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Comparison of the clinical effects between digital keratoplasty and traditional orthokeratology lenses for correcting juvenile myopia

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Abstract.
BACKGROUND: Various methods exist to intervene with and control myopia, including bifocal lenses, multifocal lenses, pirenzepine, atropine, soft gas-permeable contact lenses and aberration control frame lenses, each with its own advantages and disadvantages.
OBJECTIVE: To compare the clinical effectiveness of digital keratoplasty lenses and traditional orthokeratology (OK) lenses in correcting juvenile myopia.
METHODS: Sixty-one patients (122 eyes) with an average age of 10.43 ± 1.71 years and with myopia were enrolled from January 2021 to January 2022 in the treatment centre of our hospital. The patients were randomly divided into two groups. Group I (the experimental group) consisted of 30 patients who were treated with digital corneal shaping (MCT) lenses, while group II (the control group) consisted of 31 patients who were treated with traditional OK lenses. Clinical indicators, such as visual acuity, ocular axis, intraocular pressure, degree of central positioning, naked visual acuity and first-order spotting, were statistically analysed before and after fitting.
RESULTS: The naked eye vision of patients using MCT lenses was significantly improved compared with patients who used traditional OK lenses ($0.95 \pm 0.28 > 0.58 \pm 0.25$; $p < 0.05$). Moreover, the risk of primary spot staining was reduced ($p < 0.05$), intraocular pressure was lower ($p < 0.05$) and the centre position reached 100% in patients wearing MCT lenses, suggesting that wearing MCT lenses may be more beneficial than wearing traditional OK lenses.
CONCLUSION: Compared with traditional OK lenses, MCT lenses reduce the degree of myopia, have significant effects and have the added advantages of safety and reliability.

Keywords: Centre positioning, primary spot staining, orthokeratology contact lens, vision

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1. Introduction

In recent years, global myopia, and especially severe myopia, rates have grown rapidly. Among adolescents, there is an early age of onset and rapid progression of myopia, as well as an increased proportion of severe myopia [1–3]. According to statistics, the prevalence of myopia in East Asia accounts for nearly 50%, which is significantly higher than that in Australia, Europe and North and South America [4]. Based on current trends, it is estimated that the global myopic population will reach 4.9 billion (52%) by 2050, with severe myopia affecting 925 million (10%) [5]. Myopia has been identified by the World Health Organization as one of the top five eye diseases to be eliminated, a testament to the fact that it has become one of society's most pressing problems [6]. Adolescents may develop pathological myopia from physiological myopia, which could increase their chances of developing serious ophthalmic disorders (including retinal detachment, retinal degeneration and tear, glaucoma and even cataracts) and cause an irreversible loss of function [7]. Therefore, in patients with worsening myopia, early intervention is essential to effectively reduce ocular complications, vision loss and other risks to eye health [8].

At present, various methods exist to intervene with and control myopia, including bifocal lenses, multifocal lenses, pirenzepine, atropine, soft gas-permeable contact lenses and aberration control frame lenses, each with its own advantages and disadvantages [9,10]. Among these methods, orthokeratology lens technology is a non-surgical treatment of myopia developed from rigid contact lenses. Orthokeratology lenses flatten the central part of the cornea, increase curvature diameter and reduce corneal curvature force with a reverse geometric design and highly oxygen-permeable materials, thus reducing myopic refraction and restoring patients' visual acuity [11,12]. In addition to helping to control the exacerbation of myopia in adolescents, orthokeratology lens technology reduces the inconvenience of wearing frame glasses.

Traditional orthokeratology (OK) lenses have several disadvantages, including an insufficient parameter design, inadequate material permeability and poor predictability. With technological developments and deepening research, aspects of OK lenses, including their design, materials and fitting principles, have undergone significant changes. Especially through the maturity of angular mode video analysis and the application of corneal topography in recent years, the design parameters of OK lenses and the effects of wearing them, reflected in corneal morphology, have made great progress. At the same time, a new method for the control and reduction of myopia has emerged. Digital orthokeratology (MCT) lenses have the advantages of long-term wearing safety and effectiveness, good visual stability, and strong predictability and reversibility and have shown promising results in controlling and reducing myopia in adolescents [13–15]. But do MCT lenses improve naked eye vision substantially compared with traditional OK lenses? Clinical data are lacking on the effects of MCT lens usage on complications, such as the incidence of primary spot staining and intraocular pressure. To investigate the clinical efficacy of MCTs and traditional OK lenses in the treatment of adolescent myopia, 61 patients admitted to our hospital from January 2021 to January 2022 with myopia were treated with either MCT or OK lenses, and the results were analysed and compared. The effects of MCT and traditional OK lenses on naked eye vision and intraocular pressure and the incidence of other complications were discussed. This study has value and significance as a reference and as a guide for future clinical treatment.

