

Analysis of tear film breakup on Etafilcon A hydrogel lenses

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Abstract

Purpose: There is a need to understand better the biomaterial characteristics responsible for tear film stability during hydrogel lens wear. The underlying cause of pre-lens tear film instability may be indicated by the distribution of sites of breakup. The purpose of this study was to compare the distribution of rupture sites during wear of a common biomaterial to that without lenses. **Methods:** A videokeratography unit, the Topographic Modeling SystemTM, was used to capture an image of the tear film at the moment of breakup. Forty measurements were made for each of ten subjects, and the resultant rupture site distributions evaluated. The pre-lens tear film breakup locations were studied for Acuvue (Etafilcon A) disposable contact lenses using the same technique. **Results:** There was a statistically significant trend for pre-corneal tear film breaks to occur more commonly in parameniscal zones than in areas overlying the central cornea (ANOVA, $p = 0.002$). With the Etafilcon A lenses, a significant difference in breakup frequency between the two regions was not observed. **Conclusions:** The pre-corneal tear film findings are consistent with the meniscus model of tear film stability; however, the biomaterial surface characteristics of Etafilcon A give other factors a more dominant role in tear film rupture. © 2001 Elsevier Science Ltd. All rights reserved.

Keywords: Tear film breakup; Tear film stability; Tear film meniscus; Hydrogel lens; Acuvue

1. Introduction

The tear film stability on the surface of hydrogel contact lenses is often reduced compared to the stability of the normal pre-ocular tear film [1–3]. The wearing of hydrogel lenses is also associated with an increased incidence of symptoms of dryness [4–6]. In order to improve vision and comfort during lens wear, there is a need to understand better the biomaterial characteristics responsible for tear film stability during hydrogel lens wear.

A variety of methods have been applied in the assessment of tear film stability. The pre-lens tear film stability is defined as the time for breaks or dry spots to appear in the surface tear film layer, in the absence of blinking. Clinical instruments such as the keratometer have been applied to detect tear film breakup, without the instillation of fluorescein; however, only a limited area of the tear film is monitored [7]. The custom [8] and clinical [9] instruments that assess non-invasive

breakup time over the entire cornea or lens, provide the most complete information as to pre-lens tear film stability.

The underlying cause of tear film instability on hydrogel biomaterials may be indicated by the distribution of sites of breakup. One theory of tear film breakup in the normal eye is that of McDonald and Brubaker, which contends that the tear film menisci induce thinning and breakup of the tear film adjacent to the menisci [10–12]. The more commonly cited theory of tear film breakup is that of Holly, which attributes tear film breakup to contamination of the mucus layer by lipid, causing hydrophobic areas to develop [13]. A number of other theories of tear film instability are also present [14]. In the latter theories, the tear film breakup sites would be expected to be more randomly distributed.

In this study, we used a non-invasive assessment technique to examine the distribution of pre-corneal tear film rupture sites in normal subjects, and compared them to tear film breakup location patterns during wear of Etafilcon A hydrogel lenses.

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2. Methods

2.1. Subjects

The research procedures adopted in this study followed the tenets of the Declaration of Helsinki. Ten subjects were recruited for the study, five males and five females. Subjects were drawn from the staff and student population at the Queensland University of Technology (QUT) School of Optometry, and ranged in age from 20 to 47 yr. All ten subjects were in good general health, were free of significant anterior ocular pathology, and were asymptomatic for dry eye, achieving a score of less than 14 on the McMonnies dry eye survey test [15]. Individuals taking prescribed systemic medication (apart from oral contraceptives) were excluded from the study, as were those using topical ophthalmic preparations. None of the subjects wore contact lenses routinely. In accordance with the requirements of the QUT Research Ethics Committee, informed consent for participation in the study was obtained from each subject after the nature of the experimental procedures had been explained.

2.2. Apparatus and procedures

Breakup of the tear film is normally studied by instilling fluorescein into the eye and watching for the formation of dark areas in the coloured tear film. These dark areas are presumed to represent breaks or dry spots [16,17]. Despite the popularity of this test, it has been suggested that fluorescein itself may have an adverse effect on tear stability, and for this reason, non-invasive methods are preferable for the examination of tear film breakup [8,18]. Several non-invasive assessment techniques have been developed. Most rely on the detection of discontinuities in an illuminated pattern that has been reflected in the pre-corneal tear film. Distortions and discontinuities will occur in the reflected pattern after the eye has been held open for a period of time. It has been postulated that distortions indicate local thinning of the pre-corneal tear film, whereas frank discontinuities represent breaks [8].

