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MONITORING OF CONTACT LENS WEARERS FOR ORTHOKERATOLOGY IN ORDER TO DETERMINE THE DEGREE OF VISUAL COMFORT

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Abstract: *The paper analyzes the opportunity to use contact lenses in the field of orthokeratology and their effect on the level of visual comfort for human subjects who have myopia or keratoconus. in the first part of the paper are reviewed some general aspects related to the importance of the characteristics of hard contact lenses for the development of the visual correction process, the management of human subjects with visual dysfunction, and, for the second part to identify the set of optometric evaluations that must form a portfolio of structural analysis. in the third part of the paper, the authors present case studies for subjects wearing orthokeratology contact lenses to identify the evolution of the visual aid procedure and the moments and situations where the most effective, complete and useful level of comfort can be achieved. The results and conclusions from the analysis are presented at the end of the paper.*

Key words: *orthokeratology, visual comfort, ergonomics, tracking, contact lens.*

1. INTRODUCTION

Orthokeratology or ortho-k is an innovative and non-surgical method of correcting vision function and temporarily compensates for refractive defects. This method involves the use of hard, specialized, customized and overnight contact lenses to reshape the cornea, resulting in improved vision during the day. The unprecedented development of the field of orthokeratology (orto-K) is a proof of extensive research efforts, technological and technical advances in the calculation and design of lenses, and the implementation of modern and rapid methods of evaluation of corneal shape and topography [1].

As is known, the cornea determines 60% (~2/3) of the focusing power of the eyeball and therefore minor changes in the thickness of superficial epithelial cells can lead to changes in refractive vices. Thus, obtaining the effect of applying the ortho-K procedure by thinning the central epithelial of the cornea and redistribution of the stroma layer from the central area towards the peripheral epithelium, following the action of a hard contact lens with nocturnal port [2]. Therefore, the ortho-k procedure involves wearing hard but gas permeable contact lenses designed to reshape slightly the cornea overnight (in the field of corneal material elasticity). As the cornea deforms and reshapes, the light radiation from the visible domain, which enters the eyeball, focuses correctly on the surface of the retina. This process leads to improved vision function during the day without the need for glasses or contact lenses to correct refractive errors. After removing the harsh ortho-k contact lens worn overnight, its visual - optical effect has a reduction of about 0.50-0.75 DS [3]. Therefore, ortho-k models incorporate a compression factor (known as Jessen factor) that overcorrects the refractive error to compensate for this regression [4].

Traditionally, a conventional compression factor (CCF) of the same magnitude as regression (0.50-0.75 D) is used. However, numerous studies have found that this overcorrection may not always be equivalent to the correction test [5-7]. Consequently, a higher compression factor (FCI) was introduced in

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prescribing ortho-k lens variants to compensate for this difference.

As stated by [6] the ortho-K lens has a temporary and reversible action, because the corneal and refractive changes that occur after the application of this procedure are of short and medium duration. References [7, 8] performed on batches of patients who wore ortho-K lenses every night for about a month, it has been identified as good vision during the day, and after lens removal, it usually takes 12 to 48 hours. Therefore, specialists recommend patients to wear regularly and consistently this type of lens to maintain a constant good vision during the day. It also works on issues related to patient awareness, which must be informed and guided in what way, during what duration and how to use ortho-K lenses, and so that these set stages become a routine applied permanently.

It has also been observed in ortho-K lens wearers that if the wearing of lenses is interrupted in the long term, the refractive values return to the initial ones after about 4-7 days [9]. Thus, analysis of corneal topographic changes, after long term interruption of wearing the ortho-K lens, highlights the fact that it takes longer to return to their original value. A study [10] showed that it is possible to have an interval of 2 weeks to 2 months to return to the topography of the base cornea.

In conclusion, both corneal topography and refractive power changes that occur in the process of using ortho-K lens are temporary and reversible, as the effects are beneficial and lasting.

2. ANALYSIS OF THE BEHAVIOR OF THE SYSTEM CONSISTING OF ORTHO-K AND CORNEA LENS

As mentioned in various theoretical and experimental studies the port of an ortho-k lens causes temporary mechanical deformation, manifested in the elastic domain, which is the characteristics of the corneal structure and which is subject to the laws of biomechanics. Although examining the corneal surfaces rigorously before any refractive or surgical intervention on them, using classical methods of topography, tomography and pachymetry, however, none of the current screening tools can reliably and accurately identify biomechanical instability. From the point of view of biomechanical principles, the corneal structure has been extensively studied, using several available methods and techniques, such as analysis of uniaxial or biaxial traction forces [11], indentation procedure [12, 13] and other more complex techniques in terms of theoretical approaches or simplifying assumptions.

