Ophthalmol Ther (2023) 12:281–291
https://doi.org/10.1007/s40123-022-00610-y

ORIGINAL RESEARCH

The Effect of Meibomian Gland Dysfunction on Laser-Assisted In Situ Keratomileusis in Asymptomatic Patients

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Received: September 5, 2022 / Accepted: October 28, 2022 / Published online: November 8, 2022

ABSTRACT

Introduction: To evaluate the impact of asymptomatic meibomian gland dysfunction (MGD) on laser-assisted in situ keratomileusis (LASIK) outcomes and dry eye signs and symptoms.
Methods: A retrospective analysis of patients who underwent LASIK surgery between July 2017 and February 2018 at Care Vision Refractive Clinic, Tel Aviv, Israel, was done. Patients were divided into those who had preoperative asymptomatic significant MGD (MGD group) and those who did not have preoperative significant MGD (control group). Outcomes were the postoperative presence of punctate epithelial erosions, dry eye symptoms, the number of postoperative visits as a measure of adverse events, visual acuity, spherical equivalent, safety index, efficacy index, and the type of refractive error (myopia or hyperopia).
Results: A total of 497 eyes were included in this study. Both groups had similar rates of punctate epithelial erosions, 30 (12.9%)

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Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s40123-022-00610-y.

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patients vs. 39 patients (14.8%) ($p = 0.31$); postoperative complaints of dryness, 75 patients (32.3%) vs. 90 patients (34.2%) ($p = 0.36$); and postoperative number of visits, 3.15 ± 0.75 vs. 3.12 ± 0.54 ($p = 0.59$). Uncorrected visual acuity (logMAR) at 1 month (0.026 ± 0.09 vs. 0.026 ± 0.17, $p = 0.99$) after surgery was similar in both groups. Mean spherical equivalent was 0.03 ± 0.17 and -0.03 ± 0.18 ($p = 0.99$) in both groups. Safety index was 1.024 ± 0.06 in the clinically significant MGD group and 1.029 ± 0.07 in the control group ($p = 0.45$). Efficacy index was also similar in both groups (0.966 ± 0.155 and 0.979 ± 0.14, respectively, $p = 0.31$). No differences were found between patients with myopia and hyperopia.

Conclusions: Patients with preoperative asymptomatic MGD have similar LASIK outcomes to patients without preoperative asymptomatic MGD. Accordingly, no preoperative MGD treatment or special caution is needed in these cases.

Keywords: Dry eye; Laser-assisted in situ keratomileusis; LASIK; Meibomian gland dysfunction

Key Summary Points

It is not known whether patients with asymptomatic dry eye-related findings, such as meibomian gland dysfunction (MGD), are at risk for inferior laser-assisted in situ keratomileusis (LASIK) outcomes and increased risk of postoperative dry eye signs and symptoms.

In this study, clinically significant asymptomatic preoperative MGD was not found to have a significant impact on LASIK outcomes, nor on postoperative dry eye complaints.

Probably, before LASIK, no specific treatment or special caution is needed in cases of clinically significant asymptomatic preoperative MGD.

INTRODUCTION

Meibomian gland dysfunction (MGD) describes a functional abnormality of the meibomian glands and it is one of the most common disorders encountered in ophthalmic practice [1, 2]. Meibomian glands secrete meibum, a compound made of polar lipids (phospholipids) which provides tear film stability, and organic matter and nonpolar lipids (cholesterol, wax esters, and cholesterol esters) [1] which prevent excessive evaporation of tear fluid [3]. The presentation and impact of MGD on the ocular surface is variable and include altered secretions, changes in eyelid morphology, gland dropout, and ocular surface disease [1, 2]. In practice, the morphologic changes in MGD are mainly assessed by slit-lamp inspection. Patients may complain of ocular and eyelid discomfort and discharge, especially in the morning, and commonly have evaporative dry eye signs and symptoms. As the tear film lipid layer provides a smooth optical surface for the cornea [3], alterations in this layer can have implications for visual acuity and quality [2]. MGD is a frequent cause of dry eye disease and a common finding among patients undergoing refractive surgery [4].