To determine the distribution of sites of pre-corneal and pre-lens tear film rupture, a videokeratography unit, the Topographic Modeling System™ (TMS-1™, Computed Anatomy Incorporated, New York), was used to capture an image of the tear film at the moment of breakup. Measurements were made on the right eye only. Following alignment of the instrument by the examiner, the subject was asked to blink three times, and then to refrain from blinking whilst fixating the centre of the TMS-1™ mire target. The reflected image of the mires in the pre-corneal or pre-lens tear film was observed on the video display (Fig. 1A), and monitored for the development of a discontinuity in the circular

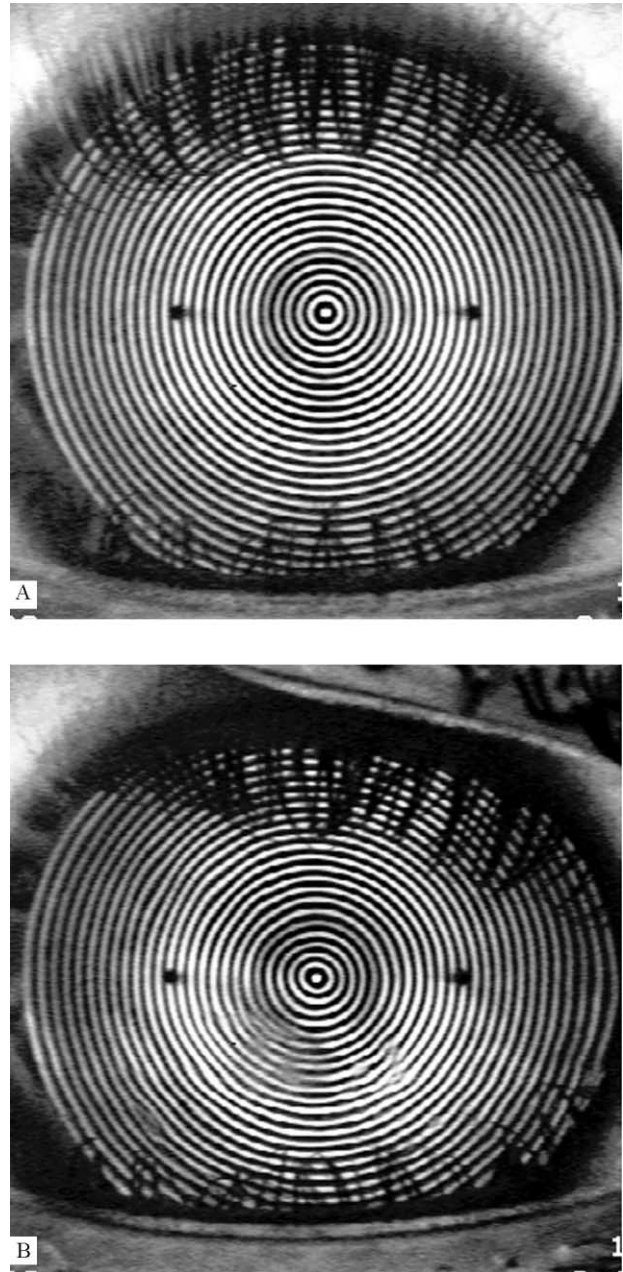


Fig. 1. (A) Normal tear film showing reflection of the TMS-1™ mires. Shadows from the subject's eyelashes are visible inferiorly and superiorly. (B) Tear film rupture as evidenced by discontinuity of the mires inferiorly. Multiple breakup locations may be observed.

pattern (Fig. 1B). The disrupted image was then captured on the TMS-1™ screen. Video modification of the TMS-1™ apparatus enabled magnified examination of the reflected mires, thereby enhancing the ease with which discontinuities could be detected. Captured images were stored on the hard disk for later analysis.

