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## Effects of the rigid gas permeable contact lens use on tear and ocular surface among keratoconus patients

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### ABSTRACT

**Purpose:** To investigate changes in tear and ocular surface of patients with keratoconus using rigid gas permeable contact lenses (RGPCL) and compare them against keratoconus patients who were not using lenses as well as a control group of healthy subjects.

**Methods:** 24 keratoconus patients using RGPCL (Group 1) 22 patients who were not using lenses (Group 3) and 21 healthy subjects (Group 3) were included in the study. Subjective complaints about the subjects' eyes have been investigated using the ocular-surface disease index (OSDI). After the control of best-corrected visual acuity, anterior chamber and fundus examinations were performed.

**Results:** Schirmer ( $p$ -value = 0.01) and tear break up mean comparison tests ( $p$ -value = 0.002) revealed significant differences across different groups but tear osmolarity analysis did not ( $p$ -value > 0.05). Oxford and OSDI scores were compatible with Schirmer and tear break up test comparisons. (for both  $p$ -value = 0.001) Moreover, no statistical differences were seen in impression cytology measures between groups. ( $p$ -value > 0.05)

**Conclusions:** The erosion in the tear film stability is in line with the erosion in the ocular surface epithelium. Taking into account the statistical indifference between the impression cytology measures across groups, the break up time differences may be attributed to the collagen destruction in tear.

### 1. Introduction

As well known, keratoconus is one of the most widely seen cornea illnesses with estimates of rates in a range from 50 to 230 in 100.000 people [1–3].

Significant research has been conducted on the diagnosis and progression of keratoconus in the literature. Genetic as well as mechanic factors, atypical diseases, connective tissue diseases (e.g. Marfan syndrome, Ehler Danlos syndrome etc.) have been mentioned as etiological factors [3–5]. However, recent studies have focused on the analysis of inflammation mediators of the patient at molecular level [6–9]. Moreover, there are also studies that argue that the effects of keratoconus are not limited to the cornea but spreads to the whole ocular surface [10–12]. Additionally, there are also findings in the literature that the rigid gas permeable contact lenses (RGPCL) also affect the cornea surface [11].

This study investigates the etiology of keratoconus and its effects from a cytopathological point of view. Motivated from the recent findings discussed above, a broad ocular surface analysis has been conducted, not only limited to the conjunctiva but also tear film layer

and corneal surface changes have been incorporated to the analysis. In this regard, changes in tear and ocular surface of patients with keratoconus using rigid gas permeable contact lenses (RGPCL) have been analyzed and their analysis results have been compared against those of keratoconus patients who are not using lenses as well as a control group of healthy subjects. Even though some modern soft lenses are also suitable for eyes suffering from keratoconus, using RGPCL is still the norm. Therefore, the present study only focused on the effects of using RGPCL.

### 2. Method

The current study was conducted at the Cerrahpasa School of Medicine of Istanbul University, Turkey in 2015 following the approval of the Faculty Ethics Committee. 118 eyes of 67 individuals have been examined. All effort was made to have the largest sample size possible before the ethics committee approval expires (3 months). Subjects were divided into three groups: Groups 1 and 2 consisted of keratoconus patients who use (all using Conflex-Air 100 UVK, Carl Zeiss- Germany) and don't use RGPL contact lenses, respectively and Group 3 included

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**Table 1**  
Descriptive Statistics.

	Group 1 (RGPL users)	Group 2 (non-RGPL users)	Group 3 (Healthy Subjects)	p-value (Kruskall-Wallis Test)
Number of Subjects	24	22	21	
Number of Eyes	41	35	42	
Gender (F/M)	14/10	14/8	10/11	
% Female	0.56 ± 0.50	0.66 ± 0.48	0.48 ± 0.51	p = 0,403
Age	34.95 ± 11.77	31.97 ± 9.19	30.71 ± 4.36	p = 0,142
Keratoconus duration (years)	11.90 ± 6.95	4.63 ± 3.67		p = 0,001
RGPL lense use (years)	10.10 ± 6.18			

**Table 2**  
Findings from Biomicroscopic Examination.

Slit lamp findings	Group 1 Number (% of Total)	Group 2 Number (% of Total)	Group 3 Number (% of Total)
Corneal nerve	7 (17.1%)	6 (17,1%)	2 (4.8%)
Punctate-epithelial erosions	25 (61,0%)	15 (42.9%)	4 (9.5%)
Fleischer ring	7 (17.1%)	5 (14.3%)	- (0%)
Vogt striae	13 (31. 8%)	7 (20.0%)	- (0%)
Apical scarring	14 (34. 1%)	2 (5.7%)	- (0%)
Mid-stromar scarring	5 (12.2%)	1 (2.9%)	- (0%)
Munson sign	5 (12.2%)	1 (2.9%)	- (0%)

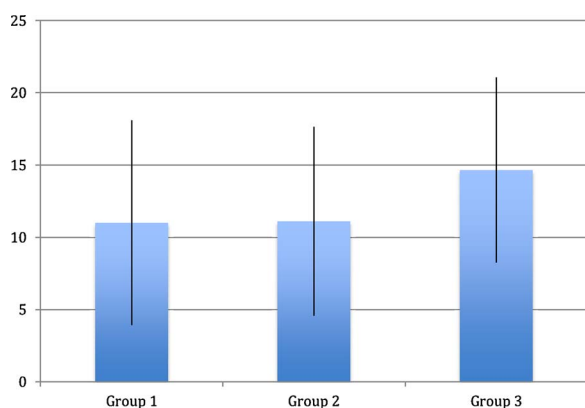


Fig. 1. Schirmer Test Bar Chart.

