



## Comparison of Tear Film Parameters and Ocular Surface Disease Index (OSDI) Scores in Pregnant vs Non-Pregnant Female: A Cross Sectional Study.

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Abstract

### **Objective:**

To examine and compare the results of the Schirmer's test (ST), tear film break up time (TBUT), and ocular surface disease index (OSDI) during the first three trimesters of a healthy pregnancy with not pregnant women as control.

### **Methods:**

Cross-sectional, observational study from a tertiary care teaching institute. In this study, 156 healthy pregnant women (46, 54, and 56 in the first, second, and third trimesters, respectively) without any pre-existing eye illnesses had their ST (mm), TBUT (sec), and OSDI scores recorded, and they were compared to 52 healthy non-pregnant women (controls). The three trimesters' ST, TBUT, and OSDI scores were also compared.

### **Results:**

Pregnant and non-pregnant females had mean ages of  $26.88 \pm 3.34$  and  $27.4 \pm 4.7$  years, respectively. First, second, and third trimester mean ST (mm) values were  $18.18 \pm 6.78$ ,  $13.12 \pm 2.31$ , and  $10.12 \pm 5.78$ , respectively. For each trimester, the mean TBUT values (sec) were

$\pm 7.09$ ,  $12.34 \pm 4.13$ , and  $11.76 \pm 6.43$  correspondingly. In control groups, the mean ST and TBUT values were  $21.9 \pm 9.21$  mm and  $30.43 \pm 14.12$  sec, respectively. When compared to the first trimester, the mean ST and TBUT values at the second and third trimesters were significantly lower. The third trimester had the highest mean OSDI scores ( $16.59 \pm 8.64$ ). Pregnant women had lower ST, TBUT values, and higher OSDI scores than non-pregnant women.

### **Conclusion:**

Specifically during the second and third trimesters of pregnancy, pregnant women had considerably lower ST and TBUT values and higher OSDI scores, which indicated increased lacrimal dysfunction and dry eyes.

**Keywords:** Schirmer's test, tear film break up time, pregnancy, dry eye

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### **Introduction**

The female reproductive system is just one of the many human organ systems that are impacted by pregnancy. Apart from haematological, cardiovascular and immunological changes, ocular changes in pregnancy are fairly common [1,2]. Ocular changes in pregnancy can be physiological or pathological. Important physiological changes includes change in refraction, decreased corneal sensation, increased thickness of cornea and decreased intraocular pressure [3,4]. Whereas important pathological abnormalities are Central serous chorioretinopathy, retinal vascular occlusions, progression of diabetic retinopathy and optic neuropathy [5-7].

Pregnancy may impact tear film formation, which is primarily physiological. However, studies have reported a higher prevalence of dry eye during pregnancy when compared with non-pregnant women [8,9]. Also tear film changes are more during last trimester of pregnancy [10].

This study was designed to examine changes in tear film parameters and OSDI scores throughout the course of three trimesters of pregnancy and compare them to non-pregnant women as controls because there is little information available on these changes in normal pregnancy, particularly in Indian individuals. This may facilitate early recognition and prompt treatment of dry eye wherever deemed necessary.

### **Materials & Methods**

Over the course of four months (Sep 2022-Dec 2022) this cross sectional study was carried out at a tertiary care teaching institute in Eastern India. The study procedure corresponds to the principles of "The Declaration of Helsinki" and was approved by the Institute ethics committee of RIMS Ranchi, India .All healthy pregnant females attending the antenatal clinic and willing to participate in the study were included. As controls, healthy women between the ages of 19 and 30 who were not

pregnant and went to the eye OPD for refractive correction were included. Women with any type of systemic or ocular disease, such as diabetes, blepharitis, conjunctivitis, or use of topical eye medications within three months of presentation, that may potentially influence tear film function were excluded from the study. Each of the females gave their written, informed consent.

