Summary

Demodex mites are minute arachnoids, members of the Acarina subclass, which inhabit skin structures of humans and many animal species. They are all highly specialised organisms, characterised by an obligate dependence on their host. Currently, there are two known species specific for humans: *Demodex folliculorum* and *D. brevis*. A growing number of recent studies suggests that parasitic mites may contribute to the pathogenesis of human diseases, including ocular conditions.

Chalazion, pterygium, chronic blepharitis, keratoconus are examples of conditions of the ocular surface and ocular protective structures, which ophthalmologists encounter in their daily practice. The aetiology and pathogenesis of these diseases with their signs and symptoms remain unclear.

Also, the causes of contact lens-associated discomfort and discontinuation of contact lens use among wearers who previously reported no tolerance issues, have yet to be explained.

Taking into account the growing number of contact lens wearers, the identification of such causes could significantly impact the number of contact lens dropouts and reduce associated losses incurred by the industry. Discomfort, especially dryness, is the main reported cause of dissatisfaction among soft contact lens wearers and is by far the leading cause of discontinuation of use. It is suggested that the discomfort experienced by these patients is related to dry eye syndrome (DES), a condition which is currently the subject of much research.

Dry eye syndrome, as defined by DEWS, *is a multifactorial disease of the tears and ocular surface that results in symptoms of discomfort, visual disturbance, and tear film instability with potential damage to the ocular surface. It is accompanied by increased osmolarity of the tear film and inflammation of the ocular surface*. The basic test assessing the stability of precorneal tear film is the breakup time (BUT). There are also other, more novel, non-invasive methods to assess tear film stability using Mengher's keratoscope, the Tearscope device or the latest Keratograph 5M by Oculus with NIBUT (Non-Invasive Break-Up Time) assessment software. These devices eliminate reflex tearing induced by instillation of fluorescein into the conjunctival sac, thus improving the test's specificity. Tear film stability and osmolarity are the two

invariably altered parameters in all types of DES. Hence, BUT is one of the staple tests in the diagnostic assessment of DES.

There is reason to believe that infestation with *Demodex* mites could be one of the potential aetiological factors behind the above-mentioned ocular conditions, i.e. chalazion, pterygium, chronic blepharitis, keratoconus as well as soft contact lens intolerance among habitual users, and DES with tear film instability, its excessive evaporation and reduced NIBUT.

With the above in mind, our study had the following aims:

1. To test for the presence of mites (*Demodex* spp.) in eyelash follicles and assess their potential role in the aetiology of selected diseases of the ocular surface and ocular protective structures i.e.:
    - chalazion,
    - pterygium,
    - chronic blepharitis,
    - keratoconus.
2. To determine the role of mite infestation of eyelash follicles in the emergence of soft contact lens intolerance in habitual users.
3. To assess the potential impact of mites on BUT and tear film stability.

The study enrolled 710 subjects who had given informed consent in writing.

The subjects were allocated to one of 7 study groups presented in Table 1, page 46.

Additionally, subsets of subjects from groups 3, 5, 6 and 7 underwent a non-invasive breakup test (NIBUT) and were allocated to:

- group 8, if they were found to have mites,
- group 9, if they were found to have no mites.

All subjects from the respective groups underwent random sampling of at least 10 eyelashes from the upper and lower lid of either eye. The sampled material was

assessed by light microscopy. The test result was deemed positive with the finding of at least one adult, larva, protonymph or nymph form of *D. folliculorum* or *D.brevis*.

In order to verify the hypothesis suggesting that the presence of selected ocular conditions as well as the presence of discomfort symptoms leading to intolerance of contact lens wear in habitual contact lens users correlate with the presence of Demodex mites in eyelash follicles, we conducted a statistical analysis of collected data. We applied the χ^2 independence test with a two-by-two contingency table. As the χ^2 test does not inform about the strength of association, we also calculated Chuprov's T, the values of which are included in an interval of <0;1>. We calculated percentages of mite infestation for each group with a defined disease entity, the group of healthy subjects, as well as the groups of subjects tolerant and intolerant of contact lenses.

We also computed descriptive statistics of the datasets of the first and mean NIBUT measurements for healthy and mite-infested subjects. The differences were shown by calculating arithmetic means of the first and the mean (as defined by Oculus for the videokeratograph 5M) breakup time, maximum and minimum values, variance and the standard deviation of the measurement sets.

The results of our observations are presented in the tables below.

Table I. Percentages of infested subjects.

	chalazion	pterygium	chronic blepharitis	keratoconus	healthy	contact lens intolerance	contact lens tolerance
Percentages of infested subjects	96%	96%	98%	55%	22%	94.37%	9.09%

Table II. χ^2 and Chuprov's T values.

	chalazion	pterygium	chronic blepharitis	keratoconus	contact lens intolerance
χ^2	163.20	91.25	129.32	30.91	107.45
Chuprov's T	0.75	0.67	0.73	0.33	0.85

Table III. First and mean breakup time.

NIBUT	*Demodex* present	*Demodex* absent
First breakup	8.47 s	14.76 s
Mean breakup	12.47 s	18.02 s

Based on the results of our study, we propose the following conclusions:

1. Infestation with *Demodex spp.* mites can be an underlying aetiological factor of ocular diseases such as: chalazion, pterygium, chronic blepharitis. Patients with the mentioned conditions should be examined for demodicosis as this may lead to more effective treatment.
2. Long-standing presence of mites on eyelid margins leads to tear-film instability and chronic inflammation of the ocular surface, which may in turn lead to the development of pterygia.
3. *Demodex* mite infestation does not directly lead to the development of keratoconus but it is possible that it plays an indirect aetiological role, *inter alia* through an increased frequency of eye-rubbing in patients with eyelid demodicosis. Infestation with *Demodex spp*. could be a risk factor for the development of keratoconus.
4. Infestation with *Demodex spp.* should be considered one of the significant causes of discontinuation of contact lens use in habitual wearers who earlier had no tolerance issues. Discomfort reported by contact lens users should trigger appropriate testing to rule out or confirm demodicosis as a potential cause of discomfort experienced with contact lens use.
5. Non-invasive breakup time (NIBUT) points to eyelid demodicosis as a possible cause of dry eye syndrome associated with instable tear-film and its excessive evaporation.
6. The correlations determined in the present paper provide further evidence of the pathogenic role of *Demodex* mites in the development of diseases of the ocular surface and ocular protective structures confirm the need for establishing a disease entity name: *demodicosis ophthalmica*.

KEY WORDS: *Demodex folliculorum*, *Demodex brevis*, demodicosis, chalazion, pterygium, chronic blepharitis, keratoconus, contact lenses, tear-film.