Dry eye is the most common complication of laser-assisted in situ keratomileusis (LASIK). Despite excellent postoperative uncorrected visual acuity obtained for most patients, some are dissatisfied because of dry eye symptoms. In most patients, signs and symptoms of dry eye resolve by 12 months postoperatively [5]; however up to 20% of patients can have persistent dry eye after the procedure [6]. This is encountered more often in LASIK than in other laser refractive procedures [7]. The pathophysiological association between LASIK and dry eye is related to reduced tear film stability and interfered ocular surface due to corneal nerve damage [4, 7, 8]. Among the potential causative factors of tear film dysfunction following LASIK are pre-existing ocular surface disease, postoperative medicamentosa and surgery-induced ocular surface changes [5]. Management of dry eye includes artificial tears which are the most simple and available treatment. Topical

corticosteroids, cyclosporine A, tacrolimus, and punctal plugs are also available management options [9].

It has been widely reported that patients with preoperative dry eye disease undergoing LASIK are at an increased risk for worsening of symptoms and regression of visual acuity and refraction [8]. However, it was not reported whether patients with asymptomatic dry eye-related findings, such as MGD, are at risk for inferior LASIK outcomes and increased risk of postoperative dry eye signs and symptoms. This question is of importance to whether patients with significant asymptomatic MGD need treatment before undergoing refractive surgery. It was suggested that existing meibomian gland disease, whether symptomatic or not, should be treated before refractive surgery [4]. The presence of significant meibomian gland atrophy may also affect the decision whether to carry out LASIK, photorefractive keratectomy (PRK), or other refractive procedure [4]. The purpose of this study is to compare LASIK outcomes in asymptomatic patients with and without clinically significant preoperative MGD.

METHODS

The charts of all patients who underwent microkeratome-assisted LASIK, by a single high-volume surgeon (IK, more than 10,000 refractive surgeries), in Care-Vision Laser Center, between July 2017 and February 2018, were reviewed. Inclusion criteria were patients age at least 18 years old, stable refraction for at least 12 months, normal intraocular pressure, not wearing rigid contact lenses for at least 2 weeks or soft contact lenses for at least 4 days. Excluded were patients with previous ocular surgery, ocular comorbidities, history of autoimmune disease or diabetes mellitus, best corrected visual acuity (BCVA) $< 20/25$ before the surgery, and patients with symptomatic MGD/dry eye or Sjogren's syndrome.

The study design and data collection complied with the principles of the Declaration of Helsinki and was approved by the Institutional Review Board of the Edith Wolfson Medical Center (reference number WOMC-0188-19).

Data Collection

The following demographic and data were collected: age, gender, contact lens use before the surgery, manifest sphere and cylinder, mean keratometric power, central corneal thickness (CCT) measured by ultrasonic pachymetry (Sonomed Escalon, NY, USA), uncorrected visual acuity (UCVA) and BCVA. MGD severity, the presence of punctate epithelial erosions (PEE) (yes/no), and the presence of dry eye-associated patient symptoms (yes/no) were also collected. In addition, the number of visits between surgery to the last visit was documented. All patients had a normal anterior segment, normal cornea without staining, normal topography, regular astigmatism, clear lenses, and normal fundus.

MGD Evaluation

The meibomian gland function was assessed preoperatively by a single observer (IK), according to meibomian gland expression (1, clear; 2, opaque with normal viscosity; 3, opaque with increased viscosity; 4, severe thickening/toothpaste) [10]. All patients were asymptomatic without dry eye or MGD-associated symptoms.

Study Groups

The patients were divided into one of two groups: patients with preoperative asymptomatic clinically significant MGD (defined as MGD score ≥ 3), and patients with preoperative asymptomatic clinically unsignificant MGD (defined as MGD score 1–2).

Outcome Measures

The main outcome measures were post-LASIK dry eye diagnosis based on the criteria of the Tear Film and Ocular Surface International Dry Eye Workshop [11] and the number of postoperative visits. The secondary dependent variables were the presence of PEE, visual acuity and refractive outcomes, safety index (postoperative

BCVA/preoperative BCVA), and efficacy index (postoperative UCVA/preoperative BCVA).

