Novel Concept of Dry Eye and Blepharitis Syndrome (DEBS) and Therapeutic Implications

Conceito de Síndrome de Olho Seco e Blefarite e Implicações Terapêuticas

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Conjunctivochalasis (CCH) is a common, chronic conjunctival condition often underdiagnosed on clinical practice. The hallmark of CCH is loose, redundant, non-edematous conjunctival folds, typically located Blepharitis was initially described by Elschnig (1908) as "chronic inflammation of the lid border".[1] Since then, there was a shift towards its definition according to anatomical location or according to the presence of eyelid findings as anterior blepharitis (seborrheic or staphylococcal), *Demodex* blepharitis, or posterior blepharitis. However, this classification has evident limitations: 1) many patients have overlapping findings of anterior and posterior blepharitis; 2) diagnosing blepharitis only in the presence of biomicroscopic lid signs is insufficient, since many patients with meibomian gland dysfunction (MGD) present without obvious MGD signs in the early stages;[2] and 3) the correlation between eyelid signs and symptoms is poor.[3]

Blepharitis is one of the most common ophthalmic disorders, and can affect individuals of all ages. Dry eye disease (DED), another common ocular disorder of multifactorial aetiology,[4] is strongly associated with blepharitis, with a high prevalence of DED in patients with blepharitis and MGD, and an even higher incidence of blepharitis or MGD in patients with DED.[5] This strong epidemiological and clinical association has led to the emergence of a unifying theory for these two conditions – the "dry eye and blepharitis syndrome (DEBS)", as coined by Rynerson and Perry.[6] DEBS can be thought as a multi-step process stemming from increased bacterial survival and biofilm production, occurring over many years or decades.[6] Blepharitis has long been associated with staphylococcal over-colonization of the eyelids,[5] which is possible due to biofilm production, a defence mechanism from host antimicrobial agents which protects bacteria from antibiotics and povidone-iodine scrubs. Bacterial over-colonization results in the activation of genes that lead to production of virulence factors and toxins, which trigger an inflammatory reaction in the eyelid that causes structural damage, causing the clinical signs of collarettes and scale formation, MGD, and dry eye (Table 1).

Primary prevention has long been considered a powerful tool in controlling disease and preventing long-term sequelae, and "improving the local environment of the ocular surface and eyelids" is the mainstay of treatment for blepharitis.[7] Remarkably however, until recently, the only available options for primary prevention were home-based treatments (HBTs), including lid hygiene, warm compress

Table 1. Stages of dry eye and blepharitis syndrome (DEBS), according to Rynerson and Perry.[6]

Stage 1	Stage 2	Stage 3	Stage 4
Lash follicle involvement: the biofilm accesses the potential space between the lash and the surrounding follicle, triggering inflammation, then collarette and scale formation, end-stage poliosis	Lash follicle plus meibomian gland involvement: the biofilm grows into the gland ductule causing dysfunctional meibum ("meibofilm"), then clinically apparent MGD	Lash follicle plus meibomian gland + accessory lacrimal glands of Krause and Wolfring: the biofilm infiltrates the accessory lacrimal glands, causing aqueous-deficient dry eye	Loss of eyelid structural integrity: damage of connective tissue, muscle and nerve endings, leading to severe eyelid changes (laxity, floppy eyelid) with remarkably few symptoms

treatment (WCT), and detergent-assisted cleansing; these have been met with low compliance and variable efficiency.3 It is unlikely that home scrub regiments can eliminate completely the biofilm layer upon the lid margin, and thus patients will gradually have increased bacterial population of the eyelid, setting the stage for the development of DEBS over the course of years or decades.

Understanding the pathophysiology of dry eye and blepharitis as a syndrome for which the root cause may be the overcrowded bacterial biofilm, and the recognition that HBTs are often ineffective, has increased the interest in novel therapeutic options (including warming and humidity devices to improve the results of HBTs) and especially in-office technologies.

