· Clinical Research ·

Safety and effectiveness of Bian-stone and moxibustion in treatment of meibomian gland dysfunction

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Abstract
● **AIM:** To propose a novel Bian-stone and moxibustion (BSM) therapy for meibomian gland dysfunction (MGD) treatment, and to evaluate its clinical efficacy and safety based on objective ocular surface parameters.
● **METHODS:** A total of 140 patients with MGD were enrolled in this randomized controlled study and equally allocated (1:1 ratio) into the BSM group and the intense pulsed light (IPL) group. Patients in the BSM group received 30-minute BSM treatment every other day. Subjects in the IPL group completed four independent treatment sessions. The evaluated outcomes included the Ocular Surface Disease Index (OSDI), eyelid margin morphology, meibomian gland (MG) morphology and function, tear film breakup time (TBUT), ocular surface staining (OSS) score, Schirmer's test (ST), and tear meniscus height (TMH). All assessments were performed at baseline, as well as at 1- and 3-month follow-ups after treatment.
● **RESULTS:** The BSM group consisted of 24 males and 47 females with a mean age of 59.04±16.50y, while the IPL group included 27 males and 42 females with a mean age of 60.39±15.90y. No significant differences in age, sex distribution, and clinical history were observed between the two groups. At 1 and 3mo post-treatment, the BSM group exhibited significant improvements in OSDI scores, eyelid margin hyperemia and neovascularization, MG expression, secretion status and gland loss, conjunctival hyperemia, and TBUT. Notably, the BSM group achieved superior improvements in OSDI scores and eyelid neovascularization compared with the IPL group at the 3-month follow-up. Additionally, significant reductions in eyelid margin edema and irregularity were only observed in the BSM group at 3mo after intervention.
● **CONCLUSION:** BSM therapy can effectively relieve clinical symptoms and restore tear film homeostasis in patients with MGD, serving as a promising and viable therapeutic approach for MGD management.
● **KEYWORDS:** Bian-stone; dry eye; meibomian gland dysfunction; moxibustion; intense pulsed light
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INTRODUCTION

Meibomian gland dysfunction (MGD) is a chronic diffuse abnormality of the meibomian glands (MGs), characterized by terminal duct obstruction and qualitative/quantitative alterations in glandular secretion[1-2]. MGD can lead to a deficiency of the tear film lipid layer and a loss of ocular surface homeostasis, resulting in inflammatory responses, continuous damage, and neurosensory abnormalities of the ocular surface[3-4]. As the leading cause of evaporative dry eye[2], more than 60% Asian populations are complained with MGD[2,4]. MGD seriously deteriorates patients' lives and has becoming a public health problem[1-2].

The treatment goal of MGD is to improve the quality and quantity of meibum, increase tear film stability as well as eliminate inflammation, and finally provide a healthy ocular surface homeostasis[1]. Among a variety of treatment options, intense pulsed light (IPL) has been shown to be a promising therapy which could improve clinical symptoms, increase tear film stability, and ameliorate ocular surface inflammation and damage by suitable infrared spectra (580–1200 nm)[5-8]. Since the narrow wavelength spectrum, a local high-intensity radiation is always used in ophthalmology clinics to meet the demands of extensive application. The operation of IPL device must be completed by the professional medical staff and patients must go to the hospital for treatment, which greatly limits its development and popularization. Therefore, it is urgent to develop a new therapeutic instrument with wide infrared spectrum and low intensity to meet the increasing MGD patients.

Bian-stone and moxibustion (BSM) are widely adopted in traditional Chinese medicine for thousands of years[9-10]. Both of them can stimulate the circulation of vessel blood, reduce pain, and relax muscles and joints by utilizing its stable infrared thermal radiation properties[10]. The infrared radiation spectrum of moxibustion ranges from 500 to 2500 nm, which covers from the near infrared to far-infrared and reaches the radiation peak in the near infrared band, resulting in a series of photothermal biological effects[11-16]. The Bian-stone have good thermal radiation conductivity and heat-storing properties, great infrared absorption and reflection capability as well as light photoelectricity transformation rate[17-18]. Those characteristics enhance the infrared emission capability of Bian-stone and ensure a stable spectrum of 8000–14 000 nm[17-18]. The wavelength spectrums of BSM are more widely than the MGD treatment demands. The wide wavelength spectrums may play more effective roles in the ocular surface. In this study, we put BSM in a spectacle pattern (Figure 1), which can simultaneously play therapeutic roles in warm compress and infrared therapy. Moreover, the suitable intensity and less damage to the treatment area make it more suitable for family long-term use.