Surgical Technique

The procedure included a drop of a topical anesthetic (benoxinate hydrochloride 0.4%) instilled in the conjunctival fornix of the eye before the insertion of a lid speculum. Then, a Moria microkeratome with a thickness plate of 90 mm was used to create the flap. After creating the flap, the WaveLight Allegretto Wave (Alcon Surgical, Santa Rosa, CA, USA) excimer laser system was used. The flap was then reposed. Postoperative topical care included moxifloxacin 0.5%, dexamethasone 0.1%, and non-preserved artificial tears containing hyaluronic acid. Patients were routinely examined postoperatively at 1 day, 1 week, and 1 month, and were encouraged to return as necessary at any time.

Statistical Analysis

Following LASIK, we estimated a 30% incidence of symptomatic dry eye in the clinically significant MGD group, and 15% incidence in the control group. Combined with a power of 0.80 and an alpha of 0.05, we calculated a required sample size of at least 242 patients. Therefore, a total of 250 patients were included in this study.

Data were analyzed using the Minitab software (version 19, Minitab Inc., PA, USA). For continuous variables with a normal distribution an independent *t* test was used. For categorical variables, the χ^2 or Fisher's tests was used, as appropriate. A general linear model was used to compare the baseline parameters while adjusting for age. A mixed effect model was used to account for correlation between eyes in the same patient (within-subject factor) to confirm the results [12]. Normality of the data was assessed by the Kolmogorov–Smirnov test. *p* values less than 0.05 on a two-sided test were considered statistically significant. Visual acuity was converted to logMAR for statistical analysis. All presented means are accompanied by their respective standard deviations.

RESULTS

A total of 497 eyes (264 eyes with MGD score 1–2 and 233 eyes with MGD score ≥ 3) were included in the study. Mean patients' age was 31.2 ± 11.4 years (range 18–58 years, 49.9% female). Mean preoperative spherical equivalent was -2.68 ± 2.05 (range -7.75 to $+3.63$). Mean postoperative spherical equivalent was -0.04 ± 0.26 (range -1.25 to $+1.50$). Preoperative contact lenses were used in 205 (41.2%) patients. Postoperative subjective dryness symptoms occurred in 165 (33.2%) patients and included foreign body sensation, stinging, tearing, transient vision obscuration, and feeling of dryness. Postoperative PEE was present in 69 (13.9%) patients.

Demographic and Preoperative Data

Comparison of preoperative parameters between the two groups is detailed in Table 1. Except for age, there was no significant difference between the two groups in baseline parameters, including visual acuity, spherical equivalent, and keratometry readings. Figure 1 depicts the correlation between preoperative MGD and preoperative spherical equivalence among the subjects included in the study.

Postoperative Outcomes

There was no significant difference in the primary outcomes between the two groups. The postoperative subjective dryness symptoms were similar: 75 (32.2%) of the patients in the clinically significant MGD group and 90 (34.1%) of the patients in the control group had dry eye symptoms ($p = 0.36$). The number of postoperative visits were also similar: 3.15 ± 0.75 in the clinically significant MGD group and 3.12 ± 0.54 in the control group ($p = 0.59$).

PEE was present in 30 (12.9%) of the clinically significant MGD group and in 39 (14.8%) of the control group ($p = 0.31$). After adjusting for age, there were no significant differences between both groups in dryness symptoms ($p = 0.498$), PEE ($p = 0.670$), and postoperative

Table 1 Comparison of the preoperative parameters between patients with (MGD[a] score ≥ 3) and without (MGD[a] score 1–2) preoperative clinically significant asymptomatic meibomian gland dysfunction

