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Efficacy, predictability and safety of long-term orthokeratology: An 18-year follow-up study

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ABSTRACT

Purpose: To determine the efficacy, predictability and safety of long-term orthokeratology in children and adults.
Methods: Case histories of 300 orthokeratology patients (596 eyes; 34.3% children; 65.7% adults) were reviewed to collect information on demographics, corneal and refractive parameters, visual acuity, residual refraction and adverse effects. Predictability was defined as the percentage of eyes with absolute values of spherical equivalent refraction $\leq$ 0.5 D of emmetropia, and efficacy as the ratio of post-orthokeratology uncorrected and pre-orthokeratology corrected distance visual acuity.
Results: Median duration of treatment was 37 and 28.5 months in children and adults, respectively ($p = 0.022$). During the first year, 17.2% of children and 33% of adults ceased lens wear ($p < 0.001$). For children and adults with a successful *ortho*-k treatment of at least one year of duration, 88.7% and 95.9% of eyes had a predictable refractive outcome, and efficacy was 0.98 and 1.01, respectively. A larger percentage of children (65.7%) were free of complications than of adults (55.4%) ($p = 0.015$). One event of microbial keratitis occurred in adults (6.8 cases per 10,000 patient-years) and none in children. Corneal staining was the most frequent complication, with a higher incidence in adults ($p = 0.007$) and in higher myopia ($p < 0.001$), higher anterior corneal eccentricity ($p = 0.019$) and smaller anterior horizontal radius ($p = 0.027$).
Conclusion: Orthokeratology is a safe and predictable long-term procedure in children and adults, with a low incidence of serious adverse effects. Corneal staining episodes are relatively frequent throughout the course of the treatment, thus highlighting the relevance of education of experienced users.

1. Introduction

Orthokeratology (*ortho*-k) is a clinical procedure in which specially designed rigid corneal contact lenses are worn overnight to induce a controlled and reversible corneal deformation aiming at correcting refractive error after lens removal in the morning [1,2]. Orthokeratology has been approved for the correction of myopia of up to −6.00 D and astigmatism of −1.75 D or less, although off-label use for hyperopia and even presbyopia has been described [3,4]. Similarly, myopia control through *ortho*-k is becoming increasingly popular, albeit few lens designs have been granted marketing authorization for this purpose in Europe, thus also remaining an off-label option in many countries [5–7].

Research on the efficacy and predictability of *ortho*-k is commonly conducted within a relatively short time frame, given that refraction stability is reached between seven and 30 days, depending on target refraction and age of patients, with younger patients showing a more rapid corneal response [8–12]. Conversely, studies on the safety of orthokeratology have focussed mainly on children using their lenses for myopia control, describing their findings in terms of incidence, with limited information on the predominant moment of occurrence of each type of adverse effect within the course of the *ortho*-k treatment. In this regard, an overall incidence of 7.7 cases per 10,000 patient-years (95% CI 0.9–27.8) was reported for microbial keratitis, which is considered one of the most threatening adverse effects of any modality of contact

Abbreviations: Ortho-k, Orthokeratology; ACA, Anterior corneal astigmatism; SE, Equivalent spherical refraction; ε, Anterior corneal excentricity; CDVA, Corrected distance visual acuity; UCVA, Uncorrected distance visual acuity; Rh, Horizontal corneal radius.

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lens wear [13]. Besides, published incidence of microbial keratitis tends to be higher in children than adults [13,14], although studies may suffer from significant patient selection and participation bias, and data must be interpreted with caution [15]. Other studies of *ortho*-k in children have reported an incidence of less threatening complications, including conjunctivitis and superficial corneal staining, of 11.1% (95% CI 8.2–14.6%), over a 10-year follow-up period in Japan [16], or 9.2% eyes per year (95% CI 5.2–15.7%) in Europe [17].

Corneal staining has been described as the most frequent adverse effect of *ortho*-k [17–23]. For instance, Charm and Cho observed an incidence between 8.3% and 25% of grade 1 corneal staining over a follow-up period of two years in a group of children aged 8 to 11 years [19]. Similarly, in a recent research, Hu and co-workers followed for one year a sample of 489 eyes of children aged 8 to 15 years, noting that adverse effects occurred twice more frequently in patients with myopia of 4 D or more than in those with <4 D of myopia, and that these complications were three times more severe in the former group [20]. The same authors also found an increased incidence of corneal staining in younger than older children, in agreement with previous research by Lipson [21]. Evidence also suggests a tendency for increased corneal staining with increasing duration of *ortho*-k lens wear in low to moderate myopes, although this research has generally been conducted in a reduced sample of children and with a mid-term follow-up [22,23].

