Comparison of Two Different Bandage Contact Lens Types Used After Corneal Crosslinking

Kornea Kroslink Sonrası Kullanılan İki Farklı Tip Bandaj Kontakt Lensin Karşılaştırılması

Elvin HALİLİ,[a]
Banu ACAR,[a]
N. Melda YENEREL[a]

[a]Clinic of Ophthalmology, Haydarpaşa Numune Training and Research Hospital, İstanbul

Geliş Tarihi/*Received:* 06.01.2015
Kabul Tarihi/*Accepted:* 09.03.2015

Yazışma Adresi/*Correspondence:*
Elvin HALİLİ
Haydarpaşa Numune Training and Research Hospital,
Clinic of Ophthalmology, İstanbul, TÜRKİYE/TURKEY
elvinhalili@mynet.com

ABSTRACT Objective: To compare the efficiacy of two types of silicone hydrogel bandage contact lenses (BCLs) after corneal collagen crosslinking (CXL) in keratoconus patients. **Material and Methods:** In this prospective study, 36 keratoconus patients received CXL in both eye. Each patient received a BCL composed of balafilcon A (Pure Vision; Bauch&Lomb) (14.0 diameter, 8.6 base curve) in 1 eye and lotrafilcon B (Air Optix Aqua; Ciba Vision) (14.2 diameter, 8.6 base curve) in the fellow eye. Patients were masked to the lens type in each eye. Postoperative medication regimen was the same with both eye. Epithelial defect size, contact lens debris, conjunctival and limbal hyperemia, reepithelization and responses to a subjective-comfort questionnaire were assessed postoperatively at 1, 3, and 5 days. A paired Student's t test and chi-square tests were used when appropriate. **Results:** Seventy-two eyes of 36 keratoconus patients who underwent CXL were analyzed. There was no statistically significant difference in epithelial defect size, conjunctival or limbal hyperemia between the 2 lenses at any postoperative visit. Three days postoperatively, re-epithelization was complete in 77.8% of eyes (28 eyes) in the balafilcon A group and 83.3% of the eyes (30 eyes) in the lotrafilcon B group. Lens deposition and patient discomfort was significantly higher with the balafilcon A group 5 days postoperatively ($p<0.01$ for both comparisons). **Conclusion:** There were no differences in corneal re-epithelization between the 2 types of BCLs ($p>0.01$). However, lens deposition and patient discomfort was higher with balafilcon A ($p<0.01$).

Key Words: Contact lenses; keratoconus; riboflavin

ÖZET Amaç: Keratokonus hastalarında kornea kollajen kroslink (KKK) sonrası kullanılan iki farklı tip bandaj kontakt lensin etkinliğinin karşılaştırılması. **Gereç ve Yöntemler:** Bu prospektif çalışma ile KKK uygulanan 36 keratokonus hastası değerlendirildi. Hastaların bir gözüne balafilcon A içerikli bandaj kontakt lens (BKL) (Pure Vision; Bauch&Lomb) (14,0 çap, 8,6 temel eğri), diğer gözlerine lotrafilcon B içerikli BKL (Air Optix Aqua; Ciba Vision) (14,2 çap, 8,6 temel eğri) önerildi. Hastaların her bir gözüne bu lens tiplerinden biri uygulandı. Ameliyat sonrası her iki göz için aynı medikal tedavi rejimleri uygulandı. Ameliyat sonrası 1.,3.,ve 5. günlerde epitel defektinin büyüklüğü, kontakt lens debris, konjonktival ve limbal hiperemi, tekrar epitelizasyon ve subjektif konfor anketine cevaplar değerlendirildi. Sonuçların değerlendirilmesinde eşleştirilmiş Student t test ve ki-kare testi kullanıldı. **Bulgular:** KKK olan 36 keratokonus hastasının 72 gözü değerlendirildi. Ameliyat sonrası epitel defekt büyüklüğü, konjonktival ve limbal hiperemi açısından değerlendirildiğinde her iki kontakt lens arasında istatistiksel olarak anlamlı fark saptanmadı. Ameliyat sonrası 3. günde, balafilcon A kontakt lens kullanan grubun %77,8 (28 göz)'inde ve lotrafilcon B kullanan grubun %83,3 (30 göz)'ünde epitelizasyon tamamlanmıştı. Ameliyat sonrası 5. günde lens depoziti ve hasta konforsuzluğu balafilcon A kontakt lens kullanan grupta önemli derecede yüksek olarak değerledirildi (iki grup karşılaştırıldığında $p<0,01$). **Sonuç:** Korneanın tekrar epitelizasyonunda her iki tip BKL kullananlar arasında fark bulunmamaktadır ($p<0,01$). Bununla birlikte, balafilcon A kontakt lens ile lens debris ve hasta konforsuzluğu daha fazladır ($p<0,01$).

