

EFFECT OF SILICON HYDROGEL CONTACT LENS MATERIALS ON TEAR FILM STABILITY AND CENTRAL CORNEAL RADIUS OF CURVATURE: A COMPARATIVE STUDY OF BALAFILCON A AND LOTRAFILCON B

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ABSTRACT

PURPOSE: To understand the effect of Silicone Hydrogel Contact Lens material on tear film stability and central corneal radius of curvature (CRC) after wear time of 4 weeks on daily wear basis.

METHOD: The study participants were allocated RE with BALAFILCON A and LE with LOTRAFILCON BB, Single Blinded – (Patient) Study. The clinical performance of 2 lenses were measured as following:

1. **Assessment of Non-invasive tear break-up time (NIBUT) assessed using Bausch & Lomb keratometer H-135A.**

The keratometer was adjusted and focused on the right eye. With the mires in focus, the subject was asked to blink once and refrain from blinking. A stopwatch was started immediately after the last complete blink. At the first appearance of any distortion of the focusing mire, the stopwatch was stopped and the time noted. If subject blinks between measurements, the test is halted, and then repeated after several blinks. The interval between the last blink and the doubling/distortion of mires was recorded in seconds as the NIBUT. Five measurements were taken for each subject and the average of three closest NIBUT values was taken as the mean value.

2. **Contact Lens Materials and Corneal Radius of Curvature: -**

The corneal curvature of the subject was measured immediately after NIBUT assessment. The distorted mire was sharply focused with the focusing knob. The corneal curvature was converted to corneal radius of curvature (in millimetres) by dividing 337.5 by the dioptric power of the flatter meridian.

RESULTS:

25 subjects (50 eyes) were participated in this study. The corneal radius of curvature (CRC) and non-invasive tear break-up time (NIBUT) were assessed with the Bausch and Lomb Keratometer H-135A. Participants were allocated RE with BALAFILCON A and LE with LOTRAFILCON B, Single Blinded – (Patient). The difference in mean NIBUT between pre-insertion, 8th day, 15th day, 22th day and 29th day of BALAFILCON A and LOTRAFILCON B Contact Lens wear was statistically significant where p value is <0.05 with paired T test. The difference in mean CRC between pre-insertion, 8th day, 15th day, 22th day and 29th day of BALAFILCON A and LOTRAFILCON B Contact Lens wear was statistically not significant where p value is > 0.05 with paired T test.

CONCLUSION:

Balafilcon A having greater corneal tearfilm stability compare to Lotrafilcon B. The corneal curvature was not significantly affected by any of the Silicone Hydrogel Contact Lens materials during the period under study.

KEY WORDS: - Contact Lens, Central Corneal Radius of Curvature, Silicon Hydrogel

Abbreviations:

- TBUT : Tear Break Uptime
- NIBUT : Non-Invasive Tear Break Uptime
- CRC : Central Corneal Radius of Curvature
- SiHy CL: Silicon Hydrogel Contact Lens

- mm : Milimeter
 - SD : Standard Deviation
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INTRODUCTION

The tear film protects and nourishes the ocular surface and provides a smooth anterior surface to promote clear vision.^{1,2} It is laid down during the blink by the action of the upper lid spreading the thin tear film over the ocular surface.³⁻⁶

The tears are distributed by normal, non-voluntary action of eyelid and each blink refreshes the pre-corneal tear film. When blinking is held, evaporation of aqueous layer of tear film started which causes thinning of the tear film in a localized area.

Subsequently dry spots are formed in tear film when the tears evaporate⁷. Tear film stability is usually measured by its lack of stability, by a test called Tear film break-up time (TBUT).⁸

The human tear film is rather unstable, but it is regenerated by frequent blinking, and when a Contact Lens is placed in the eye, the lens alters the normal structure of the tear film and affects its rate of evaporation.¹⁰

NIBUT is the time taken in seconds for the tear film to break following a blink cessation.⁷ NIBUT of 6 to 20 sec is considered normal.²

Normal sequence of tear film action is most affected by lens wear.¹¹

This division and new interface induce changes in biophysical properties of tear film.⁹ When a Contact Lens is placed on the eye, it affects the stability of tear film, evaporation rate of tears, thickness of lipid layer and volume of tears. The Contact Lens use mainly alters the normal sequence of tear film function and cause distractions in quantity and quality of the tear film, which lead to Contact Lens intolerance.¹⁰

