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THE EFFECT OF HORMONAL CONTRACEPTIVES ON TEAR SECRETION AMONG WOMEN AGED BETWEEN 26-45 YEARS ATTENDING FEDERAL MEDICAL CENTRE ASABA, DELTA STATE.

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ABSTRACT

The study aimed to determine the effect of hormonal contraceptives on tear secretion Delta State. An experimental study, which included 52 healthy women between 26-45 years, who presented in family planning clinic. Two groups were made according to the use of hormonal contraceptives. Study group consists of 26 women who were on hormonal contraceptives and 26 women as control group were not taking any hormonal contraceptives. Quantitative test for tear secretion was done by Schirmer's test. Statistical analysis was done to determine the correlation between use of hormonal contraceptives and tear secretion. The results showed that tear secretion was significantly reduced in study group as indicated by decreased Schirmer's test values in study group (6.08±1.74) as compared to control group (7.79±1.97). The tear secretion was also affected by age, the type of contraceptive used and the duration of use of the hormonal contraceptive. These results support that use of oral contraceptives may be an important etiological factor in pathogenesis of dry eye disease among women of reproductive age.

Keywords: *Dry Eye, Hormonal Contraceptives, Tear Secretion, Family Planning*.

INTRODUCTION

Tears are fluid secreted by the lacrimal glands of the eye which helps to moisten the eyes. Tears contain a wide variety of biologically active substances like mucin, electrolytes and other substances. They play an important role in maintaining the clarity of the cornea, also aids in providing a clear vision, in defense mechanism of the eye and in providing soothing effects to the eyes (1). Precorneal (tear) film is spread across the eye and it has three layers namely; lipid layer, aqueous layer and mucous layer. Lipid layer (secretes lipid) acts as a hydrophobic barrier and

prevents the overflow of tears. Aqueous layer (contains water and tear proteins) acts as a physiological barrier and controls infection to the eyes. Mucous layer (secrete mucin) acts as a hydrophilic layer. In a day, 0.75-1.1 grams of tears is secreted which decreases with age (2).

Tears And Its Effect On Aging

During aging all physiological processes tend to decrease and this attributes to decrease in tear secretion. Sometimes there is overflow of tears due to inefficient drainage function of the gland and blocks in the lachrymal ducts. Epiphora is a symptom which results from deficiency in the drainage of tear film. There are two types of epiphora: chronic and acute conditions. Dry eye is caused in old age due to less tear secretion

Physiology Of Tear Secretion

The sensory nerve for tear reflexes is the fifth cranial nerve- the trigeminal nerve. If this nerve is cut, reflex tears alone are affected. The tear secretion is regulated physiologically by cholinergic fibers of the parasympathetic nervous system, sympathetic stimulation to adrenal gland, certain peptides and humoral factors. Tear secretion is also controlled by epidermal growth factors (4). Due to the absence of developed nervous system, an infant tends to cry without weeping. In the absence of the gland, the accessory glands take up the role of tear secretion and are sufficient to produce tears needed for normal functioning of the eye. Thus, the accessory glands prevent the risk of dry eye (4)

Hormonal Contraceptives

This refers to birth control methods that act on the endocrine system. Almost all methods are composed of steroid hormones, although in India one selective estrogen receptor modulator is marketed as a contraceptive. The original hormonal method—the combined oral contraceptive pill—was first marketed as a contraceptive in 1960. In the ensuing decades, many other delivery methods have been developed, although the oral and injectable methods are by far the most popular. Altogether, 18% of the world's contraceptive users rely on hormonal contraceptives (4).

ETHICAL CONSIDERATIONS

Approval was gotten from the Head, Department of Optometry Madonna University Nigeria, Elele Campus Rivers State. Permission was also sought from the Medical Director of the Hospital where the study was done. Informed consent and ascent forms were obtained from all participants

of the study. Standard procedures were used and the rights of the participants were protected. Results from the study were made available to the participants confidentially, to maintain this confidentiality, data collection sheets did not bear the names of the participants.

RESEARCH DESIGN

An experimental design was used for the study.

STUDY POPULATION

This study involved 52 healthy women of child bearing age, within the ages of 26 to 45 years, who visited the family planning unit of Federal Medical Centre, Asaba, Delta State.

AREA OF STUDY

Federal Medical Centre Asaba is a Federal Government owned Medical Centre in Oshimili South Local Government area of Delta State, Nigeria.