Subjects attended for two sessions on separate days. Pre-corneal tear film breakup locations were measured at one session, and pre-lens tear film breakup locations at the other. The order in which these assessments were made (e.g. pre-corneal first, followed by pre-lens) was

varied randomly from subject to subject. The same group of subjects was used for both assessments so that individual variability would not unduly influence the nature of the tear film breakup location distributions observed under the two conditions. For the pre-lens tear film assessments, subjects were fitted with Acuvue (Etafilcon A, 58% water content, $-3.00D$) disposable contact lenses (Vistakon, Jacksonville, FL). Lenses were allowed to settle on the eye for 2–3 min before tear breakup assessment commenced. Care was taken to ensure that the contact lenses were comfortable for the subjects before measurements were made. Room temperature and humidity were recorded for each subject, and for each session. Room temperature ranged from 22.3°C to 26.1°C, and relative humidity from 48% to 71%.

In total, 40 measurements were made for each subject at each of the two sessions. Measurements were grouped in sets of four, with subjects having 1–2 min break between each set. For any one measurement, if the subject blinked before a discontinuity was observed in the mire image, the procedure was repeated.

2.3. Image analysis

Stored images for each subject were viewed on the video monitor ($12.3 \times$ magnification), and the distribution of tear film rupture sites recorded by marking each breakup location on a transparency overlying the screen. Upper lid, lower lid and limbal positions were also marked on the transparency. Pre-corneal and pre-lens data were recorded separately. Multi-zone breaks were noted individually, so that if the tear film ruptured in three sites simultaneously, three breaks were recorded. Each topographical “map” of tear film breakup was scanned into a Macintosh Quadra 605 computer, and then analysed using NIH Image software (National Institutes of Health, USA).

The tear film in the interpalpebral zone overlying the cornea was divided into three sectors: (i) the superior parameniscal band, a 1.5 mm wide zone inferior to the margin of the upper lid; (ii) the inferior parameniscal band, a 1.5 mm wide zone superior to the margin of the lower lid; and (iii) the central corneal zone. The total number of breakups in each zone was calculated for each subject, and for each tear film assessment. Zone sizes were also determined by counting the number of pixels in each sector for each digital image, so that the density of breaks (breaks per area) could be estimated for every sector.

The density of breaks in the central and parameniscal areas was compared statistically using an analysis of variance (ANOVA) for repeated measures. The statistical comparison was made for the two conditions of pre-corneal tear film breakup and pre-lens tear film breakup.

3. Results

3.1. Pre-corneal tear film

Pre-corneal tear film breakup locations for each of the ten subjects are illustrated in Fig. 2. Table 1 gives parameniscal and central corneal zone proportions and breakup counts for each subject. The breakup densities in these zones are also given for each subject. Mean results for the ten subjects are shown. It may be seen from Table 1 that for each subject, the total number of breakup sites recorded exceeded the number of NIBUT measurements made (40), and this total varied between subjects. This variability may be explained by the inclusion of multi-zone breaks in the data.

Overall, there was a trend for breaks to occur more frequently in parameniscal areas than in the central corneal zone. This predilection for parameniscal tear film breakups was statistically significant (ANOVA $F = 17.89$, $df = 9, 1$ $p = 0.002$). Not all subjects demonstrated substantially more breakups in the parameniscal zones compared with the central corneal zone, however, with subjects 6, 7 and 9 having breakup density ratios close to unity.

3.2. Pre-lens tear film

Pre-lens tear film rupture patterns for the ten subjects are shown in Fig. 3. Table 2 gives the associated zone size and breakup count distributions for the two tear film zones described above. In addition, the breakup densities in these zones are shown for each subject. As for the pre-corneal tear film data, the total number of breaks recorded for any one subject was always greater than 40.

Analysis showed that there was no significant difference between the group results for the central and parameniscal zones (ANOVA $F = 0.38$, $df = 9, 1$ $p = 0.55$). Only five subjects (subjects 1, 3, 4, 7 and 9) showed substantially more breakups in the parameniscal zones than in the central corneal zone. Subjects 2 and 10 showed the reverse effect, while subjects 5, 6 and 8 demonstrated similar distributions for the two tear film regions.

