

*Original Article*

## Effect of Soft Contact Lens Materials on Tear Film Stability and Central Corneal Radius of Curvature: A Comparative Study of Polymacon and Lotrafilcon B

Iyamu Eghosasere<sup>1\*</sup>, Iyamu Joy E<sup>2</sup> and Omoruyi Joy<sup>1</sup>

<sup>1</sup>Department of Optometry, Faculty of Life Sciences, University of Benin, Nigeria; <sup>2</sup>Eye Clinic, Faith Medical Complex, Benin City, Nigeria

### ABSTRACT

This study investigated the effects of soft contact lens material on the corneal radius of curvature and the tear film stability. A total of thirty (n=30) subjects aged between 17 and 33 years with mean age  $22.3 \pm 3.4$  years, made up of 11 males and 19 females were recruited for 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 (Bausch and Lomb Corp., USA). The subjects were categorised into two groups: Polymacon (conventional soft contact lens) group (n = 17) and lotrafilcon B (O<sub>2</sub> optix contact lens) group (n = 13). The difference in NIBUT between pre-task and 2, 4, 6 and 8 weeks of polymacon contact lens wear was statistically significant (ANOVA:  $P = 0.003$ ). However, for lotrafilcon B, the difference in mean NIBUT was not statistically significant ( $P = 0.22$ ). The difference in mean CRC between pre-task and 2, 4, 6 and 8 weeks of polymacon and lotrafilcon B contact lens wear was not statistically significant (ANOVA:  $P > 0.05$ ). The degree of association between CRC and NIBUT was also not statistically significant ( $p > 0.05$ ). This indicates that the tear film stability measured as non-invasive tear break-up time varied under conventional soft (polymacon) lens wear while it remained stable under silicone hydrogel (lotrafilcon B) lens wear. The corneal curvature was not significantly affected by the contact lens materials during the period under study. In conclusion, Lotrafilcon B was a preferred contact lens material since it demonstrated no significant effect on tear film stability as measured as NIBUT.

**Keywords:** Corneal curvature, Lotrafilcon B, Polymacon, Tear break-up time

Received 25 April 2011/ Accepted 30 November 2011

### INTRODUCTION

The role of the tear film in successful contact lens wear cannot be over-emphasised as its stability and flow rate determine comfort and tolerance of lens wear. For this to be achieved, a well-fitted lens should have the least effect on the cornea, the tear film and the blinking process. The most contacted tissue in the anterior segment of the eye during contact lens wear is the cornea. 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. 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.

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. When the integrity of the tear film, whether stability or flow rate, is compromised, lens adhesion to the cornea and rapid build-up of deposits on the lens surface are imminent (Sharma and Ruckenstein, 1985).

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 (Korb, 1994). Disturbances of the quality and quantity of the tear film whether

\*Corresponding author: Tel: +234 8023370562; E-mail: eghosaiyamu@yahoo.com

because of aqueous deficiency or evaporative tear problems, results in intolerance of contact lens wear and damage (Foulks, 2003). Normal sequence of tear film action is most affected by lens wear (Bahgat, 1985). Nichols and Sinnott (2006) reported that contact lens-related dry eye may be due to increased tear film thinning time, evaporation or dewetting, resulting in increased osmolality. The disruption of the tear film by soft contact lenses has been implicated in the greater optical deterioration observed after break-up time for contact lens wearers than non-wearers (Albarra *et al.*, 1997).

However, Guillon *et al.* (1997) found no changes in tear film stability between contact lens wearers and non-wearers. Chopra *et al.* (1985) claimed neither contact lens wear nor type and duration of lens wear affected the tear film stability. Other workers showed that clinical measures of tear film characteristics were not affected by silicone hydrogel lens wear (Santadoming-Rubido *et al.*, 2006). The authors concluded that both materials and wearing schedule showed similar performance. Corneal warpage, a change in corneal curvature under a contact lens, has been reported as contact lens complication (Miler, 1968; Bailey, 1998; Plugfelder, 2000). Since this condition can either be due to mechanical moulding of the cornea or metabolic stress, rigid and soft lenses are implicated (Bailey, 1998). This is in fact different from the moulding of the corneal shape by the programmed application of rigid gas permeable contact lenses for the purpose of reducing, eliminating or modifying the refractive error (especially myopia) as demonstrated in orthokeratology (Gasson and Morris, 1998).

