This cross sectional descriptive study was conducted in the menopausal women. Menopause as a risk factor for causing Dry eye syndrome highlighting and also studying the importance of the physiological event of to dry eye by causing reduced corneal thickness as well as alterations in eye irritation when reading or driving, ocular pain, photophobia, and alterations. This leads to a number of symptoms, including ocular surface inammation and damage, and neurosensory abnormalities play etiological roles. It is the most common cause of ocular morbidity and discomfort especially in older females causing debilitating symptoms of dryness, irritation, causing psychological comorbidity and reduced work capacity. It is the most common complaint seen by ophthalmologists making one fourth of their patients. Dry eye represents a disturbance of the lacrimal functional unit affecting tear film integrity, ocular surface health and corneal transparency thereby signicantly inuencing the quality of images projected onto the retina.

Due to a lack of uniform diagnostic criteria, different studies have reported different prevalence rates of Dry eye disease in different regions and populations. Diagnosis of Dry eye is based on a variety of objective diagnostic tests and subjective reporting of associated symptoms. In India, prevalence varying between 18.4% and 40.8% has been reported. A study from higher altitudes reported a higher prevalence of 54%.

The female sex is a significant risk factor for Dry eye disease due to the effects of sex steroids (e.g. androgens, estrogens and progesterone). Ocular tissue is also a target organ for these hormones since there are estrogen, progesterone, and androgen receptor mRNAs in ocular tissues. These hormones exert their effect possibly by inuencing gene expression through various pathways and eliciting acute responses that affect ocular surface homeostasis.

Menopause is characterized by aging and decrease in the levels of sex steroid hormones, resulting in Dry Eye Syndrome that affects the ocular surface, lacrimal glands, thereby leading to tear lm alterations. This leads to a number of symptoms, including ocular dryness, burning, foreign body sensation, redness, blurring, watering eye irritation when reading or driving, ocular pain, photophobia, and sensitivity. The loss of sex steroid hormones after menopause may lead to dry eye by causing reduced corneal thickness as well as alterations in homeostasis and in the layers of the tear lm. The present study was aimed at studying the dry eye prevalence in postmenopausal women and also studying the importance of the physiological event of Menopause as a risk factor for causing Dry eye syndrome highlighting the importance of Dry eye assessment on a regular basis in post-menopausal women.

**OBJECTIVE:** The objective was to study and compare the prevalence of Dry eye disease in pre-menopausal and post-menopausal women and emphasize the importance of Menopause in causing dry eye disease.

**METHODS AND MATERIALS:** This was a cross sectional study carried out at a tertiary care hospital. Consenting patients were randomly selected following strict diagnostic criteria to rule out the all, local, systemic and exogenous factors affecting the ocular surface and causing dry eye to exclusively study the effect of menopause on Dry eye disease. Dry eye assessment was done on 400 eyes of 200 patients divided into two groups i.e. the pre-menopausal and post-menopausal groups The symptomatic assessment of dry eye was done by administering a Dry Eye Questionnaire along with objective tests such as Tear lm break up time, Schirmer's test and Ocular surface staining performed to complete the diagnosis.

**RESULTS:** 52% patients had symptoms consistent with Dry eye disease in post menopause group compared to 36% in pre-menopausal patients. 41% eyes were diagnosed as having dry eye disease with the objective tests in post menopause group compared to 23% in control group with more eyes having mild to moderate forms compared to severe forms in both the groups. The results were statistically significant.

**KEYWORDS:** Dry Eye Disease, Menopause, Ocular Surface Staining, Schirmer’s Test, Tear Film Break Up Time.

**OBJECTIVES:**

1. **INTRODUCTION:**

Dry eye is a multifactorial disease of the ocular surface characterized by a loss of homeostasis of the tear film, and accompanied by ocular symptoms, in which tear film instability and hyperosmolarity, ocular surface inflammation and damage, and neurosensory abnormalities play etiological roles. It is the most common cause of ocular morbidity and discomfort especially in older females causing debilitating symptoms of dryness, irritation, causing psychological comorbidity and reduced work capacity. It is the most common complaint seen by ophthalmologists making one fourth of their patients. Dry eye represents a disturbance of the lacrimal functional unit affecting tear film integrity, ocular surface health and corneal transparency thereby significantly influencing the quality of images projected onto the retina.

Due to a lack of uniform diagnostic criteria, different studies have reported different prevalence rates of Dry eye disease in different regions and populations. Diagnosis of Dry eye is based on a variety of objective diagnostic tests and subjective reporting of associated symptoms. In India, prevalence varying between 18.4% and 40.8% has been reported. A study from higher altitudes reported a higher prevalence of 54%.