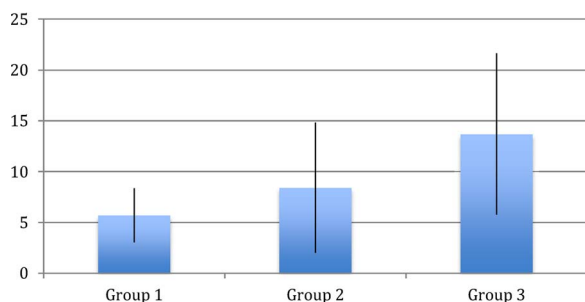
**BUT**

Fig. 2. Bar Chart of Tear Break Up Time Measures.

healthy subjects as a control group. Table 1 below summarizes the descriptive statistics of all the groups.

OSDI survey was applied to all subjects prior to the examination and an OSDI score was calculated for each subject. Before the biomicroscopic examination, tear osmolarity levels were measured. Next, 0,5% proparacaine hydrochloride was applied to all subjects as the topical anesthesia and subsequently the Schirmer test was conducted. Once the effect of the anesthesia and the mechanic irritation of the Schirmer test disappears, all subjects were taken to biomicroscopic examination.

Oxford scores as well as the tear breakup time were calculated. Oxford scores were constructed using fluorescein paper strips and following the Oxford scheme where epithelium damage has been classified in six categories from 0 to 6. The tears were collected after 30 s of removing contact lenses to avoid irritation factors and reflex tear secretion. About 7–10  $\mu$ L tear were collected from each subject. Finally, before the conjunctiva impression cytology topical anesthesia were applied again. Conjunctival epithelium samples were classified according to the Saini grading system [13] in the pathology lab. Finally, videokeratoscopy was applied to evaluate the anterior segment structures. All the subsequent statistical analysis using the collected data has been done in Stata 12 programme. Specifically, *t*-test was used to compare means of two groups, whereas the Kruskal-Wallis test was conducted to compare means of three groups. A p-value of less than 0.05 is taken as an indication of statistical significance. Moreover, given the sample sizes of the study, in all mean comparison assuming a default 0.05 level of significance (i.e. the alpha level), all the powers of the conducted tests were above 0.65 and much larger in some cases.

**3. Results****3.1. Basic findings**

Findings from the slit lamp biomicroscopic examination were presented in Table 2. Specifically, for each group the number of each finding as well as its corresponding percentage out of the total number of eyes in each group were illustrated in the table.

Next, Fig. 1 illustrated the bar chart of the Schirmer test results. Accordingly, the mean score for Group 1, Group 2 and Group 3 subjects were  $11 \pm 7.08$  mm,  $11.1 \pm 6.53$  mm, and  $14.64 \pm 6.41$  mm, respectively. The p-value of the mean comparison test between groups 1 and 2 was 0.95, between groups 1 and 3; 0.02 and between groups 2 and 3 is 0.03. The Kruskal-Wallis mean comparison test indicated a significant difference between the three groups (p-value = 0.01).

Fig. 2 presented the bar chart of the tear break up times of the three study groups. Group 1 had a tear break up time of  $5.68 \pm 2.66$  s, whereas for Group 2 and Group 3, it was calculated to be  $8.14 \pm 6.41$  and  $13.68 \pm 7.93$  s, respectively.

The p-value of the mean comparison test between groups 1 and 2 was 0.042, between groups 1 and 3, 0.001 and between groups 2 and 3 it was 0.001. The Kruskal-Wallis mean comparison test again indicated a significant difference between the three groups (p-value = 0.002).

Next, comparisons of the tear osmolarity levels were presented in Fig. 3. The three groups had an osmolarity level of  $290.29 \pm 8.72$ ,  $293.12 \pm 9.97$ , and  $293.03 \pm 9.06$  mOsm/L, respectively. However, in this case, the *t* and the Kruskal-Wallis tests indicated no significant difference for any of the comparisons, all having a p-value larger than 0.05.

Fig. 4 presented the mean Oxford scores of all the three groups. The mean score for Group 1 subjects was  $0.82 \pm 0.72$  whereas it was  $0.57 \pm 0.74$  for Group 2 subject and  $0.08 \pm 0.28$  for the control group. According to these levels, there was no significant difference between Group 1 and Group 2 subjects. (p-value 0.152) However, the Oxford score of the Group 3 subjects was significantly lower than the

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