2. Materials and methods

2.1. General information

This study is based on a cohort of school-aged adolescents. The objective was to observe changes in clinical parameters in adolescents wearing different types of orthokeratology lenses. A total of 61 patients

(122 eyes) with myopia who were admitted to our treatment centre from January 2021 to January 2022 were enrolled, including 22 males (36.1%) and 39 females (63.9%) ranging in age from 8 to 16 years, with a mean age of 10.43 ± 1.71 years. Patients were randomly assigned to one of two groups. Group I, the experimental group, was treated with MCT lenses. The 30 patients in this group had a refractive range between $+1$ and -6.25D (mean: -2.56 ± 1.45D) and an astigmatic range between -0.25 and -1.25D (mean: -0.75 ± 0.45D). Group II, the control group, was treated with conventional OK lenses. The 31 patients in this group had a refractive range between $+0.5$ and -6.25D (mean: -2.34 ± 1.25D) and an astigmatic range between -0.5 and -1.25D (mean: -1.05 ± 0.35D).

The inclusion criteria were as follows: (1) myopic patients admitted to our hospital from January 2021 to January 2022; (2) patients whose fundus and auxiliary examinations were completed for all items; and (3) subjects and their guardians whose consent to participate in the examination could be obtained. The exclusion criteria were as follows: (1) patients with other eye diseases; (2) patients who were unable to cooperate with visual acuity and optometric examinations; (3) patients who were unable to wear OK lenses; and (4) patients with pathological myopia. Study procedures followed the requirements of the Declaration of Helsinki and were approved by the ethics committee of the hospital. Examination procedures, including their purpose and significance, were explained to test subjects and their guardians, and written informed consent was obtained from all study participants.

2.2. Study design and method

2.2.1. General examination

Before treatment, patients underwent anterior eye and fundus examinations to rule out other eye diseases and lens wear contraindications. Myopic refraction, horizontal curvature, vertical curvature, uncorrected visual acuity and tear film were simultaneously examined. Auxiliary examinations, including intraocular pressure and axial length, were measured three times, and averages were taken.

2.2.2. Lens fitting

According to the patient's data and the design characteristics of the lens, the diameter, base curve and second arc of MCT lenses were determined, and optimal lens parameters were determined and fixed. During the wearing process, patients were taught the correct method of inserting, removing and caring for lenses, and wearing and review schedules were set.

2.2.3. Lens wear and inspection

The wearer should soak the lenses with special care solution upon removal and rinse them with cool white water before wearing them again. Wearing time should be maintained to about 8 h and should not exceed 10 h. After removing the lenses the next morning, the wearer should clean them with cool white water and soak them in a lens case with a care solution. Patients were reviewed four times per quarter (one day, one week, one month and three months after first use). The review included a corneal examination and an uncorrected visual acuity test. Lens centration, spot staining, intraocular pressure and eye axis were all measured. Both MCT lenses and traditional OK lenses are orthokeratological treatments for myopia. Orthokeratology is a non-surgical method of changing the radius of curvature in the centre of the cornea to reduce myopia, resulting in a temporary improvement in the patient's uncorrected visual acuity. Thus, after achieving maximal uncorrected visual acuity, nightly lens maintenance is required to consolidate the effect.

2.3. Statistical methods

During follow-ups, patients' visual acuity, axial length, intraocular pressure, refraction, keratometry

Table 1
Basic characteristics of patients

Group	Horizontal curvature	Vertical curvature	Intraocular pressure	Uncorrected visual acuity	Axis (mm)
Experimental group	42.32 ± 1.58	43.64 ± 1.75	16.48 ± 2.27	0.28 ± 0.22	24.66 ± 0.99
Control group	43.54 ± 1.33	44.78 ± 1.82	16.31 ± 2.48	0.25 ± 0.21	0.85

Table 2
Comparison of uncorrected visual acuity differences after clinical treatment

Group/uncorrected visual acuity	First review	Second review	Third review	Fourth review	P
Experimental group	0.29 ± 0.12	0.58 ± 0.08	0.85 ± 0.25	0.95 ± 0.28	< 0.05
Control group	0.26 ± 0.06	0.40 ± 0.15	0.53 ± 0.21	0.58 ± 0.25	< 0.05
P	< 0.05	< 0.05	< 0.05	< 0.05	

Table 3
Comparison of axial length difference after clinical treatment

Group/axis (mm)	First review	Second review	Third review	Fourth review	P
Experimental group	24.65 ± 0.97	25.10 ± 1.02	24.66 ± 1.05	24.74 ± 1.03	> 0.05
Control group	24.58 ± 0.95	24.97 ± 1.05	24.36 ± 1.21	24.48 ± 1.24	> 0.05
P	> 0.05	> 0.05	> 0.05	> 0.05	

and other clinical indicators were recorded. Measurement data were presented as $\bar{x} \pm s$, and SPSS v. 23.0 statistical software was used to process the data. An independent sample t-test was also used. Enumeration data were expressed as n (%), and comparison between groups was analysed using the chi-square test. p-values of less than 0.05 were considered statistically significant.

