

A Comparative Evaluation of Tear Film Dynamics and Ocular Surface Integrity in Gestational Diabetes Mellitus and Healthy Pregnant Controls

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Abstract

Purpose: To determine the prevalence of dry eye disease in pregnant women with gestational diabetes mellitus (GDM) and to compare ocular surface and tear film parameters with age-matched nondiabetic pregnant women.

Methods: This prospective comparative study included 90 pregnant women (45 with GDM and 45 age-matched nondiabetic controls) attending the outpatient departments of Ophthalmology and Obstetrics & Gynaecology. Ocular surface evaluation comprised Schirmer's test 1 and 2, tear break-up time (TBUT), Ocular Surface Disease Index (OSDI) questionnaire, and corneal fluorescein staining score. Dilated fundus examination was performed to exclude diabetic retinopathy. Statistical analysis was performed using independent t-test and chi-square test. A p-value < 0.05 was considered significant.

Results: Mean Schirmer's test 1 and 2 values were significantly lower in the GDM group compared with controls ($p < 0.001$ and $p = 0.046$, respectively). OSDI scores were significantly higher in women with GDM ($p = 0.018$). TBUT values were lower in the GDM group, but the difference did not reach statistical significance ($p = 0.125$). Corneal fluorescein staining scores were higher in the GDM group. No participant showed diabetic retinopathy changes.

Conclusion: Gestational diabetes mellitus is associated with reduced aqueous tear secretion and higher symptom scores on the OSDI, indicating an increased risk of dry eye disease. Routine ocular surface evaluation in pregnant women with GDM may facilitate early detection and timely management.

Keywords

Gestational diabetes mellitus; Dry eye disease; Tear film; Schirmer's test; Ocular Surface Disease Index; Pregnancy

INTRODUCTION

Pregnancy is accompanied by profound hormonal, metabolic, and immunological changes that can affect the ocular surface and tear film homeostasis. Fluctuations in estrogen and progesterone levels have been linked to altered lacrimal gland function, reduced tear secretion, and an increased prevalence of dry eye symptoms, particularly in the second and third trimesters [6,9,10]. Concurrently, gestational diabetes mellitus (GDM), defined as glucose intolerance first recognized

during pregnancy, introduces additional systemic microvascular, inflammatory, and neuropathic stressors that may further compromise ocular surface integrity [1–3,11].

Diabetes mellitus is a well-established risk factor for dry eye disease through multiple mechanisms, including autonomic neuropathy of the lacrimal gland, reduced corneal sensitivity, chronic low-grade inflammation, oxidative stress, and meibomian gland dysfunction [4,5,7,8,12–16]. Recent systematic reviews and meta-analyses have confirmed that type 2 diabetes is strongly associated with shorter tear break-up times, lower Schirmer's values, reduced tear meniscus height, and higher Ocular Surface Disease Index (OSDI) scores [7,12]. Hyperglycemia itself has been shown to impair tear film stability and exacerbate meibomian gland dysfunction [13,15].

Although several studies have examined ocular surface changes in GDM, data specifically comparing pregnant women with and without GDM remain limited [1–3]. Singh and Savur reported significantly reduced basal tear secretion (Schirmer's II) in GDM [1]. Kan et al. and Susmitha et al. similarly observed impaired tear film parameters and elevated symptom scores in GDM cohorts [2,3]. Understanding whether GDM independently exacerbates pregnancy-related ocular surface changes is clinically relevant, as early detection may improve maternal comfort and quality of life during gestation.

The present prospective comparative study was therefore undertaken to evaluate tear film dynamics and ocular surface integrity in pregnant women with GDM versus age-matched nondiabetic pregnant controls, using standardized clinical tests (Schirmer's tests 1 and 2, tear break-up time, OSDI questionnaire, and corneal fluorescein staining) while excluding the presence of diabetic retinopathy.

MATERIALS AND METHODS

Study design and setting

This prospective, comparative, single-center study was conducted over a 12-month period in the Departments of Ophthalmology and Obstetrics & Gynaecology at Naraina Medical College & Research Center, Kanpur Nagar, Uttar Pradesh, India. The protocol was reviewed and approved by the Institutional Ethics Committee (Approval Letter No. NMC&RC-Cell/2022/17, dated 12 January 2022) and adhered to the tenets of the Declaration of Helsinki. Written informed consent was obtained from every participant after a full explanation of the study procedures.