All these experiments indicated nonlinear behavior of stress (voltage)-deformation variation. This is because the cornea is mainly made up of the layer called the stroma, which accounts for 90% of the thickness of the cornea and which is structured with the blades made of collagen fibers.

Experimental research by which the cornea was subjected to the action of traction or indentation indicated that the stiffness of its tissues decreases with the measured depth on the outer surface [14]. To develop a detailed analysis of the biomechanical behavior of the cornea, theoretical and experimental research used three nonlinear hyper-elastic models (the Hamilton-Zabolotskaya model, the Ogden model and the Mooney-Rivlin model) which were shown the effort-deformation curves obtained in the traction tests and then statistically compared [15].

According to initial estimates, the behavior of corneal structures showed a nonlinear variation mode. As shown in [15] this behavior is best described by the Hamilton-Zabolotskaya model, obtaining in this case the highest coefficient of determination ($R2 > 0.95$). In addition, the specialists tried to develop a comparative analysis between the effects of biomechanical deformations produced in the cornea by the ortho-k lens and corneal topography. Thus, it was tried to compare refractive state changes and corneal thickness before and after the procedure of using ortho-k lens, with the shape and size of the corneal topography recorded with specialized equipment.

This analysis is complex, with many personalized parameters, with very different forms of cornea that complicate both measurement and modeling - simulation or calculation of effects [16]. In the study [16] dedicated to the analysis of the combination of the ortho-k lens and the cornea, the finite element modeling procedure was used for the interaction between the ortho-k lens and the cornea. This modeling aims to develop a procedure for identifying responses to corneal stress produced by changing the parameters of ortho-k lenses and placing these lenses on various forms of cornea and cornea with different refractive stages of myopia. The loading of the corneal structure must balance the external pressures with the internal ones, which is why the corneal layers (especially the stroma) must distribute this charge equally (Fig. 1).

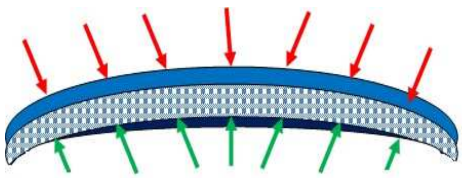

Fig. 1. Loading of corneal structure.

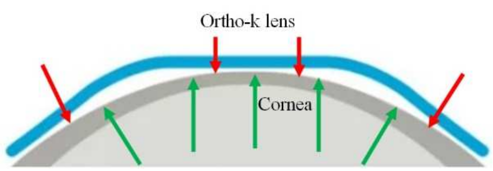

Fig. 2. Loading corneal-lens assembly ortho-k.

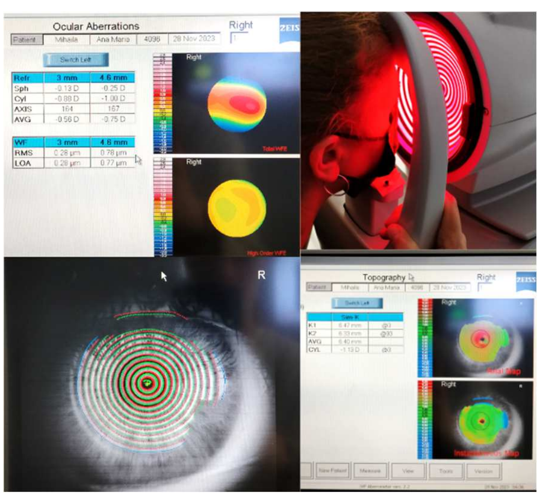

Fig. 3. Measured sizes with iProfiler [21].

Fig. 4. Visualization of the anterior pole of the eyeball using the biomicroscope [21].

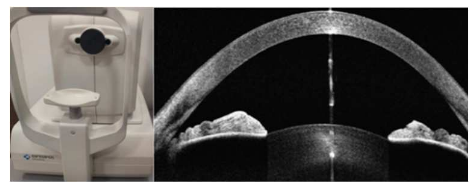

Fig. 5. Corneal thickness measurement [20].

