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Level of Compliance in Orthokeratology

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Objectives: To investigate the level of compliance with orthokeratology (ortho-k) guidelines and the main behaviors of poor compliance to guide clinical care.

Methods: A questionnaire was sent to ortho-k patients in the Eye Hospital of Wenzhou Medical University (EHWMU) in Mainland China who were prescribed ortho-k lenses after January 2013 and have worn ortho-k lenses for more than 1 year to determine the compliance rate for eight wear and care behaviors. Follow-up visit compliance was then investigated among these patients using a retrospective survey.

Results: A total of 1,500 questionnaires were distributed, and 405 patients responded. The mean age of the patients was 13.1 ± 3.9 years (range 9–22 years); 60.5% of the patients were female, and 98.3% were younger than 18 years. The full compliance rate was 14.1%, the compliance rate for wear and care behaviors was 18.5%, and the compliance rate for follow-up visits was 63.3%. The three highest noncompliance categories for wear and care behaviors were exposure to nonsterile solution, not removing lens depositions according to the eye care practitioners' (ECPs) recommendations and inadequate hand washing. No correlation was observed between the compliance for wear and care behaviors and age, sex, and wearing experience. The follow-up visit compliance rate significantly decreased from the third month to the ninth month. The common reasons for discontinuing follow-up were lack of time, no symptoms, and inconvenience.

Conclusions: The level of compliance with ortho-k lens wear in Mainland China is not high, necessitating ECPs to stress to patients the details of wear and care behaviors, especially avoiding exposing lenses to nonsterile solution. Improving monitoring of follow-up visits, particularly within the first 9 months of wearing ortho-k lenses, is needed.

Key Words: Orthokeratology—Compliance—Mainland China.

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Orthokeratology (ortho-k) is a method that uses specially designed rigid gas-permeable (RGP) contact lenses overnight to reshape the cornea to temporarily reduce or eliminate myopia. Ortho-k can slow myopia progression^{1–3} and has some other advantages such as improving the uncorrected visual acuity during the daytime. The number of people who wear ortho-k lenses has exceeded 1.5 million and continues to increase in China.⁴ However, because ortho-k lenses can cause a number of complications, including visually threatening microbial keratitis (MK),^{5,6} the safety of ortho-k has been a constant concern. When ortho-k was first introduced in China, ortho-k-related keratitis, which was potentially due to inappropriate lens care procedures, patient noncompliance with practitioner instructions, and persisting in lens wear despite discomfort, frequently occurred.⁷ This painful history has led to our continued focus on the safety of ortho-k. In recent years, the overall environment of ortho-k in China has significantly improved, and the incidence of MK has significantly decreased, which is mainly attributed to the training and certification of ortho-k practitioners, universal education of ortho-k wearers, and a series of regulations promulgated by China's Food and Drug Administration.⁸ These regulations include standard wear and care procedures for ortho-k patients, as well as standard follow-up visit procedures.

However, according to previous studies, not all contact lens patients fully comply with standard wear and care or follow-up visit procedures. In addition, different types of contact lenses have different compliance rates, which vary greatly from 0% to 60%.^{9–12} In a study by Morgan et al.,¹¹ different countries also had varying compliance rates for contact lens wearers. However, to the best of our knowledge, no study has examined the compliance rates for ortho-k lenses in Mainland China. Because patient compliance is one of the major risk factors for contact lens-related complications,^{13–15} and an increasing number of people are choosing to wear ortho-k lenses in Mainland China, we suggest that investigating the compliance of ortho-k wearers, identifying possible problems, and taking measures to improve these issues are important and will help to enhance the safety of ortho-k in clinical practice. Cheung et al.¹⁶ demonstrated that in addition to effectiveness, safety is another major factor that affects parents' decisions in selecting a myopia control strategy for their children, and one of the main methods by which patients learn about myopia control options is through word-of-mouth. Thus, we suggest that enhancing patient compliance may also be beneficial for the healthy development of the ortho-k market and enable ortho-k to play a greater role in myopia control.

METHODS

To determine whether a difference exists between the compliance for wear and care behaviors and the compliance for follow-up

visits, we investigated the compliance for wear and care behaviors and the compliance for follow-up visits separately. Our study used two different methods to collect these two types of data. For wear and care information, data were collected by a questionnaire. Then, after receiving the patients' questionnaires to confirm their consent to participate in the study, we collected their follow-up visit information using a retrospective survey.

