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A Comparative Analysis of Topical Medication Verses IPL Therapy for Moderate Meibomian Gland Dysfunction

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***Abstract*:-**

- ***Aim:***

To investigate the potential efficacy of Topical medication group (0.1% preservative free Sodium Hyaluronate, Warm compression & Lid massage) and Intense Pulse Light (IPL) therapy in treating moderate Meibomian gland dysfunction (MGD).

- ***Methodology:***

The study included 135 patients with moderate MGD, randomly assigned to either the IPL group (2 sessions one week apart) or the Topical medication group (0.1% preservative-free Sodium Hyaluronate drops 6 times daily, along with warm compresses and lid massages). Baseline assessments of OSDI score, TBUT, and Schirmer I tests were conducted, with follow-ups at 1 week (only for IPL group) and 4 weeks.

- ***Result:***

Following treatment, the IPL group showed significant improvement in TBUT scores, with OD increasing from 3.90 ± 0.80 sec to 9.34 ± 0.72 sec and OS from 4.00 ± 0.79 sec to 9.63 ± 0.75 sec ($p < 0.0001$ for both). The Topical group also improved significantly, with OD increasing from 4.01 ± 0.74 sec to 7.41 ± 1.77 sec and OS from 4.22 ± 0.79 sec to 7.60 ± 2.07 sec ($p < 0.0001$). Schirmer I test scores showed no significant change in the IPL group: OD from 11.32 ± 1.97 mm to 12.03 ± 2.30 mm and OS from 11.63 ± 1.84 mm to 12.35 ± 1.70 mm (p = ns). The Topical group also had no significant changes in OD (11.25 ± 1.96 mm to 11.50 ± 1.83 mm) and OS (11.55 ± 1.77 mm to 11.63 ± 1.72 mm) (p = ns). Both groups had significantly reduced OSDI scores, with the IPL group improving more (29.34 ± 2.28 to 11.39 ± 4.81) than the Topical group (28.68 ± 2.57 to 17.70 ± 6.19; $p < 0.0001$).

- ***Conclusion:***

Both treatments improved MGD-related dry eye symptoms, with IPL therapy showing greater clinical benefits in alleviating symptoms, increasing tear film stability, and improving Meibomian gland function in patients with moderate MGD.

Keywords:- *Meibomian Gland Dysfunction; Dry Eye Disease; Schirmer's Test; Tear Break Up Time; OSDI Questionnaire; IPL Therapy; Sodium Hyaluronate.*

I. INTRODUCTION

A. Dry Eye Disease

According to the DEWS convention, dry eye disease (DED) "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." [1]

The tear film is a complex multi-layered structure essential for eye health. It comprises;

- Lipid layer
- Aqueous layer
- Mucin layer

An outermost lipid layer is secreted by the meibomian glands, this layer acts as a barrier, minimizing the evaporation of the underlying aqueous layer and stabilizing the tear film.

A middle aqueous layer is produced by the lacrimal glands, this layer is the most abundant component. It provides essential nutrients, maintains a balanced salt concentration (osmolarity), and contains antimicrobial substances to protect the eye

An innermost mucin layer is secreted by goblet cells, this layer adheres directly to the eye's surface. It serves as a lubricant, enhancing the spread of the tear film and reducing friction between the eyelid and the cornea. Additionally, it helps to maintain a hydrophilic surface on the eye, promoting tear film stability.

B. Meibomian Gland Dysfunction

Meibomian gland dysfunction (MGD) is a leading cause of dry eye syndrome.[2]

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Meibomian gland dysfunction (MGD) is a chronic, diffuse abnormality of the meibomian glands, commonly characterized by terminal duct obstruction and/or qualitative/quantitative changes in the glandular secretion. This may result in alteration of the tear film, symptoms of eye irritation, clinically apparent inflammation, and ocular surface disease.[3]

As one of the most common disorders encountered in ophthalmic clinics, the prevalence of MGD ranges from 3.5% to 70% worldwide.[4]

Current treatments for MGD often involve a combination of lifestyle modifications, warm compresses, lid hygiene, and occasionally, oral medications. However, the effectiveness of these treatments can vary, and there is a need for more effective therapeutic options.