Study population

Ninety consecutive pregnant women between 24 and 32 weeks of gestation were enrolled and allocated into two equal groups:

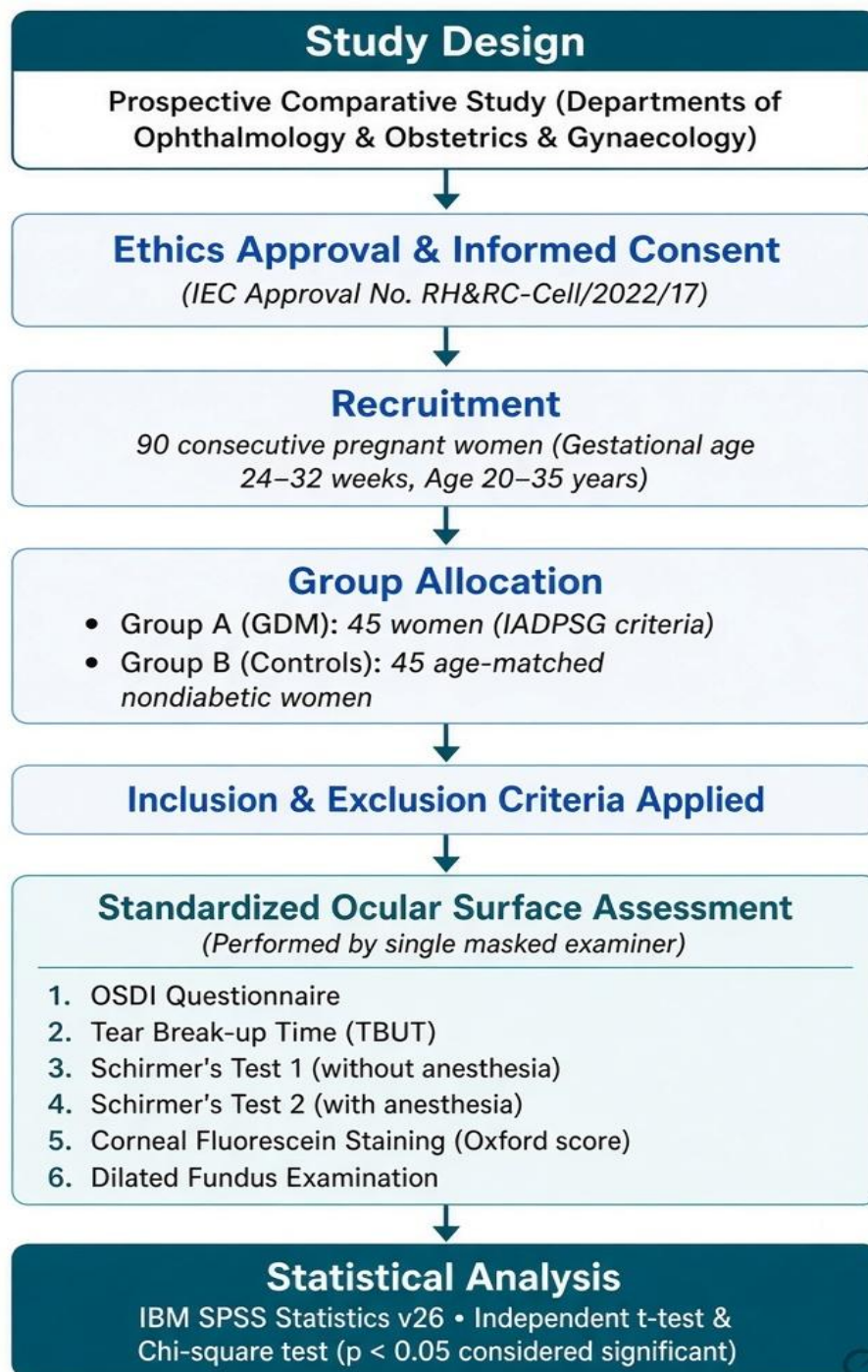
- Group A (GDM): 45 women newly diagnosed with gestational diabetes mellitus according to the International Association of Diabetes and Pregnancy Study Groups (IADPSG) criteria.
- Group B (Controls): 45 age-matched pregnant women with documented normal glucose tolerance.