The questionnaire (see Appendix 1, Supplemental Digital Content 1, <http://links.lww.com/ICL/A83>) contained the following contents: patient demographic information, the independence of wear and care of the lenses, the reasons for missing follow-up appointments, and eight wear and care behaviors. The eight wear and care behaviors included methods of hand washing before handling lenses, lens cleaning procedures, use of expired solution, procedures for soaking lenses, the interval of lens case replacement, exposure to nonsterile solution, the interval of lens deposition removal, and removal of lenses without suction holders (Table 1). Importantly, all these behaviors increase the risk of contact lens-related keratitis or were identified as risk factors for contact lens-related complications in the literature.^{9,11,14,17–20} Because a study by Boost and Cho¹⁴ showed that suction holders showed a high contamination rate among ortho-k wearers, suction holder use was included in our survey. This behavior has not been surveyed in previous studies.

Before the questionnaire was released, it was sent to four eye care practitioners (ECPs) at the Eye Hospital of Wenzhou Medical University (EHWMU) (who had worked in the ortho-k field for more than 5 years) for modification and to ensure that the questions and answers were reasonable. Next, 10 ortho-k patients were selected to answer the questions in person to modify statements in the questionnaire that patients considered ambiguous or obscure. Finally, each patient was judged to be compliant or noncompliant according to the compliance behaviors outlined in Table 1. At the beginning of the questionnaire, we described the purpose and content of the questionnaire in detail so that the patients could voluntarily choose to participate in the survey. Patients were free to discontinue participation at any time. The survey passed ethical

review and complied with International Chamber of Commerce/European Society for Opinion and Marketing Research (ICC/ESOMAR) International Guidelines for Market Research and Social Surveys to ensure the confidentiality of data processing.

The questionnaire link was then sent as a text message to adult patients and parents of minor patients younger than 18 years in EHWMU. Our survey was conducted between July and September 2017. The inclusion criteria comprised patients who were prescribed ortho-k lenses after January 2013 and only patients who had worn ortho-k lenses for more than 1 year to ensure that patients were familiar with the schedule of the ortho-k process.

The EHWMU is a tertiary eye care facility and is ranked second in the field of ophthalmology among the most influential hospitals in Science and Technology in China in 2017. The EHWMU was also one of the first medical institutions in Mainland China to provide ortho-k and has been providing ortho-k for more than 10 years. Its ortho-k guidelines are presented in video and written materials, which include a follow-up visit schedule and eight compliant behaviors outlined in Table 1. In addition, professionally trained practitioners provide each patient with one-to-one guidance until the patient has completely mastered the guidelines. At each follow-up visit, the ECP always reminds patients about the next follow-up visit time. If patients do not adhere to their follow-up visit schedule, staff will promptly call to remind them.

Data were analyzed using SPSS Version 23.0 (IBM Inc., Armonk, NY) statistical software. The mean ± SD was used to represent data as appropriate. The Pearson chi-square test (χ^2), the Fisher exact test, or the Mann-Whitney *U* test was used to analyze differences between two groups. Logistic regression was used to analyze the association between compliance and age or sex. A *P* value less than 0.05 was considered as statistically significant.

RESULTS

In total, 1,500 questionnaires were distributed, and 405 patients responded; 60.5% of patients were females. The mean age was 13.1 ± 3.9 (range, 9–22) years, and 98.3% of patients were younger than 18 years. The full compliance rate, including wear and care behaviors and follow-up visits, was 14.1%.

Compliance for Wear and Care Behaviors

The full compliance rate for wear and care behaviors was 18.5%, and the compliance rate for each behavior is detailed in Table 1. Among these behaviors, the behavior with the worst compliance was avoiding exposing lenses to nonsterile solution, and the behavior with the best compliance was avoiding using expired solution (Fig. 1).

To analyze the relationship between compliance and wearing experience, patients were divided into three groups according to the duration of lens wear (Table 2). The Pearson chi-square test (χ^2) was used for multiple comparisons, and after Bonferroni correction, a *P* value less than 0.0167 was considered statistically significant. The results showed no difference in the level of compliance among the three groups (Table 2).