The purpose of the present research was to determine the long-term efficacy and predictability (defined in terms of refractive correction, not of myopia control) of *ortho*-k, as well as the time course of the most common adverse effects, in a large sample of children and adults recruited from three optometric centres in Barcelona within the years of 1997 and 2015. In addition, given the noted sample or temporal limitations of previous research, the association between adverse effects and several demographic, refractive, corneal topography parameters, as well as duration of lens use, was further explored.

2. Methods

A retrospective, observational study was designed in which the case histories dating from 1997 to 2015 of 300 overnight *ortho*-k lens wearers from three optometric centres in Barcelona were retrieved and examined. For this purpose, each of the three centres provided 100 records to the study. To avoid possible bias, as patients with more complications would attend clinics more frequently, all *ortho*-k patients of each clinic were identified and, from these, 100 patients were randomly selected. For each of the selected *ortho*-k patients, all records were reviewed to verify the completeness of the information and to determine predictability, efficacy and safety. Thus, the only exclusion criterion was incomplete information.

At the start of the *ortho*-k treatment all patients had signed an informed consent form which contemplated both their consent to the *ortho*-k procedure and to the collection and treatment of their clinical data for future statistical and investigative purposes. Patient anonymity was ensured throughout the study and the research followed the tenets of the Declaration of Helsinki (as revised in Tokyo in 2004). The study received the approval of the institution review board of the Universitat Politècnica de Catalunya.

Information was collected on the following five categories: demographic, anterior segment and tear film parameters, refraction and visual acuity, *ortho*-k treatment and adverse effects. Demographic information included sex and age at the start of the *ortho*-k treatment. Anterior segment and tear film parameters included horizontal and vertical anterior corneal radii, anterior corneal astigmatism (ACA), anterior corneal eccentricity (ε) and the presence or absence of tear film abnormalities (defined as a fluorescein tear film break-up time inferior to 10 s). The category of refraction and visual acuity included spherical equivalent refraction (SE) and distance corrected visual acuity (CDVA) prior to the start of *ortho*-k (baseline), and SE and uncorrected distance visual acuity (UDVA) at the last follow-up visit (the last follow-up visit corresponded to a time interval between two weeks and one month of the last change of lens, to ensure visual, refractive and corneal topography stability). With this information, predictability was defined as the percentage of eyes with absolute values of spherical refraction $\leq$ 0.5 D of target refraction, which was emmetropia, and the efficacy index as the ratio of post-*ortho*-k UDVA and pre-*ortho*-k CDVA. Thus defined, predictability only referred to refractive correction, and not to myopia control, even if a percentage of the patients included in the study were children aiming at both the correction of refractive error and at myopia control. Overall predictability and efficacy values were determined and, to explore the effect of early lens drop-out on these parameters, the analysis was repeated only for those patients with successful *ortho*-k treatment of more than one year.

The *ortho*-k treatment category included reason for starting *ortho*-k, duration of treatment, lens design (spherical or toric), use of tear substitutes and cleaning procedures (basic or enhanced with protein removal). Finally, the adverse effects category included type and severity of adverse effect (determined, when applicable, with the Cornea and Contact Lens Research Unit scales [CCLRU], currently Brien Holden Vision Institute scales [24]), time of occurrence (from the start of *ortho*-k treatment) and number of adverse effects per eye. It must be noted that for long-term users of *ortho*-k requiring many lens modifications over the years as their refraction progressed, the last set of records, corresponding to the last change of lens, was used to determine efficacy and predictability, albeit all records were explored to determine *ortho*-k safety. In addition, given that episodes of corneal staining are frequent after the first night of *ortho*-k and mainly related to unskilled manipulation, these instances were not included in the analysis [20]. The association between the occurrence of adverse effects and other demographic, refractive, corneal topography and lens use parameters was explored only for those patients with a duration of the *ortho*-k treatment longer than one year.

The IBM Statistical Package for the Social Sciences (SPSS) Statistics v.26 (IBM Corp. NY, US) was used for statistical analysis. For comparison purposes, patients were classified according to age (17 or younger [children]; 18 or older [adults]). Other factors considered in the analysis were duration of the *ortho*-k treatment (less than one year; one year or more) and adverse effects (present or absent, as well as number of adverse effects per eye). Following a normality check with the Kolmogorov-Smirnov test, outcomes were summarized as frequency, mean and standard deviation, or median and range, as appropriate. Non-parametric analysis was employed for inferential statistics (Kruskal-Wallis or Chi-square tests). A p-value of 0.05 or less was considered to denote statistical significance.