INCLUSION AND EXCLUSION CRITERIA

Inclusion Criteria

Women within age bracket of 26-45 years who were on hormonal contraceptives for at least a period of one year.

Exclusion Criteria

Pregnant and menopausal women. Women with history of systemic diseases and on systemic medications. Ocular factors which were excluded from the study are ocular surgery, contact lens use, chronic topical medications, laser treatment, chemical injury, blepharitis and any other obvious ocular disorder.

SAMPLING SIZE AND SAMPLING TECHNIGUE

Sample Size: A sample size of 52 volunteers, which consisted of 26 for the control group and 26 for the experimental group; this was aimed at minimizing researchers' bias.

Sampling Procedure: A simple random sampling procedure was used, whereby the women who were willing to participate were selected from family planning unit of the hospital.

INSTRUMENT FOR DATA COLLECTION

Instruments used for data collection included

- Stop watch: This was used to check for the time in the course of carrying out the tests.
- Schirmer's strips: These were used in measuring the tear volume of the participants in the course of the research.
- A bottle of topical antibiotic: This was instilled into the patient's eye after the test so as to prevent secondary bacterial infection that may arise, as result of handling the materials used for the purpose of the study.

DATA COLLECTION PROCEDURE

The 52 participants were equally divided into two groups. The case group consists of 26 females who were currently on hormonal contraceptives. The control group consists of 26 females who were not using any hormonal contraceptive. The control and case group were demographically matched. Informed consent was obtained from each participant. Detailed history regarding personal data, gynecological history, systemic medication uses and duration of hormonal contraceptive, any ocular complaint was taken. Detailed ocular examination was done to rule out any ocular surface and anterior segment abnormality. Schirmer's test was done to measure the total tear secretion. Schirmer's strip (Whatman filter paper 41) was gently put at the junction of middle and outer 2/3 of lower lid, taking care not to touch the cornea or eye lashes. Participants were asked to look up and blink normally or to close the eye whichever the participant feel comfortable with. The strip was then removed 5 minutes after insertion. The wet portion of strip from bent portion was measured in mm. Average of three readings were taken, value less than 10 mm/after 5 minutes was considered as dry eye.

METHOD OF DATA ANALYSIS

The analysis was done using SPSS (statistical package for social sciences), version 25.0 for Windows. Descriptive statistics using percentage frequency distribution mean and the standard deviation was employed; while one sample t-test and one-way analysis of variance (ANOVA) were used to analyze the data for this study. The level of significance was set at $p<0.05$.

RELIABILITY AND VALIDITY

To ensure reliability, all data were collected by the lead researcher alone. Data were presented in this study with same situation and phenomenon.

To ensure the validity of this study, data were collected with the appropriate instruments in order to achieve the real objective of this study.

RESULTS

Demographic profiles of the participants

Fifty-two (52) participants were included in this study and their ages ranged from 26 to 45 years with a mean age of 34.42 and standard deviation of ±5.93 years. In the 26-30 age range, there were 16 (30.8%) participants, for the 31-35 age group there were 15 (28.9%) participants, for the 36-40 age group there were 11 (21.15%) participants and for the 41-45 age group there were 10(19.2%) participants. And this is shown in the table below:

Table 1: Shows the Demographic Data of Participants.

Age Group (Years)	Frequency	Percentage (%)	Mean	S. D
26 – 30	16	30.76	27.56	1.59
31 – 35	15	28.85	33.20	1.37
36 – 40	11	21.15	38.18	1.47
41 – 45	10	19.24	43.10	1.60
Total	**52**	**100**	**34.42**	**5.93**

EFFECT OF HORMONAL CONTRACEPTIVES ON TEAR SECRETION:

The mean total tears secretion in mm per 5 minutes in the control and experimental groups were 7.79 ± 1.97 mm/5 min and 6.08 ± 1.74 mm/5 min, respectively as shown in the table below:

Table2: Shows reduction in Tear secretion between the Control Group and Experimental Group.

Age Group (Years)	Control Group		Experimental Group	
	Mean	S. D	Mean	S. D
26 – 30	9.64	1.18	7.61	1.50
31 – 35	7.79	1.52	5.81	0.70
36 – 40	7.25	2.32	5.40	1.52
41 – 45	6.17	1.13	4.00	1.08
Total	**7.79**	**1.97**	**6.08**	**1.74**

On way anova test and independent sample T test was carried out to check if there was a significant difference between the tear secretion of the control group and experimental group, it revealed that there was a statistically significance (p=0.002). This shows that hormonal contraceptive causes a reduction in tear secretion.