Measurements aimed at arriving at the Contact Lens parameters are related in most cases to the cornea to make sure that its activities are not affected.²

The pre-corneal tear film which supplies the oxygen requirement for normal metabolism of the corneal epithelium should not be destabilized by Contact Lens wear.¹²

The fit of the lens must be adequate enough to allow for the elimination of metabolic wastes through the tear film by proper circulation of tears between the lens and the cornea.¹²

The most contacted tissue in the anterior segment of the eye during Contact Lens wear is the. Cornea.¹²

A well-fitted lens should have the least effect on the cornea, the tear film and the blinking process.¹²

Silicone Hydrogel lenses allow more oxygen to reach the surface of the eye, the added silicone can reduce the surface wettability of the lenses, potentially making it harder for them to stay moist on the eye.¹³

Lenses used in study were Balafilcon A - FDA lens Group 3 (ionic, low water content), WC-36%, Dk-101, Dk/t-110, modulus-1.1MPa, wetting strategy-plasma oxidation.

Lotrafilcon B -FDA lens Group 1 (non-ionic, low water content) WC- 33%, Dk -110, Dk/t-138, modulus 1.2MPa, wetting strategy- plasma treatment.

Biotrue multi-purpose solution is used-uniquely formulated to match the pH of healthy tears¹⁴ optimizing the performance of our dual disinfectants.

PURPOSE of Study: The Effect of Silicone Hydrogel Contact Lens Material on Tear Film Stability and Central Corneal Radius of Curvature (CRC) After Wear Time Of 4 Weeks on Daily Wear Basis.

REVIEW OF LITERATURE

- In 2011, a study Effect of Soft Contact Lens Materials on Tear Film Stability and Central Corneal Radius of Curvature: A Comparative Study of polymacon and LOTRAFILCONB. The study showed the Silicon Hydrogel

soft Contact Lens material shows better tear film stability than conventional lenses, the corneal curvature was not significantly affected by any of the Contact Lens materials during the period under study.

- In 2015, a study of the comparison between LOTRAFILCONB and BALAFILCON A was published in the post photorefractive keratotomy. The study showed the LOTRAFILCONB lens resulted in significantly less postoperative pain and discomfort after PRK, especially in the first 24 h after PRK.
- In 2019 another study was published; the purpose of this study is to compare AIR OPTIX® plus HydraGlyde (AOHG) Contact Lenses to ACUVUE® VITA® (VITA) Contact Lenses for total lipid uptake (total of surface and bulk uptake) after 30 days of wear by high lipid depositors. The study showed higher number of deposits in the senofilcon A material than the LOTRAFILCON B material.
- In 2002, a study A 1-year prospective clinical trial of BALAFILCON A (PureVision) Silicone Hydrogel Contact Lenses used on a 30-day continuous wear schedule. The results look promising for the success of Silicone Hydrogel as the material of choice for continuous wear Contact Lenses. Despite the slightly higher levels of visible deposit on the Silicone Hydrogels, superior subjective responses suggest that the plasma coating technology on these lenses is effective in providing comfortable lens wear.

MATERIALS & METHODOLOGY:

Study design: Prospective Experimental observational study was done at Shri C. H. Nagri Municipal Eye Hospital within a period of November 2018 to October 2019.

MATERIALS: Following instruments were used in this study:

1. Keratometer
2. Slit lamp
3. Silicon Hydrogel Contact Lenses (Balafilcon A Lotrafilcon B)
4. Contact Lens solution
1. Stopwatch

BALAFILCON A	LOTRAFILCONB
Water content: 36%	Water content: 33%
Dk/t: 130	Dk/t: 138
Base curve: 8.6mm	Base curve :8.6mm
Diameter: 14.00mm	Diameter :14.2 mm
Wetting Strategy- Plasma Oxidation	Wetting Strategy- plasma treatment.
Modulus –1.1MPa	Modulus- 1.2MPa

Inclusion Criteria:

1. Age group 18 to30
2. Subjects with spherical error of refraction with power range between - 0.75 D to-5.00D
3. Astigmatism ≤-1.00

Exclusion criteria:

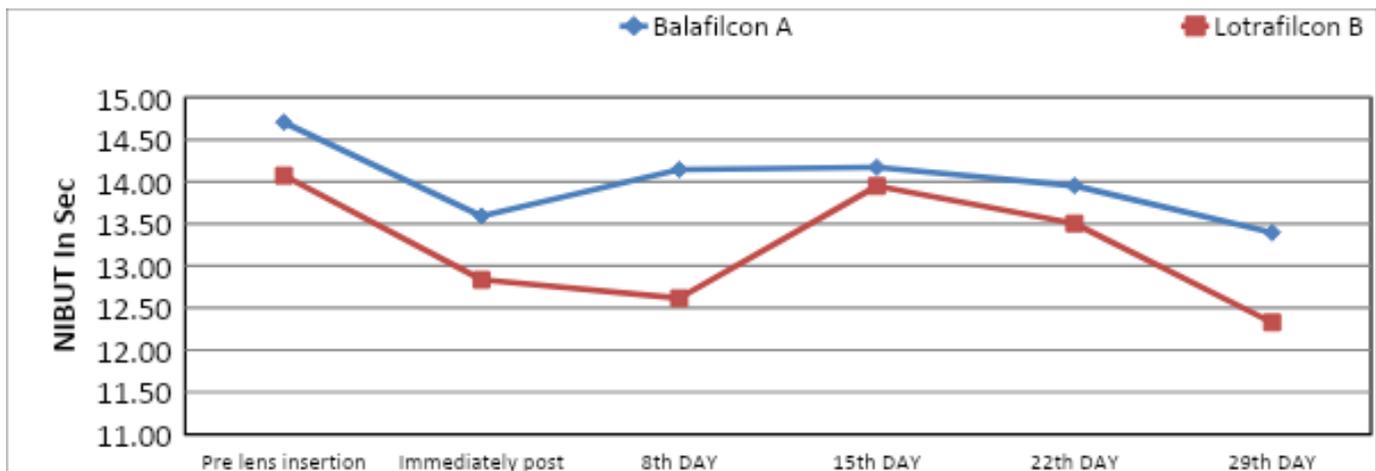
1. Any ocular and systemic allergies or disease that may interfere with Contact Lens wear.
2. History of previous ocular or intraocular surgery such as RK, PRK, LASIK etc.
3. Any ocular infection.
4. Any infectious disease such as hepatitis, tuberculosis or immunosuppressive disease such as HIV.
5. Who were not ready to part of study?

Methodology:

1. All Procedure Done After Subjective Refraction
2. The Test Was Conducted in Quiet Room Conditions with Low Air Speed and Low General Illumination
3. The Patient Was Inform Regarding the Procedure and Agreement for Compliance
4. 1st Reading Taken Without CL (NIBUT & CRC) And Then With CL
5. The Keratometer Was Adjusted and Focused to Observer, The Right Eye with The Mires in Focus
6. A Stopwatch Was Started Immediately After the Last Complete Blink
7. At the First Appearance of Any Distortion of The Focusing Mire, The Stopwatch Was Stopped and The Time Noted –NIBUT
8. If Subject Blinks Between Measurements, The Test Was Repeated Again After Several Blinks
9. Five Measurements Were Taken for Each Subject
10. Average of NIBUT Values Was Taken as The Mean Value
11. The CRC Of the Subject Was Measured Immediately After NIBUT Assessment.
12. The Distorted Mire Was Sharply Focused with The Focusing Knob
13. Same Procedure Performed for Left Eye