	MGD ≥ 3 (*N* = 233)	MGD 1–2 (*N* = 264)	*p* value
Age (years)	33.2 ± 12.0	29.5 ± 10.5	< 0.05
Gender (female)	115 (49.4%)	133 (50.4%)	0.85
Preoperative UCVA (logMAR)	1.19 ± 0.63	1.30 ± 0.64	0.19
Preoperative BCVA (logMAR)	0.01 ± 0.02	0.01 ± 0.02	0.40
Sphere (D)	− 2.17 ± 2.13	− 2.43 ± 1.94	0.22
Cylinder (D)	− 0.69 ± 0.67	− 0.80 ± 0.68	0.29
Spherical equivalent (D)	− 2.52 ± 2.14	− 2.83 ± 1.96	0.17
K1 (D)	43.55 ± 1.27	43.36 ± 1.30	0.84
K2 (D)	44.42 ± 1.24	44.35 ± 1.40	0.60
Mean keratometry (D)	43.99 ± 1.22	43.86 ± 1.31	0.70
Pachymetry (μm)	545.27 ± 28.95	547.64 ± 24.56	0.22
Contact lens use	96 (41.2%)	109 (41.3%)	1.00

Data are presented as mean ± SD or *n* (%)
MGD meibomian gland dysfunction, *UCVA* uncorrected visual acuity, *BCVA* best corrected visual acuity

visits ($p = 0.104$). There were no significant differences in visual acuity and refractive outcomes between the two groups. Keratometry readings were also similar. Visual acuity and refractive outcomes for both groups are summarized in Table 2.

Figures 2, 3, and 4 depict the correlation between the basic preoperative MGD and the postoperative PEE, uncorrected visual acuity, and spherical equivalence among the subjects included in the study.

Safety index was 1.024 ± 0.06 in the clinically significant MGD group and 1.029 ± 0.07 in the control group ($p = 0.45$). Efficacy index was also similar in both groups (0.966 ± 0.155 and 0.979 ± 0.14, respectively, $p = 0.31$). When patients with preoperative myopia or hyperopia were evaluated separately, there was no significant difference in the outcomes between the two groups (Supplemental Tables 1 and 2).

DISCUSSION

In this study, we analyzed patients who underwent LASIK refractive surgery and evaluated the impact of preoperative MGD on postoperative dry eye and surgical outcomes after 1 month. According to our results, clinically significant asymptomatic preoperative MGD did not have a significant impact on LASIK outcomes. There was no difference in the postoperative dry eye complaints, PEE presence, number of visits, refraction, and visual acuity outcomes between patients with clinically significant MGD as compared to patients without clinically significant MGD.

Many patients will have transient dry eye signs or experience dry eye symptoms immediately after refractive surgery. In cases of persistent dry eye, LASIK may be associated with inferior results. However, it is unclear if patients with preoperative asymptomatic dry eye-related diseases such as MGD are at risk for inferior