The first trimester of pregnancy was defined as pregnancy of one to thirteen weeks, the second trimester as pregnancy of fourteen to twenty-eight weeks and the third trimester as pregnancy of twenty nine to forty weeks. Each pregnant woman was divided into one of three groups, depending on trimesters of pregnancy. Group 4 served as the control group of non-pregnant women.

In the study proforma, patient information such as sociodemographic information and prenatal history for pregnant women was recorded. A pre-validated Ocular Surface Disease Index (OSDI) questionnaire for assessing the subjective severity of dry eye symptoms was completed by each participant [11]. Afterwards they underwent a detailed ocular examination including visual acuity, intra ocular pressure measurement, slit lamp examination and posterior segment evaluation. The same ophthalmologist conducted the Schirmer test II and tear film break up time on each subject. For each eye, these were performed three times consecutively, and the mean was used as the final reading. Since there was very high agreement between the left eye and the right eye for both tests, only the data for the worse eye were taken.

### ***Tear film break up time***

The test was performed using fluorescein strips, which were introduced to the conjunctival sac with minimal stimulation. The patient was asked to blink several times and then to keep the eyes open. Cornea was examined under cobalt blue filter on the slit lamp. The dry area was indicated by the presence of black spot. The time between the last blink and the appearance of first random dry spot was recorded in seconds.

### ***Schirmer's test II***

Following instillation of one drop of proparacaine hydrochloride 0.5%, the eye was wiped dry and the folded end of a 35×5 mm pre-calibrated (mm) Whatman no. 41 paper was gently inserted into the junction between the lateral 1/3rd and medial 2/3rd of the lower fornix without touching the cornea. Both eyes were tested simultaneously. The strip was removed after 5 minutes, the wet portion of the strip measured and recorded.

Ocular Surface Disease Index (OSDI) score [developed by the Outcomes Research Group, Allergan Inc. (Irvine, California, USA)] (Table 1)

Parameters	All of the time	Most of the time	Half of the time	Some of the time	None of the time
1. Eyes that are sensitive to light?	4	3	2	1	0
2. Eyes that feel gritty?	4	3	2	1	0
3. Painful or sore eyes?	4	3	2	1	0
4. Blurred vision?	4	3	2	1	0
5. Poor vision?	4	3	2	1	0
6. Reading?	4	3	2	1	0
7. Driving at night?	4	3	2	1	0
8. Working with computer?	4	3	2	1	0
9. Watching TV?	4	3	2	1	0
10. Windy conditions?	4	3	2	1	0
11. Places or areas with low humidity? (very dry)	4	3	2	1	0
12 Areas that are air conditioned	4	3	2	1	0

Table 1: Ocular Surface Disease Index (OSDI) Questionnaire

The survey has 12 scoring items, and the overall score ranges from 0-100, with higher scores indicating greater impairment. Ocular symptoms (three items), vision-related function (six items), and environmental factors (three items) are the three subscales that make up the OSDI's total score. Each OSDI item is given a score between 0 and 4, with 0 representing never and 4 representing always. The following formula was used to determine the OSDI score:

OSDI is calculated as follows:  $25 / (\text{total of scores})$  questions answered

### Statistical analysis:

Each patient's worse eye was chosen for the analysis. The acquired data was analysed using SPSS for Windows software version 20.0 (SPSS, Inc., Chicago, IL, USA). The mean and standard deviation were used to express continuous variables. Repeated analysis of variance (ANOVA) test was performed to examine changes in mean ST and TBUT values and OSDI scores across all four groups. Independent t-test was used to compare mean values between cases

and controls, as well as between the three trimesters. Statistical significance was defined as P values of 0.05 or less.