Intense pulsed light (IPL) is a high-intensity, non-coherent, and non-laser light source ranging from 500-1200 nm. It was originally developed for dermatologic applications, and was introduced for treating MGD in 2015. The llight pulses are applied into the cheek skin, although protocols vary widely, and some authors apply pulses directly into the upper eyelids (protecting the eye with cover shields). The intensity of light therapy is determined by the Fitzpatrick scale for scoring skin types, to minimize the risk of melanin damage and subsequent hypopigmentation.[8]

Although the exact mechanisms underlying its beneficial effects are complex and still not well understood, it has been suggested that it reduces telangiectasia by producing a selective vessel photothermolysis, inducing thrombosis and therefore reducing cytokine leakage, thus modulating the secretion of pro-inflammatory molecules such as interleukin-17A, interleukin-6, and prostaglandin E2. Another proposed mechanism states that IPL reduces the bacterial load of the eyelid margin and eradicates Demodex mites. Lastly, the warming effect of the light may result in softening and liquefaction of meibum. This hypothesis is related to the photomodulation effect that can stimulate the mitochondria of the meibomian glands (MG), improving its function.9 Several studies including meta-analyses have shown consistent improvements in OSDI, TBUT, and MG function, without changes in tear production and tear osmolarity.[8,10] Furthermore, the ocular effects of IPL are cumulative, lasting for at least 6 weeks after the completion of treatment. Therefore, repeated treatments with IPL potentiates its effects.

Vectored thermal pulsation (VTP) is an FDA-approved therapy (Lipiflow®, Johnson & Johnson) that delivers 42.5ºC heat and simultaneous pulsated pressure specifically to the eyelids and MG, evacuating the MG of upper and lower eyelids with great safety. Recent meta-analyses have shown that a single 12-minute VTP treatment is an effective treatment option for MGD, improving MG function as well as objective and subjective measures of DED symptoms for up to 3 months, and is more efficacious than traditional WCT.[11] In addition, the effects of a single treatment may be long lasting.[12]

Microblepharoexfoliation (MBE) consists of the mechanical debridement and exfoliation at the lid margin performed in-office by trained ophthalmologists (because of the proximity and vulnerability of the eye), using a commercially available, patented, hand-held device consisting of an electromechanical unit and a disposable sponge-tipped microsponge that spins at 2600 rpm (BlephEx® LLC, Alvaton, KY). Published experience shows that MBE effectively cleans and exfoliates the eyelid and lashes in depth and with great precision, improving lid margin changes, meibum quality and MG scores, tear film stability. and dry eye symptoms (Table 2). MBE may also be superior to lid hygiene and pediculicides to reduce *Demodex* lash infestation, although this is not definitive.[13–15] It is likely that MBE is cost-effective in blepharitis treatment (regardless of anatomical location) compared with standard HBTs. Microblepharoexfoliation may additionally be considered in patients with dry eye symptoms without obvious signs of blepharitis, including contact lens wearers and keratorefractive surgery patients, in whom continuous exposure to bacteria, biofilm and bacterial virulent factors contributes to dry eye symptoms, decreased optical quality, and even to complications, such as marginal ulcers. Furthermore, MBE may be considered preoperatively for keratorefractive and intraocular surgery to prevent infectious complications. Potential benefits from MBE in candidates for cataract surgery are two-fold: 1) improved ocular surface status, and therefore improved postoperative optical quality and dry eye symptoms; and 2) reduced biofilm and bacterial load before surgery may help decreasing the incidence of postoperative bacterial endophthalmitis.16 This same rationale may be applied to the preoperative preparation in intravitreal injections and glaucoma or vitreoretinal surgery. Finally, regular MBE may be advised in patients with dry eye symptoms and mild blepharitis, as repeated, in-depth removal of bacterial biofilm will likely reduce the likelihood of severe blepharitis decades later in life.

Transcutaneous electrical stimulation (TES) consists of the application of low-power, microcurrent electrical

Table 2. Reported results of microblepharoexfoliation (BlephEx®) for the treatment of *Demodex* blepharitis and for meibomian gland dysfunction