We developed a new therapy delivering BSM for the treatment of MGD and performed a randomized controlled study to examine the efficacy and safety of BSM.

PARTICIPANTS AND METHODS

Ethical Approval This randomized and controlled treatment study was performed according to the principles of the Declaration of Helsinki and was approved by the Human Research and Ethics Committee, Peking University Third Hospital (No.M2019140). Written informed consent was obtained from each study participant. The study was registered at http://www.chictr.org.cn/ (Study No.ChiCTR1900027643).

Participants and Clinical Study Patients with MGD were recruited from department of ophthalmology of Peking University Third Hospital from May 2020 to November 2020. The diagnosis of MGD was according to the Chinese Experts Consensus on Diagnosis and Treatment of Meibomian Gland Dysfunction in 2017[19]. They were randomly assigned in a ratio of 1:1 into BSM group or IPL group using a random number table. According to the international diagnostic classifications for dry eye disease (DED) and MGD[2-4], inclusion criteria were as follows, 1) age from 18 to 80y; 2) at least one of the symptoms more than 3mo: dryness, foreign body sensation, burning, and tearing; 3) two or more of the ocular signs in both eyes: lid margin hyperemia, edema, irregularity, vascularity, MG plugging, and reduced meibum quality and quantity, among others. Patients with 1) acute or infectious ocular surface diseases; 2) eye trauma; 3) eye surgery within the past 1y; 4) use of eye drops other than preservative-free artificial tears within the past 1mo; 5) under other treatments for MGD; 6) systemic diseases or medications affecting the ocular surface; 7) pigmented lesions or other skin diseases around the eye that not suitable for IPL treatment; 8) pregnancy and lactating women were excluded.

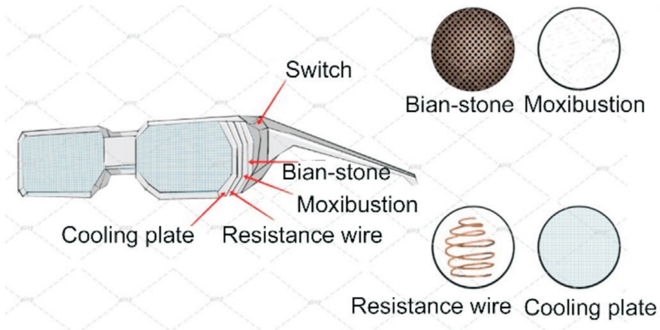

Figure 1 The Bian-stone and moxibustion spectacle ideograph The spectacle frame is composed of a hot poor conductor with a battery position and a thermo-switch. The lens part is mainly composed of four layers, from the outside to the inside, which are cooling plate, resistance wire, moxibustion, and Bian-stone with small holes to facilitate moxibustion spectrum penetration.

Treatment Procedure MGD patients were randomly assigned to receive either BSM or IPL. Patients in BSM group underwent treatment for 30min every other day. The subjects in IPL group received four separate treatment sessions on day (D)1, D15, D45, and D75 by the same doctor. After 1-month and 3-month treatment, each patient underwent two follow-up examinations. All patients used 0.1% sodium hyaluronate eyedrops (URSAPHARM Arzneimittel GmbH, Germany) four times a day during the study and follow-up period. The same observers who blinded to the treatment group complished the clinical assessments before and after the treatment.

BSM spectacle ideograph is shown in Figure 1. The spectacle frame is composed of a hot poor conductor with a battery position and a thermo-switch (equipped with a heat protection). The lens part is mainly composed of four layers, from the outside to the inside, which are cooling plate, resistance wire, moxibustion, and Bian-stone. There are small holes in the Bian-stone layer to facilitate moxibustion spectrum penetration. Turn on the thermo-switch, the moxibustion and Bian-stone will be warmed by the resistance wire and release infrared rays. Then both infrared rays and warm compress act the therapeutical effects on the eyes together. Patients only need to close their eyes to under treatment while sitting or lying at home. The thermo-switch will turn off automatically when the local temperature increases to 45°C or the treatment duration exceedes 30min. During the treatment, patients can turn on the thermo-switch when they feel it is not warm enough. Since the good thermal conductivity and heat-storing capability of Bian-stone, the BSM spectacle can be warmed to the treatment temperature (40°C) within 2min and maintained for more than 10min. The intensity output of the BSM ranged of 5–9 J/cm^2.