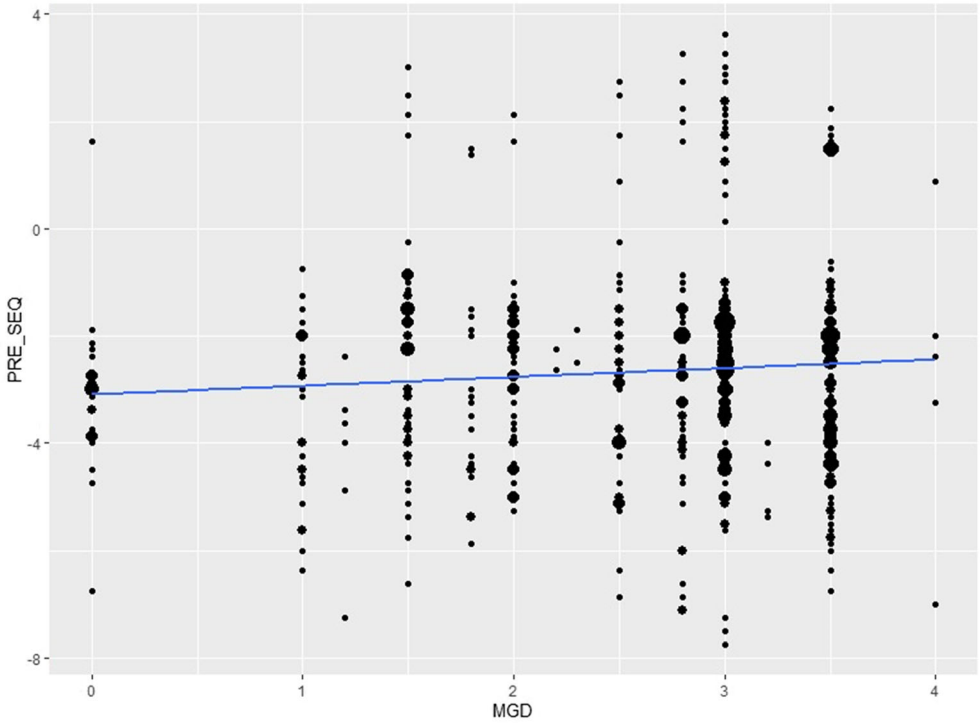

Fig. 1 Correlation between preoperative meibomian gland dysfunction and preoperative spherical equivalence among the patients included in the study

LASIK outcomes and increased risk of postoperative dry eye disease. We could not find previous reports on this issue. It has been reported that patients with preoperative chronic dry eye symptoms undergoing LASIK are at an increased risk for worsening of symptoms [8, 9, 13–16], and regression of uncorrected visual acuity [9, 13, 15]. These patients were shown to have worse tear function and more ocular surface vital staining after the surgery. Dry eye findings were reported not only during the first year after LASIK but also months and years after the surgery [9, 14, 15]. Even mild signs and symptoms of preoperative dry eye were related to significant post-LASIK complications, including recurrent corneal abrasions [17]. As MGD is associated with dry eye, we speculated that significant MGD would result in inferior outcomes, even in asymptomatic patients, and if so, preoperative treatment will need to be weighed. Optimization of ocular surface disease and managing MGD before cataract surgery was found to be effective and optimal in alleviating MGD and dry eye induced by cataract surgery [18]. As for refractive surgery, according to the TFOS DEWS II iatrogenic report, prophylactic treatment includes topical cyclosporine A, non-preserved artificial tears and ointments, alpha omega fatty acids, addressing the lid component with lid hygiene, and possibly a course of doxycycline or azithromycin [19]. Nevertheless, the current study results do not support the assumption that significant MGD in asymptomatic patients may result in inferior surgical outcomes. Therefore, in patients with significant MGD but without dry eye, it seems that there is no need for preventive treatment prior to LASIK.

Jung et al. studied the ocular surface of patients who underwent corneal refractive surgery and compared it with controls to evaluate the impact of corneal refractive surgery on the ocular surface [5]. Subjective symptoms, tear film stability, lid margin abnormalities, and MGD were worse in the post-refractive surgery patients than in the controls [5]. Nevertheless,

Table 2 Comparison of visual acuity and refractive outcomes between patients with (MGD[a] score ≥ 3) and without (MGD[a] score 1–2) preoperative clinically significant asymptomatic meibomian gland dysfunction

	MGD ≥ 3 (*N* = 233)	**MGD 1–2 (*N* = 264)**	***p* value**
UCVA (logMAR)			
1 day	0.047 ± 0.11	0.055 ± 0.16	0.55
1 week	0.037 ± 0.09	0.024 ± 0.15	0.27
1 month	0.026 ± 0.09	0.026 ± 0.17	0.99
BCVA (logMAR)	0.99 ± 0.02	0.99 ± 0.03	0.84
Sphere (D)	− 0.01 ± 0.26	− 0.01 ± 0.21	0.94
Cylinder (D)	− 0.05 ± 0.18	− 0.04 ± 0.13	0.29
Spherical equivalent	− 0.03 ± 0.17	− 0.03 ± 0.18	0.99
Refractive error	− 0.038 ± 0.26	− 0.021 ± 0.24	0.46

Data are presented as mean ± SD or *n* (%)
MGD meibomian gland dysfunction, *UCVA* uncorrected visual acuity, *BCVA* best corrected visual acuity