Studies on the efficacy of various types of contact lenses (silicone acrylate, hydrophilic, hydrogel contact lenses) in halting myopia progression have long been considered (Perrigin *et al.*, 1990; Andreo, 1990; Grosvenor *et al.*, 1991; Dumbleton *et al.*, 1999). The mechanism of the rigid contact lens halting the progression of myopia as a consequence of altering the shape of the cornea includes the transient flattening of the cornea (Morris, 1956). Contrary to this, Horner *et al.* (1999) found no significant difference in the rate of progression of myopia between the contact lens and control groups. The aim of this study was to investigate the effect of lotrafilcon B (silicone hydrogel contact lenses) and Polymacon (Bescon contact lenses) on the tear film stability and corneal radius of

curvature in a Nigerian population.

## **MATERIALS AND METHODS**

### **Study Design and Population**

This was an observational, prospective, cross-sectional study involving subjects drawn from patients visiting the Optometry Clinic located at University of Benin, Nigeria. All subjects were healthy and normal volunteers with no history of eye disease or surgery. The subjects were divided into two groups: one group wore contact lenses made of polymacon (Bescon lenses) considered as conventional lenses, while the other group wore lotrafilcon B (O<sub>2</sub> Optix) lenses, the trade mark for silicone hydrogel lenses. The NIBUT and corneal radius of curvature were assessed using Bausch & Lomb keratometer H-135A (Bausch & Lomb Corp., USA). The Departmental Ethics and Research Committee approved the study in accordance with the declaration of Helsinki.

### **Assessment of Non-invasive tear break-up time (NIBUT)**

The subject was comfortably seated with chin on chin rest and forehead on headrest of the keratometer. The keratometer was then 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.

### **Measurement of Corneal Radius of Curvature (CRC)**

The corneal curvature of the subject was measured immediately after NIBUT assessment. The distorted mire was sharply focused with the focusing knob. With the vertical power drum the (-) sign below vertical mire (on top of the focusing mire) was superimposed with that of the focusing mire while with the horizontal power drum, the (+) sign of the horizontal mire (by the side of the focusing mire) was superimposed with that of the focusing mire. This is called alignment of mires. The power of the vertical meridian was read off the vertical power drum while the power of horizontal meridian was

read off the horizontal power drum. The corneal curvature is the flatter (smaller) of the two readings (in dioptres). The corneal curvature was converted to corneal radius of curvature (in millimetres) by dividing 337.5 (the change in index of refraction between air and keratometer) by the dioptric power of the flatter meridian.

## RESULTS

A total of thirty ( $n = 30$ ) subjects within the age range of 17 to 33 years with mean age of  $22.3 \pm 3.4$  years made up of eleven (11) males and nineteen (19) females were used for this study. Seventeen subjects wore contact lenses made of polymacon while 13 lotrafilcon B contact lenses. For polymacon contact lens group, the difference in mean NIBUT between pre-task and 2, 4, 6 and 8 weeks of lens wear was statistically significant (ANOVA:  $F = 4.53, p = 0.003$ ). Post hoc (Hochberg) test showed that the least NIBUT was observed after 2 weeks of wear with mean difference of 2.88 seconds and increased slightly by 1.1 second after 4 weeks and gradually decreased through the 6<sup>th</sup> and 8<sup>th</sup> week of lens wear with mean difference of 2.64 and 2.70 seconds respectively. However, the difference in mean corneal radius of curvature (CRC) between pre-task and 2, 4, 6 and 8 weeks of lens wear was not significant ( $p > 0.05$ ). The corneal

radius of curvature steepens by 0.03, 0.15 and 0.13mm after 2 to 6 weeks and flattens by 0.04mm after 8 weeks. These differences in mean CRC were not significant.