Before the IPL treatment, the machine (E-Eye; E-SWIN, Paris, France) was adjusted to the appropriate intensity (range of 9.8–13 J/cm^2) according to the Fitzpatrick Skin Grading[20]. At each treatment, both eyelids were closed and protected with opaque goggles. After use of ultrasound gel on the treatment area, patients received 4 overlapping flashes on the skin area below the lower eyelid with no pressure.

Clinical Assessment The safety of BSM treatment was evaluated by measurement of best spectacle-corrected visual acuity, intraocular pressure, lens opacity, and assessment of the ocular surface and around the skin areas of redness, swelling and blistering, among others, before and after the treatment.

For assessment of treatment efficacy, the clinical parameters were evaluated before treatment (baseline) and at both follow-up time points in the following order: a careful clinical history and Ocular Surface Disease Index (OSDI), complete examination of eyelid margin and MG abnormalities with a slit lamp microscope, tear production measured by the Schirmer's test (ST) without anesthetic and central lower tear meniscus height (TMH) using a Keratograph 5M (OCULUS, Wetzlar, Germany), tear film breakup time (TBUT) determined with fluorescein staining and ocular surface stain (OSS) score evaluated with fluorescein and lissamine green staining[3-4], MG function assessments (MG expression, secretion quality, and the area of MG loss). Five signs of lid margin were assessed: hyperemia, debris, edema, irregularity, and neovascularization (score 0 equals normal; score 1 equals abnormal)[2,19]. MG morphology assessments include plugging and stenosis (score 0 equals no; score 1 equals yes)[2,19]. MG expression was evaluated in five glands on the temporal, central, and nasal eyelid using the following standards: 0 (all glands expressible), 1 (three to four glands expressible), 2 (one to two glands expressible), and 3 (no glands expressible)[2,21]. Both upper and lower eyelids were evaluated, and the average value was obtained. The MG secretion was scored as follows[19,22]: 0 (clear meibum), 1 (cloudy meibum), 2 (granular meibum with debris), and 3 (inspissated meibum and toothpaste-like). The MG loss was graded as follows[19,23]: 0 (no dropout), 1 (<1/3 total area dropout), 2 (1/3–2/3 total area dropout), and 3 (>2/3 total area dropout). Conjunctival hyperemia was evaluated under a slit lamp microscope with score 0 representing no and score 1 meaning yes[19]. All examinations were carried out in the same examination room under the same conditions.

A 5-minute interval was required between different examinations. All measurements were performed three consecutive times by the same two masked observers and the average values would be recorded.

Statistical Analysis Sample sizes were calculated by Stata/SE 15.0 for Mac (Stata Corp., USA). The sample size of each group was determined to be 65 eyes (α=0.05, β=0.10, and lost follow-up rate=15%), which was suitable for 71 eyes (BSM group) and 69 eyes (IPL group) in our study. Statistical analysis was performed using SPSS version 26.0 (IBM Corp., Armonk, New York, USA). The normality of the data distribution was verified by the Kolmogorov-Smirnov test. Continuous variables are described as the mean±standard deviation (SD). Categorical variables are expressed as frequencies and percentages. Categorical variables were compared with the Chi-square test. Paired Student's t-test was used to compare normally distributed numrical variables between before and either 1 or 3mo after treatment onset as well as the unpaired t-test to compare pretreatment or posttreatment variables between the BSM and IPL groups. Bonferroni's correction was applied to correct for multiple comparisons. P<0.016 was considered significant for comparisons in before and 1mo after treatment between the two groups. P<0.01 was considered significant for comparisons in baseline and 3mo after treatment between the two groups.

RESULTS

Basic Characteristics One hundred and ninety-six patients were screened for this study, nine patients failed to meet the criteria, and 35 subjects declined to take part in this study because of their inconvenience with follow-ups. Finally, one hundred and fifty-two patients were enrolled and randomized. Five patients in BSM group and seven patients in IPL group subsequently withdrew from the study because of failure during the follow-up, leaving a total of 71 patients in the BSM group and 69 patients in the IPL group (Figure 2). Patient demographics are shown in Table 1. The age, sex, and clinical history showed no difference between the two groups. Only the right eyes were chosen at random for evaluation.

Safety of BSM and IPL Among all visits, the best spectacle-corrected visual acuity, intraocular pressure, ocular surface condition, and lens opacity showed no change between before and after treatment in both groups. Half of the patients in BSM group complained about eye redness after treatment but disappeared within 10min. No skin and systemic adverse event was observed during this study.