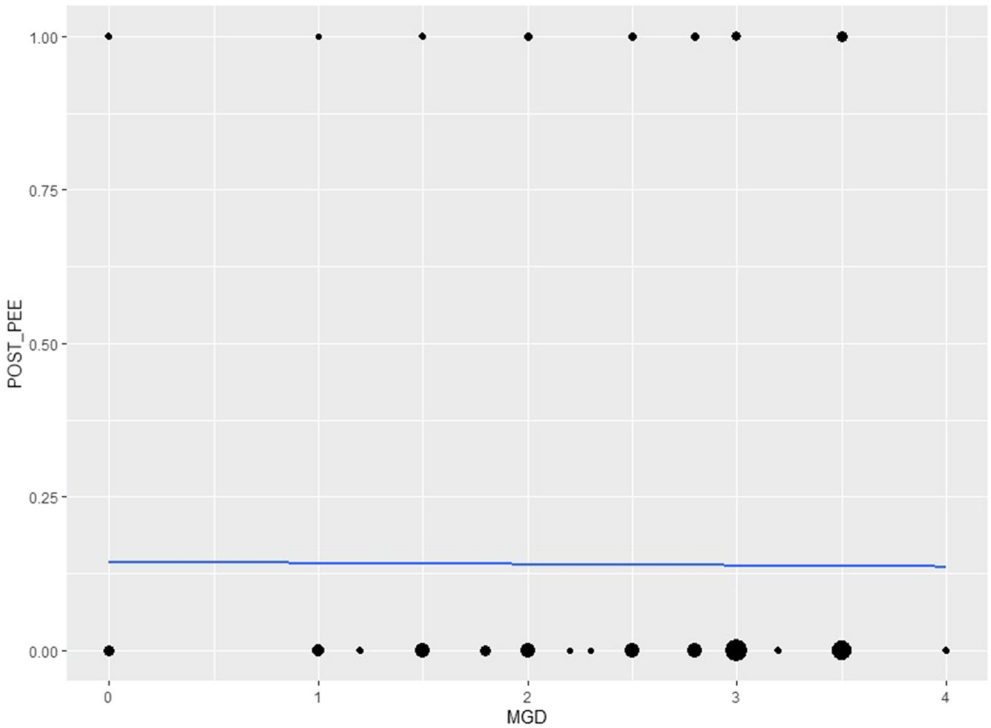

Fig. 2 Correlation between preoperative meibomian gland dysfunction and postoperative punctate epithelial erosions among the patients included in the study