The ortho-k lens being rigid but with oxygen permeability alters this charge and produces it differently on the cornea contact areas (Fig. 2). Therefore, an important aspect identified during the ex-vivo research allowed the obtaining once again of the biomechanical confirmation that the cornea exhibits nonlinear behavior [17]. This claim was made possible by the demonstration that there are low rigidity values at low pressures, but also significantly higher rigidity values at pressures exceeding those experienced in vivo [18]. Thus, this happens because of the different dominant factors that contribute to the deformation of the corneal structure in each of these states [19].

3. ANALYSIS OF THE EVOLUTION OF THE RECOVERY EFFECTS THROUGH THE PORT OF THE ORTHO-K LENS

From a practical point of view, the evaluation of the use of an ortho-k lens is made following the anamnesis and corneal measurements made with a complex and performant device. This device (iProfiler) allows recording at the same time several parameters (total refractive power, keratometric parameters, etc., corneal topography and the level of aberration of the eyeball), thus being able to acquire complete information (Fig. 3).

In addition to these values obtained from the iProfiler system, it is also important to view the anterior pole of the eyeball (biomicroscopy) (Fig. 4) and precision biometric measurements of corneal thickness (pachymetry) (Fig. 5). For the development of the procedure for assessing the evolution of the recovery effects through the ortho-k lens port, from the database of an optometric specialist cabinet was used, a sample of 5 subjects that fit into the requirements of the research activity.

Fig. 6. Measurement of corneal topography: (a) initially, (b) after one week of ortho-k port, (c) after one month, (d) after three months, (e) after six months, and (f) after one year [22].

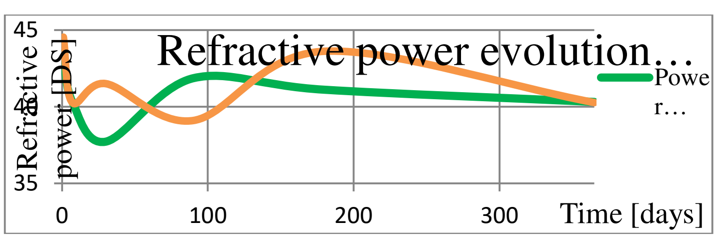

Fig. 7. Evolution of right and left eyeball refractive power during monitoring for subject no. 1.