3. Results

3.1. Sample demographics

The study included 596 eyes from 300 patients (46.0% females), with ages ranging from 7 to 53 years (median of 22 years). At the start of the *ortho*-k treatment, 34.3% of patients (204 eyes) were 17 years old or younger (median of 13 years, range from 7 to 17, 44.6% females) and 65.7% patients (392 eyes) were 18 years or older (median 27 years, range from 18 to 53, 46.4% females), of whom 19 patients (36 eyes) were older than 40 years. Considering all patients, the percentage of children starting their treatment increased yearly from 2003 onwards.

The main reasons for children to start *ortho*-k were myopia control (92.1% of patients), cosmetic reasons (6.9%) and sports (1.0%), whereas adults reported job opportunities (38.7%), cosmetic reasons (31.5%), soft contact lens intolerance (9.9%) and myopia control (5.5%) as their main reasons to opt for *ortho*-k. Differences in distribution of reasons for *ortho*-k in children and adults were statistically significant ($p < 0.001$), with the reason "myopia control" showing the highest difference between age groups.

Overall duration of *ortho*-k treatment ranged from 2 to 138 months

(median 37 months) in children and from one week to 217 months (median 28.5 months) in adults ($p = 0.022$). During the first year, 17.2% of children and 33.2% of adults ceased lens wear ($p < 0.001$). At the end of the study period (2015), 79.4% of children and 46.4% of adults were still using their *ortho*-k lenses ($p < 0.001$). For these patients, duration of *ortho*-k treatment ranged from 17 to 130 months (median 45 months) in children and from 13 to 217 months (median 52 months) in adults.

The majority of patients (92.6%) used their contact lenses every night, whereas 3.7% used them on alternate nights and 3.7% used them less frequently, without differences between age groups.

3.2. Efficacy and predictability

Overall, baseline median SE refraction was −2.50 D, similar in children and adults. A larger percentage of children had myopia higher or equal to −5.00 D than adults (13.7% and 7.9% of eyes, respectively). Only 2.5% of eyes had astigmatism higher than −1.50 D.

Overall efficacy index was 0.98 in children and 1.00 in adults, respectively. Overall predictability of *ortho*-k treatment for the correction of refractive error was similar in children and adults: 70.6% of eyes had residual SE values within ±0.25 D of target emmetropia, 88.6% of eyes within ±0.50 D and 94.0% of eyes within ±1.00 D. Table 1 displays refractive information as well as predictability and efficacy when considering only those patients with a successful *ortho*-k treatment of at least one year of duration and still using their *ortho*-k lenses at the end of the data collection period (150 patients, 299 eyes: 46.5% children, 139 eyes; 53.5% adults, 160 eyes). For these patients, the efficacy index was 0.98 in children and 1.01 in adults, and 88.7% and 95.9% of eyes of children and adults reached residual SE values within ± 0.50 D of target emmetropia, respectively.

3.3. Adverse effects

During the course of the *ortho*-k treatment, 134 (65.7%) eyes of children were free of adverse effects, 37 (18.1%) eyes suffered one complication, 18 (8.8%) eyes two complications, 8 (3.9%) eyes three complications and 7 (3.4%) eyes more than three complications. As for adults, 217 (55.4%) eyes were free of complications, 89 (22.7%) eyes suffered one complication, 43 (11.0%) eyes two complications, 23 (5.9%) eyes three complications and 20 (5.1%) eyes more than three complications. Overall, albeit 478 complications were reported (134 in children and 344 in adults), none caused a clinically significant loss of visual acuity. A larger percentage of children were free of any type of adverse effect than adults ($p = 0.015$).

Table 2 presents a summary of the documented adverse effects in children and adults. Overall, the most frequently reported complication was corneal staining (73.2% of the total of complications), with an incidence of 1591.39 cases per 10 000 patient-years, followed by corneal erosion (9,2% of total, 200.6 cases per 10,000 patient-years) and non-infectious corneal infiltrate (5.6% of total, 122.76 cases per 10,000 patient-years). One instance of microbial keratitis was reported in adults (6.8 cases per 10,000 patient-years) and none in children. No statistically significant difference was found between children and adults in the incidence of the most frequent complications.