According to the independence of wear and care of lenses, we divided patients into the following groups: self-care patients who were responsible for their own wearing behaviors and lens care, and a non-self-care patient group, in which wearing compliance and lens care were monitored/conducted by their parents. The Pearson chi-square test showed that the non-self-care group

TABLE 1. Eight Compliance Behaviors and Their Sub-behaviors Included in the Questionnaire and the Percentage of Compliance

Compliance Behaviors	Percentage (%)
1 Adequate hand washing	64.7
Washing hands before handling lenses	64.7
Washing hands with soap	65.4
2 Adequate lenses cleaning	80.2
Clean lenses before wearing	96.5
Clean lenses after wearing	87.7
Rubbing and rinsing lenses	91.1
3 No use of expired solution	97.5
4 No topping off solution	95.3
All solution replaced with fresh solution	99.8
Replacing solution after each use	95.6
5 Lens case replacement according to ECPs' recommendation	84.4
6 No exposure to nonsterile solution	55.6
Drying hands after washing with tap water	66.4
No exposure when washing lens case	85.4
No exposure when washing lenses	91.8
7 Removal of lens deposition interval according to ECPs' recommendation	58.5
8 Removing lenses without suction holders	87.7

ECPs, eye care practitioners.

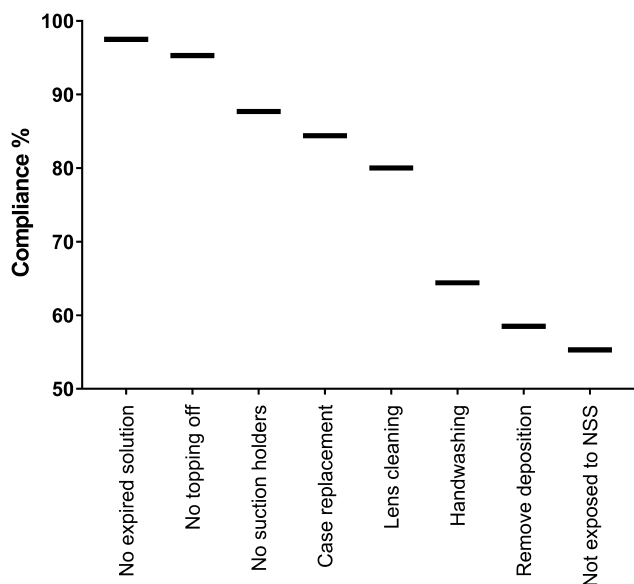


FIG. 1. Proportion of compliance with wear and care behaviors. NSS, nonsterile solution.

(29.3%) exhibited significantly greater compliance than the self-care group (16.3%) ($P=0.046$) (Table 3).

Because the demographic information of parents was not collected, when analyzing the relationship between compliance and age or sex, we included only the self-care group to eliminate the impact of care provided by parents. Logistic regression analysis showed no correlation between compliance and age ($P=0.941$) or between compliance and sex ($P=0.954$).

As shown in Table 4, patients were divided by sex to analyze the relationship between independence and sex. Although the average age of females was younger than that of males, regardless of whether wearing or caring for lenses was considered, the independence rate of females was higher than that of males.

Compliance for Follow-up Visits

The full compliance rate for follow-up visits was 63.3%. After lenses were provided to patients, follow-up visits were scheduled at EHWMU at 1 day, 1 week, 1 month, 3 months, and then every 3 months thereafter (the window after 3 months was ± 1 month). The follow-up visit compliance rates for each follow-up visit within 2 years were 100%, 100%, 100%, 98.8%, 95.6%, 90.9%, 90.4%, 87.9%, 87.9%, 86.2%, and 86.6% (Fig. 2). As shown in Figure 2, the compliance rate decreased with wearing experience; therefore, to determine the stage at which the compliance rate significantly decreased, we used the Pearson chi-square test to compare adjacent follow-up visits. Significant differences in follow-up visit compliance rates were found between the third and sixth months and between the sixth and ninth months only (Table 5).

The percentages and reasons for lack of follow-up visits are shown in Figure 3. The most common reasons were lack of time, no symptoms, and inconvenience.

DISCUSSION

In our study, most ortho-k wearers were adolescents; this result is consistent with a previous study that found that on average, 80%

TABLE 2. Multiple Comparison of Wear and Care Compliance for Groups With Different Wearing Experience

Group	n	Compliance (%)	Multiple Comparison	P^a
I	166	82.5	I vs. II	0.400
II	146	78.8	I vs. III	0.783
III	93	83.9	II vs. III	0.329

^a P values are from the Pearson chi-squared test (χ^2) and corrected by Bonferroni correction.

$P \leq 0.0167$ (0.05/3) was considered statistically significant.

Group I=patients wearing ortho-k lenses for 1 to 2 years, Group II=patients wearing ortho-k lenses for 2 to 3 years, and Group III=patients wearing ortho-k lenses for more than 3 years.

of Chinese people who wear ortho-k lenses are younger than 18 years.²¹ Because ortho-k wearers in Mainland China are predominantly juveniles, we should pay more attention to the safety of ortho-k. Therefore, investigating the compliance of ortho-k users in Mainland China is important and necessary.