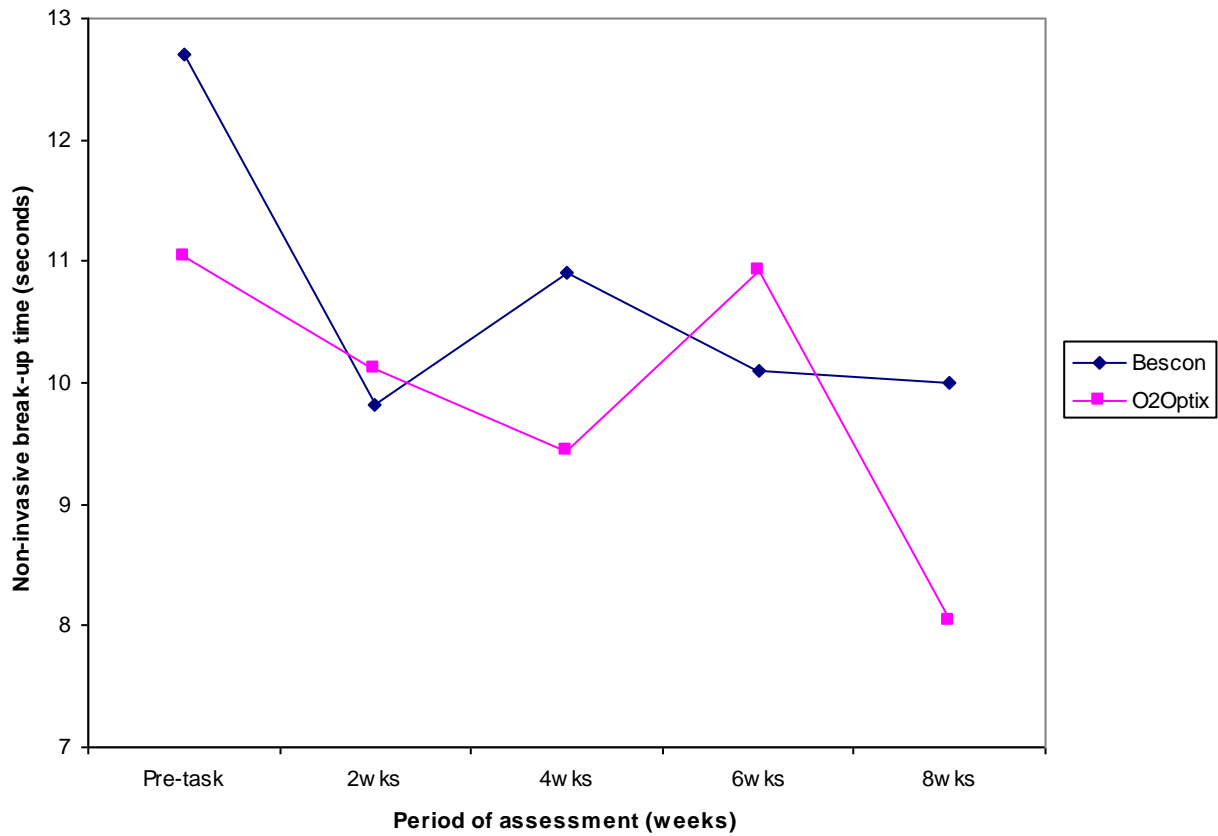
For lotrafilcon B (O<sub>2</sub> Optix) lens group, the difference in mean NIBUT between pre-task and 2, 4, 6 and 8 weeks of lens wear was not statistically significant. The NIBUT decreased by 0.92 and 1.6 seconds after 2 and 4 weeks of lens wear and by the 6<sup>th</sup> week, increased by 1.48 seconds. After 8 weeks, the difference in mean NIBUT was 2.88 seconds. These differences in mean NIBUT were not significant ( $p > 0.05$ ). Similarly, the difference in mean CRC between pre-task and 2, 4, 6 and 8 weeks of lens wear was not significant ( $F = 0.38, p = 0.82$ ). The degree of association between corneal curvature and tear film stability was significant (Pearson correlation coefficient:  $r = 0.03, p = 0.89$ ). Table 1 shows contact lens materials and non-invasive tear break-up time. Table 2 shows contact lens materials and radius of corneal curvature. Figure 1 shows the distribution of the non-invasive break-up time at different period of lens wear for the lens materials, and Figure 2 shows the distribution of the mean radius of corneal curvature at different periods of lens wear for the lens materials.