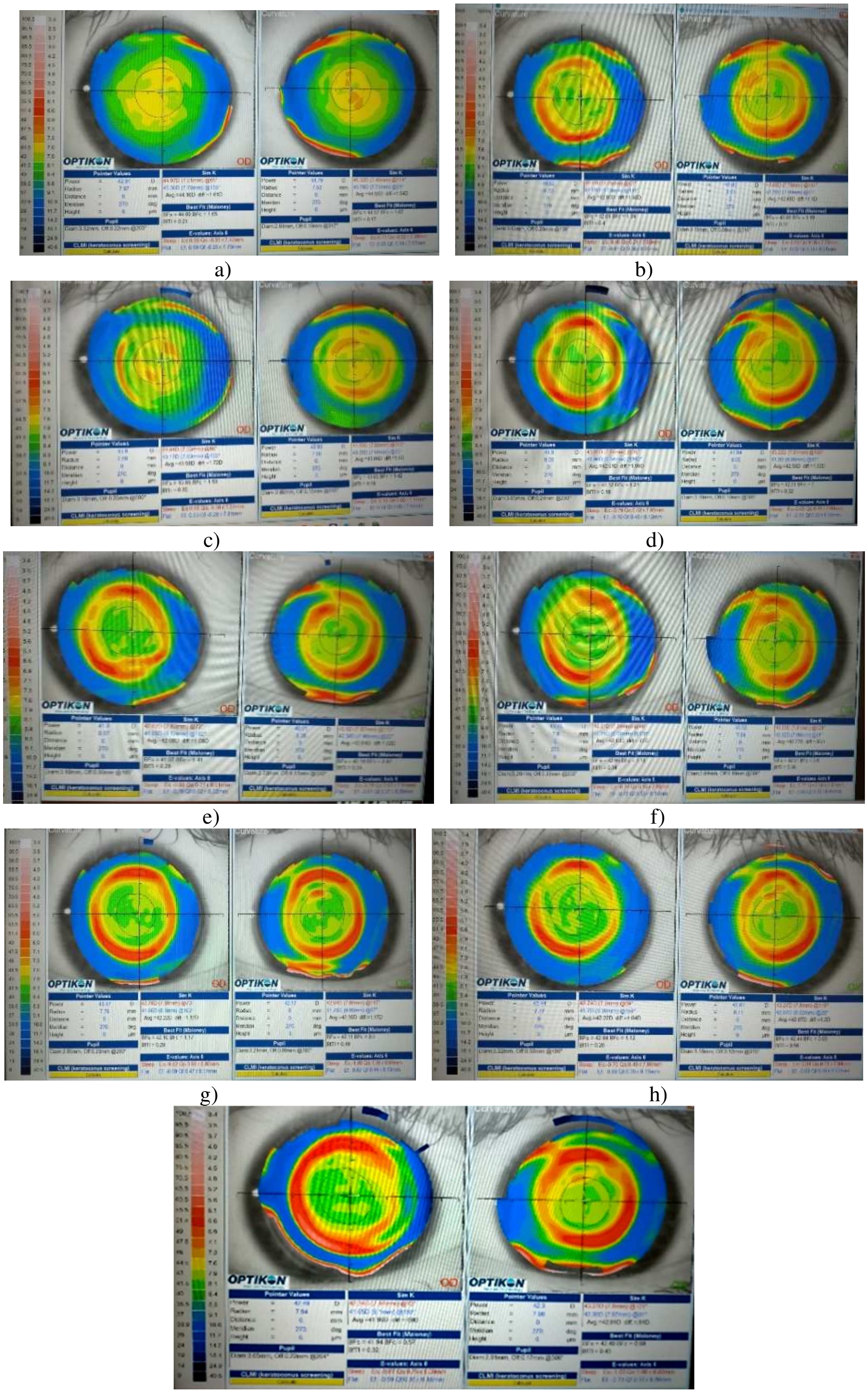

Fig. 8. Measurement of corneal topography on subject no.3: (a) initially, (b) sample port lens orthokeratology (c) after one week of ortho-k port, (d) after one month, (e) after three months, (f) after six months, (g) after nine months, (h) after one year, (i) after three years [22].

These subjects have, after processing the data from the anamnesis, an average degree of myopia (refractive power difference < -5 DS).

Measurements made by means of the said apparatus are recorded at different time intervals, established as standard intervals: one week from the initial control, one-month, three months, six months, respectively one year. Thus, the first subject presents in the initial phase the next configuration of the corneal topography, the decision in the anamnesis being that intervention through orthokeratology is necessary (Fig. 6).

Patient number one began correcting refractive vice by orthokeratology at the age of 16 in 2023. The starting refraction power being OD: -3.50 DS and -0.50 DC ax 170^0, and OS -2.25 DS and -0.50 axis 5^0, respectively, the axial length of the eyeball is at OD of 24.77 mm and OS of 24.47 mm. For another subject in the sample (no. 3) the analysis of the variation of refractive powers in the right eye (OD) and left eye (OS), respectively, showed a different evolution during the monitoring period, which has been extended to achieve the desired results.

For this topic, correction of refractive vice by the method of orthokeratology began at the age of 29 years, in 2019. The refractive powers measured in the initial phase were at the right eye (OD) of - 1.25 DS and - 1.25 DC axis at 155^0 and at the left eye (OS) - 1.50 DS and - 1.00 DC axis 17^0, the axial length of the eyeball is 23.72 mm at OD and 23.59 mm at OS.

According to Fig. 8 the checks were carried out at one week, at one month, at three months, at six months, at nine months, at twelve months and after three years of wearing the orthokeratology lens.

On subject no. 3 the evolution of refractive power change was monitored over 3 years because the changes were slower and the final value in both eyes exceeds the average value of corneal refractive power (~40 DS) which prompted this procedure.

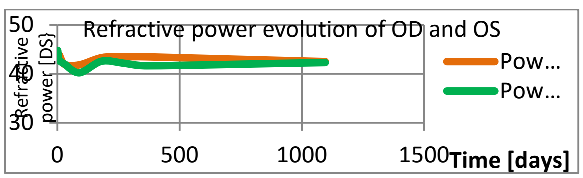

Fig. 9. Evolution of right and left eyeball refractive power during monitoring for subject no. 3.

Table 1

Comparison between the variation of the refractive powers of the cornea (S1 and S3).

Time [days]	Power OS [DS] S1	Power OD [DS] S1	Power OS [DS] S3	Power OD [DS] S3
1	43.22	44.54	44.79	42.91
7	40.31	40.26	42.85	43.9
30	37.71	41.50	41.94	41.9
90	41.85	39.09	40.21	41.8
180	41.09	43.60	42.52	43.29
270	-	-	42.17	43.47
365	40.31	40.26	41.61	43.44
1095	-	-	42.3	42.49

Table 2

Visual comfort index values.

