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International survey of orthokeratology contact lens fitting

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ABSTRACT

Purpose: . To determine the extent of orthokeratology (OK) contact lens fitting worldwide and to characterize associated demographics and fitting patterns.
Methods: . Survey forms were sent to contact lens fitters in 45 countries between January and March every year for 14 consecutive years (2004 – 2017, inclusive). Practitioners were asked to record data relating to the first 10 contact lens fits or refits performed after receiving the survey form.
Results: . Data were obtained for 295,044 contact lens fits, of which 2,702 were with OK lenses and 292,342 were with other lens types (non-OK). Overall, OK lenses represented 1.2% of all contact lens fits, with significant differences between nations ($p < 0.0001$), ranging from no fits recorded in Brazil, Egypt, Indonesia, Iran, Lithuania, Nepal and the United Arab Emirates, to 6.0% in The Netherlands. There has been a slight overall increase in OK lens fitting over the survey period ($p < 0.0001$). OK lenses were fitted to younger persons (OK, 25.0 ± 12.8 years vs. non-OK, 39.8 ± 14.9 years) ($p < 0.0001$). A higher proportion of males (55%) were fitted with OK lenses versus non-OK lenses (30%) ($p < 0.0009$). There was a skewed distribution towards OK lenses being fit with higher oxygen permeable materials ($p < 0.0001$) and on a planned replacement basis ($p < 0.0001$).
Conclusions: . OK contact lens prescribing is a niche activity, with this lens type typically being fitted in high oxygen permeable materials on a planned replacement basis to younger males. The slightly increasing rate of OK fitting, albeit at a very low level, may be attributed to practitioner interest in the reported myopia control properties of this lens type.

1. Introduction

Orthokeratology (OK) has been discussed in the refereed literature for over half a century, with a PubMed search for the term 'orthokeratology' revealing the first paper on the subject to have been published by Ziff in 1968 [1]. In its original form, OK involved wearing flat-fitting hard lenses made from polymethyl methacrylate (PMMA) during the waking hours, with the intention of progressively flattening the cornea to reduce the degree of myopia, so as to afford reasonable vision following lens removal [2].

The introduction of highly gas-permeable rigid materials, reverse geometry designs and instrumentation to monitor changes in corneal topography has allowed the correction of low to moderate levels of myopia and astigmatism with OK lenses, shifting the approach from daytime wear of lenses to overnight wear (so-called 'overnight orthokeratology' [3]). Contemporary OK lenses are worn overnight to induce a flattening of central corneal curvature to temporarily correct myopia, and are removed upon waking to provide reasonable vision throughout most of the waking hours [3]. Practitioners fitting such lenses are obliged to weigh up the benefits of this approach (minimizing lens discomfort due to closed-eye lens wear during sleep) versus the disbenefits (increased risk of microbial keratitis during overnight lens wear [4]).

More recently, it has been proposed that OK has an additional benefit of arresting the progression of myopia (so-called 'myopia control') [5–19]. This is thought to occur as a result of the optical configuration of reverse geometry lenses and its impact on peripheral corneal molding, whereby positive spherical aberration in the molded corneal periphery creates an apparent reduction in the optical stimulus for eye

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growth [20].

Although there has been much discussion about OK in the referred literature, clinical magazines, internet forums, conferences and the like, little is known of the true extent to which these lenses are fitted around the world. This paper examines trends in, and factors associated with, OK contact lens fitting in 45 countries over a 14 year period (2004-2017, inclusive). Such information can provide (a) a valuable yardstick for contact lens clinicians, against which they can assess their own prescribing approaches to OK, and (b) useful guidance to the contact lens industry on the clinical utilization of this specialist lens category.

2. Materials and methods

2.1. Conduct of the annual survey

Between January and March each year from 2004 to 2017, a contact lens fitting survey was distributed in 45 countries. This was achieved through the offices of members of the International Contact Lens Prescribing Survey Consortium (see Acknowledgements), which is a network of academics, industry representatives, and clinical colleagues who have agreed to manage the survey in their country or geographic region, as outlined below.

Each Consortium member was requested to send a paper or electronic (e-mail) survey form to as many contact lens practitioners (opticians, optometrists and/or ophthalmologists, depending on the market) in their country as possible, with a notional target of 1,000 surveys sent. Some smaller countries were unable to reach this target due to the limited number of practitioners in that region.