The full compliance rate in this study was 14.1%. In reviews of previous studies, the rates of compliance varied among studies for different types of contact lenses. Cho et al.⁹ found that the “good” compliance rate for ortho-k in Hong Kong was 52% ($n=38$). Sapkota¹² showed that the “good” compliance rate for traditional soft-lens wearers was 28.2% ($n=78$). A multinational investigation by Morgan et al.¹¹ showed that the full compliance rate was 14.7% for daily disposable contact lens wear, 0.2% for extended wear contact lenses, and 0% for ordinary RGP contact lenses. Morgan et al. also found that compliance rates vary among different regions. As shown in the above studies, different individuals, types of contact lenses, and regions exhibit various compliance rates. As Efron²² stated, compliance is a complex issue. Many factors such as personality traits, education, socioeconomic status, occupation, and race are unrelated to compliance.²³ In the literature, many measures, such as intense initial education, noting the severe consequences of noncompliance, reducing the cost of goods, procedural documents, humorous videos, or signing a contract of shared responsibility, do not have any significant effect on the level of compliance.^{24–26} Fortunately, although compliance is a complex issue that is difficult to improve, some improvements can be made. Compliance can be improved by constantly reminding patients of correct procedures at aftercare visits,⁹ and simpler guidelines may result in increased patient compliance.²²

The full compliance rate of our study (including wear and care behaviors and follow-up visits) was not high; this was mainly due to the poor compliance rate for wear and care behaviors, particularly for the three worst compliance behaviors, including

TABLE 3. Difference in Wear and Care Compliance Between the Self-care and Non-self-care Groups

	Self-care	Non-Self-care	P^a
n	303	41	—
Compliance (%)	16.3	29.3	0.046

^a P value from the Pearson chi-squared test (χ^2); self-care indicates that patients wore and cared for lenses by themselves; non-self-care indicates that patients did not wear and care for lenses by themselves.

TABLE 4. Difference in Independence of Wearing and Caring Lenses Between Males and Females

	Males	Females	P
Age (mean±SD, y)	13.6±2	12.8±1.9	≤0.001 ^a
Independence of wearing lens (%)	84.4	91.8	0.014 ^b
Independence of caring lens (%)	67.5	80.0	0.004 ^b

^aValue from the Mann–Whitney U test.

^bValues from the Pearson chi-squared test (χ^2).

Independence indicates that patients wore and cared for lenses by themselves.

avoiding exposing lenses to nonsterile solution, removing deposits according to the ECPs’ recommendations and adequate hand washing. After further observation of the details of these three behaviors, we found that the main reason for the low compliance rate for avoiding exposing lenses to nonsterile solution was the lack of drying hands after washing, and the main reason for the low compliance of hand washing was not a lack of hand washing but washing hands without soap. As shown above, the low compliance was not due to lack of the behavior but improper performance of the behavior. Therefore, we hypothesized that the cause of the low compliance rate for wear and care behaviors might be the same as that in Claydon’s survey.²⁷ Claydon’s survey found that most patients were not intentionally noncompliant but rather engaged in noncompliant behaviors because of misunderstandings, forgetting, and poor guidance. Only a small portion of noncompliant behaviors were intentional, because of reasons such as inconvenience, neglect, or denial of risk. Therefore, increased attention should be focused on the details of these behaviors during re-education.

A study by Morgan et al.¹¹ showed that compliance decreases with age. Although our study showed no correlation between age and compliance for wear and care behaviors, the non–self-care group showed higher compliance rates than the self-care group, indicating that the parents’ compliance rate was higher than that of the children. We speculate that the reason for this finding may be that patients in our survey were mainly adolescents; very few adult patients were included, resulting in a limited age range. However, the influence of age on compliance may exist between adolescents and adults or among different age groups of adults.