4. Discussion

The Etafilcon A biomaterial appears to modify the surface properties of the system, in that the distribution of tear film rupture sites differed to that of the normal eye. The tendency for pre-corneal tear film breakup to occur more commonly in parameniscal zones than in areas overlying the central cornea is consistent with predictions based on the meniscus model of tear film stability [10]. Results for tear film breakup in the

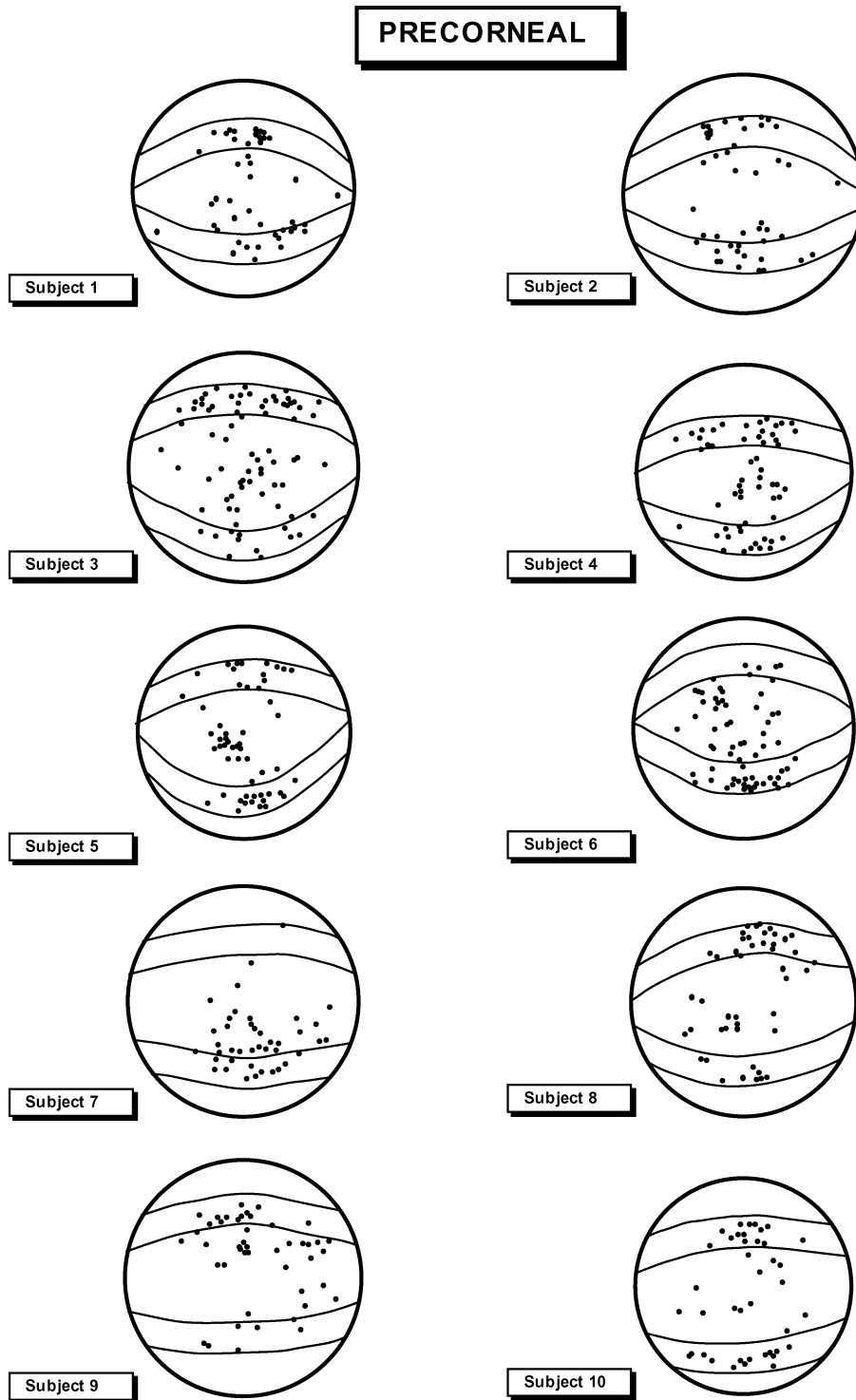


Fig. 2. Precorneal tear film breakup locations for each of the ten subjects. Locations are shown relative to the superior and inferior parameniscal bands, a 1.5 mm wide zone adjacent to each lid margin; and the central corneal zone.

Etafilcon A lens wear do not support a predilection for any of the tear film zones, suggesting that either the lipid diffusion model is supported, or that other factors may complicate the meniscus model for pre-lens tear film breakup. Only one lens type was assessed, and so we cannot be certain if the result is due to a unique property

of the Etafilcon A biomaterial or due to a more generic property of contact lenses in general. This is discussed further below.

