Follow-up Study on the Effect of Long-Term Wearing Orthokeratology Lens on Tear Film Stability in Adolescents

Min Xiao
College of Clinical Medicine, Faculty of Medicine, Loudi Vocational and Technical College, Hunan, China

Abstract: This study aims to explore the dynamic effect of long-term wearing orthokeratology lens (OK lens) on tear film stability and ocular surface related indicators in adolescent myopia patients. This was a prospective cohort study. We selected 120 cases of adolescent myopia patients (120 eyes, taking right eye data) who visited the ophthalmology department of a top-class hospital from January 2023 to January 2024. We used the randomized block design method. The patients were divided into the orthokeratology group (60 cases) and the frame glasses control group (60 cases). Both groups of patients completed a 12-month follow-up. Before wearing (baseline), 1 month, 3 months, 6 months and 12 months after wearing, we respectively measured the non-invasive tear break-up time (NIBUT), Schirmer I test (SIT), corneal fluorescein staining (CFS) score and Ocular Surface Disease Index (OSDI) questionnaire score of the subjects in the two groups. We used repeated measures ANOVA and independent sample t-test for data statistics. The results showed that at the baseline level, the differences in all indicators between the two groups had no statistical significance ($P > 0.05$). At 1 month and 3 months after wearing the lenses in the orthokeratology group, the NIBUT was significantly shorter than before wearing ($P < 0.05$), and the OSDI score and CFS score were significantly higher than before wearing ($P < 0.05$). At 6 months and 12 months after wearing the lenses, the NIBUT and OSDI score gradually recovered, and compared with the baseline, the differences had no statistical significance ($P > 0.05$). The SIT temporarily increased at 1 month of wearing the lenses, and then recovered to the baseline level. The indicators in the control group had no obvious fluctuation during the follow-up period. In conclusion, long-term wearing of orthokeratology lens will cause a temporary decrease in tear film stability and slight changes in the ocular surface microenvironment in adolescents during the initial wearing period (1 to 3 months). But with the extension of wearing time (after 6 months), the tear film function and subjective symptoms can gradually compensate and tend to be stable. We should strengthen the monitoring of the ocular surface during the initial wearing period in clinical fitting.

Keywords: Orthokeratology lens; Adolescent; Myopia; Tear Film stability; Follow-up Study

1. Introduction

In recent years, the incidence rate of adolescent myopia is very high. It brings a great influence to the health of adolescents. How to control the progress of myopia is a very important topic. As we all know, orthokeratology lens (OK lens) is a very popular method for adolescent myopia control at present. It can reshape the cornea and provide good vision, so it is widely used in the clinic [1]. However, orthokeratology lens is a foreign body on the eye surface. When patients wear it at night, it will touch the cornea for a long time. It will change the tear distribution. This will bring some influence to the ocular surface microenvironment [2].

The tear film is a very important barrier to keep the ocular surface healthy. If the tear film stability is broken, it is the core reason for Contact Lens-induced Dry Eye (CLIDE) [3]. Adolescents have a heavy study burden and they often use electronic products. These reasons make them easy to get ocular surface problems. At present, about the effect of long-term wearing orthokeratology lens on adolescent tear film stability, different research conclusions still exist [4]. Some people think orthokeratology lens will affect the lipid layer. But other studies show that the eye surface can adapt to the lens after some time [5].

Based on the above reasons, our study selected

120 adolescent myopia patients. We aims to observe the dynamic changes of tear film indicators after wearing orthokeratology lens for 12 months. We hope to give more evidence for the safety of myopia control.

2. Subjects and Methods

2.1 Subjects

This study is a prospective cohort study. We selected 120 cases of adolescent myopia patients who visited the optometry center of our hospital from January 2023 to January 2024.

2.1.1 Inclusion criteria: (1) Age from 10 to 15 years old; (2) Need orthokeratology lens for myopia control; (3) No history of wearing any contact lenses; (4) Good compliance, can come back for follow-up examinations on time.

2.1.2 Exclusion criteria: (1) Patients with active ocular surface diseases, such as dry eye, blepharitis, and conjunctivitis; (2) Patients with glaucoma, cataract, or fundus diseases; (3) Patients with systemic immune system diseases or using systemic/local drugs that affect tear secretion for a long time.

A total of 120 patients were selected. We used the randomized block design method. The patients were divided into the orthokeratology group (60 cases, 60 eyes) and the control group (60 cases, 60 eyes). Because the two eyes can influence each other, we only used the right eye data for statistical analysis.

We compared the basic data (age, gender, equivalent spherical lens degree, and baseline tear film indicators) between the two groups. The differences had no statistical significance (P>0.05). The two groups were comparable. This study was approved by the ethics committee of our hospital. All subjects and their guardians signed the informed consent form.