Efficacy of BSM The clinical parameters of the patients in the BSM group and the IPL group before as well as 1 and 3mo

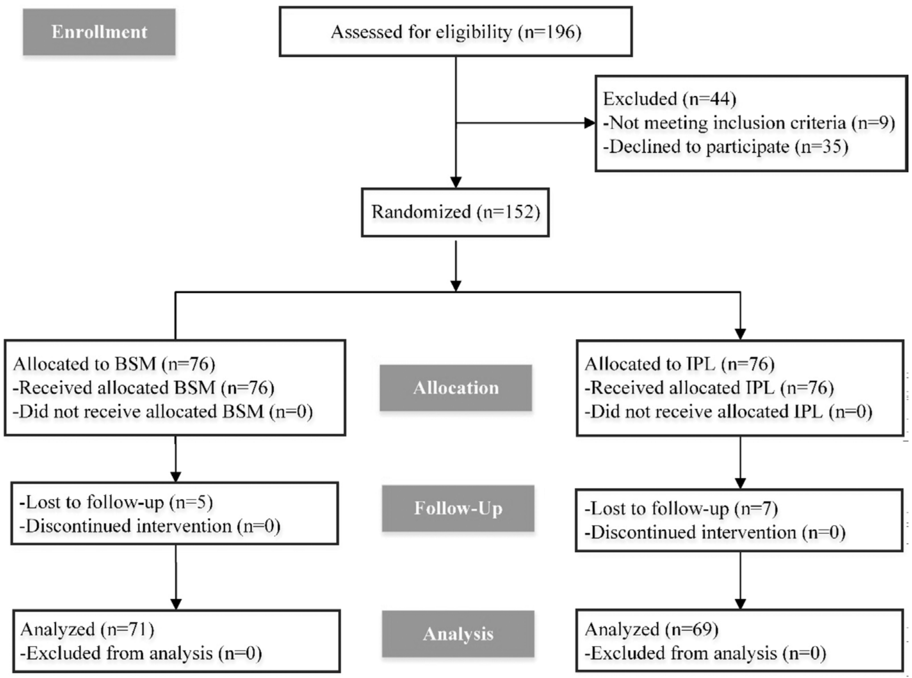

Figure 2 Consort and follow-up protocol for the Bian-stone and moxibustion (BSM) and intense pulsed light (IPL) groups.

Table 1 Characteristics of the subjects in the BSM and IPL groups

Characteristic	BSM group (*n*=71)	IPL group (*n*=69)	*P*
Age (y), mean±SD	59.04±16.50	60.39±15.90	0.623
Sex, *n* (%)			
Male	24 (33.8)	27 (39.1)	0.516
Female	47 (66.2)	42 (60.9)	
Duration of MGD (y), mean±SD	4.25±1.50	4.04±1.64	0.768
History of contact lens wear, *n* (%)	29 (40.8)	27 (39.1)	0.965

SD: Standard deviation; MGD: Meibomian gland dysfunction; BSM: Bian-stone and moxibustion; IPL: Intense pulsed light.

after treatment onset are shown in Table 2 and Figure 3. No significant differences in ocular surface symptoms/signs were observed between the two groups at baseline. The OSDI score was significantly reduced at both 1 and 3mo after treatment initiation and OSDI score at 3mo was less than score at 1mo in both groups (baseline BSM: 25.55±15.57, IPL: 26.29±15.75; 1mo BSM: 22.23±13.72, IPL: 22.57±14.93; 3mo BSM: 15.68±6.84, IPL: 18.82±8.10; all *P*<0.01). Whereas the OSDI score did not differ significantly between the two groups at 1mo, it was significantly smaller in the BSM group than in the IPL group at 3mo (*P*=0.005).

Significant decreases in lid margin hyperemia, neovascularization, MG expression, MG secretion, MG loss, and conjunctival hyperemia as well as significant increases in TBUT were also obvious at both time points after treatment onset compared with baseline in the two groups (all *P*<0.01). Moreover, the eyes in BSM group showed a significantly better improvement in lid margin neovascularization compared with those in the IPL group at 3mo after treatment initiation (BSM: 2.8%, IPL: 11.6%; *P*=0.004). Additionally, the MG secretion in BSM group and TBUT in both groups were apparent improvement at 3mo as compared with 1mo after treatment onset (all *P*<0.01). Significant decreases in lid margin edema and irregularity were detected at 3mo after treatment only in the BSM group (edema baseline: 22.5%, 3mo: 15.5%, *P*=0.004; irregularity baseline: 15.5%, 3mo: 8.5%, *P*=0.004). Lid margin debris, MG plugging and stenosis, OSS scores, ST and TMH at both time points after treatment initiation did not differ significantly from the baseline in both groups.