Anahtar Kelimeler: Kontakt lensler; keratokonus; riboflavin

doi: 10.5336/ophthal.2015-43379

Turkiye Klinikleri J Ophthalmol 2015;24(3):146-51

Crosslinking (CXL) for keratoconus treatment was used for the first time in 1998.[1,2] Biomechanical characteristics of the cornea consist of a frame formed of ligaments between collagen fibrils. Using riboflavin and UVA light, photo-oxidative collagen crosslinking technique prevents the progression of corneal thinning and keratoconus. Crosslinking treatment can be performed using two different procedures epithelial and trans-epithelial type.[2-4] Bandage contact lens in epithelial crosslinking is used to reduce ocular irritation and accelerate epithelial healing. Different types of contact lenses contribute differently to the healing process. Bandage contact lenses we used for therapeutic purposes have high-low level hydration (>50%, <50%). The degree of hydration in hydrogel lenses is clinically important. Oxygen permeability usually differs relatively to the extent of hydration and oxygen permeability is critical for epithelial health.

The use of silicone hydrogel lenses intended at mitigating hypoxy related lens complications was first introduced in 1998.[5] Compared to traditional soft hydrogel contact lenses, silicone hydrogel contact lenses have better oxygen permeability. The cornea has no veins so oxygen permeability is important. It also reduces contact lens related complications. There are several studies supporting the therapeutic use of silicone hydrogel bandage contact lenses in various conditions of the anterior segment.[6-8] However, there are also studies, which suggest material hardness related mechanical effect and inflammation related corneal damage. To the best of our knowledge, there have been no reports about bandage contact lens wearing after CXL with epithelial debridment.

This study investigates the therapeutic effectiveness of silicone hydrogel contact lenses using two different bandage contact lenses after corneal crosslinking.

MATERIAL AND METHODS

This prospective randomized clinical study enrolled 72 eyes of 36 keratoconus patients who had undergone CXL with riboflavin and UVA at Haydarpasa Numune Training and Research Hospital, Ophthalmology Clinic. Immediately after treatment, balafilcon A (Pure Vision; Night & Day) bandage contact lens was used on 36 eyes and lotrafilcon B (Air Optix Aqua; Ciba Vision) bandage contact lens was used in the fellow eye.

Patients were considered eligible for the study if they were older than 18 years, had a diagnosis of keratoconus, a corneal thickness of >400 μm and had not surgical interventions previously.

Exclusion criteria included a corneal thickness of <400 μm, central/paracentral scars either in epithelial or stromal layers, history of herpetic keratitis, active ophthalmic infection or inflammation, pregnancy, lactation and dry eye. The cases, patients were applied contact lenses which had inclusion and exclusion criteria for the investigation, were selected randomly. Patients were follow up outpatient. Smokers and people use other oral medication were among cases of this study.

Detailed information regarding each procedure was provided to all patients before their participation to the study, including need for close postoperative follow-up and possible outcomes of the intervention. Written informed consent was obtained from each patient in accordance with Declaration of Helsinki before study procedures were commenced. The research protocol was approved by the Clinical Research Ethical Committee of Haydarpaşa Numune Training and Research Hospital.

SURGICAL TECHNIQUE

All surgical interventions were performed by the same author (B.T.A.) under sterile conditions and topical anesthesia using proparacain HCl 0.5% (Alcain®, Alcon Inc, Ft Worth, TX) at a dose of 1 drop every 5 minutes for 4 times, starting 20 minutes before the intervention. To reduce the risk of UV exposure, miosis was induced with pilocarpine 1.0% 30 minutes before the procedure. Pre-medication or sedation was not required in any subjects.