The female sex is a significant risk factor for Dry eye disease due to the effects of sex steroids (e.g. androgens, estrogens and progesterone). Ocular tissue is also a target organ for these hormones since there are estrogen, progesterone, and androgen receptor mRNAs in ocular tissues. These hormones exert their effect possibly by influencing gene expression through various pathways and eliciting acute responses that affect ocular surface homeostasis.

Menopause is characterized by aging and decrease in the levels of sex steroid hormones, resulting in Dry Eye Syndrome that affects the ocular surface, lacrimal glands, thereby leading to tear film alterations. This leads to a number of symptoms, including ocular dryness, burning, foreign body sensation, redness, blurring, watering, eye irritation when reading or driving, ocular pain, photophobia, and sensitivity. The loss of sex steroid hormones after menopause may lead to dry eye by causing reduced corneal thickness as well as alterations in homeostasis and in the layers of the tear film. The present study was aimed at studying the dry eye prevalence in postmenopausal women and also studying the importance of the physiological event of Menopause as a risk factor for causing Dry eye syndrome highlighting the importance of Dry eye assessment on a regular basis in post-menopausal women.

**MATERIALS AND METHODS**

This cross sectional descriptive study was conducted in the Department of Ophthalmology in a tertiary care institute in Maharashtra after approval from Institutional Ethics Committee. This study was conducted from March 2016 to October 2017 for a period of 20 months. Female Patients were selected from those visiting the outpatient department of the hospital. The patients were selected randomly and informed about the nature of the study. Informed written consent was taken from all subjects willing to participate in the study. History of present illness and symptoms, any significant past surgical or medical history, menstrual history, history of major systemic illness and personal history were thoroughly recorded.

**INCLUSION CRITERIA:**

The patients were divided in two study groups, Pre-menopausal group and post-menopausal group comprising of 100 patients each. Pre-menopausal group consisted of 100 randomly selected patients, more than 30 years in age, who hadn’t attained menopause while post-menopausal group consisted of 100 randomly selected patients, less than 65 years of age who had attained menopause for at least one year.

**EXCLUSION CRITERIA:**

Pre-Menopausal group (Group I): Female patients less than 30 years of age, Pregnant women and those on Oral contraceptive pills or any other hormonal therapy were excluded from this study.

**POST-MENOPAUSAL GROUP (GROUP II):**

Women more than 65 years of age and those on hormone replacement therapy were excluded from this group.

**BOTH GROUPS:**

Contact lens wearers, Patients having conjunctival degenerative conditions, Active Infections, Local Conditions affecting eyelids, History of Ocular Surgeries, Connective tissue or autoimmune diseases, significant medications and trauma, History of Benign or Malignant Gynaecological malignancies or hormone secreting tumours etc. were excluded from this study. The purpose of this strict exclusion criteria was to study the effect of menopause exclusively.

**EXAMINATION:**

Visual acuity was recorded with Snellen’s chart. Slit lamp examination was done to assess Eyelids, adnexa, Anterior and posterior eyelid margins, tear film, Conjunctiva (fornices, palpebral and bulbar conjunctiva), Cornea, Anterior chamber, Iris pupil and lens. The symptomatic assessment of dry eye was done by administering a Dry Eye Questionnaire based on the Standardized Patient Evaluation of Eye Dryness Questionnaire. The frequency and severity of four main symptoms were assessed - a) Dryness and Grittiness b) Irritation c) Burning d) Eye Fatigue and blurring. The frequency was rated as...
patients experiencing the symptoms – Never, sometimes, often or constant. The severity of the symptoms was reported as patients having no symptom, tolerable symptoms - not perfect, but not uncomfortable, Uncomfortable but not interfere with daily activities. Bothsomes - interfering with daily activities and Intolerable - unable to perform daily tasks.

Objective assessment of Dry eye was done with tear film break up time. Tear film break-up time less than 10 seconds was considered abnormal and Dry Eye Severity grading was done according to the DEWS classification.1 Schirmer’s test was performed to evaluate aqueous tear production. Less than 10 mm of strip wetting in 5 minutes was considered abnormal and Severity grading was done according to the DEWS classification.2 Grade 1 – Variable, Grade 2 – ≤ 10 mm/5 min, Grade 3 ≤ 5 mm/5 min, Grade 4 – ≤ 2 mm/5 min. Ocular surface staining was done to estimate surface damage in dry eye. It was performed using saline moistened Rose Bengal Ophthalmic Strip. The results were interpreted using van Bijsterveld staining system. Intensity was scored in 2 exposed conjunctival zones and cornea and a Score of 0-3 was given for each zone making a maximum score of 9. A total score of greater than or equal to 4 was taken as significant for Dry Eye Diagnosis3.