DISCUSSION

This study proposed a new traditional medicine approach (BSM) for the treatment of MGD, which appeared to be effectively and safely by clinical results. BSM have played important roles in the treatment of various diseases for more than thousand years[9-10,24-25]. Based on the stable infrared thermal radiation property[10,17-18], BSM might be a feasible therapy for MGD and might achieve a remarkable improvement on clinical parameters.

To the best of our knowledge, this is the first study introducing BSM therapy in MGD. We also conducted a randomized and controlled study to show that BSM treatment sessions significantly improved clinical symptoms and signs in patients with MGD. We evaluated a total of 16 parameters including

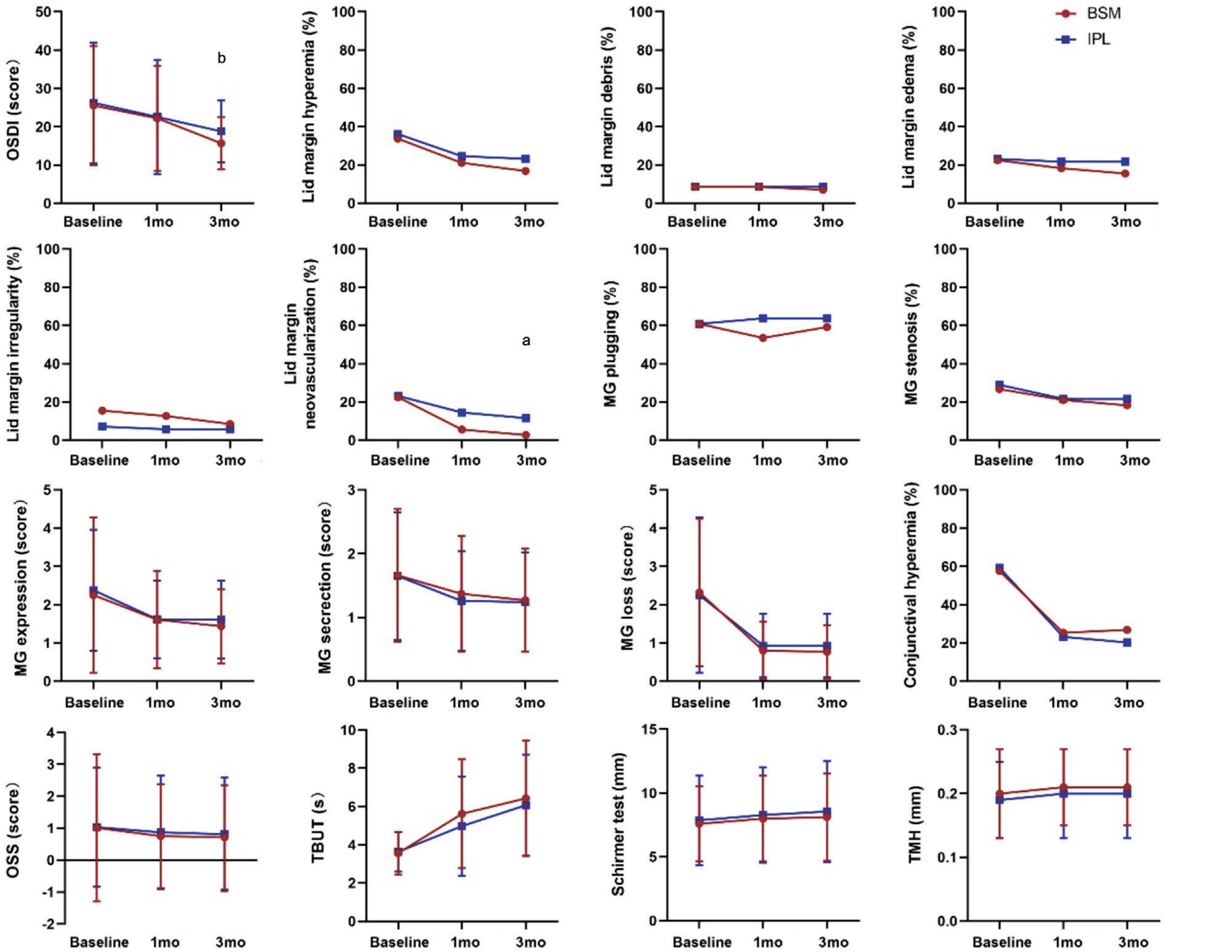

Figure 3 Clinical parameters at baseline and each follow-up between Bian-stone and moxibustion (BSM) and intense pulsed light (IPL) groups
OSDI: Ocular surface disease index; MG: Meibomian gland; OSS: Ocular surface stain; TBUT: Tear film breakup time; TMH: Tear meniscus height; IPL: Intense pulsed light. ^{a}P<0.016 between groups; ^{b}P<0.01 between groups.

eyelid margin morphology, MG morphology and function, tear production as well as stability both before and after treatment of 1 and 3mo. Our results indicate that BSM is a promising therapeutic approach for patients with MGD.

IPL therapy is generally adopted in the cosmetic industry[26] for treatment of benign cavernous hemangiomas, telangiectasia, port-wine stains, pigmented lesions, hypertrichosis, and so forth[26-28]. An improvement in dry eye was observed serendipitously when a patient underwent IPL for the dermatologic manifestations of rosacea. Since then, many studies have gradually shown its benefits as a potential therapy for MGD[1,5-7]. Similar to the previous literature, the clinical symptoms and signs improved notably within 1 and 3mo after the initiation of IPL treatment (Table 2 and Figure 3).

