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Orthokeratology Procedure Computer Simulation Analysis †

Gyuri Bodi, Mihaela Ioana Baritz *, Angela Repanovici, Alexandra Maria Lazăr and Anca Ioana Tătaru (Ostafe)

Design Product and Environment Faculty, University Transylvania of Brașov, 500036 Brașov, Romania; g_bodi@yahoo.com (G.B.); arepanovici@unitbv.ro (A.R.); alexandra.lazar@unitbv.ro (A.M.L.); anca.tataru@unitbv.ro (A.I.T.)

* Correspondence: mbaritz@unitbv.ro

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Abstract

The cornea, a transparent avascular connective tissue, is the most important refractive component of the eye system, along with the overlapping tear film. In addition, due to its protective, transparent and refractive characteristics, it protects the sensitive content of the eyeball and provides clear vision. However, both experimental and clinical modeling/simulation studies are needed for a holistic understanding of corneal behavior alongside tear film and contact lenses. As such, this study develops a simulator for analyzing the orthokeratology procedure, with the aim of highlighting the biomechanical aspects of contact between the cornea, tear fluid and the ortho-K lens in different situations. The computer simulator (Matlab) allows the development of multiscenario variants for effective and practical understanding and applicability.

Keywords: cornea; orthokeratology; biomedical simulation; myopia; analyze

1. Introduction

The cornea is a transparent, avascular anatomical structure located in the anterior part of the eyeball with a major role in the visual process. This structure contributes to the formation of the retinal image with about 2/3 of the refractive power of the eye and functions as a fixed biological lens, respecting the principles of optics. The cornea, as a smooth cellular structure, is a tissue with a convex outer surface and a concave inner surface that forms a meniscus lens surface. This tissue, along with the sclera, represents the outer portion of the eyeball and plays an important role in maintaining clear vision and eye health. The main functional purpose of this structure is to protect the structures inside the eyeball and to transmit and focus, together with the lens, light radiation on the retina, which is possible due to its transparency characteristics and curved and smooth surfaces. The cornea is a connective tissue that also acts as a structural barrier protecting the eye from the aggression of harmful material particles in the environment [1–4].

As is known, the structure of the human cornea consists of five layers, namely, from the outside to the inside, the corneal epithelium (thickness of 50 μm), the Bowman membrane (basal) (12 μm), the corneal stroma (480–500 μm), the Descemet (basal) membrane (8–10 μm) and the endothelium on the internal surface (5 μm). Each of these layers has its own role in maintaining normal visual function [3–7]. The development of the corneal structure begins with the initial formation of the corneal epithelium from the adjacent cranial ectoderm in the ocular vesicle. As mentioned in the literature [8], the horizontal diameter of an average adult human cornea is 11.7 mm, and the vertical diameter is about 1.00 mm smaller than

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the horizontal diameter. The diameter of the cornea varies between 11.04 and 12.50 mm in men and 10.70–12.58 mm in women. The horizontal diameter of an average cornea is 11.77 ± 0.37 mm in adult men, while it is 11.64 ± 0.47 mm in adult women, and the vertical diameter is about 1 mm smaller than the horizontal diameter. The cornea, convex and aspherical, has a refractive index of 1.376. The radius of curvature of the anterior surface is 7.80 mm, and the radius of curvature of the posterior surface is about 6.50 mm [9–11]. Dimensionally, there is a gradual increase in corneal thickness from the central area to the limbus due to an increase in the amount of collagen in the peripheral stroma. In many studies, in normal eyes, the thickness of the central cornea ranges from 500 μm to 600 μm in the central area and from 600 μm to 800 μm in the peripheral area [12–14]. However, the thickness of the cornea decreases as age progresses.

Currently, the measurement of the biomechanical properties of the corneal structure represents one of the most interesting research and experimentation fields of modern ophthalmology and applied optometry and has medical engineering implications. The physiological properties of the cornea are defined by the biomechanical response of this tissue to an external and/or internal force of the eyeball. Mechanically, as established by various studies, the complex structure of the cornea is defined as viscoelastic, which means that it exhibits both viscous and elastic biomechanical behavior, determining an integrated approach to the deformation mode.

From a practical point of view, this is considered extremely important because the measurements of biomechanical characteristics are numerous and many forms of visual system dysfunction, such as keratoconus or evolutionary myopia, have their origin in the modification of the biomechanical properties of the cornea. Before the thickness or curvature of the cornea changes due to the evolution of the dysfunction, the rigidity and elasticity of the cornea are already altered and will contribute to the even stronger degradation of the quality of the images formed by the visual system.