## Results

The study included 52 eyes from non-pregnant females and 156 eyes from 156 pregnant females (46 in the first trimester, 54 in the second trimester, and 56 in the third trimester). The mean age of the pregnant patients was  $26.88 \pm 3.34$  years (range 19-32 years). Females mean ages in the first, second and third trimesters were  $25.23 \pm 5.19$ ,  $27.57 \pm 0.42$ , and  $28.00 \pm 2.81$  years respectively. The non-pregnant females in the control group had an average age of  $27.4 \pm 4.7$  years. Comparing the mean age of females in all four groups, ANOVA test found equal age between the groups ( $p=0.621$ ), i.e. not varied statistically. The mean duration of pregnancy (weeks) was  $8.15 \pm 6.3$  in first trimester,  $24.20 \pm 2.30$  in second trimester and  $34.15 \pm 0.4$  in third trimester. The median number of prior pregnancies among the 96 females (61.5%) was three. Table 2 displays the demographic features of pregnant patients.

Total n=206	Mean $\pm$ SD	Range
Age (years)	$26.88 \pm 3.34$	19 -32
Duration of Pregnancy (weeks)	$22.16 \pm 6.80$	9 -35
Gravida	Primigravida	60
	Polygravida	96
Occupation	Housewives	145
	Working	61

Table 2: demographic profile of study population

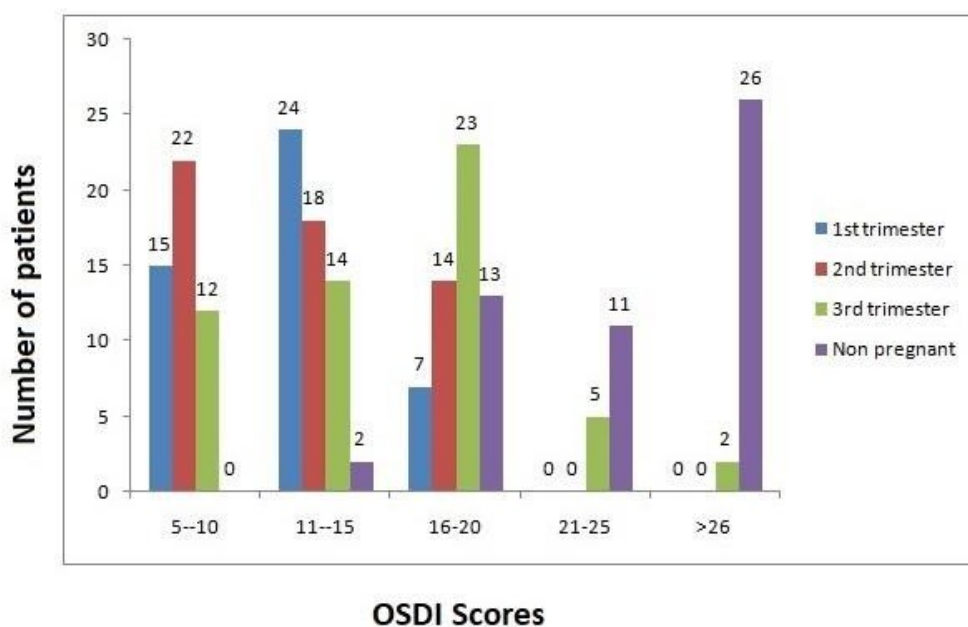
In Table 3, the mean Ocular Surface Disease Index (OSDI) scores, the mean ST (mm) values, and the mean TBUT (sec) values in the first, second, and third trimesters and control (groups 1, 2, 3, and 4) are displayed.

	Group 1	Group 2	Group 3	Group 4	
Total n=206	First trimester n=46	Second trimester n=54	Third trimester n=56	Control n= 52	p value (ANOVA)

OSDI score mean±SD	12.15±4.61 (range 5-16)	14.24±3.11 (range 9-18)	16.59±8.64 (range 8-27)	30.65±11.32 (range 14-32)	0.003
Mean Schirmer's test ± SD (mm)	18.18±6.78 (range 12-23)	13.12±2.31 (range 11-16)	10.12±5.78 (range 5-19)	21.9±9.21 (range 12-30)	<0.001
Mean Tear film Break-up Time ± SD (seconds)	20.01±7.09 (range 12-28)	12.34±4.13 (range 8-16)	11.76±6.43 (range 5-18)	30.43±14.12 (range 15-37)	<0.001

Table 3: Comparison of ocular parameters across all groups

Figure 1 shows how OSDI scores were distributed throughout all groups.