It is noteworthy that MGD patients also revealed a significant improvement in various measured clinical parameters compared with the pretreatment values of BSM treatment (Table 2 and Figure 3). BSM group significantly improved the OSDI score, eyelid margin conditions such as hyperemia and neovascularization, MG function including expression, secretion and loss, conjunctival hyperemia, as well as TBUT after treatment. Furthermore, irregularity, which is considered the irreversible result of traction after MG dropout, was ameliorated in the BSM group at 3mo. The mechanisms underlying those findings are not yet fully understood, and there we assumed five potential mechanisms of BSM ameliorating ocular surface symptoms and signs in patients with MGD. First, as many previous researches described, BSM able to produce a heat effect that warms MGs and thereby melts the pathologically dysfunctional meibum[9-11,15-18,24-25]. This was consistent with our results, as MG secretion improved at 1 and 3mo after the treatment of BSM. Since the improved quality of meibum, an increased TBUT was found at 1 and 3mo after BSM. Becaused of the good thermal conductivity and heat-storing capability of Bian-stone, the BSM can be warmed to the treatment temperature (40°C) quickly and maintained for more than 10min, which can continue to warm and melt the abnormal meibum and improve ocular surface homeostasis. Second, the BSM emits energy in a wide band from the visible spectrum (500 nm) to far infrared (14 000 nm)[11,15,18], then the

Table 2 Characteristics of BSM and IPL groups before as well as 1 and 3mo after treatment onset

