

Professional Practice Guidelines on Orthokeratology

1. Introduction

1.1. Orthokeratology (often known as "**Ortho-K**") refers to the fitting of specialty gas permeable contact lenses to correct refractive error, mainly due to myopia. It is also known as Corneal Reshaping or Corneal Refractive Therapy (CRT).

1.2 For Ortho-K lenses, the user is only required to wear them while sleeping overnight. The lenses work when the user's eyes are closed by temporarily reshaping the front surface of the cornea, resulting in an alteration in the refractive status of the eye.

1.3 The user is able to see clearly the following day once the lenses are removed upon waking up; the clarity in vision can be sustained even when the lenses are no longer on the eyes. The effect is temporary and reversible; it would gradually wear off as the cornea restores to its original shape with time toward the end of day. The maximum duration of the effect is dependent on the amount of refractive error and may last more than a day for lower refractive error. With the user's continued use of the lenses on a prescribed schedule, the effect can last longer.

1.4 Ortho-K is suitable for people looking for a temporary vision correction and do not want to wear spectacles or contact lens during daytime, especially those who participate in contact sports or work in dusty environments that may pose issues for contact lens wear.

1.5 Several research has shown promising results that Ortho-K is effective in reducing the progression of axial myopia in children, the fitting of ortho-K is gaining popularity in recent years, especially for children and adolescents as an enhanced way to manage myopia.

1.6 Similar to any other types of contact lenses, improper use of Ortho-K lenses and nonadherence to the prescribed care regime and review may lead to undesirable complications. As it involves overnight wearing of the lenses, there are increased risks of developing complications, including corneal ulceration, which is potentially sight threatening should the lenses be poorly fitted and/ or the user is non-adherent to the cleaning regimen, instructions for use and regular review. Children are especially more vulnerable to adverse events.

1.7 To protect public safety, the Optometrists and Opticians Board ("**OOB**") has commissioned for the development of these professional guidelines (referred to as "**Ortho-K Practice Guidelines**") to set minimum standards and provide guidance to ensure competent practice in Ortho-K and to safeguard patient safety in wearing Ortho-K lenses. The Ortho-K Practice Guidelines took reference from the established practice standards of other developed countries; it is not intended to replace, but to be used in conjunction with the current Code of Professional Conduct and Professional Practice Guidelines ("**PPG**") issued by the OOB.

2. Professional Certification for Qualified Practitioners

2.1 All registered optometrists and qualified opticians (contact lens practice) are trained to prescribe, fit and dispense contact lenses. Ortho-K is an area of specialty contact lens practice which requires greater practical experience, expertise, and standard of care by the registered optometrists and qualified opticians (contact lens practice) who are keen to fit (collectively refer to as "**Ortho-k practitioners**").

2.2. It is strongly advised that the Ortho-k practitioners undergo relevant professional certification(s) or academic programme(s) conducted locally or overseas that is accredited by OOB for Continuing Professional Education (CPE) before offering Ortho-K to their patients.

2.3 A good Ortho-k courses/ programme **must** include <u>both</u> theoretical and practical teaching, as listed in the Annex.

2.4 Ortho-k practitioners should continuously attend relevant CPE programme to stay current in practice.

3. Indication for use

3.1 Professional roles and responsibilities: Ortho-k practitioners must exercise professional judgment to assess suitability of individual patients on a case-by-case basis, and closely refer to the approved uses for the respective lens products, as well as to recognize when the use of Ortho-K must be halted and reviewed in existing patients.

3.2 Lens Assessment: Ortho-K practitioners should perform corneal topography before and after lens fitting, and perform trial fitting where possible. The lens to be fitted and subsequently dispensed must be in good condition, free from defects.

3.3 Patient Selection: Ortho-k can be fitted on patients, subject to thorough evaluation and considerations such as patient's age, maturity, refractive error, anterior eye and adnexa's health, motivation level and ability to handle rigid gas permeable lenses.

3.4 Myopia Control: Ortho-K may be used as an adjunctive method of myopia control in children.

4. Contraindication for use

4.1 Professional roles and responsibilities: Ortho-k practitioners should exercise professional judgment to assess the suitability of individual patients on a case-by-case basis.

4.2 Excluding conditions: As with any other types of contact lens, Ortho-k lenses must not be fitted when any of the following conditions exist:



- a) Active inflammation/infection of the anterior segment of the eye such as blepharitis, vernal conjunctivitis;
- b) Eye disease, injury or condition that affects the cornea, conjunctiva or eyelids;
- c) Reduced corneal sensation
- d) Systemic disease and/ or use of medication that may affect the eye or be exacerbated by wearing contact lenses;
- e) Allergic reactions of ocular surfaces or adnexa which may be induced or exaggerated by wearing contact lens or use of contact lens solutions;
- f) One seeing eye patient

4.3 Conditions that may affect comfort: Ortho-k practitioners should exercise discretion in fitting Ortho-k lenses for any of the following conditions:

- a) Severe insufficiency of tears (dry eyes);
- b) Corneal hypersensitivity;

4.4 Optical considerations: Pupil size and correction zone are important factors to consider when assessing the risk of glare and subsequent vision impairment in Ortho-K.

5. Prescribing, Dispensing & Sale of Ortho-K Lenses

5.1. Under the risk classification of medical device by Health Science Authority (HSA), all prescriptive contact lenses are regulated as Class B medical devices, including Ortho-K lenses, which must be supplied through authorised/ registered personnel.

5.2 Practitioners shall ensure that the Ortho-K lenses dispensed or fitted on patients comply with the current product regulation and manufacturing safety standards approved by relevant local health authorities.