Author / Journal (Year)	Study design	Patients (n)	Diagnosis	F-U (weeks)	OSDI score		Corneal staining		Conjunctival staining		MG dysfunction		*Demodex* infestation		TBUT		Schirmer 1		Tear MMP-9 levels		Lid margin score		Other outcomes	Comments	Conclusions
					Before	After	Before	After	Before	After	Before	After	Before	After	Before	After	Before	After	Before	After	Before	After			
Murphy *et al*[13] / Contact Lens and Anterior Eye (2017)	RCT: MBE *vs* hygiene + pediculicide	86	*Demodex* blepharitis	4 weeks	30.1 ± 19.8	12.8 ± 12.8	N/R		N/R		N/R	M/R	6.5/lash	2.7/lash	N/R		N/R		N/R		N/R		Improvement in BCVA after treatment	No statistically significant differences in *Demodex* density and OSDI score between MBE and hygiene + pediculicides	All methods tested showed good ability to reduce *Demodex* density and improve symptoms
Epstein *et al*[14] / Cornea (2020)	RCT: MBE+P scrubs *vs* MBE + sham scrubs	50	*Demodex* blepharitis	8 weeks	MBE+P 19.1 ± 8.5	MBE+P 16.6 ± 7.9	MBE+P 0.5 ± 0.2	MBE+P 0.5 ± 0.2	N/R		MBE + P 2.4 ± 0.3	MBE+P 2.4 ± 0.3	MBE+P 4.7 ± 1.5 /4 lashes	MBE+P 2.6 ± 1.2 /4 lashes	N/R		MBE+P 11.0 ± 2.1	MBE+P 10.8 ± 2.3	MBE+P Elevated levels in 43.5%	MBE+P Elevated levels in 37%	MBE+P 2.7 ± 0.3	MBE+P 2.3 ± 0.4	MBE significantly improved MG expression and lid margin score	In the subgroup of patients with OSDI > 20, MBE+sham improved OSDI scores from 53.1 ± 19.6 to 16.3 ± 43.2	MBE leads to significant reduction in *Demodex* density, but conclusions on clinical significance not made; terpinen-4-ol scrubs no significant improvement over sham scrubs
					MBE + sham 16.9 ± 7.9	MBE + sham 7.7 ± 5.4	MBE + sham 0.3 ± 0.2	MBE + sham 0.1 ± 0.2			MBE + sham 2.4 ± 0.3	MBE + sham 2.1 ± 0.3	MBE + sham 5.1 ± 1.4 /4 lashes	MBE + sham 2.5 ± 0.9 /4 lashes			MBE + sham 10.8 ± 2.2	MBE + sham 7.8 ± 1.8	MBE + sham Elevated levels in 50%	MBE+ sham Elevated levels in 52.8%	MBE + sham 2.8 ± 0.3	MBE + sham 2.0 ± 0.3			
Choi and Stein[15] / Acta Scientific Ophthalmology (2020)	RCT: MBE + hygiene *vs* hygiene alone	50	*Demodex* blepharitis	4 weeks	MBE + hygiene 15.67 ± 5.73	MBE + hygiene 14.30 ± 6.06	MBE + hygiene 0.48 ± 0.32	MBE + hygiene 0.35 ± 0.27	MBE + hygiene 1.05 ± 0.40	MBE + hygiene 0.90 ± 0.38	MBE + hygiene 1.98 ± 0.28	MBE + hygiene 1.82 ± 0.32	MBE + hygiene 5.32 ± 3.21 /4 lashes	MBE + hygiene decrease 3.88 ± 1.31	MBE + hygiene increase 1.13 ± 2.15 sec		MBE + hygiene 10.75 ± 3.54	MBE + hygiene 10.41 ± 3.79	MBE + hygiene Elevated levels in 52%	MBE + hygiene Elevated levels in 50%	N/R		No statistically significant differences between MBE and hygiene in tear osmolarity, lipid layer thickness	MBE did not provide additional benefit in symptom scores and lid margin signs compared with lid hygiene alone (except *Demodex* density)	MBE + hygiene was superior to hygiene alone in reducing *Demodex* density, and improved TBUT
					Hygiene alone 19.41 ± 6.99	Hygiene alone 13.14 ± 6.00	Hygiene alone 0.32 ± 0.30	Hygiene alone 0.45 ± 0.31	Hygiene alone 0.98 ± 0.39	Hygiene alone 1.07 ± 0.43	Hygiene alone 2.07 ± 0.33	Hygiene alone 1.85 ± 0.27	Hygiene alone 4.08 ± 2.61 /4 lashes	Hygiene alone decrease 0.04 ± 1.36	Hygiene alone 11.22 ± 3.05		Hygiene alone 11.22 ± 3.05	Hygiene alone 12.81 ± 4.16	Hygiene alone Elevated levels in 62%	Hygiene alone Elevated levels in 57%					
Connor *et al*[17] / ARVO Annual Meeting Abstract (2015)	Prospective study: MBE	20	MGD	4 weeks	43.74 ± 14.27	20.33 ± 14.35	N/R		N/R		1.65 ± 0.05	0.76 ± 0.59	N/R		3.31 ± 1.30	5.47 ± 4.30	N/R		N/R		(Efron scale) 1.24 ± 0.69	(Efron scale) 0.58 ± 0.54	Increased MG function	Subjects were 50% less symptomatic after treatment	MBE improved TBUT, MG function and symptoms
Byeon *et al*[18] / J Korean Ophthalmol Soc - Abstract (2020)	Prospective study: MBE	24	MGD	4 weeks	38.84 ± 17.13	18.67 ± 15.01	1.85 ± 2.98	1.65 ± 2.32	N/R		MGD score 21.60 ± 6.95	MGD score 18.02 ± 6.68 (p = 0.001)	N/R		2.65 ± 1.16	3.77 ± 1.80	9.25 ± 7.74	9.31 ± 8.11	N/R		N/R		Lipid layer thickness changes not statistically significant	Topical steroid drops provided synergistic effect in improvement	MBE improved OSDI score, MGD score and TBUT
Moon *et al*[19] / BMC Ophthalmol (2021)	Retrospective case series: MBE + MG expression	24	MGD	4 weeks	55.79 ± 3.18	45.27 ± 2.98	1.67 ± 0.10	1.15 ± 0.09	N/R		84.8% MGD stage ≥ 3	21.7% MGD stage ≥ 3	N/R		4.21 ± 0.30	5.55 ± 0.21	10.65 ± 1.32	11.12 ± 1.49	Elevated levels in 83.3%	Elevated levels in 50%	Lid margin telangiectasia and MG plugging significantly improved, but lid margin irregularity did not		Significant improvement in meibum color, consistency and grade	Lid margin irregularity and mucocutaneous junction changes are chronic changes which may require extended session of MBE+MG expression	Significant improvements in TBUT, ocular surface staining, lid margin telangiectasia, meibum, MGD stage and OSDI score