2.2 Fitting and Intervention Methods

In the orthokeratology group, patients used orthokeratology lens with high oxygen permeability. Different from other lenses, the patients wore the lenses at night when they slept. The wearing time was about 8 hours every night. In the morning, they took off the lenses. They used standard care solution to clean the lenses. The control group wore ordinary frame glasses.

2.3 Observation Indicators

All subjects received the following tests before wearing glasses (baseline) and 1 month, 3 months, 6 months, 12 months after wearing glasses. The tests were completed by the same technician who did not know the grouping information:

2.3.1 Ocular Surface Disease Index (OSDI) score: Used the international OSDI questionnaire to evaluate the subjective eye symptoms, visual functions, and environmental triggers in the past week. The total score is 0-100 points. A higher score means worse subjective dry eye symptoms [6].

2.3.2 Non-invasive tear break-up time (NIBUT): Used Oculus Keratograph 5M comprehensive ocular surface analyzer. The subject was asked to blink twice and keep eyes open. The machine automatically recorded the time of the first tear film break-up (first NIBUT, seconds).

2.3.3 Schirmer I test (SIT): Did not use surface anesthesia drops. Put the folded end of the standard filter paper strip into the middle and outer 1/3 of the lower conjunctival sac. The patient closed eyes for 5 minutes. Then we took it out and measured the wet length of the filter paper (mm/5min).

2.3.4 Corneal fluorescein staining (CFS) score: Used 1% sodium fluorescein paper to wet and point into the lower fornix. Observed the cornea under slit lamp cobalt blue light. The cornea was divided into 5 areas: up, down, nasal, temporal, and central. No staining was 0 point. 1-30 dot staining was 1 point. >30 dot staining but no fusion was 2 points. Staining fusion or ulcer was 3 points. The total score is 0-15 points [7].

2.4 Statistical Methods

SPSS 26.0 statistical software was used for data analysis. Measurement data were expressed as mean ± standard deviation ($\bar{x} \pm s$). Independent sample t-test was used for comparison between two groups of normal distribution data. Repeated measures ANOVA was used for longitudinal data comparison at multiple time points. Bonferroni correction was used for post hoc pairwise comparison. Non-parametric Mann-Whitney U test was used for non-normal distribution data and grade data like CFS score. P<0.05 meant the difference had statistical significance.

3. Results

3.1 Changes of Subjective OSDI Score in Two Groups

At baseline, the OSDI scores between the two

groups had no statistical significance (P > 0.05). At 1 month and 3 months after wearing glasses, the OSDI score in the orthokeratology group was significantly higher than the baseline level (*P*<0.01), and was significantly higher than the control group at the same time (*P*<0.01). After 6 months of wearing glasses, the OSDI score in the orthokeratology group gradually decreased. At 12 months, compared with the baseline level, the difference had no statistical significance (P > 0.05). See Table 1.

Table 1. Comparison of OSDI Scores Between the Two Groups at Different Time Points (points, $\bar{x}$±s)

Group	Before wearing (Baseline)	1 month	3 months	6 months	12 months
Control group (n=60)	5.32 ± 2.14	5.40 ± 2.31	5.38 ± 2.18	5.51 ± 2.20	5.60 ± 2.25
Orthokeratology group (n=60)	5.45 ± 2.20	12.85±3.45*#	10.62±2.90*#	6.85 ± 2.40	5.82 ± 2.30

Note: Compared with baseline, **P*<0.01; compared with control group at the same time, #*P*<0.01.

3.2 Changes of NIBUT and SIT in Two Groups

At 1 month and 3 months after wearing orthokeratology lens, the NIBUT of the orthokeratology group was significantly shortened (7.15±1.42 s and 8.40±1.55 s). Compared with the baseline (12.55±2.10 s) and the control group at the same time, the difference had statistical significance (P<0.05). After 6 months of wearing the lens, the NIBUT gradually extended. At 12 months (11.85±2.05 s), it recovered to near the baseline level.

For the SIT, at 1 month of wearing orthokeratology lens, the tear secretion had a temporary increase (16.50 ±2.85 mm/5min). It was significantly higher than the baseline and the control group (P<0.05). At 3 months and later time points, the SIT recovered and became stable near the baseline level. See Table 2.