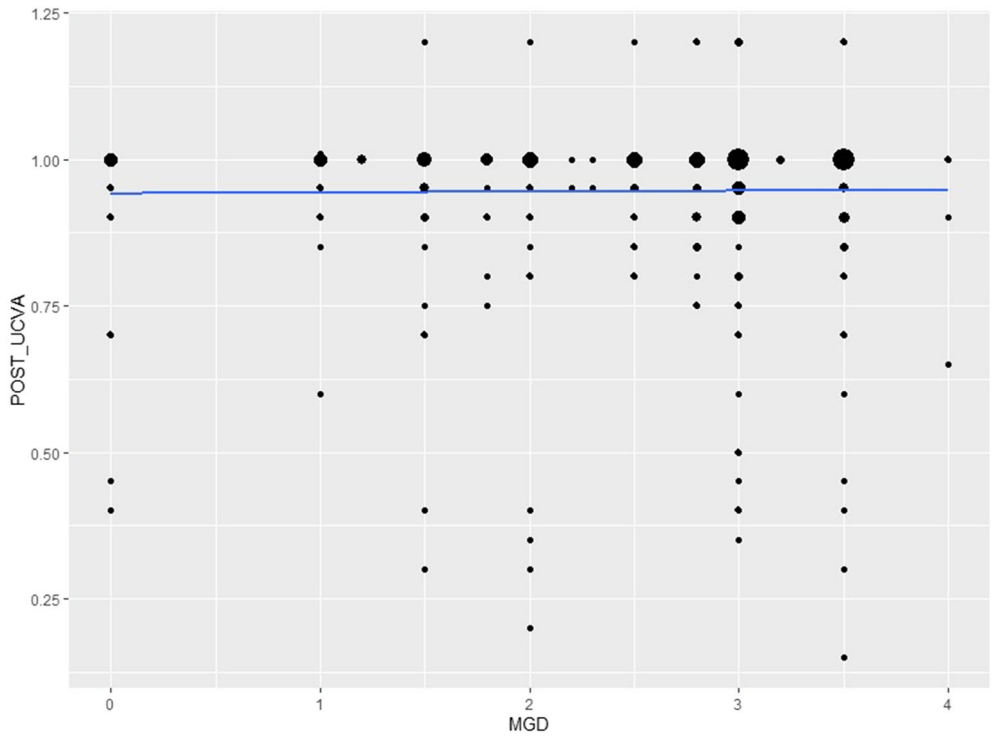

Fig. 3 Correlation between preoperative meibomian gland dysfunction and postoperative uncorrected visual acuity among the patients included in the study

the ocular surface and meibomian gland changes that existed before the refractive surgery were not examined, and the impact of MGD on the refractive results was not reported. Brooks and Gupta reported that 72.5% of patients presenting for refractive surgery evaluation had meibomian gland atrophy and 69.2% had meibomian gland tortuosity. Given the correlation of meibomian gland atrophy with MGD, ocular surface disease, and dry eyes, these authors suggest it could guide counseling of patients with potentially increased susceptibility to MGD and dry eyes [4]. Preoperatively, we have educated the patients with MGD about their condition and counseled them about the potential for some worsening after surgery. Nevertheless, the findings of asymptomatic meibomian gland atrophy/tortuosity/MGD do not preclude patients from undergoing refractive surgery. Brooks and Gupta concluded in their study that physicians should consider screening and potentially addressing MGD when evaluating candidates for refractive surgery. Our results do not seem to support these conclusions, as all our patients underwent LASIK which is more commonly associated with postoperative dry eye than PRK, and yet no difference was found in dry eye signs and symptoms and in the outcomes between preoperative asymptomatic patients with and without significant MGD.

Post-refractive surgery patients frequently visit dry eye clinic for the management of dry eye symptoms [5]. Dry eye was also reported as the most common diagnosis in patients who were unsatisfied with results after LASIK and were referred to Cornea Clinic [20]. In the current study, the number of postoperative visits was similar between patients with clinically significant and without clinically significant MGD. The number of postoperative of visits is a measure of complications and adverse events. If the patient has more postoperative visits, it is likely due to more postoperative adverse events. The number of postoperative visits may be affected by confounders such as personal, social, and cultural characteristics. Nevertheless, we believe that this observation is aligned