Central corneal epithelium was removed from a 7.0 to 9.0 mm diameter area using a blunt spatula. Following de-epithelialization, the photosensitizer

solution containing riboflavin-5-phosphate 0.1% (G. Streuli & Co. AG) with dextran T500 20% (Roth AG) was applied every 5 minutes for 30 minutes. Corneal pachymetry guidance was performed in all patients prior to the operation by a Galilei dual Scheimpflug analyzer in order to ascertain a minimal corneal thickness greater than 400 μm throughout the cornea and to define the area with minimal thickness. Intraoperatively, ultrasonic pachymetry readings (Accupach V, Accutome Ultrasound, Inc, Malvern, PA) were used to identify the area that approximately corresponded to the area of minimum thickness and to ensure that minimum thickness exceeds 400 μm. During UVA irradiation for 30 minutes, isoosmolar riboflavin 0.1% solution was administered every 3 minutes (six 5-minute steps).

An UVA System device (UV-X; Peschke Meditrade, GmbH, Huenenberg, Switzerland) was used for UVA application. A target surface irradiance of 3.0 mW/cm^2 was ascertained by an UVA meter (YK-34UV, Lutron Electronic Enterprise Co, Ltd, Taipei, Taiwan) preoperatively. Before UVA was administered, riboflavin penetration through the cornea was checked by visualization of riboflavin into the anterior chamber by slit-lamp examination under cobalt blue light.

At the end of the procedure, a silicon-hydrogel bandage contact lens (balafilcon A or lotrafilcon B) was applied until full epithelialization. In addition, following topical agents were given to each patient: preservative-free antibiotic (single-dose netilmicin sulfat 0.3%; Netira, SIFI S.p.A, Italy) four times daily and artificial tears (sodium hyaluronate 0.2%; Artelac® Advanced, Bausch & Lomb, Germany) six times daily for 20 days. On postoperative days 1, 4 and 7 patients were examined to ensure healing and epithelization.

Table 1 shows the characteristics of the bandage contact lenses. The lens type fitted in each eye was counterbalanced, i.e the right eyes of the patients were fitted with 36 balafilcon A and 36 lotrafilcon B lenses. Contact lens fitting was evaluated in all cases by the same clinician (EH) a slit lamp biomicroscope and was found to be satisfactory in both eyes of all subjects. Both the clinician and the patient were unaware of the contact lens type fitted in each eye.

TABLE 1: Bandage contact lens characteristics.

	Bandage Contact Lens	
Trade name	Pure Vision	Air Optix Aqua
Generic name	Balafilcon A	Lotrafilcon B
Type	Silicone hydrogel	Silicone hydrogel
Dk/t	110	110
Water content (%)	36	33
Diameter (mm)	14.0	14.2
Back vertex power (D)	Plano	Plano
Back optik zone radius (mm)	8.60	8.60

On the 1st, 3rd, and 5th day patient examinations, besides subjective evaluation of pain and tearing, foreign body sensation (discomfort), epithelial defect size, reepitelization, contact lens debris level, and extent of conjunctival and limbal hyperemia was evaluated with slit-lamp biomicroscopy by an experienced ophthalmologist who was unaware of the type of bandage contact lens used for eyes. *Pain scores* were evaluated on scale of 0 to 4 as follows.[9] 0=no discomfort or pain; 1=mild discomfort; 2=moderate burning pain; 3=burning pain requiring oral medication; 4=severe constant or sharp pain not mitigated with oral medication. *Epithelial defect size* was calculated by the equation $A=\pi[(a+b)/4]^2$, where the longest dimension of the defect was *a* and the shortest dimension of the defect was *b*.[10] While there was no epithelial defect observed, bandage contact lens was removed. Flourescein was instilled to confirm the absence of an epithelial defect. Epithelial healing day was recorded. *Contact lens debris* level was graded using a scale from 0 to 4.[11-13] The score of debris was determined by estimating the percent area of the lens that was covered by the deposits (0=No, 1-4=yes,extent:1-100%). *Conjuctival and limbal hyperemia* was evaluated using the Efron grading scale (*Conjuctival hyperaemia*; 0=None"Normal", 1=slight injection of conjunctival vessels"Trace", 2=mild injection, 3=moderate injection, 4=severe injection, *limbal hyperemia* 0=None"Normal", 1=Trace, 2= Mild, 3=Moderate,

4= Severe). The data obtained and treatment protocol was assessed by an experienced ophthalmologist (MY).[14]

STATISTICAL ANALYSIS

Statistical analysis was performed using the Statistical Package for Social Sciences, SPSS Inc, Chicago, Ill, USA), version 17.0. Subjective and objective outcomes were compaired using paired Student's *t* and chi-square tests. A *p* value of <0.05 was considered statistically significant.