C. Warm Compression And Lid Massage

Warm compresses (WC) are considered the first line of treatment for MGD.[5] Eyelid-warming therapies can be expected to improve MG secretion by melting the pathologically altered meibomian lipids. The warming can be achieved by many diverse means, including simple warm compresses (e.g., hot wet towel, heated rice bag) or devices such as infrared or hot air sources. Properly performing lid massage may help the patient's therapy; proper instruction to the patient is therefore necessary.[6]

D. Topical Sodium Hyaluronate

Topical sodium hyaluronate (SH) ophthalmic drops (preferably preservative free) have emerged as a first-line treatment of choice for DED. Hyaluronic acid (HY) is widely used today and has been shown to result in both subjective and objective improvement in DED subjects.[7]

E. Recent Therapies

Recent therapeutic approaches for Meibomian Gland Dysfunction (MGD) are designed to improve the quality and quantity of the natural oils produced by the eyelids. These therapies often involve the application of heat to liquefy thickened oil and either manually or automatically express it from the glands. Examples of such treatments include Lipi Flow, iLUX MGD, Tear Care, and Intense Pulsed Light (IPL).

Intense Pulsed Light (IPL) therapy is a relatively new treatment option that has shown promise in improving symptoms. IPL delivers pulses of light to the eyelid margin, targeting the Meibomian glands. The mechanism is thought to involve reducing inflammation, improving gland function and enhancing meibum quality.

Intense pulsed light (IPL), originally developed for use in dermatology, was introduced for treating MGD in 2015. The IPL device, also referred to as flashlamp therapy, is a light-emitting system that irradiates filtered polychromatic broad-bandwidth wavelengths with varying pulse durations for selective thermal damage of the target.[8]

IPL produced heat that was transferred to the thin periocular skin of the eyelid, which allowed the softening of meibum and melted pathologically dysfunctional secretions. Plugging of Meibomian gland orifices would therefore be ameliorated.[9]

This study is hospital based randomised, prospective and comparative study aimed to investigate the potential efficacy of Topical medication group (0.1% preservative free Sodium Hyaluronate, Warm compression & Lid massage) and Intense Pulse Light(IPL) therapy (2 sessions on Day 1,Day 7) in treating moderate meibomian gland dysfunction(MGD) by studying OSDI score, Schirmer I test and Tear Break-Up Time (TBUT) measured before both treatment and their changes after treatment.

II. AIM AND OBJECTIVE

➢ *Aim:*

To investigate the potential efficacy of Topical medication group (0.1% preservative free Sodium Hyaluronate, Warm compression & Lid massage) and Intense Pulse Light (IPL) therapy in treating moderate meibomian gland dysfunction (MGD)

➢ *Objectives:*

- To assess the baseline OSDI score, Schirmer and TBUT values in patients with before Topical medication group and IPL therapy.
- To re-evaluate OSDI score, Schirmer and TBUT values in participants after completing Topical medication group and IPL therapy (2 sessions) after 1 month post treatment.
- To compare post-treatment OSDI score, Schirmer and TBUT values with baseline values to determine any significant changes & compare both treatment modalities.

III. METHODOLOGY

A total of 135 patients who visited cornea department of tertiary eye hospital, M M Joshi Eye Hospital Gokul Road, Hubli, Karnataka, India was taken. It was a hospital based randomized, prospective and comparative study.

➢ *Study design:* Prospective, randomized comparative study.
➢ *Study place:* M M Joshi Eye Institute, Hubli.
➢ *Data collection technique:* Based on severity of MGD, inclusion and exclusion criteria subjects were enrolled in this study.

➢ *Inclusion criteria:*

- Stage III Meibomian gland dysfunction
- OSDI score between 23 and 32.
- Age between 21 and 60 years.
- Dry eye symptoms (dryness, foreign body sensation, burning, tearing) for over 3 months and current diagnosis of MGD.

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- Fitzpatrick skin type I-IV (IPL therapy only).

➢ *Exclusion criteria:*

- Active infectious blepharitis or ocular infection.
- Obvious abnormalities in eyelid margins or severe ocular surface abnormalities (other than MGD).
- Uncontrolled systemic conditions or use of systemic medications affecting the tear film.
- Pigmented lesions in the treatment area (IPL therapy only).
- Fitzpatrick skin type V-VI (IPL therapy only).
- Pregnancy and lactation.
- Patients unable or unwilling to provide informed consent.