Items	Group	Baseline		1mo after treatment onset			3mo after treatment onset			
		Mean±SD/ *n* (%)	*P* (BSM *vs* IPL)	Mean±SD/ *n* (%)	*P vs* baseline	*P* (BSM *vs* IPL)	Mean±SD/ *n* (%)	*P vs* baseline	*P* (1 *vs* 3mo)	*P* (BSM *vs* IPL)
OSDI score	BSM	25.55±15.57	0.798	22.23±13.72	<0.001[b]	0.978	15.68±6.84	<0.001[b]	0.005[b]	0.005[b]
	IPL	26.29±15.75		22.57±14.93	<0.001[b]		18.82±8.10	<0.001[b]	0.005[b]	
Lid margin hyperemia	BSM	24 (33.8)	0.764	15 (21.1)	0.012[a]	0.622	12 (16.9)	0.001[b]	0.083	0.261
	IPL	25 (36.2)		17 (24.6)	0.004[b]		16 (23.2)	0.004[b]	0.899	
Lid margin debris	BSM	6 (8.5)	0.959	6 (8.5)	1.000	0.969	5 (7.0)	0.708	0.658	0.717
	IPL	6 (8.7)		6 (8.7)	1.000		6 (8.7)	1.000	1.000	
Lid margin edema	BSM	16 (22.5)	0.927	13 (18.3)	0.083	0.613	11 (15.5)	0.004[b]	0.159	0.344
	IPL	16 (23.2)		15 (21.7)	0.658		15 (21.7)	0.658	1.000	
Lid margin irregularity	BSM	11 (15.5)	0.119	9 (12.7)	0.159	0.162	6 (8.5)	0.004[b]	0.083	0.544
	IPL	5 (7.2)		4 (5.8)	0.321		4 (5.8)	0.321	1.000	
Neovascularization	BSM	16 (22.5)	0.927	4 (5.6)	<0.001[b]	0.082	2 (2.8)	<0.001[b]	0.159	0.004[b]
	IPL	16 (23.2)		10 (14.5)	0.013[a]		8 (11.6)	0.009[b]	0.919	
MG plugging	BSM	43 (60.6)	0.971	38 (53.5)	0.024	0.220	42 (59.2)	0.321	0.055	0.576
	IPL	42 (60.9)		44 (63.8)	0.321		44 (63.8)	0.321	1.000	
MG stenosis	BSM	19 (26.8)	0.770	15 (21.1)	0.021	0.930	13 (18.3)	0.013	0.159	0.613
	IPL	20 (29.0)		15 (21.7)	0.024		15 (21.7)	0.024	1.000	
MG expression	BSM	2.25±2.03	0.229	1.61±1.27	<0.001[b]	0.558	1.44±0.97	<0.001[b]	0.033	0.287
	IPL	2.38±1.58		1.62±1.02	<0.001[b]		1.61±1.02	<0.001[b]	0.988	
MG secretion	BSM	1.66±1.04	0.921	1.37±0.91	<0.001[b]	0.506	1.27±0.81	<0.001[b]	0.007[b]	0.909
	IPL	1.65±1.00		1.26±0.78	<0.001[b]		1.24±0.78	<0.001[b]	0.978	
MG loss	BSM	2.32±1.93	0.269	0.80±0.75	<0.001[b]	0.385	0.77±0.70	<0.001[b]	0.483	0.313
	IPL	2.25±2.03		0.93±0.83	<0.001[b]		0.93±0.83	<0.001[b]	1.000	
Conjunctival hyperemia	BSM	41 (57.7)	0.841	18 (25.4)	<0.001[b]	0.766	12 (16.9)	<0.001[b]	0.013	0.354
	IPL	41 (59.4)		16 (23.2)	<0.001[b]		14 (20.3)	<0.001[b]	0.976	
OSS	BSM	1.01±2.31	0.448	0.75±1.63	0.220	0.740	0.72±1.64	0.148	0.597	0.875
	IPL	1.03±1.87		0.87±1.78	0.321		0.81±1.78	0.212	0.103	
TBUT	BSM	3.56±1.12	0.597	5.62±2.85	<0.001[b]	0.372	6.43±3.02	<0.001[b]	<0.001[b]	0.654
	IPL	3.64±1.04		4.98±2.59	<0.001[b]		6.07±2.64	<0.001[b]	<0.001[b]	
ST	BSM	7.59±2.94	0.630	7.99±3.37	0.197	0.583	8.12±3.43	0.095	0.119	0.418
	IPL	7.87±3.51		8.28±3.74	0.387		8.55±3.96	0.130	0.105	
TMH	BSM	0.20±0.07	0.134	0.21±0.06	0.239	0.277	0.21±0.06	0.108	0.923	0.164
	IPL	0.18±0.06		0.19±0.07	0.038		0.19±0.07	0.040	0.726	

SD: Standard deviation; OSDI: Ocular Surface Disease Index; MG: Meibomian gland; OSS: Ocular surface stain; TBUT: Tear film breakup time; ST: Schirmer's test; TMH: Tear meniscus height; BSM: Bian-stone and moxibustion; IPL: Intense pulsed light. *P*-values of 1 and 3mo after treatment onset were adjusted using Bonferroni correction. [a]$P<0.016$; [b]$P<0.01$.