RESULTS

Seventy two eyes of 36 keratoconus patients who underwent CXL with riboflavin and UVA were analyzed. The mean age of the patients were 26.85±8.88 years (range:16 to 30).

The mean attempted spherical equivalent was -3.80+1.72 (SD) in balafilcon A group and -3.77+1.71 (SD) in the lotrafilcon B group; the difference was not statistically significant (p<0.59). Slit-lamp biomicroscopy at the end of surgery showed the fit of contact lens was satisfactory in all eyes.

The mean epithelial defect size after surgery was 52.95±14.32 mm^2 in the balafilcon A group and 53.16±14.23 mm^2 in the lotrafilcon B group (p=0.340). Figure 1 shows the correlation for epithelial defect size between the two bandage contact lenses after surgery (day 0) (r^2= 0.998). At day 1 (22.63±3.09 mm^2 versus 21.71±2.28 mm^2; p=0.136), day 3 (0.41±0.80 mm^2 versus 0.32±0.74 mm^2; p=0.287), and day 5 (0.03±0.10 mm^2 versus 0.02±0.07 mm^2; p=0.651) there was no statistically significant difference between two bandage contact lenses (Figures 2, 3).

The rate of re-epithelialization on post-op day 3 was 77.8% (28 eyes) with balafilcon A and 83.3% (30 eyes) with lotrafilcon B. Five days postoperatively, re-epithelialization was complete in 32 eyes (88.8%) and 32 eyes (88.8%), respectively (Figure 3). The difference between groups was not statistically significant (p=1.00).

There was no difference in levels of conjunctival-limbal hyperaemia between the lenses (p=0.58).

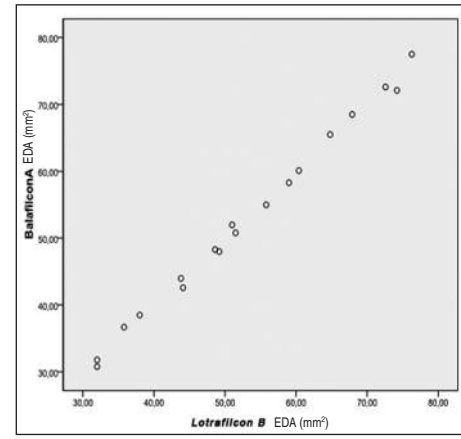

FIGURE 1: Correlation of the epithelial defect area (EDA) (mm^2) between the two lenses after surgery (day 0). The dashed line represents the least square reg-ression fit (r^2=0,998).

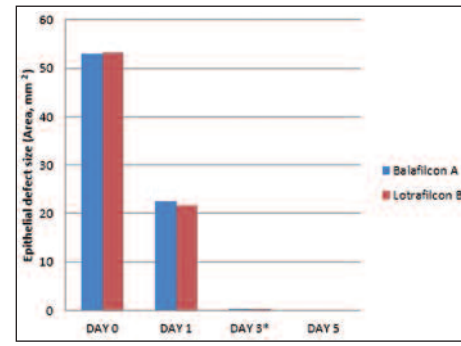

FIGURE 2: Plot of the mean epithelial defect size on all postoperative days (Day 0=day of surgery).
Error bars represents±1 SD (significant difference)*
(See color figure at http://www.turkiyeklinikleri.com/journal/oftalmoloji-dergisi/1300-0365/)

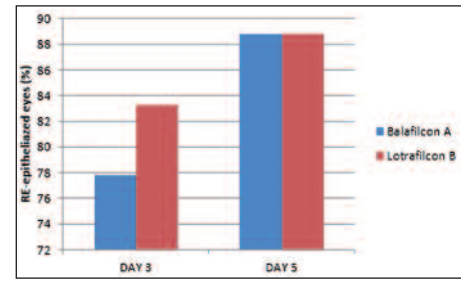

FIGURE 3: Plot of the proportion of eyes achieved complete re-epithelization for the two silicon hydrogel lenses, at days 3 and 5, post-operatively.
(See color figure at http://www.turkiyeklinikleri.com/journal/oftalmoloji-dergisi/1300-0365/)

Contact lens debris was more in balafilcon A than lotrafilcon B 5 days after the surgery (p=0.01) (Table 2). There was a significant difference be-

TABLE 2: Contact lens debris 5 days after surgery.