Therefore, the complete analysis (identification, evaluation) and measurement of the biomechanical properties of the cornea are crucial actions not only for detecting these manifestations but also for finding solutions to rehabilitate the functioning of the eyeball affected by myopia or keratoconus. Also, the elasticity of the cornea is based on the reversible stretching of the elastic domains of the collagen existing in the corneal stroma. A linear elastic material can be described by Hooke's law, which establishes a simple relationship between external stress σ and material deflection ε, and, consequently, the following equation applies: $\sigma = E\varepsilon$. The cornea does not have the properties of a linear elastic material; that is, its modulus of elasticity depends linearly on the level of deformation. However, some nonlinear materials exhibit almost linear behavior at low external stresses, and therefore a constant elastic modulus for the structure of the cornea can be specified.

Also, the cornea is not an isotropic (homogeneous) material; its biomechanical properties depend on the position. As mentioned in the literature, the average modulus of elasticity of the central cornea is 4.2 ± 1.2 MPa anteriorly and 2.3 ± 0.7 MPa posteriorly [15–17]. So, the cornea is a mechano-transducer; that is, an external mechanical stress (for example, intraocular pressure, shear forces of the blink, contact lenses) causes a measurable change in the structure of the cornea, and energy dissipation prevents damage to the cornea by mechanical stress, phenomena used in the orthokeratology procedure.

The orthokeratology procedure uses specially designed, hard, gas-permeable contact lenses that temporarily reshape the cornea to reduce common refractive errors such as myopia and keratoconus. These lenses are usually worn during the night, allowing the wearer to enjoy clear vision during the day without having to correct vision with corrective glasses or contact lenses. The process is temporary and reversible, and the interruption of lens use will bring the cornea back to its original form [12,17].

2. The Cornea-Tear Film-Ortho-K Lens System Biomechanical Modeling

From the point of view of the presence of the Ortho-K lens, it can be stated that it radically alters the border conditions of the contact problem, and geometric changes occur (central corneal aplatization, increased peripheral curvature, the appearance of a post-lentile lacrimal space ($h(x,t) = h_{film}(x,t) + h_{reservor}(x)$). Also, mechanical changes occur (additional pressure, mechanical pressure exerted by the lens, redistribution of tear film pressure). In addition, a change in the evaporation process occurs because the lens reduces direct evaporation but can induce stagnation areas and promote peripheral thinning.

That is why one can ask the question, "Is the tear film more stable by using Ortho-K lens?" and the full answer is more nuanced. From the point of view of the contact regions of the Ortho-K lens with the cornea and tear film in the central area, the stability increases apparently, in the peripheral area it decreases, and overall stability is more uneven. In other words, there is no global stability, but a redistribution of instability. Therefore, uneven stress manifests as follows: central areas with reduced stress, and transition areas with a high stress gradient. That is why the feedback of the FSI (the class of fluid–structure interaction problems, Fluid–Structure Interaction) determines a nonlinear loop accented by Ortho-K, according to the following structure: corneal deformation ⇒ modified film geometry ⇒ modified pressure ⇒ new stress. So, at this intermediate stage, the evolution of the tear film is inherently transient and nonlinear, and the introduction of Ortho-K lenses in the analysis of corneal biomechanics alters both the geometry and the boundary conditions of the system, leading to a spatial redistribution of the instability of the tear film, rather than a global stabilization of it.

Mechanically, the Ortho-K lens represents a third subsystem interacting with the tear-corneal film ensemble. Its presence simultaneously alters both the geometry of the anterior surface of the cornea and the thickness distribution in the tear film under the practically defined mechanical and kinematic border conditions. Thus, the initial fluid–structure problem (ISF) becomes a Fluid–Structure–Structure Interactions (FSSI) problem, in which the lens can be treated, as a first approximation, as a rigid solid with imposed geometry. The geometric representation of the Ortho-K lens is characterized by a central flattening area followed by a transition zone (reverse sluts) and a peripheral alignment area. In axial-symmetrical 1D modeling, the lens geometry is introduced through an imposed function of the thickness of the fluid in the tear tank (tear gland):

$$h_{0K}(x) = h_0 + \Delta h_c \exp\left(-\frac{x^2}{2\sigma^2}\right) \quad (1)$$

where h_0 is the thickness of the reference tear film; $\Delta h_c < 0$ is its central flattening; and σ controls the width of the treatment area.