F-U: follow-up time; OSDI: ocular surface disease index; MG: meibomian gland; TBUT: tear break-up time; MMP-9: matrix metalloproteinase-9; RCT: randomized controlled trial; MBE: microblepharoexfoliation; BCVA : best-corrected visual acuity; MBE+P: microblepharoexfoliation plus pediculicide; MGD: meibomian gland dysfunction; N/R: not reported.

stimuli (quantum molecular resonance, QMR®), delivered via eyelid goggles (Rexon-Eye®, Resono Ophthalmic, Sandrigo, Italy). Patients are treated in four 20-minute sessions over four weeks.[20] The rationale behind TES is the application of QMR, in which the energy is transmitted to the tissue packed in quanta, producing mechanical stimulation, electrical interaction with cell membranes and biochemical interactions at the sarcoplasmic reticulum, which may stimulate the lacrimal system, the MG tissue and the ocular annexal structures.[21,22] It is possible that TES may also stimulate the trigeminal nerve to reduce pain and photophobia symptoms related to DED,[22] and also stimulate anti-inflammatory pathways.[20] Published evidence suggests that TES is easy to perform, safe and cost-effective, and leads to significant improvements in OSDI score (particularly in patients with hyposecretory DED), tear film stability, tear production, tear inflammatory markers, and ocular surface staining.[20–23]

Besides the technologies previously described, an increasing number of methods have been developed to address MGD, with variable results.[9] In a comprehensive review of MG probing,[9] this technique showed to be highly effective in improving symptoms and signs of DED and MGD, but limited by its short lived effect (average 38 weeks) and by reduced number of expressible MG for each retreatment.[9]

In conclusion, the increasing understanding of the mechanisms underlying DEBS has brought about a revolution in the treatment arsenal available for ophthalmologists and patients. In-office treatments are valuable tools that effectively address the signs and symptoms of eyelid disease, with the choice of treatment being directed according to the main eyelid findings. Intense pulsed light and VTP are relatively established treatments, its effectiveness supported by several studies. Importantly, understanding the role of bacterial biofilm in the pathogenesis of blepharitis makes MBE an extremely promising option. Finally, we must emphasize that in-office treatments greatly enhance the patient-physician relationship, crucial for the education and management of patients with DED and blepharitis.

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