Grade	Balafilcon A (no of eyes %)	Lotrafilcon B (no of eyes %)
0	14 (38.8)	24 (66.6)
1	6 (16.7)	6 (16.7)
2	10 (27.8)	4 (11.1)
3	6 (16.7)	2 (5.6)
4	0	0

TABLE 3: Subjective patient comfort 5 days after surgery.

Grade	Balafilcon A (no of eyes %)	Lotrafilcon B (no of eyes %)
0	2 (5.6)	12 (33.3)
1	12 (33.3)	16 (44.4)
2	12 (33.3)	4 (11.1)
3	4 (11.1)	2 (5.6)
4	6 (16.7)	2 (5.6)

tween the two contact lenses in subjective comfort, patient discomfort was significantly higher with the balafilcon A group 5 days postoperatively ($p>0.01$) (Table 3) (Figure 4).

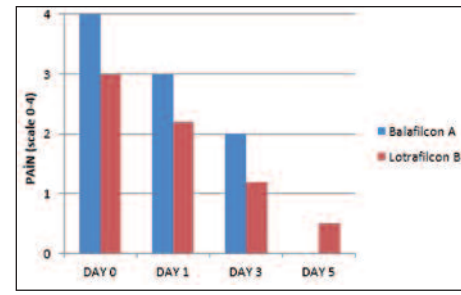

FIGURE 4: Subjective pain (top) on all postoperative days (Day 0-day of surgery).
(See color figure at http://www.turkiyeklinikleri.com/journal/oftalmoloji-dergisi/1300-0365/)

CONCLUSION

Therapeutic bandage contact lenses were first used in 1990s.[15] The most common complication after contact lens use is related to inadequate permeability capable of meeting increased oxygen requirements.[16] Therapeutic use of silicone hydrogel contact lenses increased oxygen supply and therefore reduced hypoxy related corneal surface problems. Using soft silicone hydrogel bandage contact lens after refractive surgery not only contributes to corneal structuring and epithelial healing; it reduces pain and sense of foreign object in the eye.[5,9,10]

Montero et al. and Oliveira et al. reported that the use of lotrafilcon-A for therapeutic purposes after PRK accelerates re-epithelialization and increases post-surgery patient comfort.[6,7] In this study we compared balafilcon A and lotrafilcon B silicone hydrogel contact lens after epithelial CXL. There was no statistically significant difference in re-epithelization between the two lenses at any postoperative examination. However, there was a significant difference between the two contact lenses in subjective comfort, patient discomfort was significantly higher with the lotrafilcon A group 5 days postoperatively ($p>0.01$).

Gil-Cazorla et al. compared the use of 2 different types of bandage contact lenses (balafilcon-A and galyfilcon-A) after LASEK surgery.[5] Oxygen permeability, water content, modulus and effectiveness on surface treatment of these BCLs were very different. Nonetheless, researchers were unable to identify a significant difference between the two groups in regards to vision, corneal epithelial conditions and extent of conjunctival-limbal hyperaemia. In our study, we used 2 different types of BCL after CXL. We were unable to find a statistically significant difference between these groups in regards to the same parameters.

Michael et al. used lotrafilcon-A and B BCLs after PRK.[9] They found no statistically significant difference in terms of re-epithelisation degree and pain levels. Engle et al. reported that corneal re-epithelialization after PRK was faster with less subjective complaints within the first 48 hours with lotrafilcon-A BCL compared to those with hydrogel BCL.[10] Our study identified that both groups using silicone hydrogel contact lenses had quickly completed re-epithelisation within the first 48 hours.

In a study conducted by Michael et al. performed using lotrafilcon-A and B BCLs after PRK

were unable to determine a statistically significant difference in terms of re-epithelisation degree and pain levels.[9]

The aim of using BCL is to increase patient comfort by reducing pain induced by ocular irritation. Gıl-Casorla et al. study was unable to determine a statistically significant difference concerning patient answers to questions intended at determining subjective complaints.[5] However, it has been reported that the comfort experienced by galyfilcon-A bandage contact lens users after LASIK was greater than the group using balafilcon-A bandage contact lenses. In our study, patients using lotrafilcon-B BCL contact lenses described being more comfortable compared to the group using balafilcon-A BCL. However, limitless oral medications being used by patients that may effects subjective evaluation of pain.

Deposit accumulation is a clinic finding related to tear flow and the use of ocular medication. Deposit will cause impaired vision and patient discomfort. The study performed by Gıl-Casorla et al. reported that on post-op day 5 after LASEK, patients wearing balafilcon-A BCL with traditional plasma oxidase surface activity, accumulated less deposit compared to galyfilcon-A BCL.[5] In this study, on post-op day 5 balafilcon -A BCL had more deposit accumulation and greater subjective complaints in comparison to lotrafilcon -B BCL.