Table3: showing a One Way Anova Test for Significance between the Control and Experimental Group

ANOVA

Schirmer test

	Sum of Squares	Df	Mean Square	F	Sig.
Between Groups	38.082	1	38.082	11.042	.002
Within Groups	172.433	50	3.449		
Total	210.514	51			

Table4: showing an Independent Sample T Test for Significance between the Control and Experimental Group

Independent sample test

		Levene's Test for Equality of Variances						
		F	Sig.	T	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference
Schirmer test	Equal variances assumed	1.638	.207	3.323	50	.002	1.7115	.5151
	Equal variances not assumed			3.323	49.218	.002	1.7115	.5151

EFFECT OF HORMONAL CONTRACEPTIVES WITH RESPECT TO THE TYPE OF CONTRACEPTIVES USED

Hormonal contraceptives in the study were either oral or injectables. Amongst the 26 participants in the experimental group, 19 of them were on oral hormonal contraceptives while 7 of them were on injectable hormonal contraceptives this is represented in the table below:

Table 5: A table showing The Number of Participants on Oral and Injectable Hormonal Contraceptives.

Type of contraceptive	Frequency	Percentage (%)	Cumulative percentage
Oral	19	73.1	73.1
Injectables	7	26.9	100.0
Total	26	100.0	

RELATIONSHIP BETWEEN THE TYPES OF HORMONAL CONTRACEPTIVES USED ON TEAR SECRETION

Effect of hormonal contraceptive with respect to the type of contraceptives used by the participants showed that the reduction in the tear secretion was more in participants who were using injectable hormonal contraceptives (mean 4.64 ± 1.11) than in those who were using the oral contraceptive (mean 6.61 ± 1.64). This is shown in the table 6 below:

Table 6: Shows a Summary of Reduction in Tear Secretion with Respect to The Type of Contraceptive Used by Participants.

Type of contraceptives	N	Mean	Std. Deviation
Oral	19	6.6053	1.63791
Injectables	7	4.6429	1.10733

On way anova was carried out to check if there was a significant difference between the tear secretion of participants using oral contraceptives and injectables hormonal contraceptives in the experimental group, it revealed that there was a statistically significance (p = 0.008). This shows that reduction in tear secretion was more in participants using injectables hormonal contraceptives than those using oral contraceptives. See table 7 below.

Table7: showing a One-way Anova Test for Significance between the Participants Using Oral and Injectable Hormonal Contraceptive

ANOVA

test

	Sum of Squares	Df	Mean Square	F	Sig.
Between Groups	19.700	2	19.700	8.496	.008
Within Groups	55.647	24	2.319		
Total	75.346	26			

EFFECT OF HORMONAL CONTRACEPTIVES ON TEAR SECRETION WITH RESPECT TO THE DURATION OF USE

The effect of hormonal contraceptives on tears secretion was considered with respect to duration of use of the hormonal contraceptives. The study showed there is a considerable reduction in tears secretion following an increase in the duration of use of hormonal contraceptives as shown in the tables below:

Table 8: Shows a Summary of Reduction in Tear Secretion with Respect to the Duration of Use of the Oral Contraceptive

Duration	N	Mean	Std. Deviation
1 -2 years	9	7.5556	1.58990
3 – 4 years	10	6.0000	0.84984
5 years – Above	7	4.2857	1.03510
Total	26	6.0769	1.73604

EFFECT OF HORMONAL CONTRACEPTIVES WITH RESPECT TO THE AGE GROUP OF PARTICIPANTS:

The effect of hormonal contraceptives on tears secretion was considered with respect to the age group of the participants, the study showed there is a considerable reduction in tears secretion as the age of participants increased as shown in the table below:

Table 9: Shows a Summary of Reduction in Tear Secretion with Respect to the Age.