near infrared is absorbed by hemoglobin and thereby closes abnormal vessels in the lid margin and related conjunctiva. In the present study, we believed the significant reduction of lid margin hyperemia, lid neovascularization, and conjunctival hyperemia after treatment to be related to this vessels closure effect of BMS. The third possible effect of BSM, which was verified in MGD patients by IPL therapy[25,29-30], is that BSM might further prevent the release of inflammatory factors by these abnormal vessels, such as interleukin-17A, interleukin-6, and prostaglandin E2. Therefore, our findings, including reduced OSDI scores, lid margin edema, MG expression, MG loss, and so on, could probably be explained by the reduced inflammatory factors. The fourth mechanism is that BSM may have an effect in relieving inflammatory and neurogenic pain[10], corresponding to our results of continuous OSDI reduction during the BSM treatment. Fifth, as has been well described in MGD patients with IPL treatment[31], BSM might also improve the bacterial infection and inflammation of the eyelid margin because of warm and infrared therapeutic effects. This was consistent with our results, as lid margin hyperemia and edema as well as the MG expression and loss improved after the application of BSM. Additionally, we found that BSM improved eyelid margin edema and irregularity, whereas IPL did not, with this effect of BSM possibly being due to the anti-inflammatory effect (because of the stable infrared radiation) for a long time.

Both of BSM and IPL were demonstrated to be effective for MGD patients. However, there were also some differences in certain aspects. In the present study, patients in BSM group showed a better improvement in OSDI score and lid margin neovascularization than those who received IPL treatment. Moreover, the cutoff value of TBUT for evaluation of DED is 5[2-3], with individuals with a score of 5 or lower, thus complaining of ocular symptoms of DED. Whereas the amelioration of signs by IPL was statistically significant, it might therefore not have been clinically effective at 1mo after treatment initiation. BSM treatment improved ocular clinicals to such an extent that the TBUT was substantially above the cutoff value for dry eye. TBUT is characteristically reduced in patients with MGD[32], and we observed an increase in mean TBUT from 3.56s to 5.62s after BSM sessions (1mo after treatment onset) and to 6.43s after 3mo of follow-up. These changes represent a meaningful clinical improvement, given that we previously showed the cutoff value of TBUT as 5s[33]. Our results showed that 72% and 94% of MGD patients had recovered balance in tear film stability, as indicated by the TBUT, after 1 and 3-month sessions of BSM, respectively. This improvement in tear film homeostasis remained apparent 3mo after treatment onset. We suspect that, due to its remarkable effects on warm compress and anti-inflammation, BSM could significantly relieve the complains and inflammatory response, therefore maintain the homeostasis of the tear film and ocular surface.

Compared with Caucasians (3.5%–19.9%), the prevalence of MGD (>60%) is much high in Asian populations[2,4]. IPL therapy performed in hospital could not meet the patients' demand. An average of four sessions of IPL treatment was previously shown to be required for symptomatic improvement in MGD patients[28]. In the present study, we applied every other day of BSM treatment for patients with MGD and the results showed an even more efficiency effect than IPL treatment. Moxibustion is a traditional Chinese method that uses the heat and infrared generated by burning herbals to relieve pain and treat diseases[9-10,25]. A systematic review suggests that moxibustion is more effective than drug therapy in reducing pain[12]. Bian-stone is another common method to promote blood circulation, reduce pain, and relax the body by the thermal radiation property[17-18]. We did not detect any adverse effects such as a burning sensation in any of the subjects treated with BSM treatment. Although further studies will be required to confirm and extend our findings, the results of the present study suggest that BSM treatment of every other day may be necessary for the effective treatment of MGD.

Our findings contributed to open a promising prospect for applying BSM in MGD treatment. There are some crucial advantages. First, the BSM enables continuous treatment of low intensity and wide infrared spectroscopy to its site of action for a relatively more stable effect. Second, it simultaneously achieves warm compress, anti-inflammation, and bacteriostasis effects in correspondence with the different etiology of MGD. Third, our BSM spectacles provides a home-based treatment method for MGD patients and is convenient for patients to use in daily life.

There are some limitations in our study. First, the sample size is not large enough to develop a standardized protocol for MGD treatment with BSM. Different use frequencies should be included in further studies. Second, the ocular reactivity to infrared may differ among different populations. Patients from other ethnic groups are required to validate the therapeutic effect. Third, the mechanism underlying the effectiveness of BSM treatment is still unknown and needs to be further demonstrated. Finally, further larger sample studies are needed to evaluate the effects of BSM on different MGD severity subtypes.

In conclusion, this study described a new Chinese medicine therapy with BSM, which was demonstrated to be safe and effective for the treatment of MGD. BSM group and IPL group showed parallel improvements with respect to most clinical parameters. However, patients treated with BSM demonstrated stronger effects on OSDI reduction and lid margin neovascularization improvement than IPL group. Although further studies will be necessary to develop and establish this treatment procedure in the clinic, our results suggest that repeated BSM sessions improve the symptom and homeostasis of tear film components in patients with MGD.

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