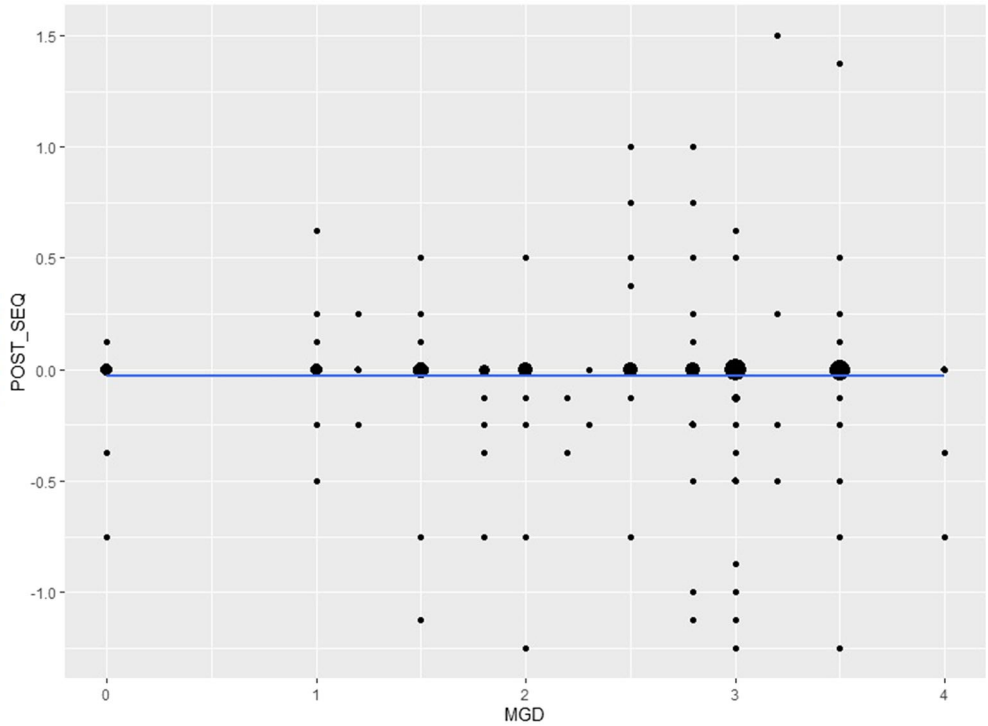

Fig. 4 Correlation between preoperative meibomian gland dysfunction and postoperative spherical equivalence among the patients included in the study

with the other study results which showed that patients with preoperative clinically significant MGD have the same rate of dry eye-related symptoms and LASIK outcomes as other patients do.

Despite the relatively large sample size of the currents study, several limitations do exist. First, the study is limited by its retrospective nature. Second, post-LASIK follow-up of 1 month is short. However, as dry eye signs and symptoms are in their highest prevalence shortly after the surgery, it seems unlikely that longer follow-up will reveal different results. Third, the study results may not be applicable to PRK or to femtosecond-assisted LASIK. Finally, the fact that the severity of MGD was assessed by observation only via manual expression of glands may have led to bias, as this is a measure that may not always be easy to quantify accurately. Also, we did not look at all aspects of MGD such as lid margin scores and meiboscores.

The post-LASIK dry eye is a crucial factor of the surgical outcome and patient satisfaction [21, 22]. Therefore, a thorough preoperative evaluation and postoperative management of refractive surgery candidates with dry eye are recommended in the initial screening and during follow-up examinations. Searching the data available in the era of asymptomatic MGD and the effect on LASIK outcomes, it was surprising to learn that it is very limited. More studies are needed to reach solid conclusions.

CONCLUSIONS

In this first study of its kind, which included a large case series of asymptomatic patients with MGD who underwent LASIK by one surgeon, clinically significant MGD did not play a role in the surgical outcomes. According to our study no specific preoperative treatment or special caution is needed in these cases.

ACKNOWLEDGEMENTS

Funding. No funding or sponsorship was received for this study or publication of this article. The journal's Rapid Service Fee was funded by the authors.

Author Contributions. Conception and design (Oriel Spierer, Achia Nemet, Stav Bloch, Asaf Israeli, Michael Mimouni, Igor Kaiserman); Data collection (Achia Nemet, Stav Bloch, Asaf Israeli); Analysis and interpretation of the data (Oriel Spierer, Achia Nemet, Stav Bloch, Asaf Israeli, Michael Mimouni, IK); Statistical expertise (Achia Nemet, Michael Mimouni); Administrative, technical, or logistical support (Stav Bloch, Asaf Israeli, Michael Mimouni, Igor Kaiserman); Writing the article (Oriel Spierer, Achia Nemet, Michael Mimouni); Critical revision of article (Oriel Spierer, Achia Nemet, Stav Bloch, Asaf Israeli, Michael Mimouni, Igor Kaiserman); and Final approval of article (Oriel Spierer, Achia Nemet, Stav Bloch, Asaf Israeli, Michael Mimouni, Igor Kaiserman). This work was performed in partial fulfillment of the M.D. thesis requirements of the Sackler Faculty of Medicine, Tel Aviv University.

Disclosures. Oriel Spierer, Achia Nemet, Stav Bloch, Asaf Israeli, Michael Mimouni and Igor Kaiserman all confirm that they have no conflicts of interest to declare.

Compliance with Ethics Guidelines. The study followed the tenets of the Declaration of Helsinki and was approved by the Institutional Review Board of the Edith Wolfson Medical Center (reference number WOMC-0188-19).

Data Availability. Data sharing is not applicable to this article as no datasets were generated or analyzed during the current study.

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