RESULTS
This study was conducted on 200 eyes of 100 pre-menopausal females (Group I) 31-46 years of age with a mean age of 38.66 and 200 eyes of 100 post-menopausal females (Group II) 47-63 years of age with a mean of 54.87 years. Subjective symptomatic assessment of Dry eye disease with dry eye questionnaire revealed 36% having symptomatic dry eye disease in Pre-menopause group as against 52% having symptomatic Dry eye disease in Post-menopause group. Dryness was the most common symptom in both the groups, 36% in pre menopause group and 52% in post menopause group followed by burning sensation and irritation. Eye Fatigue was the least encountered symptom with a frequency of 10% in pre-menopause and 32% in post menopause group. Table 1 shows the symptom profile with regards to the frequency and severity as assessed with the Dry eye questionnaire.

| Table 1: Symptomatic Assessment of Dry Eye Disease in Both Groups (in %) |

<table>
<thead>
<tr>
<th>Symptom</th>
<th>MILD (Tolerable)</th>
<th>MODERATE (Uncomfortable)</th>
<th>MODERATELY SEVERE (Bothersome)</th>
<th>SEVERE (Intolerable)</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>15</td>
<td>13</td>
<td>7</td>
<td>1</td>
<td>36</td>
</tr>
<tr>
<td></td>
<td>H</td>
<td>15</td>
<td>18</td>
<td>16</td>
<td>52</td>
</tr>
<tr>
<td>2. Irritation</td>
<td>1</td>
<td>8</td>
<td>9</td>
<td>6</td>
<td>14</td>
</tr>
<tr>
<td></td>
<td>H</td>
<td>8</td>
<td>14</td>
<td>14</td>
<td>39</td>
</tr>
<tr>
<td>3. Burning</td>
<td>1</td>
<td>12</td>
<td>10</td>
<td>6</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td>H</td>
<td>14</td>
<td>17</td>
<td>3</td>
<td>49</td>
</tr>
<tr>
<td>4. Eye Fatigue</td>
<td>1</td>
<td>6</td>
<td>2</td>
<td>2</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>H</td>
<td>14</td>
<td>10</td>
<td>6</td>
<td>32</td>
</tr>
</tbody>
</table>

**Group I – Pre-Menopause Group**

In Group I (Pre-Menopause) Tear film break up time was abnormal in 24% eyes with mild severity (≤ 10sec) in 16%, moderate (≤ 5 sec) in 7% and severe abnormality (Immediate tear film break up) in 3%. Schirmer's test was abnormal (≤ 10 mm / 5 min) in 23% eyes with Mild (≤ 10 mm / 5 min) severity in 15%, Moderate (≤ 5 mm / 5 min) in 7% and Severe (≤ 2 mm / 5 min) dry eye in 1% eyes. The Ocular surface staining score indicated damage to the ocular surface due to dry eye disease (Van bijsterveld score >4) in 16% eyes.

In Group II (Post-Menopause) Tear film break up time was abnormal in 41% eyes with mild severity (≤ 10sec) in 24%, moderate (≤ 5 sec) in 14% and severe abnormality (Immediate tear film break up) in 3%. Schirmer's test was abnormal (≤ 10 mm / 5 min) in 41% eyes with Mild (≤ 10 mm / 5 min) severity in 25%, Moderate (≤ 5 mm / 5 min) in 13% and Severe (≤ 2 mm / 5 min) dry eye in 3% eyes. The Ocular surface staining score indicated damage to the ocular surface due to dry eye disease (Van bijsterveld score >4) in 31% eyes.

**Table 2: Comparison of Dry Eye in Pre-Menopausal and Post-Menopausal Women**

<table>
<thead>
<tr>
<th>Diagnosing Modality</th>
<th>Pre-Menopausal Group I</th>
<th>Post-Menopausal Group II</th>
<th>P value</th>
<th>Remark about difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptomatic Diagnosis</td>
<td>36%</td>
<td>52%</td>
<td>0.022</td>
<td>(&lt;0.05) Significant</td>
</tr>
<tr>
<td>Tear Film Break Up Time</td>
<td>24%</td>
<td>41%</td>
<td>0.010</td>
<td>(&lt;0.05) Significant</td>
</tr>
<tr>
<td>Schirmer’s Test</td>
<td>23%</td>
<td>41%</td>
<td>0.006</td>
<td>(&lt;0.05) Significant</td>
</tr>
<tr>
<td>Ocular Surface Staining</td>
<td>16%</td>
<td>31%</td>
<td>0.022</td>
<td>(&lt;0.05) Significant</td>
</tr>
</tbody>
</table>

Using Odds ratio to find out the strength of association of Menopause with Dry Eye, the P value was found to be 0.0110 and odds ratio of 2.2006. The P value being less than 0.05 shows that the difference between the two groups is statistically significant and the odds of having Dry Eye after menopause is twice the odds of having Dry eye before menopause in women.