**Table 1: Contact Lens Materials and Non-invasive Break-up time**

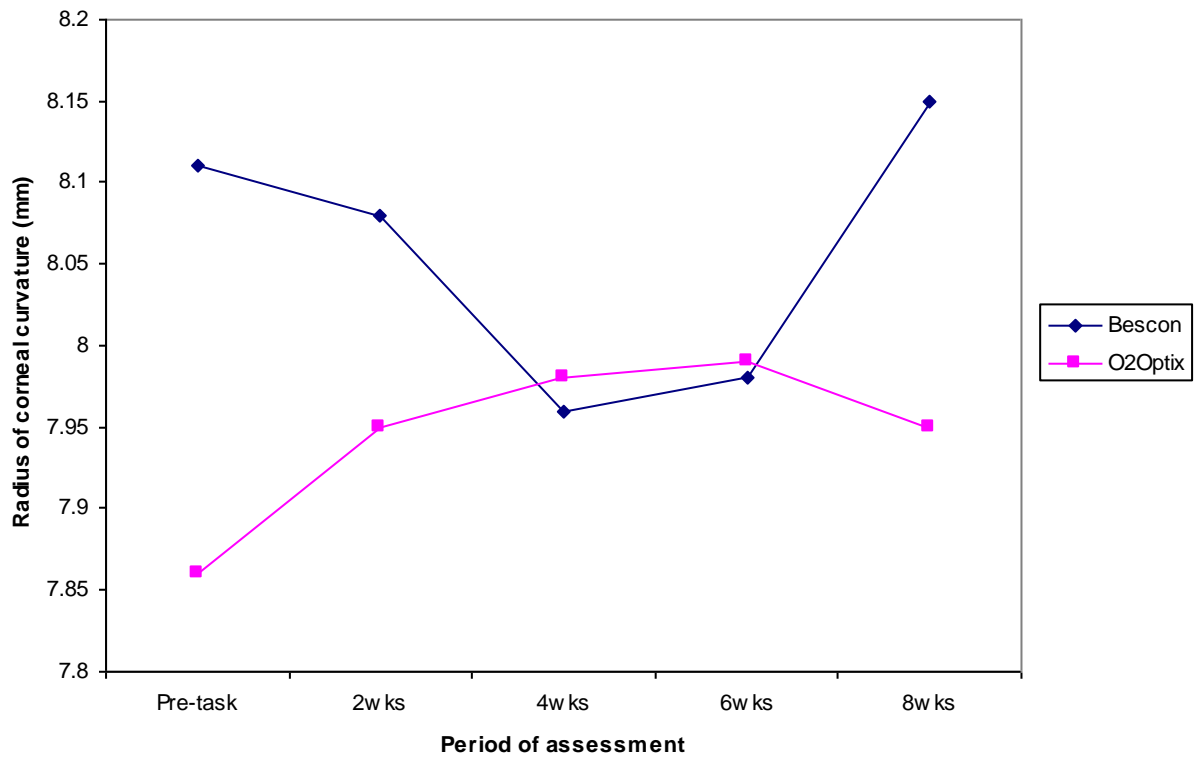
Contact lens material	Period of assessment (Weeks)	Mean NIBUT $\pm$ SD (Seconds)	95% confidence interval
Polymacon	Pre-task	12.70 $\pm$ 1.81	11.77 - 13.63
	2	9.82 $\pm$ 1.87	8.78 - 10.86
	4	10.91 $\pm$ 2.70	8.98 - 12.84
	6	10.10 $\pm$ 1.43	8.90 - 11.30
	8	10.00 $\pm$ 3.02	7.68 - 12.32
Lotrafilcon B	Pre-task	11.04 $\pm$ 2.56	9.50 - 12.60
	2	10.12 $\pm$ 2.12	8.50 - 11.75
	4	9.44 $\pm$ 2.60	7.70 - 11.20
	6	10.92 $\pm$ 3.08	8.07 - 13.77
	8	8.04 $\pm$ 2.08	5.46 - 10.62