Pucker et al. compared all silicone hydrogel bandage contact lenses in terms of corneal deposit accumulation identified that deposit accumulation on balafilcon-A contact lenses was greater compared to senofilcon-A contact lenses and that this difference was statistically significant ($p<0.005$).[11] Luensmann et al. identified that the amount of protein deposit accumulated on the balafilcon-A BCL on day 14 was statistically significant ($p<0.001$).[12]

The type of material affects both deposit accumulation on the lens and patient comfort. Extensive studies are still required before it is possible to determine the ideal bandage contact lens type. We believe that our study will be a precursor for future studies executed on the use of bandage contact lens after crosslinking.

REFERENCES

1. Hafezi F, Mrochen M, Iseli HP, Seiler T. Collagen crosslinking with ultraviolet-A and hypoosmolar riboflavin solution in thin corneas. J Cataract Refract Surg 2009; 35(4):621-4.
2. Raiskup-Wolf F, Hoyer A, Spoerl E, Pillunat LE. Collogen crosslinking with riboflavin and ultraviolet-A light in keratokonus: long-term results. J Cataract Refract Surg 2008;34(5): 796-801.
3. Filippello M, Stagni E, O'Brart D. Transepithelial corneal collagen crosslinking: bilateral study. J Cataract Refract Surg 2012;38(2): 283-91.
4. Utine CA, Çakır H, Altınsoy M. [Corneal collagen crosslinking for treatment of corneal ectatic diseases]. T. Oft. Gaz. 2009;39(2): 153-60.
5. Gil-Cazorla R, Teus MA, Hernández-Verdejo JL, Benito-Llopis L and García-González M. Comparative study of two silicon hydrogel contact lenses used as bandage contact lenses after LASEK.Optom Vis Sci 2008; 85(9):884-8.
6. Montero J ,Sparholt J, Mély R, Long B. Retrospective case series therapeutic applications of lotrafilcon A silicone hydrogel soft contact lenses. Eye Contact Lens 2003; 29(2):72-5.
7. de Oliveira PR , Bailey MD. Therapeutic contact lenses. In: Mannis MJ, Zadnik K, Coral-Ghanem C, Kara-Jose N, eds. Contact Lenses in Ophthalmic Practice. 1st ed. New York, NY: Springer; 2004. p.197-203.
8. Ambroziak AM, Szaflik J. Therapeutic use of a silicone hydrogel contact lens in selected clnical cases. Eye Contact Lens 2004; 30(1):63-7.
9. Grentzelos MA, Planis S, Astyrakakis NI, Diakonis VF, Kymionis GD, Kallinikos P, et al. Efficacy of 2 type of silicone hydrogel bandage contact lenses after photorefractive keratectomy. J Cataract Refract Surg 2009; 35(12):2103-8.
10. Engle AT, Laurent JM, Schallhorn SC, Toman SD, Newacheck JS, Tanzer DJ, et al. Masked comparison of silicone hydrogel lotrafilcon A and etafilcon A extended-wear bandage contact lenses after photorefractive keratectomy. J Cataract Refract Surg 2005; 31(4):681-6.
11. Pucker AD, Thangavelu M, Nichols JJ. In vitro lipid deposition on hydrogel and silicone hydrogel contact lenses. Invest Ophthalmol Vis Sci 2010;51(12):6334-9.
12. Luensmann D, Heynen M, Liu L, Sheardown H, Jones L. The efficiency of contact lens care regimens on protein removal from hydrogel and silicone hydrogel lenses. Mol Vis 2010;20(16):79-92.
13. Jorgen SA, Synoptik. A Handbook of Contact Lens Management. Jacksonville, Florida, USA: Vistakon; 1996. p.1-71.
14. Efron N, Morgan PB, Katsara SS. Validation of grading scales for contact lens complications. Ophthalmic Physiol Opt 2001;21(1): 17-29.
15. Gasset AR, Kaufman HE. Therapeutic uses of hydrophilic contact lenses. Am J Ophthalmol 1970;69(2):252-9.
16. Compañ V, Andrio A, López-Alemany A , Riande E, Refojo MF. Oxygen permeability of hydrogel contact lenses with organosilicon moities. Biomaterials 2002;23(13): 2767-72.