In some countries, such as Australia and Spain, survey forms were sent to virtually every practitioner (about 5,000 and 6,000 practitioners, respectively). In other countries, survey forms were sent to a selection of practitioners throughout the country; this process varied among countries, ranging for example from a computer-generated random list of exactly 1,000 recipients from the national practitioner register in the UK, to a list of practitioner-subscribers to contact lens trade publications in the USA and Russia. In large countries with dispersed populations, such as China and Russia, survey forms were sent to practitioners in a select number of major urban cities. The survey forms were sent together with a request that they be completed and returned within three months of receipt. To minimize any possible seasonal influences or potential impact of the annual business activity cycle on the types of lenses fit, the survey was conducted in the first few months of each year in all countries.

The same survey format was used each year, as published previously [21]. This standardized, one-sided survey form was locally translated. The form guided practitioners to enter a number of background details and to supply generic information about the first ten contact lens fits performed after receipt of the survey form. For each contact lens fitting, practitioners were requested to complete the following details: date of fitting, new fitting or refitting, age and sex of patient, lens material, lens design, frequency of lens replacement, times per week of lens wear, wearing modality (daily or extended wear) and care system [21]. Practitioners were asked to return the form irrespective of the number of patients seen (if fewer than 10). The returned forms were logged and data from each form were manually entered into an Excel spread sheet (Microsoft Corporation, Redmond WA) to facilitate data analysis.

The Office of Research Ethics at the University of Waterloo, Canada, granted approval for this work, and noted that, as the data being collected were (1) part of normal practice care provision, (2) transcribed from the practice patient records, and (3) de-identified in respect of the patients and source practice, then the requirement for patient informed consent was waived.

2.2. Statistical analysis

Differences among practitioners in relation to the amount of contact lens fitting performed were accounted for by assigning an appropriate weighting to each recorded contact lens fit. This was achieved by estimating the number of contact lens fits performed each year by each respondent (based on the date information provided on the survey form) and using this as a weighting factor. For example, the data generated by a practitioner completing all 10 fits in one week were given twice the weighting of a practitioner who fitted 10 patients in two weeks. Data were mined with the aid of the Excel® Pivot Table function. Analysis of the main differences within the dataset and changes over time were conducted using logistic regression models (JMP, SAS Institute Inc., Cary NC) for OK lens fits. More detailed analyses – such as comparison of materials fitted and replacement intervals prescribed – were assessed using an unpaired Wilcoxon test.

3. Results

3.1. Demographics

Data were accessed from 45 countries, each reporting information about at least 500 contact lens fits, during the 14 year survey period (2004-2017). This generated a database of 295,044 contact lens fits, of which 2,702 were with OK lenses and 292,342 were with other lens types (non-OK). The median country response rate was 3,197 fits over this period, ranging from 508 fits in Egypt to 61,731 fits in Japan.

OK lenses represented 1.2% of all weighted contact lens fits; however, there was considerable variance in OK lens fitting among the 45 countries surveyed ($\chi^2 = 1{,}120$, $p < 0.0001$), ranging from no fits recorded in Brazil, Egypt, Indonesia, Iran, Lithuania, Nepal and the United Arab Emirates, to 6.0% in The Netherlands (Fig. 1). OK fits represented 1.4% of all contact lens fits in East and Southeast Asian nations (N = 9 nations: China, Hong Kong, Japan, Indonesia, Korea, Malaysia, Philippines, Singapore and Taiwan) and 1.1% of all contact lens fits in all other nations surveyed (N = 36 nations); this difference was not statistically significant ($\chi^2 = 0.0$, $p = 1.0$). Fig. 2 is a colour-coded 'heat map', showing the extent of OK fitting around the world.

The overall extent of OK contact lens fitting has slowly risen through the 14 year survey period ($\chi^2 = 266$, $p < 0.0001$), increasing from 0.5% of all lens fits in 2004 to 1.3% in 2017 (Fig. 3).

The mean age (± standard deviation) of those fitted with OK lenses (25.0 ± 12.8 years) was lower than for non-OK fits (39.8 ± 14.9 years) ($\chi^2 = 1{,}054$, $p < 0.0001$).

Using an approach which the authors have described previously [22], data relating to the age of individual lens wearers were stratified into groups that were considered to represent different stages of maturity, in respect of a combination of factors such as the prevalence of myopia, communication skills, lens handling capabilities and level of financial and contact lens-related decision-making independence. These age groups comprised infants (≤ 5 years), children (6 – 12 years), teenagers (13 – 17 years) and adults (≥ 18 years). The distribution of OK and non-OK lens fits in respect of these four age groups is presented in Fig. 4, which highlights a significantly skewed distribution towards OK lenses being fitted to younger age groups. As expected, there were no reported OK fits to infants.