Demographic data		Initial			Final		
No.	Age	RP OD [DS]	RP OS [DS]	IVC	RP OD [DS]	RP OD [DS]	IVC
S1	16	44.54	43.22	72.4	40.26	40.3	33.2
S2	14	43.31	45.21	68.8	41.43	41.2	41.1
S3	29	42.91	44.79	63.2	42.49	42.3	45.5
S4	12	41.64	42.39	51.9	37.36	40.1	20.3
S5	15	44.72	44.94	84.7	41.32	40.2	29.5
	17.2	**43.42**	**44.11**	**68.2**	**40.57**	**40.8**	**33.9**

Note: RP=refractive corneal power, IVC=index of visual comfort, OD=right eye, OS=left eye, S1-S5=subjects from sample.

Comparing now the values of refractive powers (table 1) between the two subjects, we find the following:

- Subject no. 1 (16 years) emetropized much faster and kept this state giving it visual comfort;
- Subject no. 3 (29 years) needed a longer period of wear of ortho-k lens, the variation of refractive power in the cornea being slowed (sometimes even stagnated) making the process of emetropization difficult.

This slight inertia of reaction in the cornea, under the ortho-k lens, also alters the wearer's perception of the utility and efficiency of the port at night. In both subjects analyzed by comparison, there is a period of onset of the ortho-k lens port in which the effects are more obvious but unstable in time due to inertia and the elasticity property of corneal structure.

For the evaluation of the visual comfort state generated by the ortho-k lens port, it is proposed that, periodically, during the procedure monitoring, the most important parameters of the visual function are evaluated and determined. Currently, there is no universally valid or standardized formula for calculating visual comfort in orthokeratology, since this behavior represents a subjective and complex aspect, involving multiple variables.

However, several researchers have indicated and used several measurable and subjective characteristics and aspects with which one can create a visual comfort index (VCI) by combining them in a relationship or a score of empirical form. These parameters are comfortable visual acuity (VAC), total ocular stability (TOS), Visual quality questionnaire (CVQ), The Surface Disease Index (OSDI) [23] to calculate the visual comfort index (IVC) according to the relationship (1).

$$IVC = \alpha \cdot VAC + \beta \cdot CVQ + \gamma \cdot OSDI - \delta \cdot TOS \qquad (1)$$

where α, β, γ, δ there are weights that reflect the importance of each factor in the assessment of visual comfort (the total amount of which must be equal to 1) [24-28]. In this respect, the determined values of the visual comfort index of the chosen sample from the database, under the conditions of choosing the weights 0.3 for α, β, and 0.2 for γ, δ they are synthesized in Table 2.

From the analysis of IVC values and the evolution of refractive powers at the corneal level, before and after the ortho-k lens port, it can be established that the subjects in the chosen sample had eye responses that primarily indicate the effectiveness of this procedure. Substantial improvements in corneal refractive power (a decrease in refractive power by an average of 2.85 DS for OD and 3.28 DS for OS and proximity to the emetropic value of the mean powers of 40.57 DS for the OD cornea and 40.82 DS for the OS cornea, respectively).

These results of data confirm the usefulness of this procedure, especially in young subjects and adolescents and instruct the specialist optometrist to pay special attention to those subjects who qualify for such treatment.

4. CONCLUSIONS

The presented study investigates the effectiveness and comfort of orthokeratology (ortho-k) lenses in correcting myopia and keratoconus. The methodological approach is structured in three main phases:

1. Literature review and theoretical foundation:
   - Overview of orthokeratology as a non-surgical vision correction method using hard, gas-permeable lenses worn overnight.
   - Discussion of corneal biomechanics and the impact of lens-induced reshaping.
2. Optometric evaluation framework:
   - Identification of essential optometric parameters for monitoring: corneal topography, refractive power, pachymetry, and visual comfort indicators.
   - Use of advanced diagnostic tools like iProfiler and biomicroscopy.
3. Case studies and longitudinal monitoring:
   - Five subjects with varying degrees of myopia were monitored over periods ranging from one week to three years.
   - Measurements were taken at regular intervals to assess changes in corneal shape, refractive power, and visual comfort.