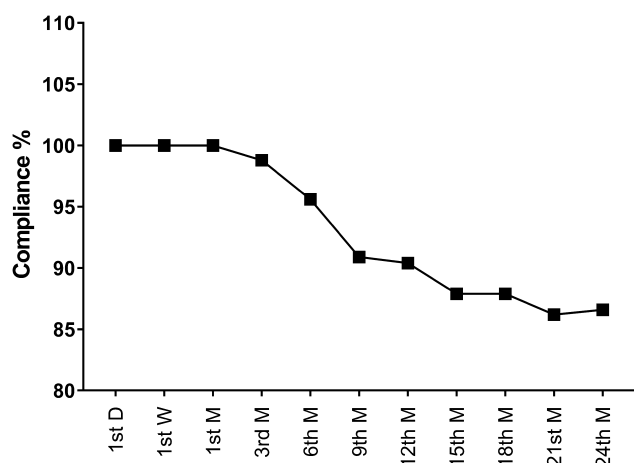


FIG. 2. Proportion of compliance with follow-up visit. D, day; M, month; W, week.

TABLE 5. Compliance of Adjacent Follow-up Visits

	P
≤1st M vs. 3rd M	0.062 ^a
3rd M vs. 6th M	0.006 ^b
6th M vs. 9th M	0.008 ^b
9th M vs. 12th M	0.810 ^b
12th M vs. 15th M	0.318 ^b
15th M vs. 18th M	1.000 ^b
18th M vs. 21st M	0.586 ^b
21st M vs. 24th M	0.894 ^b

^aValue from the Fisher exact test.

^bValues from the Pearson chi-squared test (χ^2).

No correlation was found between sex and the compliance for wear and care behaviors in our study, consistent with a study by Yeung et al.²⁸ However, other studies have shown that males exhibit lower adherence to wear and care behaviors,^{11,29} although none of these studies included ortho-k lens wearers. Sex was not correlated with compliance in our study. However, it is noteworthy that for both lens wear and care, male juveniles were less independent than female juveniles, indicating that male juveniles require more parental assistance than female juveniles. Therefore, ECPs should be more cautious when screening male juvenile patients. For example, if a male child attends boarding school, the ECP should consider whether he can manage the ortho-k care procedure independently. We also found no correlation between wearing experience and compliance for wear and care behaviors. Our result was consistent with a survey by Yung et al.³⁰; however, Claydon and Efron²⁷ found a strong association between wearing experience and compliance for wear and care. Radford et al.³¹ also found that compliance decreased rapidly within the first 2 years, with a slower rate of deterioration in hygiene compliance thereafter. The reason for this difference may be that we surveyed only patients who had worn lenses for 1 to 3 years and did not investigate patients who had worn lenses for less than 1 year.

Comparing the compliance for wear and care behaviors, we did find some differences in the compliance for follow-up visits. First, compared with the compliance for wear and care behaviors, the compliance rate for follow-up visits was much higher and may be attributed to the prompt calls from the staff of EHWMU to patients who did not attend scheduled follow-up visits. Second, the main reasons for lack of follow-up were lack of time, no symptoms, and inconvenience, whereas forgetting appointments accounted for

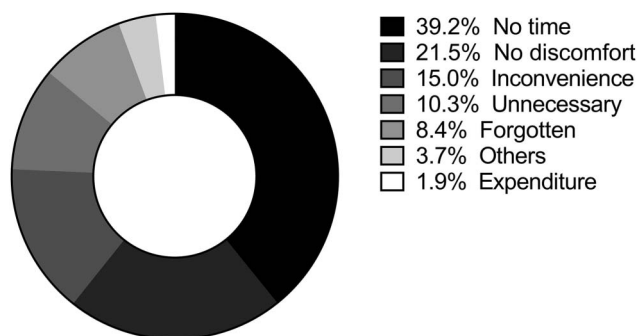


FIG. 3. Composition of the reasons for missed follow-up appointments.

only 8.4% of missed visits. In our study, patients intentionally missed follow-up visits. This finding is the opposite of Claydon's²⁷ findings regarding the reasons for noncompliance for wear and care behaviors. Claydon's survey found that most patients were not intentionally noncompliant. Our follow-up rate may also be due to reminders from our staff, which decreased the proportion of "forgotten" visits. This finding may show that constant reminders (Cho effects⁹) are indeed effective in improving compliance. In addition, we found that follow-up visit compliance was related to wearing experience. The compliance for follow-up visits declined significantly from the third month to the ninth month and began to stabilize thereafter. Therefore, ECPs should focus on compliance with follow-up visits during this period.

This study has some limitations. First, a questionnaire was used in the study. This method depends on the subjective responses of patients and may not provide accurate results. However, this method is currently the only way to obtain information regarding patient compliance. The large sample size of our study helps to increase the objectivity of our results. Second, this study was only a single-center hospital study, but as our study is the first report of the compliance with ortho-k guidelines in Mainland China, it may provide a reference for future multicenter studies.

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