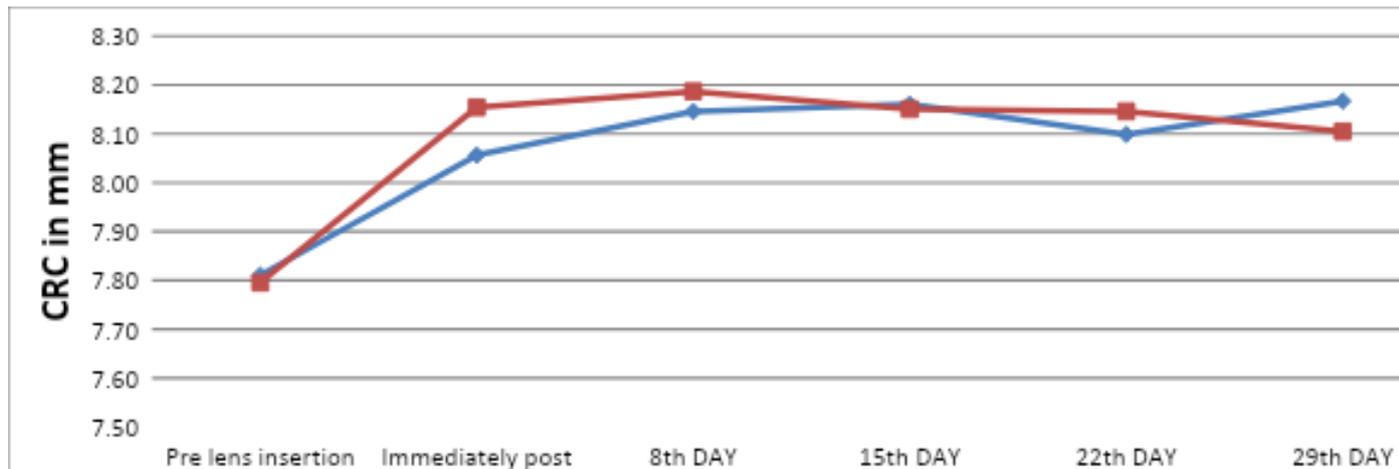
Results:

GRAPH 1: Distribution of NIBUT at Different Periods of Lens Wear for the Lens material



- This graph shows NIBUT.
- Significant changes observed in NIBUT where p value is <0.009524 with paired T test. Difference in NIBUT between pre lens insertion and 8thday ,15thday ,22thday and 29thday of BALAFILCON A Contact Lens wear was not significant (ANOVA: P >0.05).
- Difference in NIBUT between pre lens insertion and 8thday ,15thday ,22thday and 29thday of LOTRAFILCON B Contact Lens wear was significant (ANOVA: P = 0.02).

GRAPH:2 Distribution of Radius of corneal curvature at Different Periods of Lens Wear for the Lens material



- This graph shows CRC.
- Difference in CRC between pre lens insertion and 8th day, 15th day, 22th day and 29th day of BALAFILCON A and LOTRAFILCON B contact lens wear was significant (ANOVA: $P < 0.05$).
- LOTRAFILCON B shows more significant changes than BALAFILCON A.
- The difference in mean CRC was not significant changes, where p value is > 0.506873 with paired T-test.

DISCUSSION:

NIBUT levels represent the stability status of the tear film and this varies among individuals². Faber et al. (1991) reported that the NIBUT values of some subjects were found to be constant after a particular period of lens wear². These values were lower than those recorded for the pre-corneal tear film before lens insertion¹. Typically, the new Contact Lens wearer blinks too frequently during the first few days of lens wear and enters a period of infrequent blinking². For BALAFILCON A Brodsky NIBUT level increased by 0.55s, 0.53s, and slightly reduced by 0.75s after 8th, 15th and 22th day of lens wear. After 29th days mean difference in NIBUT was 1.3sec. For BALAFILCON A Brodsky, corneal radius of curvature changes after insertion of Contact Lens, 8th day, 15th day, 22th day and 29th day of period was increased respectively 0.25mm, 0.25mm, 0.29mm, and 0.36mm. For LOTRAFILCON B, NIBUT level decreased by 1.45s, then slightly improved 0.12s, 0.57s. After 29th days mean difference in NIBUT was 1.74s. For LOTRAFILCON B, corneal radius of curvature changes after insertion of Contact Lens 8th day, 15th day, 22th day and 29th day of period was respectively 0.39mm, 0.35mm, 0.35mm and 0.3mm. These differences in mean CRC were not significant.

CONCLUSION:

Current study concludes that, BALAFILCON A, Silicon Hydrogel soft Contact Lens material shows better tear film stability than LOTRAFILCON B. The corneal curvature was not significantly affected by any of the Contact Lens materials during the period under study.

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