The results for the pre-corneal tear film breakup are consistent with previous work using fluorescein breakup time, although the present study used a non-invasive

Table 1
Pre-corneal tear film breakup: distribution of rupture sites for the ten subjects

Subject no.	% Central corneal area* (Ac)	% Total parameniscal area* (Am)	No. of central corneal breaks (Bc)	Total no. of parameniscal breaks (Bm)	Density of central rupture sites Bc/Ac	Density of parameniscal rupture sites Bm/Am
1	0.510	0.490	15	29	29.4	59.2
2	0.533	0.467	17	28	31.9	60.0
3	0.615	0.385	34	42	55.3	109.1
4	0.514	0.486	18	38	35.0	78.2
5	0.539	0.461	23	31	42.7	67.2
6	0.503	0.497	33	32	65.6	64.4
7	0.627	0.373	27	14	43.1	37.5
8	0.584	0.416	15	30	25.7	72.1
9	0.606	0.394	25	21	41.3	53.3
10	0.610	0.390	13	28	21.3	71.8
Average	0.564	0.436	22	29	39.1	67.3
SD	0.049	0.049	8	8	13.6	18.6

test. Rengstorff [19] assessing fluorescein breakup in 100 normal eyes, divided the pre-corneal tear film into 8 sectors—4 central and 4 peripheral zones (each superior, inferior, temporal and nasal). He observed that breaks occurred more frequently in the inferior and temporal periphery. Cho et al. [20] and Bitton and Lovasik [21] observed a marked predilection for tear film breakup in the inferior periphery compared to the superior corneal periphery.

It is worth noting that in this study not all subjects demonstrated a preponderance of parameniscal pre-corneal tear film breakup. This suggests that other variables, such as the presence of debris or air bubbles in the tear film, may have induced tear film rupture in these subjects. Fatt [22] argued that tear debris particles act as nucleation sites for microscopic air bubbles dissolved in the tear film, and that because of this, they represent points of weakness. The relative frequency of central breaks was higher in 30% of subjects in this study (subjects 6, 7 and 9), suggesting that environmental factors exerted a greater influence on pre-corneal tear film stability in these cases.

The Acuvue lenses used in this study are cast-molded with the Etafilcon A material, which is co-polymer of 2-hydroxyethyl methacrylate (HEMA) and methacrylic acid (MAA). Etafilcon A is exclusively used by Johnson and Johnson Vistakon in all of their lenses including Surevue, Acuvue2, 1-day Acuvue, and AcuvueBifocal. Furthermore, HEMA–MAA materials are widely used for disposable lenses by other contact lens companies. Examples include Ocufilecon D (Ocular Sciences, South San Francisco CA); Vifilcon A (Ciba Vision, Duluth GA) and Methafilcon A (Cooper-Vision, Irvine CA). All of these materials are classified as ionic high water (55–60% range) materials (Food and Drug Administration Group IV). On the basis of the biomaterial characteristics, similar results to the present study might be expected for these other cast-molded

HEMA–MAA lenses, given a similar lens design and thickness [23].

The pre-lens tear film breakup findings in the present study appear to differ from those of earlier investigations. In the studies of Guillon et al. [24] and Guillon et al. [25], it was observed that there was a tendency for pre-lens tear film breakup in the inferior quadrant. This finding was attributed to the higher tear film instability associated with the “black line” junction of the lid tear meniscus and the pre-lens tear film [24]. However, the lenses used in those studies differ from the FDA Group IV (high water, ionic) Etafilcon A lenses of the present study. The study of Guillon et al. [24] used 77% water-content ultrathin lenses, which all caused desiccation staining. These lenses were presumably not normal commercial lenses, as they were thinner than normal high water lenses. Guillon et al. [25] used Bausch and Lomb 03 and 04 series lenses, which are spun-cast low water non-ionic lenses (Polymacon, FDA Group I). The difference in results here may reflect a difference in biomaterial performance.

The tear film zones employed in this study were specifically chosen so that the results for breakup location could be compared with those predicted by the meniscus model of tear film stability. If a radial division of the tear film had been selected, as it was in the Guillon studies [24,25], then a small proportion of the total parameniscal area would have been included in the horizontal quadrants, with the remainder in the vertical quadrants. The difference would be that some information regarding breakup locations close to the lids would have been lost to the horizontal sector analysis.