Inclusion criteria

- Singleton pregnancy
- Gestational age 24–32 weeks (confirmed by last menstrual period and/or first-trimester ultrasound)
- Maternal age 20–35 years

Exclusion criteria

- Pre-existing type 1 or type 2 diabetes mellitus
- History of ocular surgery, trauma, or laser treatment
- Contact-lens wear or use of topical ocular medications within the preceding three months
- Systemic autoimmune disease or connective-tissue disorders known to affect the ocular surface
- Current systemic medications that can reduce tear production (e.g., antihistamines, antidepressants, diuretics)
- Any clinically detectable diabetic retinopathy on dilated fundus examination



Ocular-surface evaluation

All assessments were performed by a single examiner who was masked to group allocation, in a standardized examination room with controlled temperature and humidity. The sequence of tests was fixed to minimize inter-test interference:

1. **Ocular Surface Disease Index (OSDI) questionnaire**
Validated 12-item questionnaire assessing ocular symptoms, visual function, and environmental triggers. Scores range from 0 to 100; a score ≥ 13 was defined as symptomatic dry eye. Severity categories were classified as normal (0–12), mild (13–22), moderate (23–32), and severe (≥ 33).
2. **Tear break-up time (TBUT)**
After instillation of a single drop of 2 % fluorescein, the participant was instructed to blink several times and then keep the eyes open. The interval between the last blink and the appearance of the first dry spot was measured under cobalt-blue illumination with a slit-lamp. Three consecutive readings were averaged; a value < 10 seconds was considered abnormal.
3. **Schirmer's test 1 (without anesthesia)**
A standard Whatman No. 41 filter-paper strip (5×35 mm) was placed in the lower fornix at the junction of the middle and lateral thirds. The participant closed the eyes gently for 5 minutes. Wetting length was recorded in millimeters.
4. **Schirmer's test 2 (with topical anesthesia)**
After instillation of 0.5 % proparacaine hydrochloride and blotting of residual fluid, the same strip technique was repeated to measure basal tear secretion.
5. **Corneal fluorescein staining**
After TBUT measurement, residual fluorescein staining of the cornea was graded according to the Oxford scheme (0–5) under cobalt-blue light.
6. **Dilated fundus examination**
After pharmacological mydriasis, indirect ophthalmoscopy was performed to exclude any diabetic retinopathy changes.

Statistical analysis

Data were entered into a spreadsheet and analyzed with IBM SPSS Statistics version 26. Continuous variables are presented as mean $\pm$ standard deviation. Independent-samples t-tests were used to compare means between the GDM and control groups. Categorical variables were compared with the chi-square test or Fisher's exact test as appropriate. A two-tailed p-value < 0.05 was considered statistically significant.

RESULTS

The two groups were comparable with respect to baseline demographic and clinical characteristics (Table 1). Mean age and gestational age showed no statistically significant difference between the groups ($p = 0.48$ and $p = 0.42$, respectively).

Table 1: Demographic and clinical characteristics of the study population

Parameter	GDM (n=45)	Controls (n=45)	p-value
Mean age (years)	28.4 $\pm$ 3.6	27.9 $\pm$ 3.4	0.48
Gestational age (weeks)	28.1 $\pm$ 2.3	27.7 $\pm$ 2.5	0.42
Primigravida, n (%)	19 (42.2%)	21 (46.7%)	0.67
Mean BMI (kg/m ²)	27.8 $\pm$ 3.1	26.4 $\pm$ 2.9	0.03
Family history of diabetes	14 (31.1%)	6 (13.3%)	0.04

Mean Schirmer's test 1 values were significantly lower in the GDM group (12.8 ± 4.1 mm) compared with controls (17.6 ± 3.9 mm) ($p < 0.001$). Schirmer's test 2 values were also significantly reduced in the GDM group (8.9 ± 3.2 mm vs 10.7 ± 3.5 mm; $p = 0.046$). Mean TBUT was lower in the GDM group (9.4 ± 2.8 seconds) than in controls (10.6 ± 3.1 seconds), but the difference was not statistically significant ($p = 0.125$). Mean OSDI scores were significantly higher in women with GDM (18.7 ± 9.4) compared with controls (13.2 ± 7.8) ($p = 0.018$). Corneal fluorescein staining scores were higher in the GDM group (mean Oxford score 1.4 ± 0.9) than in controls (0.8 ± 0.7) ($p = 0.003$) (Table 2).