3. Results

3.1. Uncorrected visual acuity

The basic characteristics of the remaining patients are shown in Table 1. No patients withdrew from the study. Patients were re-examined four times: on the first day after wearing the lenses, as well as one week, one month and three months after wearing the lenses, and the results are shown in Table 2. The uncorrected visual acuity of patients who wore MCT lenses was significantly improved compared to those who wore conventional OK lenses. Both groups had higher uncorrected visual acuity after wearing the lenses than prior to their use ($p < 0.05$). The mean uncorrected visual acuity for patients with MCT lenses was significantly higher than in those using conventional OK lenses ($0.95 \pm 0.28 > 0.58 \pm 0.25$; $p < 0.05$), and differences were statistically significant.

3.2. Axial length

Changes in axial length after lens wear are shown in Table 3. From these data, it can be concluded that after four follow-ups, compared to measurements taken before clinical treatment, there was almost no change in axial length, and any difference observed had no statistical significance ($p > 0.05$). This suggests that orthokeratology lenses change the uncorrected visual acuity of patients without changing axial length.

Table 4
Comparison of primary spot staining after wearing lens in myopic patients

Group/no. of spotted	First review	Second review	Third review	Fourth review	P
Experimental group	2	1	0	0	< 0.05
Control group	4	4	4	3	> 0.05
P	> 0.05	> 0.05	> 0.05	> 0.05	

Table 5
Comparison of intraocular pressure before and after wearing lens in myopic patients

Group/IOP (mmHg)	Before wearing lens	First review	Second review	Third review	Fourth review	P
Experimental group	16.48 ± 2.27	14.23 ± 1.86	14.56 ± 1.73	14.18 ± 1.52	14.33 ± 1.62	< 0.05
Control group	16.31 ± 2.48	14.33 ± 1.53	14.77 ± 1.02	14.03 ± 1.33	14.58 ± 1.45	< 0.05
P	> 0.05	> 0.05	> 0.05	> 0.05	> 0.05	

Table 6
Comparison of central positioning degree of lens after wearing lens for myopic patients

Group/site positioning	First review	Second review	Third review	Fourth review	P
Experimental group	29	30	30	30	> 0.05
Control group	25	24	26	25	> 0.05
P	< 0.05	< 0.05	< 0.05	< 0.05	

3.3. *Primary spot staining*

The statistical results of the incidence of primary spot staining in study patients are shown in Table 4. The probability of developing primary spot staining after wearing MCT lenses was less than with traditional OK lenses, but there was no statistical significance ($p > 0.05$). The risk of primary spot staining in the experimental group was reduced, and these results were statistically significant ($p < 0.05$), but due to the small sample size, there is a lack of theoretical certainty.

3.4. *Intraocular pressure*

Changes in intraocular pressure among study subjects after lens wear are shown in Table 5. The results show that intraocular pressure between the MCT and traditional OK lens groups was almost the same and remained consistent; however, there was a degree of reduction in intraocular pressure after lens usage generally, and the difference was statistically significant ($p < 0.05$). It is possible that the basal arc of a lens contacts and massages the central cornea, which, together with the pressure of the eyelid, forces an accelerated outflow of aqueous humour, resulting in a decrease in intraocular pressure [16].

3.5. *Central positioning degree*

The centre positioning of patients wearing MCT lenses was better than for those wearing traditional OK lenses. After the fourth follow-up examination, the centre positioning of patients wearing MCT lenses reached 100%, while that of the 25 patients remaining in the control group was 80.65%. This difference was statistically significant ($p < 0.05$). A lens's stability is closely related to corneal centring and the degree of correction of visual acuity, and central positioning is directly related to changes in both the shape of the cornea and refraction. Some scholars have found that the incidence of off-centred orthokeratology lenses is related to the design of lens, and off-centred lenses can affect the therapeutic effects of the lens [17].

4. Discussion

For juvenile myopia, there is no more effective method than optical correction to improve distance vision. Regular eyeglass wear is the simplest approach, but it is not conducive to the movement characteristics of adolescents because of the need to hang the eyeglass frame on the face to put it in place. Additionally, eyeglass wear is accompanied by optical aberrations, lateral vision deviations, lens fogging and optical contamination areas, which are not conducive to the long-term improvement of ocular vision [18,19]. In recent years, special, rigid orthokeratology contact lenses made of highly permeable materials have become one of the current points of focus in the ophthalmology community as a new, non-invasive method for correcting myopia [20]. As technology continues to develop and improve, we should pay special attention to the improvements that new materials, such as intraocular lenses, may bring to our traditional treatment methods [21–23].