➢ *Materials Required:*

- Log MAR chart
- Reduced Snellen near visual chart
- Streak Retinoscope (Welch Allyn)
- Schirmer tear strips (Care Group)
- Paracaine 0.5% eye drops
- Fluorescein strips (Care group)
- Smart watch (Noise colorfit pro 2
- Slit lamp biomicroscope (Zeiss)
- Ocular surface disease index questionnaires (Allergan)

➢ *Study Parameter:*

This study was conducted on individuals who presented to the cornea department of M.M. Joshi Eye Hospital, a tertiary care eye hospital located in Gokul Road, Hubli, Karnataka, India. Following informed consent and a thorough explanation of the study's purpose and procedures, demographic data was collected from each participant. Visual acuity assessments were conducted, including both distance visual acuity using a LogMAR chart and near visual acuity using a reduced Snellen chart. Objective refraction was performed using Retinoscopy, followed by subjective refraction. A comprehensive slit-lamp examination was conducted to identify any ocular pathologies. The Ocular Surface Disease Index (OSDI) questionnaire was administered to assess the severity of dry eye disease in each participant. Only individuals who met the predefined inclusion criteria were included in the study.

Tear Breakup Time (TBUT) was performed to assess tear film stability, followed by the Schirmer I test to measure basal and reflex tear secretion.

Subjects diagnosed with Meibomian Gland Dysfunction (MGD) comprised the study population. They were divided into two groups (Fig.1):

- Group 1 (IPL group) received two sessions of Intense Pulsed Light (IPL) treatment.
- Group 2 (Topical medication group) was treated with Sodium Hyaluronate eye drops six times daily, in conjunction with warm compresses and lid massages for one month.

IV. RESULT

A total of 135 patients were stage III MGD were enrolled in our study, including 62 patients from group 1 and 73 patients from group 2. All subjects from both groups were assessed one-month after their respective treatments. All Pre and Post treatment parameters were considered, and the analysis was performed using a paired t-test using SPSS software.

Table 1. Gender Distribution in Group-1 and Group-2

Groups	Gender	Number	Percentage
Group 1	Male	38	61.30%
	Female	24	38.70%
Group 2	Male	33	45.20%
	Female	40	54.80%

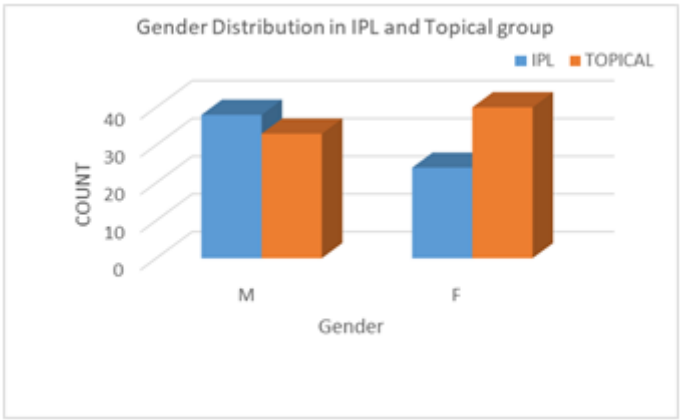

Fig.1; Gender Distribution in IPL and Topical Group

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A. OSDI Score

The Pre and Post treatment evaluation in Group-1 showed significant increase in OSDI score with p value <0.0001. Similar increase in OSDI score is observed in Group-2 with p value <0.0001.

Table 2 A. Pre and Post Mean and p-value of OSDI Score in IPL Group.

IPL		
Pre-Mean ± SD (Day 0)	**Post-Mean ± SD (Day 30)**	**p value**
29.34 ± 2.28	11.39 ± 4.81	<0.0001

Table 2 B . Pre and Post Mean and p-value of OSDI Score in TOPICAL Group.