Table 2: Comparison of ocular surface and tear film parameters between GDM and control groups

Parameter	GDM (n=45)	Controls (n=45)	p-value
Schirmer's 1 (mm)	12.8 ± 4.1	17.6 ± 3.9	<0.001
Schirmer's 2 (mm)	8.9 ± 3.2	10.7 ± 3.5	0.046
TBUT (seconds)	9.4 ± 2.8	10.6 ± 3.1	0.125
OSDI score	18.7 ± 9.4	13.2 ± 7.8	0.018
Oxford staining score	1.4 ± 0.9	0.8 ± 0.7	0.003

The proportion of participants with symptomatic dry eye (OSDI ≥ 13) was significantly higher in the GDM group (62.2%) than in controls (37.8%) ($p = 0.021$). Distribution of OSDI severity categories is shown in Table 3.

Table 3: Distribution of OSDI severity categorie

OSDI Category	GDM (n=45)	Controls (n=45)	p-value
Normal (0–12)	17 (37.8%)	28 (62.2%)	0.021
Mild (13–22)	16 (35.6%)	12 (26.7%)	
Moderate (23–32)	8 (17.8%)	4 (8.9%)	
Severe (≥ 33)	4 (8.9%)	1 (2.2%)	

No participant in either group demonstrated diabetic retinopathy on dilated fundus examination.

Figure 1 – Pie Chart

Proportion of participants with symptomatic dry eye (OSDI ≥ 13)

- **GDM Group:** 62.2% Symptomatic | 37.8% Normal
- **Control Group:** 37.8% Symptomatic | 62.2% Normal

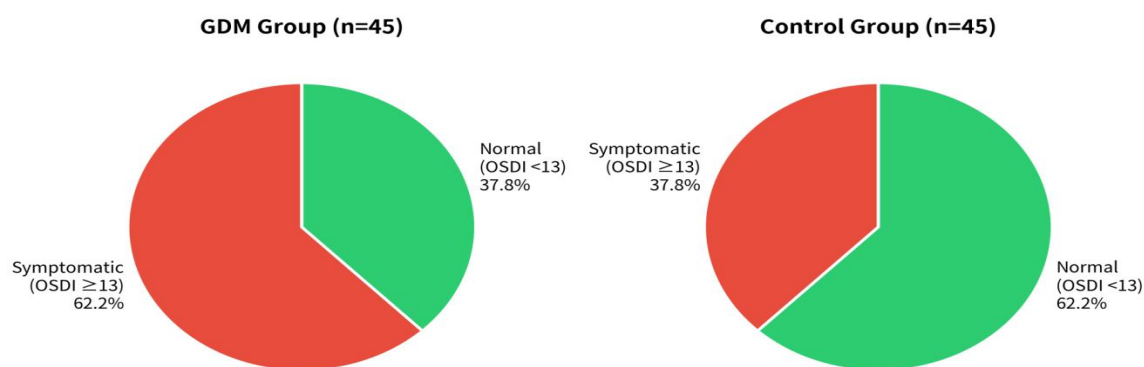
Figure 1: Proportion of Participants with Symptomatic Dry Eye (OSDI ≥ 13)

Figure 1 (Pie Chart): Proportion of participants with symptomatic dry eye (OSDI ≥ 13) in GDM group versus control group.
(GDM: 62.2% symptomatic; Controls: 37.8% symptomatic)

Figure 2 – Bar Graph

Comparison of mean values of Schirmer's test 1, Schirmer's test 2, TBUT and OSDI score

- Red bars = GDM group
- Blue bars = Control group
- Error bars = Standard deviation
- Significance markers: *** $p < 0.001$, * $p < 0.05$, ns = not significant