Thus, the change in the tear film equation in the presence of the Ortho-K lens causes a change in the total thickness of the film that becomes:

$$h(x,t) = h_{film}(x,t) + h_{0K}(x) - u_{corneal}(x,t) \quad (2)$$

So does the equation of evolution change and become:

$$\frac{\partial h}{\partial t} + \nabla \cdot \left(\frac{h^3}{3\mu}\nabla p\right) = -E(x,h) \quad (3)$$

with the pressure:

$$p(x) = -\gamma \nabla^2 h + \frac{A}{h^3} + p_{0K}(x) \quad (4)$$

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where p_{0K} is the contact pressure induced by the orthokeratology lens (Figures 1 and 2).

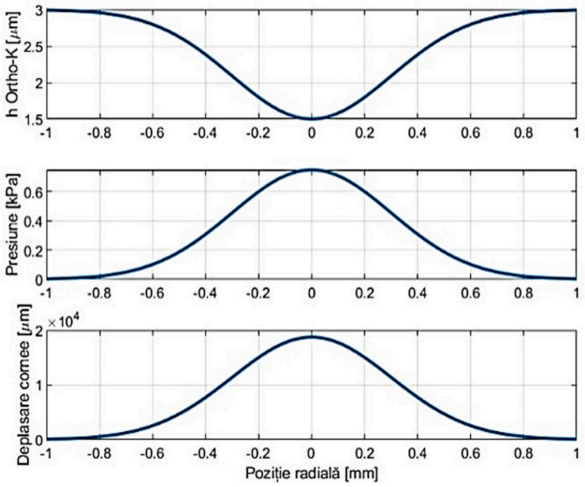

Figure 1. Corneal response to use of orthokeratology lens—(Matlab).

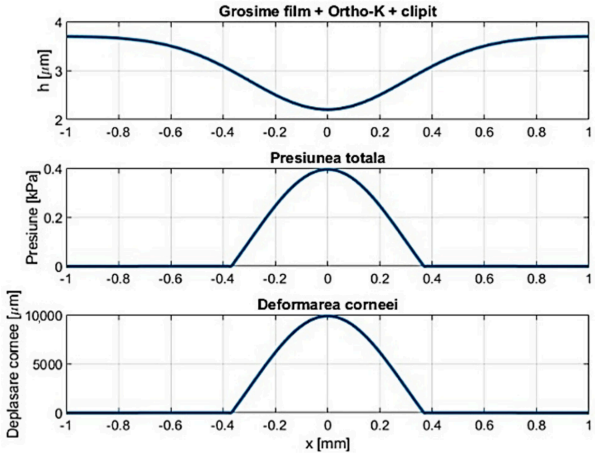

Figure 2. Corneal response to the use of lens orthokeratology in the process of blinking—(Matlab).

This expression of pressure exerted by the Ortho-K lens, in a first-order approximation, becomes:

$$p_{0K}(x) = k_{0K}(h_{ref} - h(x))^{+} \quad (5)$$

where k_{0K} is the effective rigidity of the lens; and operators $[(\cdot)+]$ indicates activation only on contact.

To achieve the coupling of the orthokeratology effect of the lens with the corneal biomechanics, the corneal equilibrium equation becomes as follows:

$$\nabla \cdot \sigma = p(x,t) + p_{0K}(x) \quad (6)$$

Thus, the stress manifested at the corneal level includes the hydrostatic component of the tear film along with the mechanical component induced by the lens. Therefore, the Ortho-K lens does not stabilize the tear film, but redistributes its thickness on the convex surface of the cornea, inducing large stress gradients and moving the instabilities to the periphery. That is why it can be said that the therapeutic effect is achieved by geometric control of the diopter surfaces of the lens and not due to static mechanical balance.

From the point of view of the dynamics of the tear film during the blink, the definition equation in (3) becomes:

$$\frac{\partial h}{\partial t} + \nabla \cdot \left(\frac{h^3}{3\mu} \nabla p \right) = -E(h) \tag{7}$$

where E(h) is the term of evaporation of the tear film, which depends only on the thickness of the layer; with border conditions: deformable cornea, lens surface.