In all three trimesters, there was a general trend towards lower ST and TBUT levels and higher OSDI values compared to non-pregnant females. The results of the repeated measure analysis of variance showed that there was a statistically significant difference in the ST, TBUT, and OSDI scores between each group. (p value <0.05).

When compared to first trimester scores, the third trimester's ST and TBUT values were significantly lower (p values = 0.004, 0.012, respectively), according to an independent t test.

When compared to the first trimester, lower ST and TBUT values were observed, and the differences were statistically significant.

Pregnant women had lower ST, TBUT values, and higher OSDI scores than non-pregnant women. A comparison within the group revealed that second- and third-trimester pregnant women had significantly lower levels than non-pregnant women.

## **Discussion**

There is a higher prevalence of dry eyes in pregnant women compared to non-pregnant women, according to various studies on changes in tear film function in both human and animal models [8,10,12].

In this cross-sectional study, 156 pregnant women of varying gestational lengths were compared to 52 non-pregnant controls to examine changes in tear film characteristics and OSDI scores.

In earlier investigations, lacrimal dysfunction during pregnancy was analysed and contrasted with non-pregnant women [8,9]. In a study by Skare et al, pregnant women had a higher prevalence of dry eyes, but there was no difference in Schirmer's reading between pregnant and non-pregnant women [8]. In another study, Ibraheem et al found that pregnant women had lower TBUT test scores than non-pregnant women, while ST scores between the two groups were not statistically significant [8]. Contrarily, in our study, pregnant women in the second and third trimesters had considerably lower mean ST and TBUT readings when compared to non-pregnant women. Because past research did not compare trimester-specific tear film properties, which could have an impact on the final result, the disparity can be explained.

Nkiru et al study was the only one to compare ST and TBUT values throughout all trimesters [10]. In comparison to the second trimester and the postpartum period, the third trimester showed a significant drop ( $p < 0.05$ ) in both TBUT and Schirmer's value, according to this longitudinal study on 134 pregnant women. In our investigation, it was discovered that the values of the Schirmer test II and TBUT were much lower in the second and third trimesters of pregnancy than in the first.

In our study, the third trimester had the highest OSDI scores (mean  $16.59 \pm 8.64$ ), which may indicate a higher prevalence of dry eyes. This rating is consistent with our observation that third trimester ST and TBUT levels are lower. In their investigations, Nkiru et al also noted that the third trimester was when OSDI levels were highest ( $18.6 \pm 6.8$ ) [10].

Due to increased hormonal changes later in pregnancy, tear film malfunction is more common during the second and third trimesters.

The levels of the sex-stimulating hormones testosterone, estrogen, and progesterone are known to rise during pregnancy, especially in the third trimester [13]. A decrease in the amount of

circulating active and free testosterone is accompanied by an increase in the steroid hormone binding globulin. In contrast to estrogen, which encourages acinar cell death and reduces the size and production of the gland, testosterone supports the development and differentiation of the gland [14-17]. Thus, the shifting hormonal milieu during pregnancy adversely affects the secretory activity of the meibomian and lacrimal glands.

There are some limitations in this study. A larger sample size may have produced more precise results. We did a cross sectional study, however a longitudinal study of changes in tear film parameters during different trimesters of pregnancy might give more accurate results. Nevertheless, we did a cross sectional study to avoid dropout that may accompany longitudinal studies.

### Conclusions

Pregnant women had considerably lower tear film parameters and higher OSDI scores, which indicated increased lacrimal dysfunction and dry eyes, particularly during the second and third trimesters. Further longitudinal studies with larger sample size is required for more precise results.

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