Age Group	N	Mean	Std. Deviation
26 – 30	9	7.6111	1.49536
31 – 35	8	5.8125	0.70394
36 – 40	5	5.4000	1.51658
41 – 45	4	4.0000	1.08012
Total	26	6.0769	1.73604

DISCUSSION

The findings from this study does not agree with the findings by (5), who concluded that Injectable hormonal contraceptives had no significant effects on tear secretion ($P = 0.929$) of healthy women of childbearing age. The finding also does not agree with a study by (6), who discovered that the oral contraceptives had no effect on normal tear physiology. The differences in the findings maybe as a result of differences in the methodology employed for the purpose of this study.

The findings from this study also showed that with an increase in the age of the participants there was a corresponding reduction in the tears secretion, this may not solely be as a result of the hormonal contraceptive as findings from other studies have suggested that aging and female gender are risk factors for dry eye disease, (7).

CONCLUSION

The results from the study showed there was a reduction in tear secretion in the experimental group and the reduction in tear secretion when compared with the control group was statistically significant. There was also more reduction in tear secretion among participants using injectable hormonal contraceptives when compared to those who were using orally administered hormonal contraceptives. The type of contraceptives being used by the participant had a statistical significance on the results from the study. Age of the participants and the duration of use of the hormonal contraceptive also had a statistically significant effect on the findings from the study.

RECOMMENDATIONS OF THE STUDY

The researchers recommend that a comprehensive eye examination should be included in the routine examination of women on hormonal contraceptives.

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APPENDIX
DATA COLLECTION SHEET

	Age	Age group	Schirmer test	Group	Type of contraceptives used	Duration of use
1	26	26-30	8.5	Control	None	None
2	32	31-35	7.0	Control	None	None
3	34	31-35	6.0	Control	None	None
4	33	31-35	6.0	Control	None	None
5	27	26-30	10.0	Control	None	None
6	28	26-30	11.0	Control	None	None
7	37	36-40	5.5	Control	None	None
8	39	36-40	6.0	Control	None	None
9	40	36-40	5.0	Control	None	None
10	40	36-40	7.0	Control	None	None
11	26	26-30	9.0	Control	None	None
12	26	26-30	10.0	Control	None	None
13	42	41-45	5.5	Control	None	None
14	41	41-45	5.0	Control	None	None
15	41	41-45	5.5	Control	None	None
16	45	41-45	7.0	Control	None	None
17	30	26-30	11.0	Control	None	None
18	29	26-30	8.0	Control	None	None
19	35	31-35	8.5	Control	None	None
20	34	31-35	9.0	Control	None	None
21	32	31-35	8.0	Control	None	None
22	45	41-45	6.0	Control	None	None
23	43	41-45	8.0	Control	None	None
24	33	31-35	10.0	Control	None	None
25	39	36-40	11.0	Control	None	None
26	37	36-40	9.0	Control	None	None
27	27	26-30	6.5	Experimental	Oral	1-2 years

28	28	26-30	6.0	Experimental	Oral	1-2 years
29	29	26-30	8.0	Experimental	Oral	1-2 years
30	26	26-30	8.0	Experimental	Oral	1-2 years
31	30	26-30	9.5	Experimental	Oral	1-2 years
32	30	26-30	7.5	Experimental	Oral	1-2 years
33	27	26-30	10.0	Experimental	Oral	1-2 years
34	26	26-30	5.5	Experimental	Injectables	3-4 years
35	26	26-30	7.5	Experimental	Oral	3-4 years
36	33	31-35	5.5	Experimental	Injectables	5-Above years
37	31	31-35	7.0	Experimental	Oral	3-4 years
38	32	31-35	6.5	Experimental	Oral	3-4 years
39	34	31-35	6.0	Experimental	Oral	3-4 years
40	31	31-35	5.5	Experimental	Oral	5-Above years
41	35	31-35	5.0	Experimental	Oral	5-Above years
42	40	36-40	3.5	Experimental	Oral	5-Above years
43	34	31-35	6.0	Experimental	Oral	3-4 years
44	45	41-45	3.5	Experimental	Injectables	5-Above years
45	36	36-40	6.0	Experimental	Oral	3-4 years
46	37	36-40	4.5	Experimental	Oral	3-4 years
47	35	31-35	5.0	Experimental	Oral	1-2 years
48	37	36-40	5.5	Experimental	Injectables	3-4 years
49	38	36-40	7.5	Experimental	Oral	1-2 years
50	43	41-45	3.0	Experimental	Injectables	5-Above years
51	42	41-45	5.5	Experimental	Injectables	3-4 years
52	44	41-45	4.0	Experimental	Injectables	5-Above years