6. Practice Facility and Clinical Equipment

6.1 The general requirements for contact lens practice as detailed in PPG prevails.

6.2 It is required for the practitioner to employ the use of slit-lamp biomicroscope, diagnostic dye (i.e. sodium fluorescein), corneal topography in practice and be competent in the operation of the said equipment/instruments and the interpretation of findings/readings obtained.

6.3 As reliable corneal topographical readings are required for the design and/ or selection of the lens parameters and subsequent assessment of the fitted lenses. It is therefore strongly recommended that the equipment for corneal topography (e.g. video keratoscope) possesses the following features/ functions:

- a) A high degree of accuracy and repeatability;
- b) Statistical analysis of repeated readings of apical radius and eccentricity or elevation;



- c) Axial, tangential, and refractive power and curvature maps (covering the area of at least 8mm of central cornea);
- d) A differential or subtractive map function;
- e) Pupil recognition; and
- f) A large area of corneal coverage with minimal interpolation.

6.4 For myopia management, an appropriate instrument for axial length measurement is advised.

7. Informed Consent and Documentation

7.1 Prior to commencing on Ortho-K, practitioners shall obtain informed consent by advising the patient, or patient's parent/ legal guardian, about the risks, benefits and alternatives of the procedure.

7.2 Practitioners shall also refrain from aggrandizing the effects and benefits of the procedure and provide realistic expectations to their patients. Ortho-K should not be advertised as a cure for myopia or any other refractive errors.

7.3 The advice to and consent by the patient must be clearly documented as part of the patient's ophthalmic record. The patient shall be given a written copy for reference.

7.4 If the patient is a child or adolescent (below 16 years old), there must be a parent or legal guardian present to give consent.

7.5 All relevant records of patient encounter shall be kept for **at least 6 years based on the date of last visit**, regardless of whether they are in electronic or paper format. Practitioners are encouraged to keep records for longer duration, if possible.

8. Patient Education

8.1 Practitioners must ensure that patient is proficient in proper lens handling and hand hygiene. Hence, practitioners shall educate patients on the following areas before dispensing any lens:

- a) Techniques for insertion, removal, re-positioning of dislocated lens and freeing up a bound lens;
- b) Adequate lens cleaning regime for Ortho-K lenses and related accessories;
- c) Recommended contact lens solutions to be used;
- d) Recommended replacement schedule for Ortho-K lenses (up to 1.5 years) and related accessories (3 months for lens storage cases); and
- e) If a suction holder is prescribed, proper cleaning and disinfecting of the suction holder is required, and it should be replaced after 6 months of use.

8.2 It is required to educate the parent or caregiver on the above if the wearer is less than 16 years old or unable to handle/ adhere to the regimen. Parent or caregiver should ensure compliance with the regime.



8.3 Information sheets should be given to patient for the retention of knowledge and adherence to proper lens-wear regimen. Regular follow-up should be conducted to ensure continued adherence.

8.4 An emergency contact for after office hours should also be provided to the patient in case of any occurrence of adverse events.

9. Aftercare and Frequency

9.1 To minimise undesirable complications and to ensure compliance, scheduled aftercare is important, especially for any patient who is prescribed, dispensed or fitted for the first time, or existing patient with a new set of lenses.

- 9.2 The recommended schedule for aftercare is detailed as follows,
 - a) First aftercare (early in the morning the following day after lenses were fitted) after the first overnight lens wear and within 2 hours from awakening with lenses on.
 - b) Subsequent aftercare to be done in 7 days, 14 days, 1 month, 3 months and followed by routine review once every 6 months.

9.3 Subject to the individual condition of the patient, the practitioner may have to schedule further aftercare and ensure proper follow up in the given period, if necessary.

- 9.4 During aftercare examination, practitioners should evaluate/examine the following:
 - a) Assessment of the lens fit after overnight wear (especially during first aftercare);
 - b) Unaided and aided vision acuity;
 - c) Anterior ocular health;
 - d) Corneal topography;
 - e) Lens condition; and
 - f) Axial length measurement (for myopia management),

10. Delegation of Duties and Care

10.1 Ortho-k practitioners may delegate any activities, and are responsible for the delegation, that would involve the examination and evaluation of ocular health and its function to other optometrists or qualified opticians (contact lens practice) and provide access to the patient's ophthalmic record for continuity of care with patient's consent.

10.2 Any relevant findings by the delegated optometrists or qualified opticians must also be clearly documented in the patient's ophthalmic record, and communicated with the original ortho-k practitioners timely.

10.3 Where it appears that a patient has developed complications which are beyond the scope of competence for the practitioner to manage, the practitioner should refer the patient to a medical professional who has the necessary expertise to advise and manage the patient.



<u>Note</u>: This guideline is not exhaustive and is subject to further changes where further evidence or knowledge in the field of ortho-k becomes available, allowing for better outcome and augmenting patient safety.



References:

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We would also like to express our sincere gratitude to our ophthalmologist colleagues in the College of Ophthalmologists, Prof Heng Wee Jin and Prof Quah Boon Long, for their invaluable inputs.



Annex:

A non-exhaustive list of recommended courses/ programme:

- a) Specialist Diploma in Community Optometry, Ngee Ann Polytechnic
- b) Vision by Design Conference, America Academy of Orthokeratology of Myopia Control (AAOMC)
- c) Global Orthokeratology and Myopia Control Conference, Asia Optometric Congress
- d) Myopia Management Accreditation Program, Asia Optometric Congress
- e) BCLA-HKAOK Orthokeratology Continuing Education (OKCE) Course, Hong Kong Polytechnic University
- f) OSO Conference, Orthokeratology Society of Oceania