A higher proportion of males (55%) were fitted with OK lenses versus non-OK lenses (30%) ($\chi^2 = 11$, $p < 0.0009$).

3.2. Lens materials

Rigid lens materials were categorized according to oxygen permeability (Dk), as zero Dk (polymethyl methacrylate), low-Dk (< 40), mid-Dk (40 – 90) and high-Dk (> 90). The proportion of rigid lens fits in respect of this categorization was: zero Dk (polymethyl methacrylate) – OK 2%, Non-OK 2%; low-Dk – OK 1%, Non-OK 13%; mid-Dk – OK 5%, Non-OK 40%; and high Dk – OK 92%, Non-OK 45% ($\chi^2 = 1447$, $p < 0.0001$). These data indicate a skewed distribution towards OK lenses being fit with higher Dk materials.

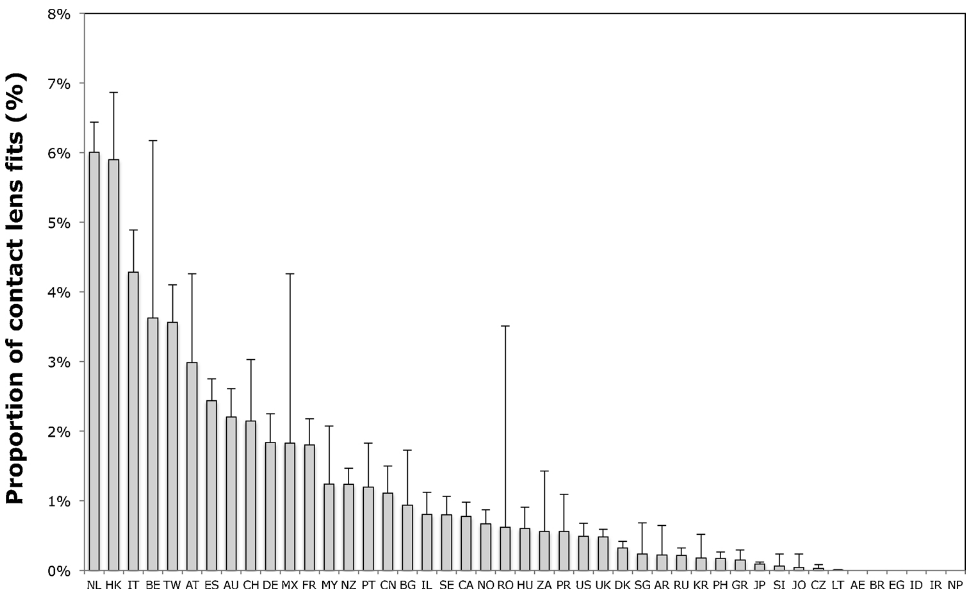

Fig. 1. Proportion of all contact lenses fitted as orthokeratology lenses in 45 countries between 2004 and 2017. Error bars represent the upper 95% confidence limit. AE United Arab Emirates; AR Argentina; AT Austria, AU Australia; BE Belgium, BG Bulgaria; BR Brazil; CA Canada; CH Switzerland; CN China; CZ Czech Republic; DE Germany; DK Denmark; EG Egypt; ES Spain; FR France; GR Greece; HK Hong Kong; HU Hungary; ID Indonesia; IL Israel; IR Iran, IT Italy; JO Jordan; JP Japan; KR South Korea; LT Lithuania; MX Mexico, MY Malaysia; NL Netherlands; NO Norway; NP Nepal; NZ New Zealand; PH Philippines; PR Puerto Rico; PT Portugal; RO Romania; RU Russia; SE Sweden; SG Singapore; SI Slovenia; TW Taiwan; UK United Kingdom; US United States; ZA South Africa.

3.3. Lens use

Lenses fitted for OK were worn 6.9 ± 0.6 days per week. Those fitted with other lens types (non-OK) wore lenses 6.7 ± 0.9 times per week. Although this difference was statistically significant ($\chi^2 = 49$, $p < 0.0001$), it is not thought to be of any clinical importance.

The frequency of lens replacement was found to be as follows: monthly – OK 0%, non-OK 4%; 3-6 monthly – OK 3%, non-OK 2%; annually – OK 68%, non-OK 36%; and unplanned – OK 29%, non-OK 58% ($\chi^2 = 730$, $p < 0.0001$). This suggests a higher proportion of OK lenses were fitted on a planned replacement basis.