The blinking reflex should be viewed as a periodic disturbance (approximately 17 flashes/min), and the equation, with the values f ≈ 0.25 Hz și $\Delta h_{blink} \sim$ 1–2 μm, by which it is calculated is:

$$h(x,t) \rightarrow h(x,t) + \Delta h_{blink} \sin(2\pi f t) \tag{8}$$

This reflex introduces cyclic redistribution and obviously peripheral instability. In order to highlight this aspect, they can be compared with clinically validated data in the literature. Thus, it can be seen that the Ortho-K lens redistributes the thickness of the film without completely stabilizing it. The blinking reflex also introduces cyclic disturbances, favoring peripheral instability, and quasi-static and dynamic models allow for the study of ocular FSSI and comparison with clinical data.

The script developed through the Matlab R2024b platform is extensible for parametric studies and subsequent clinical validations. Therefore, the cornea is modeled as a continuously deformable solid, weakly compressible, with nonlinear elastic behavior. In the regime of interest (complex combination, cornea with the Ortho-K lens (Figure 3), tear film), its displacements are of a micrometric order, and the voltages can be nonlinear due to biological material.

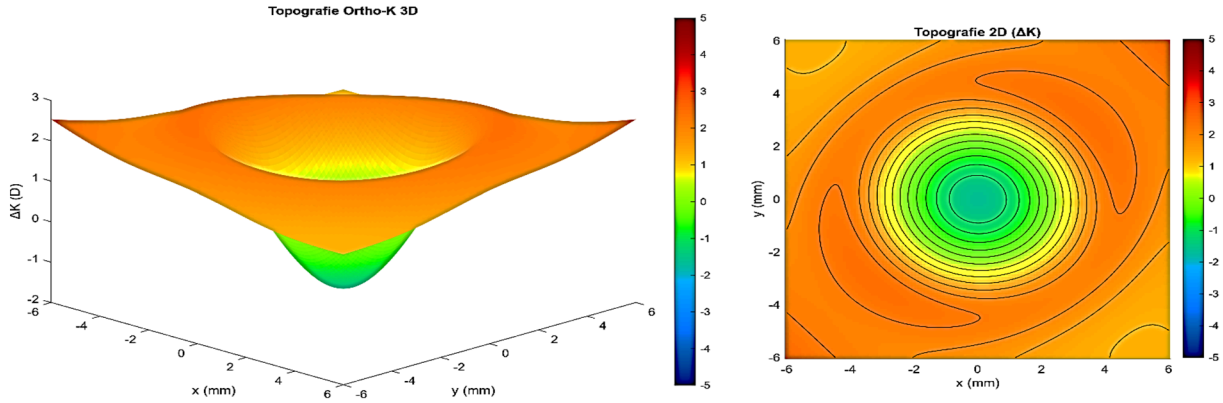

Figure 3. Representing the 3D and 2D topography of Ortho-K lens.

3. Development of the Analysis Simulator for Orthokeratology

The assumptions adopted to create the Ortho-K combination analysis simulator, tear film and cornea (S-OFC) is a continuous mechanical three-dimensional structure with small deformations but potentially nonlinear stresses. The process is carried out quasi-statically (neglected inertia), and these assumptions conform to the established models for the cornea [18]. Using a set of numerical data (from the literature) [18], the determined numerical example is consistent with similar research [16]. Material data (literature): corneal elastic mode: E = 0.3 MPa, central cornea thickness: t = 550 μm, L = 5 mm, pressure applied Ortho-K: p = 15 Pa. Thus, as an estimate of the maximum displacement (plate under uniform pressure), and using an empirical relation (9), the values (10) are obtained according to the literature [16]:

$$u_{max} \approx \frac{pL^2}{Et} \tag{9}$$

$$u_{max} \approx \frac{15 \cdot (5 \times 10^{-3})^2}{0.3 \times 10^6 \cdot 5.5 \times 10^{-4}} \approx 2.3\ \mu m \quad (10)$$

This simulator demonstrates that in regimes of interest to Ortho-K, the cornea can be treated as a quasi-static elastic solid, where displacements are proportional to the pressure of the tear film and inversely proportional to material rigidity. Thus, the HGO (Holzapfel–Gasser–Ogden) model [19] introduces progressive stretching stiffening, directional deformation dependence and pronounced nonlinear behavior at pressures due to the action of the Ortho-K lens. These effects are confirmed experimentally by corneal inflation tests (volume change) [16]. To provide a numerical example, using the following geometry parameters—spherical calotte, radius: R = 7.8 mm, thickness: t = 550 (HGO—literature): C10 = 0.04 MPa, k1 = 0.15 MPa, k2 = 250 and a pressure load Ortho-K: 10–20 Pa [18]—the maximum central displacement FEM becomes: $u_{max}{}^{FEM} \approx 1.8$–$2.6\ \mu m$, and the rigidity increases radially due to a fiber alignment → realistic remodeling profile comparable to OCT data [16]. So, the introduction of the HGO model allows the faithful capture of corneal anisotropy and tensile-dependent stiffening, which are essential for predictive simulations with the Ortho-K lens based on FEM numerical methods (Figure 4).