At present, orthokeratology lenses are primarily spherical in design with four arc regions: positioning, reverse, base and peripheral [24]. The reverse arc region is steeper than the base arc region, and the difference between the reverse arc region and the base arc region ranges from 3 to 15D. The width of the reverse arc region is usually between 0.6 and 1.0 mm. If the reverse arc region were designed as two segments with unequal curvature radius, the connection between the central parallel arc region and the base arc region could be improved. Locating the arc area can encourage the lens to centre on the cornea and ensure that the lens presents a parallel state with the cornea. A central, flat base arc area can produce mechanical pressure on the anterior corneal surface, and vacuum aspiration can be realised with a steep reverse arc area to promote the reasonable plasticity of the cornea. A peripheral arc of circumferential uplift can ensure the effective exchange of tears and realise a dynamic balance of the eyeball. Through the establishment of a mechanical model, it has been clinically found that, to achieve moulding, orthokeratology lenses rely primarily on the vacuum suction of the tear layer under the lens and the pressure of the eyelid and that the base arc area is relatively steep compared with the platform and inversion arc areas. This inverse geometric design can achieve the super positioning effect of force to produce tangential force, cause the compression, migration and redistribution of corneal epithelial cells and achieve a new balance point for the cornea, thus playing a role in correcting refraction in myopic patients [25].

MCTs are a new generation of fully anastomotic orthokeratology lenses emerging with the development of corneal topography. MCTs are digitally designed based on whole-cornea data and are more effective than traditional OK lenses. Patient comfort and satisfaction with MCTs are also higher [26]. Moreover, MCTs greatly simplify the fitting procedure of orthokeratology lenses, eliminate the need for trial wear to determine the appropriate prescription and greatly reduce the troubles caused to doctors by film adjustment. This study concludes that myopic patients who insisted on wearing MCT lenses had improved uncorrected visual acuity, and there was a corresponding, statistically significant reduction in refraction compared with traditional OK lens wearers [27]. This is consistent with reports by Xie Pei-ying [28], indicating that MCTs can effectively correct myopia and can be used to correct severe myopia in patients.

A limitation of this study is the lack of statistical data and description of the changes in corneal curvature (dioptres). If possible, this will be investigated in our follow-up study. The subjects of this study were adolescents aged 8 to 16 years with complex eye environments. We have tried our best to control for confounding variables of different degrees, but variables such as eye habits cannot be controlled. In addition, the sample size was small and should be increased to obtain more valid conclusions.

There was no significant difference in axial length before and after lens wear in this study, indicating that the mechanism of action of orthokeratology lenses in reducing refraction hinges on the changing of corneal curvature and shape by compression. Additionally, there was a degree of reduction in intraocular pressure after lens usage generally and the difference was statistically significant ($p < 0.05$). The supposed mechanism of action of this reduction is the contact and massaging that occurs between the centre of the cornea and the base arc of the lens. Coupled with the compression force of the eyelid, this could produce a continuous friction force on the eyeball, similar to the principle of intraocular pressure tracing, that could force an accelerated discharge of aqueous humour, thus reducing intraocular pressure.

Corneal epithelial injury is a common complication of orthokeratology lens wear, and some researchers have reported that critically ill patients are prone to developing corneal ulcers [29]. In this study, four patients showed primary spot staining after wear, which may have been caused by improper wearing techniques. This was generally resolved after stopping wear and administering local eyedrop treatments, and recovery followed at a later stage. MCT lenses are a reversible, non-radical treatment for myopia. The most sensitive restoration of vision throughout the study period occurred when patients stopped wearing the lenses, and this was followed by a full restoration of corneal refraction. There was less restoration of vision with traditional OK lenses than with MCT lenses.

5. Conclusion

Compared to traditional OK lenses, MCT lenses reduce myopia significantly and have the added advantages of safety and reliability. As long as prescription requirements are strictly adhered to, a person with no contraindications is selected, appropriate orthokeratology lenses are worn and timely review is performed (according to a clinician's requirements), MCTs can be a safer and more effective alternative for improving visual acuity, and has better clinical effect and further promotion value.

Ethics statement

The study was conducted in accordance with the Declaration of Helsinki and approved by the ethics committee of The Second Hospital of Anhui Medical University. Signed informed consent was obtained from all participants/legal guardians in this study.

Availability of data and materials

All data generated or analyzed during this study is included in this published article.

Competing interests

None of the authors have any personal, financial, commercial, or academic conflicts of interest to report.

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Author contributions

HP and TLM conceived the study. HP participated in its design and data analysis and TLM was responsible for statistics. HP and TLM helped draft the manuscript and read and approve the final manuscript.

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