
  - Check
    - unaided visual acuity
    - refraction
    - corneal health
    - corneal topography
    - lens condition
    - to decide if patient is suitable to continue orthokeratology lens wear based on the above examination results
- **at any of these subsequent visits**
  - if the parents (of patients under 16 yrs old) are not at any of these visits, they should be informed if any significant findings or change in treatment plan were decided
  - if the treatment or management plan was significantly modified (which may affect patients/parents decision to continue the treatment), informed consent should be renewed.
3.5. First aftercare visit

The first aftercare appointment after a delivery (of every new pair of lenses) should happen early the next morning, within two hours after awakening, with the lenses in situ. This allows the practitioner to check for corneal oedema if present. Although the Dk/t of RGP material used in ortho-k is high, there are people whose corneas have higher oxygen demand, and it is not possible to identify these individuals. So no matter how high the Dk of the lenses, it is still prudent and necessary to check the next morning to ensure that no significant oedema or central corneal staining has occurred.

The routine consists of:

1. Slitlamp examination of the lens on the eye to determine the presence of binding.
2. Slitlamp examination of the cornea for signs of oedema (e.g. striae and folds) and for staining.
3. Over-refraction to serve as a baseline for determining any increase in myopia.
4. Removal of the lens by the patient to check the competency in lens handling.
5. Unaided VA and refraction to determine the visual outcomes.
6. Corneal topography to determine the centration of the effect and the treatment zone diameter.

There is an absolute necessity to assess the presence and extent of central corneal staining early in the morning. If significant (≥Grade 2 CCLRU Scale), then clinical action must be taken since the central cornea is significantly compromised and may increase the risk of microbial keratitis. If the patient was not assessed until later in the day, any signs of corneal oedema or significant central corneal staining may have resolved, and the practitioner will have missed these significant signs, which may lead to serious clinical complications. The standard of practice therefore requires some aftercare consultations (beside the first one) to be performed in the morning, within 2 h of lens removal (see Table 2).

At this aftercare visit, advice on lens care and maintenance need to be reiterated and reinforced. Care of lenses and lens accessories cannot be overemphasized, and it is prudent to spend adequate time going through the procedures diligently. Improper or inadequate care of accessories has been shown to be the main cause of microbial contamination, so it is important for the practitioner to stress the need for daily cleaning and weekly disinfection. These procedures are presented in Table 3.

3.6. Subsequent aftercare

After the first aftercare visit, depending on the outcome of the visit, a subsequent visit is usually arranged 1 week after the first overnight wear. If indicated, it may be arranged on the next day or 2–3 days later. The recommended aftercare visit schedule is shown in Table 2. After the treatment has settled satisfactorily, regular aftercare visits, once every 3 months in the first year and every 6 months thereafter should be recommended. During the subsequent aftercare, it is important to record unaided VA, aided VA, the residual refractive error, biomicroscopic findings, and to take corneal topographic maps. The use of a modified aftercare form, e.g. with checklist of tests to perform, would be useful. It is important not to underestimate the importance of aftercare visits, particularly corneal changes, as it has been reported that subtle corneal changes can occur with ortho-k [26–31].

It is also important to review care procedures and the commitment of the parents/patients at these visits, and re-educate them if necessary. Over time, parents/patients tend to become complacent, and reviews/re-education will serve to decrease the level of non-compliance. To avoid forgetting and for documentation purposes, we suggest the use of a checklist incorporated in the aftercare form as shown in Fig. 3. If necessary, patients can be asked to sign next to the checklist.

3.7. Communication with parents/patients

Ensuring willingness for commitment from both parents and children, establishing a good rapport, and gaining the trust of patients/parents, are very important. These contribute significantly to the success of the treatment, and decrease the chance of complications due to non-compliance, and the unhappy aftermath from poor corneal response or unrealistic expectations.

3.8. Recall of patients for aftercare

In conventional contact lens wear, in particular soft contact lens wear, patients are notoriously bad at returning for aftercare consultations, especially after a few months of lens wear. In ortho-k, the risk of serious complications associated with lens wear is higher due to overnight lens wear, so it is important to ensure that patients return for scheduled aftercare consultations. It is also suggested that
the cost of the treatment should encompass the cost of all the aftercare consultations for a period of time, e.g. for a year. Patients should not be left to decide whether or not they come, and it is advisable for practitioners to ensure that they do return for aftercare. What if patients failed to show up in spite of repeated phone calls? We suggest that at least three phone calls should be made and documented, and if the patient still fails to show, a registered letter should be sent to the patient. If this is done, then the practitioner has taken reasonable steps to fulfill his/her duty and any harm resulting from future use of the lenses can be defended by citing the patient’s non-compliance. Under such circumstances, a court of law is likely to agree that the patient has been at fault as a consequence of contributory negligence, as the patient has failed to follow clinical advice.

4. Conclusion

Overnight ortho-k is gaining popularity and the interested practitioners need to be well prepared. Practitioners need to equip themselves well to practice ortho-k and diligent and vigilant care is essential. There is still a lot we do not understand about ortho-k, and rightly a lot of research is still going on to seek further understanding and to increase the safety of ortho-k practice. It is therefore important that practitioners keep abreast of latest developments in ortho-k and continue to improve their ortho-k practice to provide quality service to their patients.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.clae.2007.07.003.

References


[12] Roe vs Minister of Health. 2 All ER 131; 1954.