4. Discussion

Differences in the extent of OK lens prescribing between nations may be attributed to international differences in the training, attitudes and collective confidence of the predominant practitioner groups – opticians, optometrists and ophthalmologists. For example, ophthalmologists, who largely or exclusively manage serious contact lens-related eye infections in many regions of the world, may harbour more conservative attitudes and concerns relating to the ocular health risks of overnight OK lens wear.

The high proportion of OK lens prescribing in The Netherlands (6.0%) may relate to a long-standing enthusiasm for rigid lens fitting in this country, fuelled by highly visible opinion leaders advocating this approach, as well as ready access to local specialized rigid lens laboratories who can custom design the required lenses [23]. Relatively high rates of OK fitting in Hong Kong (5.9%) and Taiwan (3.6%) could be related to the reported myopia control capabilities of OK, as a strategy to constrain the myopia epidemic in these countries; [24] however, an elevated rate of OK fitting was not evident across all of the East and Southeast Asian nations surveyed.

OK only represents 1.2% of all contact lens fits and must therefore be considered as a niche or 'specialist' approach to contact lens fitting. The small rise in OK fitting over the 14 year time span of this survey possibly reflects (a) an increasing interest in OK lens fitting among practitioners, (b) a growing awareness among lens wearers of OK as an alternative to conventional lens wear, and (c) a greater appreciation

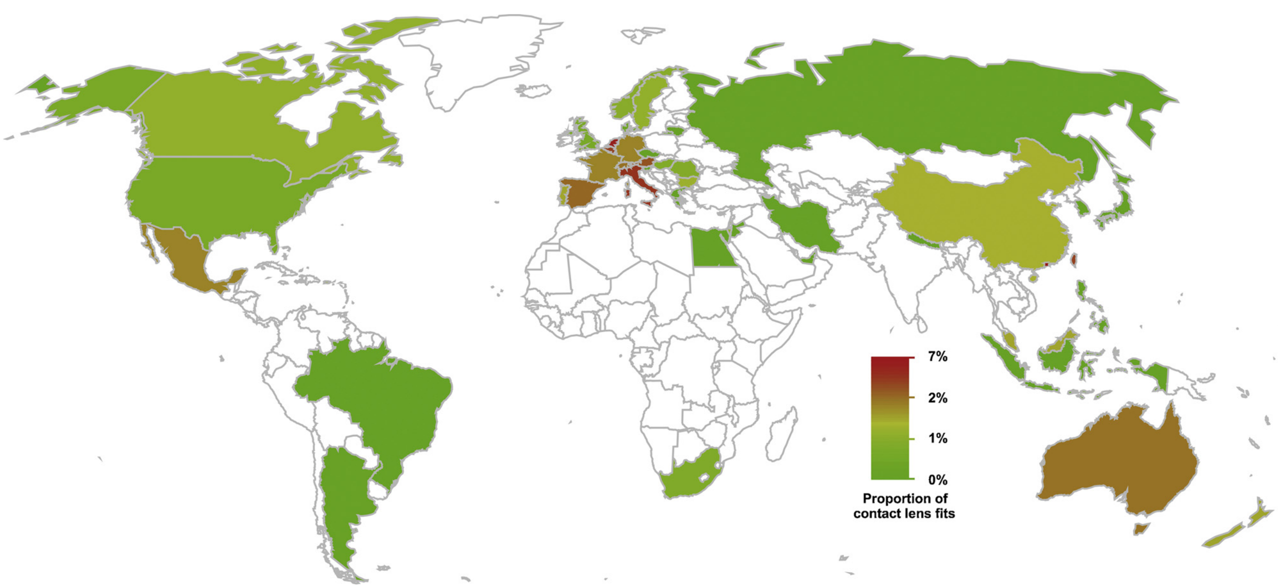

Fig. 2. 'Heat map' indicating the extent of orthokeratology lens fitting in different countries around the world. Note the logarithmic colour-coded scale. Nations shown in white (no colour) were not surveyed.