Localization of complications was similar in children and adults, with most of them appearing in the central corneal region (78.3% in children *vs* 64.8% in adults), followed by the peripheral (13.0% *vs* 18.2%) and paracentral (5.2% *vs* 11.1%) regions. Only 1.7% and 1.8% of complications involved the whole cornea in children and adults, respectively. Only four complications were considered to be visually threatening: a central corneal erosion occurring at the 29th month in a child, a paracentral microbial keratitis occurring at the 48th month in an adult, a peripheral corneal ulcer reported in a child at the 18th month and a central corneal ulcer in an adult at the 78th month.

A large percentage of complications occurred during the first year of *ortho*-k treatment (33.5% during the first four weeks, 25.7% between one and six months, 9.8% between 7 and 12 months) and the remaining complications (31.0%) were recorded between the 13th and 217th months. Complications in children following the 1-year mark were more frequent than in adults (35.1% and 29.4%, respectively, $p = 0.007$). Table 3 summarizes the time interval of occurrence of the three most frequent complications (corneal staining, corneal erosion and corneal infiltrates) in children and adults. A statistically significant difference was found in the distribution of corneal staining grades between children and adults ($p = 0.007$).

3.4. Corneal staining

Given that corneal staining was the most frequently reported adverse effect of *ortho*-k, this complication was explored in more detail. For this analysis, only patients with a duration of their *ortho*-k treatment longer than one year were considered (395 eyes of 198 patients, with ages ranging from 7 and 53 years, median age of 20 years). Of these patients, 238 eyes did not suffer any adverse effect, whereas 157 eyes suffered one or more episodes of corneal staining (83 eyes once; 42 eyes twice; 32 eyes three times or more). Overall, duration of *ortho*-k treatment was longer in those patients in which one or more than one episodes of corneal staining were recorded (41 *vs* 58 months, $p = 0.005$). The incidence of one or more episodes of corneal staining was higher in adults than children ($p = 0.007$) and in those performing a more rigorous cleaning procedure, enhanced with protein removal ($p < 0.001$) (Table 4). Most instances of corneal staining were grade 1 or grade 2 and resolved without any intervention. Those patients with corneal staining of grade 3 and grade 4 were managed by introducing tear film substitutes and/or changing cleaning and disinfection solutions, if it was determined that staining was associated to preservatives. None of the patients with corneal staining discontinued lens wear.

Statistically significant differences in baseline SE refraction, anterior corneal eccentricity and horizontal corneal radius were found between patients free of adverse effects and those suffering one, two or three or more instances of corneal staining (Table 5). Patients with higher myopia, higher anterior corneal eccentricity and smaller anterior horizontal radius were more at risk of suffering one or more episodes of corneal staining. Sex, ACA, vertical corneal radius, tear film integrity and type of contact lens (spherical or toric) did not influence the occurrence of corneal staining.

4. Discussion

The present research explored the efficacy, predictability and safety of overnight *ortho*-k in a large sample of patients, including 204 eyes of children and 392 eyes of adults, with an overall median treatment

Table 1
Spherical refraction (SE), efficacy index (ratio of post-*ortho*-k UDVA and pre-*ortho*-k CDVA) and predictability (percentage of eyes with absolute values of SE ≤ 0.5 D of emmetropia) of patients with an *ortho*-k treatment of at least one year of duration and still using their lenses at the end of the study.

	Baseline SE (D)				Efficacy Index	Predictability
	Minimum	Median	Maximum	Higher than −5 D		|SE post-ortho-k|≤0.5 D
Children	−8.00	−2.25	−0.125	14.4%	0.98	88.7%
Adults	−7.00	−2.50	−0.625	3.7%	1.01	95.9%
p-value	> 0.05	> 0.05	> 0.05	0.001	> 0.05	0.021

Table 2
Summary of the reported adverse effects in children and adults. Results are shown as number of complications and incidence (in cases per 10,000 patient-years).