The main insights provided by the research refer to five topics as presented in the following:

1. Effectiveness of ortho-k lenses:

- Significant improvement in corneal refractive power, especially in younger subjects;
- Average reduction of refractive power: 2.85 DS (OD) and 3.28 DS (OS);
- Faster emetropization (return to normal vision) observed in adolescents compared to adults;

2. Biomechanical behavior of the cornea:

- Corneal deformation under Ortho-K lenses is nonlinear and elastic, best modeled by the Hamilton-Zabolotskaya model;
- Finite element modeling confirmed stress distribution and corneal response to lens pressure;

3. Visual Comfort Index (VCI):

- A composite index was developed using parameters like visual acuity, ocular stability, and subjective comfort questionnaires;
- Younger subjects showed higher initial comfort scores, which decreased slightly over time due to adaptation;

4. Long-term monitoring:

- Consistent lens wear is crucial for maintaining vision correction;
- Discontinuation leads to regression of refractive improvements within days to weeks;
- Personalized monitoring is essential due to individual variability in corneal response;

5. Clinical recommendations:

- Ortho-K lenses should be replaced annually.
- Optometrists must tailor treatment plans based on lifestyle, age, and physiological changes;
- Patient education and adherence are key to successful outcomes.

Analysis of the effect of ortho-k lens on the evolution of myopia refractive defect, type, conducted on the sample of five subjects highlighted a series of aspects that the optometrist specialized in orthokeratology should consider. Thus, from the structure specific to the type of investigation (anamnesis, objective refraction, biomicroscopy, etc., corneal topography and biometric dimensional measurements) can obtain sufficient data to indicate the usefulness and efficiency of the ortho-k lens port.

Because orthokeratology is an overnight procedure; the special lenses that are used are made from high oxygen-permeable material and therefore these materials do have a shorter life cycle. Also, this procedure for improving the visual function, being one of the avant-garde, requires a great deal of attention from optometrist specialists regarding the impact on patients.

To achieve these goals, the patient must be very well informed and trained to identify his needs and the course of action in the case of using the ortho-k lens. For that all determinations of optometric sizes and monitoring activities during the ortho-k lens port must be personalized and periodically evaluated in relation to lifestyle, lifestyle, type of activity and finally of general health. Periodic evaluation follows the objective reactions and manifestations (dimensions, refractive powers) and subjective (visual comfort, habit, attention) of the subjects who fall into the orthokeratology procedure.

The importance given to the process of acceptance, attention and habit for the wearer of the ortho-k lens is very high and decisive in achieving the success of applying the procedure. By investigating the response, in the form of corneal topography, to the stress of the cornea due to ortho-k lens to reduce myopia levels, the authors highlight the mechanism of the orthokeratology process and develop a procedure to evaluate the usefulness, efficiency and performance of the ortho-k lens and monitoring of corneal response during treatment. In addition, the periodic evaluations of ortho-k lens wear must also consider the evolution of technology in the field of making these lens variants, as well as the patient's physiological changes. In the same context, the optometrist must be able to understand the needs and demands of the patient, aspects that can change over time depending on the evolution of the rehabilitation of the visual function. Therefore, the specialist optometrist recommends for a port without problems and with optimal efficiency results that the ortho-k lens to be replaced at least once a year.

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Monitorizarea purtătorilor de lentile de contact pentru orthokeratologie in vederea determinării gradului de confort vizual

Prezenta lucrare își propune să analizeze, în raport cu obiectivele generale sau specifice evidențiate din diferite studii, oportunitatea utilizării lentilelor de contact din domeniul de orthokeratologie și efectul lor asupra nivelului de confort vizual, pentru subiecții umani care prezintă miopie sau keratoconus. În prima parte a lucrării sunt trecute în revistă unele aspecte generale legate de importanța caracteristicilor lentilelor de contact dure pentru dezvoltarea procesului de corecție vizuală, a managementului subiecților umani cu disfuncții vizuale, pentru ca în partea a doua să se identifice setul de evaluări optometrice ce trebuie sa formeze portofoliu de analize structurale. În partea a treia a lucrării se prezintă studii de caz pentru subiecți purtători de lentile de contact de orthokeratologie cu scopul de a identifica evoluția procedurii de ajutor vizual și de asemenea, momentele și situațiile în care se poate obține cel mai eficient, complet și util nivel al stării de confort. Rezultatele și concluziile reieșite din analiza efectuată sunt prezentate în finalul articolului.

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