TOPICAL		
Pre-Mean ± SD (Day 0)	**Post-Mean ± SD (Day 30)**	**p value**
28.68 ± 2.57	17.70 ± 6.19	<0.0001

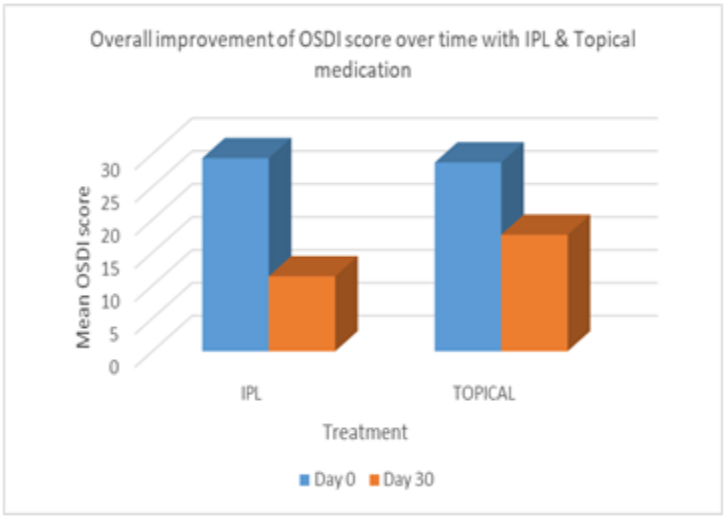

Fig.2. Pre and Post Mean Values of OSDI Score in IPL group and Topical group.

B. TBUT

The Pre and Post treatment evaluation in Group-1 showed significant increase in TBUT values in both eyes with p value <0.0001 in right eye and <0.0001 in left eye. Similar increase in TBUT is observed in Group-2 with p value <0.0001 in right eye and <0.0001 in left eye.

Table 3 A. Pre and Post Mean and p-value of TBUT Score in IPL Group.

	IPL		
	Pre-Mean ± SD (Day 0)	**Post-Mean ± SD (Day 30)**	**p value**
OD	3.90 ± 0.80	9.34 ± 0.72	<0.0001
OS	4.00 ± 0.79	9.63 ± 0.75	<0.0001

Table 3 B. Pre and Post Mean and p-value of TBUT Score in TOPICAL Group.

	TOPICAL		
	Pre-Mean ± SD (Day 0)	**Post-Mean ± SD (Day 30)**	**p value**
OD	4.01 ± 0.74	7.41 ± 1.77	<0.0001
OS	4.22 ± 0.79	7.60 ± 2.07	<0.0001

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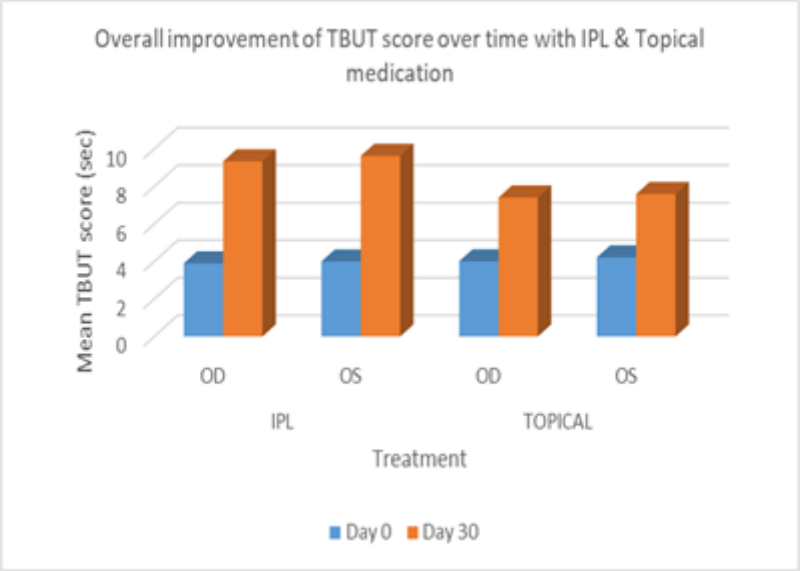

Fig.3. Pre and post mean values of TBUT Score in IPL group and Topical group.

C. Schirmer I test

The Pre and Post treatment evaluation in Group-1 showed no significant difference in Schirmer values in both eyes with p value ns in right eye and ns in left eye. Similar difference in Schirmer is observed in Group-2 with p value ns in right eye and ns in left eye.

Table 4 A. Pre and Post Mean and p-value of Schirmer Score in IPL Group.