	Cases Total	% Total	Incidence Total	Cases Children	Incidence Children	Cases Adults	Incidence Adults
Corneal staining	350	73.22	1591.39	85	1166.94	265	1801.62
Corneal erosion	44	9.21	200.06	15	205.93	29	197.16
Corneal infiltrate	27	5.65	122.76	9	123.56	18	122.37
Pigmented iron ring	10	2.09	45.47	5	68.64	5	33.99
Bulbar hyperaemia	9	1.88	40.92	6	82.37	3	20.40
Papillary conjunctivitis	8	1.67	36.37	4	54.91	4	27.19
Conjunctivitis	7	1.46	31.83	4	54.91	3	20.40
Corneal oedema	7	1.46	31.83	2	27.46	5	33.99
Palpebral oedema	5	1.05	22.73	0	0.00	5	33.99
Nebular Corneal opacity	4	0.84	18.19	1	13.73	3	20.40
Viral keratoconjunctivitis	2	0.42	9.09	0	0.00	2	13.60
Band keratopathy	2	0.42	9.09	2	27.46	0	0.00
Corneal ulcer	2	0.42	9.09	1	13.73	1	6.80
Microbial keratitis	1	0.21	4.55	0	0.00	1	6.80
Overall	**478**	**100**		**134**		**344**	

Table 3
Time interval of occurrence of corneal staining (graded with the CCLRU grading scales), corneal erosion and corneal infiltrates. Number (and the corresponding percentage) of patients is shown for each type or grade of complication and time interval.

		Corneal Staining Grade 1		Corneal Staining Grade 2		Corneal Staining Grade 3		Corneal Staining Grade 4		Corneal Erosion		Corneal Infiltrate	
		children	adults	children	adults	children	adults	children	adults	children	adults	children	adults
Up to 1 month	**N**	11	77	9	23	4	12	0	5	3	12	0	1
	%	26.83	48.43	27.28	38.98	36.37	34.28	0	41.67	20	41.38	0	5.56
1–6 months	**N**	15	44	9	9	2	5	0	2	4	7	3	8
	%	36.58	27.67	27.27	15.25	18.18	14.29	0	16.67	26.67	24.14	33.33	44.44
7–12 months	**N**	5	14	6	7	1	1	0	1	1	3	0	1
	%	12.20	8.80	18.18	11.87	9.09	2.86	0	8.33	6.67	10.34	0	5.56
13–217 Months	**N**	10	24	9	20	4	17	0	4	7	7	6	8
	%	24.39	15.09	27.27	33.90	36.37	48.57	0	33.33	46.67	24.14	66.67	44.44
Overall	**N**	41	159	33	59	11	35	0	12	15	29	9	18
	%	100	100	100	100	100	100	0	100	100	100	100	100

Table 4
Corneal staining according to age and to cleaning regime (basic or enhanced with protein removal).

		Without corneal staining *eyes*	One or more instances of corneal staining *eyes*
Age	*children*	105	48
p = 0.007	*adult*	133	109
Enhanced Care	*Basic*	57	14
p < 0.001	*Enhanced*	132	102
	Without information	49	41

duration of 33 months. Data collection started in 1997 and lasted until 2015. Patient records evidenced an increasing percentage of younger patients with time, probably accounting for the growing popularity of *ortho*-k in recent years as a means of myopia control in children. Indeed, whereas myopia control was the predominant reason leading children to opt for *ortho*-k, only 5.5% of adults were interested in myopia control, noting job opportunities and cosmetic reasons, which may be considered short or mid-term goals, as their main reasons for choosing *ortho*-k. The different typology of patients may explain the shorter duration of the *ortho*-k treatment in the older age group, with 17.2% of children and 33.2% of adults having discontinued *ortho*-k at the end of the first year. These drop-out rates are similar to those reported in previous research, with discrepancies probably accounting to differences in sample composition, treatment goals and follow-up time [19,25], and indeed to the recently described pooled 21.7% discontinuation rate across multiple contact lens modalities [26].

Table 5
Corneal staining according to baseline spherical equivalent (SE) refraction, anterior corneal astigmatism and horizontal corneal radius (Rh). Pair-wise comparisons considered a Bonferroni-adjusted p-value < 0.0083. Different letters denote a statistically significant difference in median values.

Corneal staining events	**SE (D)** *Median*		**Anterior corneal eccentricity** *Median*		**Rh (mm)** *Median*	
0	−2.31	(A)	0.43	(A)	7.75	(A)
1	−2.50	(A)	0.46	(A, B)	7.73	(A, B)
2	−2.75	(A)	0.47	(A, B)	7.65	(A, B)
3 or more	−3.87	(B)	0.52	(B)	7.68	(B)
	p < 0.001		p = 0.019		p = 0.027	

Overall, the typical *ortho*-k patient of this study was a young person (median age of 19 years) with a relatively low refractive error (median SE of −2.50 D). Ortho-k showed good efficacy and predictability in both children and adults, either considering all patients or only those with a successful *ortho*-k treatment of at least one year.