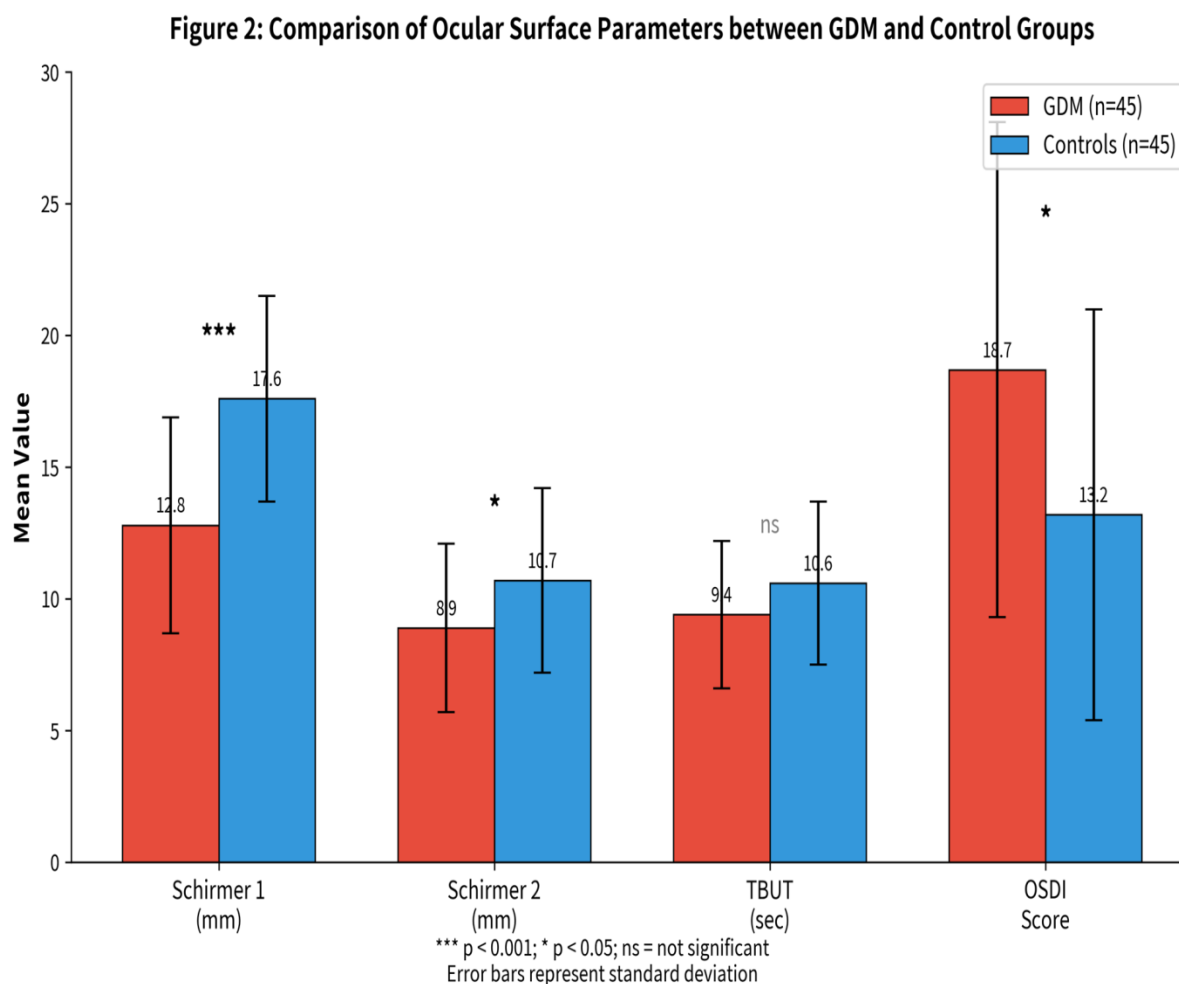


Figure 2 (Bar Graph): Comparison of mean values of Schirmer's test 1, Schirmer's test 2, TBUT, and OSDI score between GDM and control groups. (Error bars represent standard deviation. Significant differences are marked with asterisks: *** p < 0.001, * p < 0.05)

DISCUSSION

The present prospective comparative study demonstrates that pregnant women with gestational diabetes mellitus exhibit significantly impaired aqueous tear secretion and higher ocular surface symptom burden compared with age-matched nondiabetic pregnant controls. These findings reinforce and extend previous observations reported by Singh and Savur, Kan et al., and Susmitha et al. [1–3].