**DISCUSSION**

The present study was aimed at studying the Dry eye disease profile in pre and post-menopausal women and thus understanding the significant role of Menopause in causing Dry eye disease as a result of changing milieu of sex steroidal hormones in the body during this physiological phenomenon. The exclusion criteria in this study was designed carefully to exclude all the local, systemic, inflammatory, infectious and trauma related factors as well as medications which affect the ocular surface causing dry eyes so that the effect of Menopause solely could be established. Similarly, malignancies or those taking hormone replacement therapy were also not included in the present study.

Symptoms of Dry eye were seen in 36% in Group I and 52% after menopause. Dryness or grittiness was the most commonly encountered symptom, followed by burning sensation which was second most common symptom followed by soreness or irritation while eye fatigue was the least common was the least encountered. Similar trends were seen in both the groups. Ranjan et al10 too reported gritty/sandy sensation (25.4%) as the most commonly encountered dry eye symptom followed by watering of eyes (23%) and red eyes (17.8%) in their study in Western Uttar Pradesh rural based tertiary health care centre. Comparing the frequency of all the four symptoms the percentage of cases of moderately severe symptomatic dry eye was more than half the cases with mildly symptomatic dry eye disease in post-menopausal women indicating an increase in the proportion of moderately symptomatic dry eye disease. Schaumberg et al11, in their study of Prevalence of Dry Eye Syndrome Among US Women, reported that 1.0% reported experiencing dryness constantly, 5.7% often, 28.3% sometimes, and 65.0% never. Though the percentages are different, overall profile of frequency of symptoms was comparable to the present study. While assessing severity the patients mostly described their symptoms as moderate (Uncomfortable) or moderately severe (bothersome) with comparatively lesser no of patients having mild symptomatic dry eyes while Intolerable or severe forms were seen in least number of patients in post menopause group. For example, 18% patients had moderate grittiness or dryness, 16% had moderately severe dryness, 15% had mild dryness while only 3% had intolerable or severe forms of dryness while pre menopause group showed relatively milder forms. This also shows that menopause is associated with increased prevalence of moderately symptomatic dry eye disease as well as mild dry eye disease which may indicate its role in causing dry eye disease in previously normal patients or conversion of mild grades to more severe forms of the disease.

The results of Schirmer’s test and Tear film break up times show a prevalence of 41% of Dry Eye disease in Post menopause women compared to 23-24% in other group which fall within the established...
range of Dry eye prevalence by various studies in Indian population.

The mild and moderate forms were most common which emphasize that Hormonal changes might be the reason for transition of normal to dry eye and from milder to moderate forms. The least number of cases with moderately severe to sever forms of dry eye were also consistent with the fact that ocular surface staining score which represents the ocular surface damage due to tear film instability and aqueous deficiency showed significant damage in 31% which corresponds to the moderate and severe forms as diagnosed with tear film break up times and Schirmer test. Pooja Baisoya et al in their study reported 33.19% having normal, 37.87% mild, 24.68% moderate and 4.25% severely abnormal Schirmer's test values. This seems to be different then our test results, the reasons being different study populations as well as slightly different way of grading the results. Gadegone et al in their study on post-menopausal women found Dry eye prevalence rate of 37% based on Schirmer test.

An important drawback of this study is the non-availability of a comparable group as any such group will have matching difficulties. The two groups selected for this study are bound to have an age mismatch which itself is a known risk factor for Dry Eye and if same aged male patients are considered then the hormonal factors will confound the results.

**CONCLUSION**

This study shows an increase in prevalence of DED after menopause. Dry eye is a hidden disorder which could be left unnoticed for years. This study highlights the importance of early diagnosis and treatment of DED in post-menopausal women saving them from the long term ocular morbidity and future complication positively impacting their work productivity and decreasing psychological distress ultimately improving general public health.

**CONFLICT OF INTEREST:**

The authors declare that there is no conflict of interests.

**REFERENCES:**