**Table 2: Contact Lens Materials and Corneal Radius of Curvature**

Contact lens Material	Period of Assessment (Weeks)	Mean CRC $\pm$ SD (mm)	95% Confidence interval
Polymacon	Pre-task	8.11 $\pm$ 0.30	7.95 - 8.26
	2	8.08 $\pm$ 0.33	7.90 - 8.26
	4	7.96 $\pm$ 0.29	7.75 - 8.17
	6	7.98 $\pm$ 0.25	7.72 - 8.24
	8	8.15 $\pm$ 0.30	7.84 - 8.46
Lotrafilcon B	Pre-task	7.86 $\pm$ 0.29	7.68 - 8.04
	2	7.95 $\pm$ 0.25	7.76 - 8.14
	4	7.98 $\pm$ 0.30	7.78 - 8.18
	6	7.99 $\pm$ 0.35	7.67 - 8.31
	8	7.95 $\pm$ 0.29	7.60 - 8.31



**Figure 1: Distribution of Non-invasive Tear break-up time at Different Periods of Lens Wear for the Lens Materials.**



**Figure 2: Distribution of Radius of Corneal Curvature at Different Times of Lens Wear for the Lens Material**

## DISCUSSION

The cornea is the most sensitive part of the eye and its physiological make up is a very strong determinant when it comes to contact lens design and production (Santadomingo-Rubido, 2006). These contact lenses are designed in such a way that the corneal physiology is not affected negatively or altered provided all precautionary measures of contact lens wear are taken. The transparency of the cornea is as a result of the avascular nature and this must be maintained. The role of the tear film in contact lens wear cannot be overemphasised. In this study, the variation in turnout of subjects was basically due to the delicate nature of the soft contact lenses which when mishandled may tear easily (Bahgat, 1985). Among the study group, wearing of polymacon contact lenses caused a mild but insignificant steepening of the cornea after 2 to 6 weeks while lotrafilcon B lens demonstrated a mild but insignificant flattening of the corneal curvature after 2 to 8 weeks. This was consistent with the study of Grosvenor (1975). He found that wearers of N & N Lathe-cut soft lens did not cause any significant change in corneal curvature or myopia or spectacle blur. A typical patient was however noted to show a small amount of corneal flattening during the first few weeks of lens wear that gradually returned to the pre-fitting curvature.

Previously, Mandell (1974) suggested that the flattening could have been due to an overall swelling of the whole cornea rather than to the swelling (confined to the central area only) that one sees with polymethylmethacrylate lens wearers. Saunders and Goss (1975) also claimed that corneal curvature is not altered by soft contact lens wear. The difference in non-invasive tear break-up time (NIBUT) between pre-task and 2 to 8 weeks after polymacon soft lens wear was statistically significant. However, lotrafilcon B lens wear did not cause any significant change in tear film stability. NIBUT levels represent the stability status of the tear film and this varies among individuals. Faber *et al.* (1991) reported that the NIBUT values of some subjects were found to be constant after a particular period of lens wear. These values were significantly lower (Scheffe's S test,  $P < 0.05$ ) than those recorded for the pre-corneal tear film before lens insertion. Typically, the new contact lens wearer blinks too frequently during the first few days of lens wear and enters a period of infrequent blinking. In addition, there is a strong tendency for contact lens wearers to become

incomplete blinkers – the blink begins normally, but once the lid margin makes contact with the lens, the blink is completed prematurely (Stewart, 1968).