Schirmer's test 1 and Schirmer's test 2 values were both significantly lower in the GDM group, indicating a reduction in both reflex and basal tear secretion. This suggests that GDM exerts an additional detrimental effect on lacrimal gland function beyond the physiological changes of pregnancy alone. Pregnancy itself is associated with elevated estrogen and progesterone levels that can alter the lacrimal functional unit [6,9,10]. When superimposed on the metabolic stress of GDM—characterized by insulin resistance, low-grade systemic inflammation, and early microvascular changes—the net result appears to be clinically measurable aqueous deficiency [1,7,12].

Although TBUT was numerically lower in the GDM group, the difference did not reach statistical significance. This pattern suggests that the predominant mechanism in this cohort may be aqueous-

deficient rather than purely evaporative dry eye. Similar findings have been reported in non-pregnant diabetic populations, where Schirmer values are more consistently reduced than TBUT [4,5,7]. Recent systematic reviews and meta-analyses have confirmed that type 2 diabetes is strongly associated with reduced tear secretion, shorter tear break-up times, and elevated OSDI scores [7,12]. Hyperglycemia has also been linked to meibomian gland dysfunction and altered tear film lipid layer [13,15].

The significantly higher mean OSDI scores and the greater proportion of women with OSDI ≥ 13 in the GDM group indicate that the objective reductions in tear secretion translate into meaningful patient-reported symptoms. The distribution of OSDI severity categories further shows a clear shift toward mild, moderate, and severe symptomatic dry eye among women with GDM (Table 3 and Figure 1). This is clinically important because untreated dry eye can reduce quality of life, interfere with visual tasks, and potentially affect adherence to prenatal care.

Corneal fluorescein staining scores were also higher in the GDM group, supporting the presence of early ocular surface epithelial compromise. Importantly, no participant demonstrated diabetic retinopathy. This observation is consistent with emerging evidence that subclinical ocular surface and neurovascular alterations can precede clinically detectable retinal microvascular disease in GDM [11]. Molecular studies have highlighted oxidative stress, inflammatory cytokine upregulation, autonomic neuropathy, and microvascular injury to the lacrimal gland as key pathogenic pathways [8,14,16].

Taken together, the present findings suggest that GDM acts as an independent risk factor for dry eye disease during pregnancy. Simple, non-invasive tests such as Schirmer's test, TBUT, OSDI questionnaire, and fluorescein staining can identify affected women early. Incorporation of routine ocular surface evaluation into antenatal care protocols for women with GDM may allow timely initiation of lubricating therapy and improve maternal comfort during pregnancy.

Limitations

The single-center design and relatively modest sample size limit the generalizability of the results. Meibomian gland morphology and non-invasive tear film parameters (such as non-invasive TBUT and tear meniscus height) were not assessed. Longitudinal follow-up after delivery was not performed; therefore, the reversibility of these changes postpartum remains unknown. Future multicenter studies with larger cohorts, advanced ocular surface imaging, and postpartum assessment are warranted.

CONCLUSION

Gestational diabetes mellitus is associated with significantly reduced tear secretion and higher OSDI scores in pregnant women, indicating an increased risk of dry eye disease. Incorporation of simple ocular surface evaluation into routine antenatal care for women with GDM may facilitate early detection and management.

DECLARATIONS

Ethics approval and consent to participate

The study protocol was reviewed and approved by the Institutional Ethics Committee of Naraina Medical College & Research Center, Kanpur Nagar, Uttar Pradesh, India. The study was conducted in accordance with the ethical principles of the Declaration of Helsinki. Written informed consent was obtained from all participants after a full explanation of the study procedures.

Consent for publication

Not applicable. No individual patient data, images, or identifiable information are presented in this manuscript.

Availability of data and materials

The datasets generated and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

Ms. Sanjana Gupta, Prof.(Dr.)Himanshu Tripathi & Dr. Nayab Ishrat contributed to the conception and design of the study, data collection, analysis and drafting of the manuscript. Dr.Namrata Srivastava supervised the work, critically revised the manuscript for important intellectual content, and approved the final version. All authors read and approved the final manuscript.

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