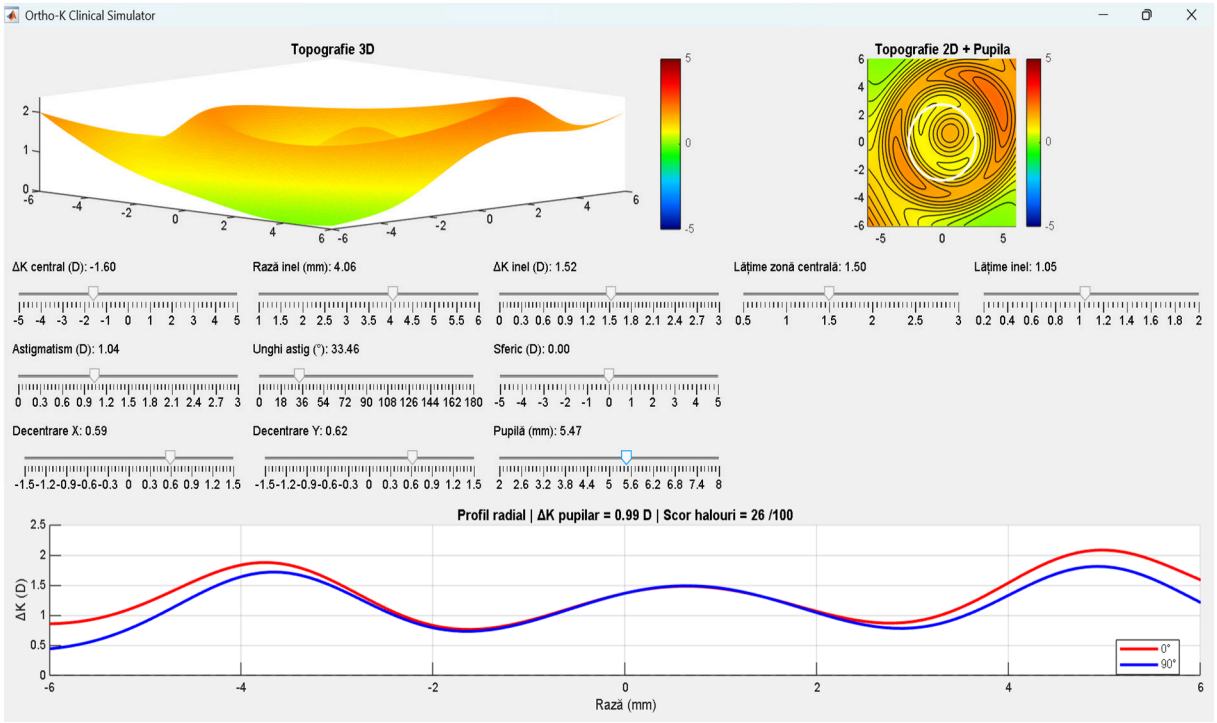

Figure 4. Interface of the Ortho-K lens combination simulator; tear film and cornea (S-OFC) developed on the Matlab platform.

4. Conclusions

The harmonization of the mechanical, fluid and numerical formulation in a unitary frame allows the predictive analysis of corneal remodeling under the action of Ortho-K lenses, with clear separation between quasi-static and dynamic phenomena. The introduction of an Ortho-K lens profile and a spatial elastic operator leads to local pressures and non-zero corneal remodeling with micrometric displacements.

As a general conclusion, the numerical model developed, S-OFC (system ortho-K-fluid-cornea), demonstrates that the reshaping of the cornea under the action of Ortho-K lenses is the result of the nonlinear interaction between corneal anisotropic stromal rigidity, the dynamics of the lacrimal film and the geometry of the orthokeratology lens. The

introduction of a spatial elastic operator and a realistic lenticular profile will thus lead to micrometric axial movements compatible with the mentioned clinical observations.

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