There have been some suggestions that reported dryness is reduced with silicone hydrogel lenses compared to low-DK soft lenses (Fonn *et al.*, 1993; Sweeney *et al.*, 2000). The mild dryness or blurry vision experienced by continuous contact lens wearers on waking was attributed to decrease in reflex tear secretion and increase in secretory immunoglobulin A (IgA) and albumin concentration during eye closure (Sack *et al.*, 1992; Wilcox *et al.*, 2000). For this reason and to reduce post lens tear debris, single-dose of non-preserved rewetting drops for use morning and night is recommended. The efficacy of this approach does seem to vary from patient to patient. Wetting drops may also be useful to reduce occasional dryness during lens wear in air-conditioned offices or other dry environment (Tonge *et al.*, 2001; Fonn, 2007).

The success of silicone hydrogel lenses for the general population has led to their use in therapeutic applications. Refinements in lens design, materials, and surface treatments will lead to further improvements in biocompatibility, tear film interaction and stability. These refinements will ensure the continued success of this long awaited addition to the contact lens practitioners' armoury. Silicone hydrogel contact lenses are healthier than conventional soft lenses because they allow up to 6 times more oxygen to pass through them and increased oxygen transmission results in better overall eye health (Eiden *et al.*, 2010). Advantages of silicone hydrogel over conventional soft lenses include more resistance to protein deposits, less drying of the lenses, lower risk of eye infection, easier handling due to increased rigidity of the material and much lower incidence of complications with extended wear use (Tighe, 1999).

In conclusion, the tear film stability varied under conventional lenses while silicone hydrogel lenses demonstrated no significant effect. Therefore the latter lens type ensures better comfort and adaptation. The lens materials did not affect the radius of corneal curvature. Soft contact lens materials and production have given optometrists and other contact lens practitioners various reliable options that can offer comfort and best vision to contact lens wearers without regrets. These options should be maximised appropriately.

## REFERENCES

- Albarran C, Pons AM, Lorente A, Monstes R and Artigas JM (1997). Influence of the Tear Film on Optical Quality of the Eye. *Contact Lens Ant Eye*. **20** (4): 129-135
- Andreo LK (1990). Long-term Effects of Hydrophilic Contact Lenses on Myopia. *Ann Ophthalmol*. **22**: 224- 227, 229
- Bahgat MM (1985). Precorneal Tear Film Changes Due to Soft Contact Lens Wear. *Indian J Ophthalmol*. **33**: 177-179
- Bailey SC (1998). Contact Lens Complications. *Optometry Today*. **10**: 26-36
- Chopra SK, George S and Daniel R (1985). Tear Film Break-up Time (BUT) in Non-contact Lens Wearers and Contact Lens wearers in Normal Indian Population. *Indian J Ophthalmol*. **33**: 213-216
- Dumbleton KA, Chalmers RL, Richter DB and Fonn D (1999). Changes in Myopic Refractive Error with Nine Months' Extended Wear of Hydrogel Lenses with High and Low Oxygen Permeability. *Optom Vis Sci*. **76**: 845-849
- Eiden BS, Davis JE, Goldberg F, Hom MM, Sorrenson L and Szczotka-Flynn L (2010). Determining the Oxygen Needs of Patients-Eyes Vary in Amount of Oxygen They Require. *Contact Lens Spectrum*. **20**:11 – 14
- Faber E, Golding TR, Lowe R and Brennan NA (1991). Effect of Hydrogel Lens Wear on Tear Film Stability. *Optom Vis Sci*. **68** (5): 380-384
- Fonn D, Situ P and Simpson T (1993). Hydrogel Lens Dehydration and Subjective Comfort and Dryness Ratings in Symptomatic and Asymptomatic Contact Lens Wearer. *Optom Vis Sci*. **76** (10): 700-704
- Fonn D (2007). Targeting Contact Lens Induced Dryness and Discomfort: What Properties Will Make Lenses More Comfortable. *Optom Vis Sci*. **84**(4): 279 – 285
- Foulks G (2003). What is Dry Eye and What Does It Mean to the Contact Lens Wearer? *Eye Contact Lens Sci Clin Pract*. **29** (1): S96-S100
- Gasson A and Morris J (1998). The Contact Lens Manual: A Practical Fitting Guide. 2<sup>nd</sup> Edition, Butterworth-Heinemann, Woburn, MA. Pp: 155-162
- Grosvenor T (1975). Changes in Corneal Curvature and Subjective Refraction of Soft Contact Lens Wear. *Am J Optom Physiol Opt*. **52**: 402-413
- Grosvenor T, Perrigin D, Perrigin J and Quintero S (1991). Rigid Gas-Permeable Contact Lenses for Myopia Control: Effects of Discontinuation of Lens Wear. *Optom Vis Sci*. **68**: 385-389
- Guillon M, Styles E, Guillon JP and Maissa C (1997). Preocular Tear Film Characteristics of Non-wearers and Soft Contact Lens Wearers. *Optom Vis Sci*. **74** (5): 273-279
- Horner DG, Soni PS and Salmon TO (1999). Myopia Progression in Adolescent Wearers of Soft Contact Lenses and Spectacles. *Optom Vis Sci*. **76**: 474-479
- Korb DR (1994). Tear Film-contact Lens Interactions. *Adv Exp Med Biol*. **350**: 403-410
- Mandell RB (1974). Sticking of Gel Contact Lenses. *ICLC*: **2**:28-29
- Miler D (1968). Contact Lens-Induced Corneal Curvature and Thickness Changes. *Arch Ophthalmol*. **80**(4):430-432
- Morris RJ (1956). Contact Lenses and the Progression of Myopia. *Optometry Weekly*. **47**: 1487-1488
- Nichols JJ and Sinnott LT (2006). Tear Film, Contact Lens and Patient-related Factors Associated with Contact Lens-related Dry Eye. *Invest Ophthalmol Vis Sci*. **47**(4): 1319-1328
- Perrigin J, Perrigin D, Quintero S and Grosvenor T (1990). Silicone-acrylate Contact Lenses for Myopia Control: 3-year Results. *Optom Vis Sci*. **67**: 764-769
- Plugfelder LZ (2000). The Effects of Long-term Contact Lens Wear on Corneal Thickness, Curvature, and Surface Regularity. *Ophthalmol*. **107** (1): 105 – 111
- Sack RA, Kah OT and Ami T (1992). Diurnal Tear Cycle-evidence for Nocturnal Inflammatory