In general, *ortho*-k in this sample of patients was a safe procedure, with 65.7% of children and 55.4% of adults facing no adverse complications. Interestingly, complications in children were not only less frequent, but also less severe than in adults, even accounting for the higher baseline SE in children. It has been suggested that children may benefit from parental oversight with regards to contact lens care and

maintenance, and may be more motivated than adults for this particularly demanding modality of lens wear [10,12]. In addition, better tear film integrity and corneal endothelium response in children may also help to explain these findings.

Only four potentially visually threatening complications were documented, including one central corneal erosion, one central and one peripheral corneal ulcer and one case of microbial keratitis involving the paracentral corneal region. Thus, the incidence of microbial keratitis was of 6.8 cases per 10,000 patient-years in adults and 0.0 cases per 10,000 patient-years in children. This finding is in agreement with the reported incidence of 7.7 cases of microbial keratitis per 10,000 patient-years (95% CI 0.9–27.8) [13], although does not support a major incidence in children than adults, as previously reported [13,14], probably as a result of a higher proportion of adults in the current sample than in other studies mainly focussed in *ortho*-k in myopia control [15]. Although long-term follow-up cohorts and randomized controlled trials are required to provide a proper estimation of risk of microbial keratitis, this level of incidence is higher than that reported for daily wear of soft disposable (annualized incidence of 2.4 per 10,000 wearers) or non-disposable lenses (1.2 per 10,000 wearers) but inferior to that documented for overnight wear of conventional hydrogel (19.5 per 10,000 wearers) or silicone hydrogel lenses (25.4 per 10,000 wearers) [27]. None of these complications led to a clinical reduction in visual acuity.

Other commonly reported and less severe or innocuous effects of *ortho*-k are corneal staining, pigmented ring deposits, lens binding, fibrillary lines, microcysts and non-infectious corneal infiltrates, amongst others [2,10,16]. In the present sample of patients, and in agreement with previous studies [17–23], the most common complication was corneal staining, with an incidence of 1591.39 cases per 10,000 patient-years, followed by corneal erosion, non-infectious corneal infiltrates, pigmented ring deposits, bulbar hyperaemia, papillary conjunctivitis and conjunctivitis. Interestingly, although one third of complications occurred during the first four weeks of *ortho*-k, another third was distributed between the 13th and 217th months of treatment, with a higher incidence in children than adults following the 1-year mark (35.1% *vs* 29.4%, respectively), although this may reflect the longest duration of *ortho*-k treatment in children. The occurrence of these late occurring adverse effects, which was also found by previous investigators exploring microbial keratitis [14], reinforces the need for patient education and periodic reminders regarding lens wear and care. It must be noted, however, that documented changes in user behavior with time are contradictory, with some authors failing to observe any correlation between compliance and wearing experience in *ortho*-k [28], and other researchers describing a fall in compliance with time in non-*ortho*-k lens wearers [29].

Corneal staining, in particular, was found to occur more frequently in adults than children and in patients adding protein removal to their cleaning habits, probably as a result of a less than optimal tear film. In addition, corneal staining events were more frequent in patients with baseline higher myopia, higher anterior corneal eccentricity and smaller anterior horizontal radius. These results are in agreement with previous research in which higher myopia was associated with more severe corneal staining [15,20], but show a different trend regarding age than some published literature, accounting for the fact that the present study compared children with adults instead of children of different age groups [20,21].

Finally, it must be acknowledged that this study was not free of limitations. Thus, as the study explored clinical data spanning 18 years, a variety of evolving contact lens designs, cleaning regimes, and even fitting strategies were included, which may not accurately reflect the current state of *ortho*-k. However, and for the same reasons, this heterogeneity may provide a better picture of global use of *ortho*-k and increase external validity. Similarly, over the years, practitioners may have employed different techniques and instrumentation for their ocular exams, leading to a loss of uniformity in clinical histories and reports. Unfortunately, some of these limitations may only be solved with well-planned prospective longitudinal studies, which may prove critically valuable in the future.

In conclusion, this 18-year long retrospective study of patients using *ortho*-k to control their myopia and as an option of refractive correction gives support to the efficacy, predictability and overall safety of the procedure. With a percentage of lens discontinuation similar to other lens wearing modalities, *ortho*-k may be considered a valid strategy to increase patient long-term loyalty to visual care providers and an effective alternative to other forms of visual correction.

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The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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