	IPL		
	Pre-Mean ± SD (Day 0)	**Post-Mean ± SD (Day 30)**	**p value**
OD	11.32 ± 1.97	12.03 ± 2.30	ns
OS	11.63 ± 1.84	12.35 ± 1.70	ns

Table 4 B. Pre and Post Mean and p-value of Schirmer Score in TOPICAL Group.

	TOPICAL		
	Pre-Mean ± SD (Day 0)	**Post-Mean ± SD (Day 30)**	**p value**
OD	11.25 ± 1.96	11.50 ± 1.83	ns
OS	11.55 ± 1.77	11.62 ± 1.72	ns

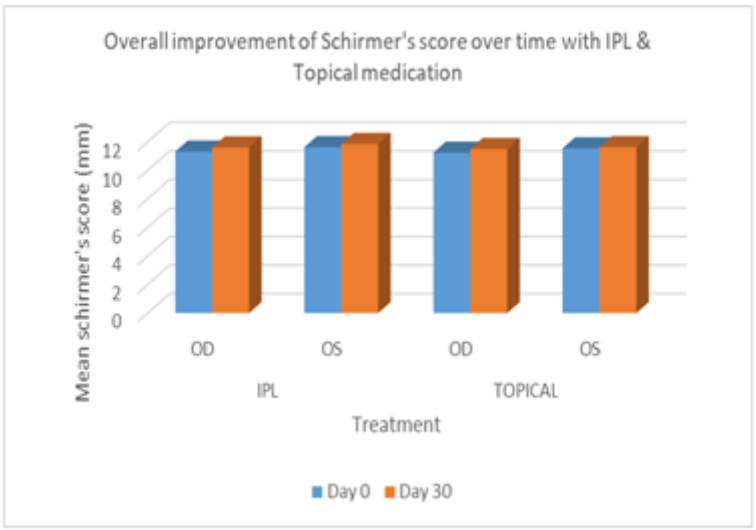

Fig.4. Pre and Post mean values of Schirmer Score in IPL group and Topical group.

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V. DISCUSSION

As of now, several studies have been carried out to assess the impact of topical drug groups and IPL on patients with MGD. There isn't any specific comparative study to examine how effective these two are in comparison to one another on moderate MGD, despite the fact that the majority of studies have shown them to be effective both separately and when compared to other possibilities.

This study revealed that both treatment groups showed improvement in TBUT and OSDI score but the result of Sit showed no significant difference.

Similar studies have shown that patients treated with the IPL Therapy experienced improvements in TBUT and OSDI scores, as indicated in studies[2, 4, 8, 9, 10, 11, 12]. These findings highlight the potential of IPL as a therapeutic modality for MGD, by addressing tear film instability and ocular surface inflammation. However, the studies[8,10,11] also found that IPL Therapy did not show any appreciable changes in their Schirmer levels. It could be that MGD is a significant contributor to evaporative dry eye, characterized primarily by alterations in tear film quality rather than tear production.

A study on Sodium Hyaluronate[13] demonstrated similar results, showing improvements in TBUT for patients.

Improvements in the OSDI score, TBUT, and also showed statistically significant change in Sit of patients given Sodium hyaluronate was demonstrated by P Prabhasawat et al.[14]

Furthermore, our result demonstrated that men showed slightly greater improvement in tear stability (TBUT) and average production (SIt). This is due to hormonal influence in women such as: Hormone fluctuations during the menstrual cycle might impact the stability and production of tears. Menopause – Due to decrease in estrogen levels leads to dry eye symptoms in some women. These Hormonal fluctuations throughout a woman's lifespan can significantly influence tear production and quality.

VI. CONCLUSION

Both treatment groups showed improvement in signs and symptoms of MGD-related dry eye symptoms. Additionally, IPL Therapy showed more clinical benefits and effectiveness over topical medication group in alleviating symptoms, increasing tear film stability and Improving Meibomian gland function in moderate Meibomian gland dysfunction patients.

VII. LIMITATIONS AND FUTURE SCOPE

The relatively small sample size may limit the generalizability of the findings to a larger population. The follow-up period of 30 days may not be sufficient to fully assess the long-term effectiveness of both treatments.

Conduct a larger, multicenter trial to confirm the findings and improve generalizability. Investigate the long-term efficacy of both IPL and topical medication for MGD management. Explore the potential benefits of combining IPL therapy with topical medications for synergistic effects.

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