Constitutive Tear Fluid. *Invest Ophthalmol Vis Sci.* **33** (3): 626-630

Santadomingo-Rubido J, Wolffsohn JS and Gilmartin B (2006). Changes in Ocular Physiology, Tear Film Characteristics, And Symptomatology with 18 Months Silicone Hydrogel Contact Lens Wear. *Optom Vis Sci.* **83** (2): 73-81

Saunders T and Goss A (1975). Role of the Cornea in Emmetropia and Myopia. *Optom Vis Sci.* **75**: 132-145

Sharma A and Ruckenstein E (1985). Mechanism of Tear Film Rupture and its Implications for Contact Lens Tolerance. *Am J Optom Physiol Opt.* **62** (4): 246-253

Stewart L (1968). Effect of Contact lens Materials on Tear Physiology. *Optom Vis Sci.* **81**: 194-204

Sweeney DF, Keay I and Jalbert I (2000). Clinical Performance of Silicone Hydrogel Lenses. In *The Rebirth of Continuous Wear Contact Lenses: Sweeney DF (ed.) Silicone Hydrogels.* Butterworth-Heinemann, Oxford. Pp: 90-149

Tighe B (1999). Silicone Hydrogels: What Are They And How Should They Be Used in Everyday Practice? *Optician.* **218**: 31-32

Tonge S, Tighe B, Franklin V and Bright A (2001). Contact Lens Care, Part 6: Comfort Drops, Artificial Tears and Dry-eye Therapies. *Optician.* **222**: 27 - 32

Wilcox M, Sankaridurg PR and Lan J (2000). Inflammation and Infection and the Effects of the Closed Eye. In *Silicone Hydrogels: The Rebirth of Continuous Wear Contact Lenses.* Sweeney DF (Ed.). Butterworth-Heinemann, Oxford. Pp: 45-75