Table 2. NIBUT and SIT Results Between the Two Groups at Different Time Points ($\bar{x}$ ± s)

Indicators / Group	Before wearing	1 month	3 months	6 months	12 months
NIBUT (s)					
Control group	12.60 ± 2.15	12.45 ± 2.20	12.50 ± 2.18	12.55 ± 2.25	12.40 ± 2.10
Orthokeratology group	12.55 ± 2.10	7.15 ± 1.42*#	8.40 ± 1.55*#	10.95 ± 1.90	11.85 ± 2.05
SIT (mm/5min)					
Control group	13.80 ± 2.50	14.10 ± 2.45	13.95 ± 2.60	14.05 ± 2.55	13.90 ± 2.40
Orthokeratology group	14.00 ± 2.65	16.50 ±2.85*#	14.50 ± 2.50	14.20 ± 2.35	14.15 ± 2.45

Note: Compared with baseline, *P < 0.05; compared with control group at the same time, #P < 0.05.

3.3 Changes of CFS Score in Two Groups

During the follow-up period, the CFS score in the control group stayed at a low level (0-1 point). In the orthokeratology group, at 1 month and 3 months after wearing the lens, the incidence of punctate corneal fluorescein staining increased. The average CFS scores were (1.25±0.65) points and (1.05±0.55) points. They were significantly higher than the baseline level (P < 0.05). The staining was mainly located at the central cornea or the mid-peripheral area. This is because the lens presses and rubs the cornea at night. After increasing lubrication and standard care, the CFS score dropped to (0.45±0.30) points at 6 months and 12 months. The difference had no statistical significance compared with the baseline. There were no severe corneal ulcer or infection cases during the study.

4. Discussion

As we all know, orthokeratology lens is a very effective tool for adolescent myopia control. But its influence on the tear film cannot be ignored. When the lens is worn overnight for 8 hours, it puts pressure on the cornea to change the shape. This mechanical effect and the presence of the lens will change the tear film stability [8].

The results of this study showed that at the first 3 months, the NIBUT shortened and the OSDI score increased. This is because the eye surface needs time to adapt to the orthokeratology lens. The lens might affect the lipid layer and make the tears evaporate faster [9]. At the same time, patients often feel foreign body sensation and dry eyes in the early wearing period. They also shed tears. In our study, the SIT value increased at 1 month. SIT includes basic tears and reflex tears. Because the lens is a hard foreign body, it stimulates the corneal nerve endings. Therefore, the eyes produce more tears to compensate for the stimulation.

However, at 6 months and 12 months of follow-up, the eyes had an obvious adaptation. In the orthokeratology group, the NIBUT increased

step by step. It went back near the baseline level. The OSDI score dropped to normal. The patients felt comfortable again. The SIT also became stable in the normal range. What is the reason? It is the human body adaptation mechanism. Because the patients blink their eyes every day, the cornea and conjunctiva get used to the mechanical friction. So, the eye sensitivity is lower. The reflex tears become less. In addition, the lens moves very stably on the cornea. The tears under the lens can renew well and reach a balance. Wang et al. [10] studied orthokeratology lenses for a long time. They found that the goblet cells on the children's ocular surface will decrease at first. Then, after 3 months of wearing lenses, these cells will grow again to repair the surface. This time window is the same as our study results.

CFS is a good indicator to check the cornea damage. In this study, the orthokeratology group had mild punctate staining at first. The staining was often at the 3 o'clock and 9 o'clock positions. In clinical work, doctors call it "3 and 9 o'clock staining". Why does it happen? Because the orthokeratology lens is smaller than the cornea. When patients sleep at night, the lens edge rubs the local cornea. The epithelium becomes dry and falls off. In our treatment, we gave patients artificial tears without preservatives. We also adjusted the lens edge. After that, the corneal damage disappeared in the later follow-up.

In the clinic, many parents worry about the eye safety of adolescents. They think long-term wearing orthokeratology lens will bring bad influence. But our study uses data to prove it is safe. The tear film changes and eye stimulation only happen in the first 3 months. This is a temporary reaction. After wearing the lens for 6 to 12 months, the eye surface builds a new balance. It will not cause permanent dry eye. Orthokeratology lens is very safe for myopia control. It is worthy of clinical promotion.

For clinical management, doctors must pay attention to the first 3 months. We call it the "initial wearing window". For new patients, 1 week, 1 month, and 3 months are very important review times. If the NIBUT drops or CFS staining is positive, the doctor must check the lens. The doctor should adjust the lens fitting state. At the same time, the doctor should give patients sodium hyaluronate eye drops. This helps patients pass the adaptation period smoothly.

Our study still has some limitations. First, the follow-up time is only 12 months. We do not have 2 or 3 years of data. Second, we did not record the lifestyle of the patients. For example, we do not know how long they use electronic phones or computers every day. This may affect the tear film. We need to do more studies in the future. We need more patients and a longer time to improve our research.

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