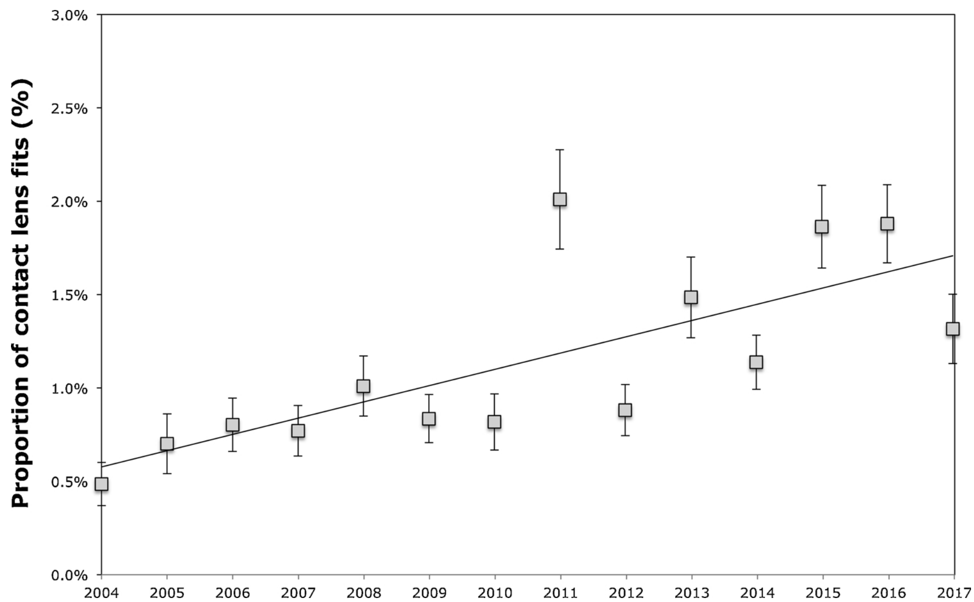

Fig. 3. Trend in the proportion all contact lenses fitted as orthokeratology lenses in 45 countries between 2004 and 2017. Error bars represent the 95% confidence limit.

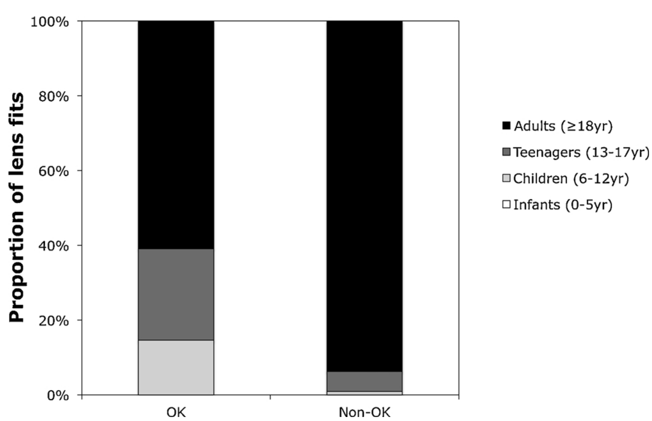

Fig. 4. Age categories of persons fitted with contact lenses for orthokeratology (OK), and for persons fitted with all other lens types (Non-OK), in 45 countries between 2004 and 2017.

among practitioners and lens wearers of the potential for these lenses to reduce the rate of myopia progression [25].

The much younger age at which people are fitted with OK lenses is consistent with the perceived ability of this modality of lens wear to slow the progression of myopia during the critical stages of myopia development. Given that the active years for myopia development from an ocular growth perspective relate to those in the 'children' and 'teenager' age groups as defined in this study [26], it is not surprising that a disproportionately greater number of OK fits were recorded for these groups. The reason for the higher proportion of OK fits among males is unclear.

There is a school of thought that contends OK lenses may not need to be worn every night of the week to maintain their efficacy; however, data from this survey suggests OK lenses are being worn every night to maintain the daily corneal moulding effect required to improve vision [3]. The high frequency of use of non-OK lenses (predominantly soft lenses in this survey) reflects the safety, efficacy, convenience and cost effectiveness of current-generation contact lenses.

The predominance of higher Dk materials used for OK fits versus non-OK fits can be attributed to the requirement to wear OK lenses overnight, in order to optimise corneal oxygen availability during sleep [27] and thus minimize ocular health complications [28].

That approximately two-thirds of OK lenses are replaced annually (compared with one-third of non-OK lenses) probably reflects the requirement to periodically alter lens design so as to maintain the desired corneal moulding effects [2].

5. Conclusion

OK is a niche contact lens fitting modality, which is employed to a greater extent by eye care practitioners in some European countries where there is a culture of rigid lens fitting supported by local laboratories capable of fabricating these lenses. Typically, OK lenses are fitted in high Dk materials on a planned replacement basis to younger patients, presumably for the primary purpose of arresting the progression of myopia.

6. Declaration of interests

None.

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