Numerous factors may play a role in the variability of tear film breakup location in contact lens wear. Doane [26] has found that for rigid lenses, pre-lens tear film breakup time is prolonged if the lens is fitted so that its edges are not in contact with either of the tear film

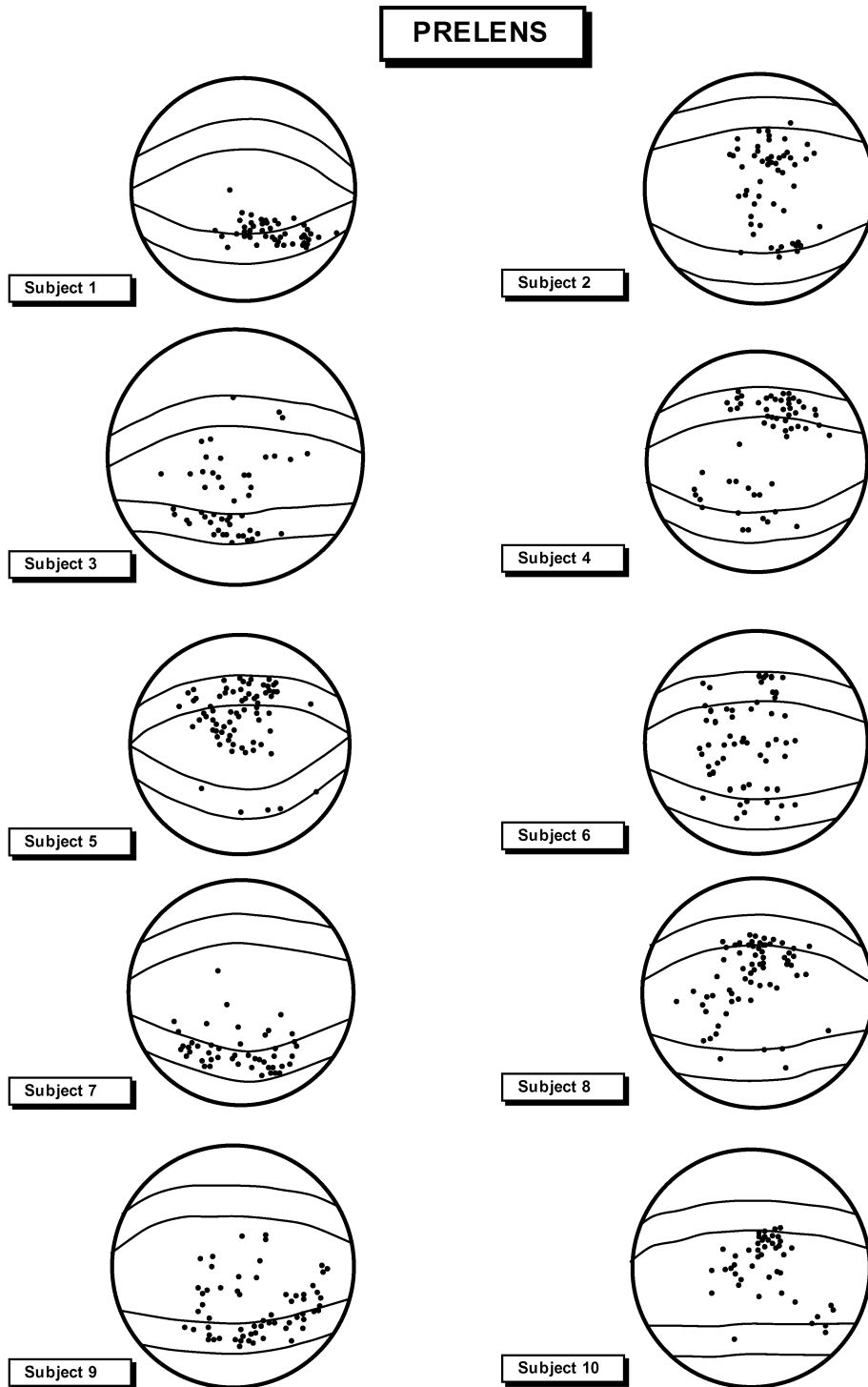


Fig. 3. Pre-lens tear film breakup locations for each of the ten subjects.

menisci. Thus, lid position and lens fit have the potential to influence tear stability. Guillon [27] has suggested that mucus coverage of a contact lens will vary according to the lens material, lens design and lens type, and that the establishment of a uniform tear film mucus layer after the blink will be hampered by the surface discontinuity at the lens edge. Creech et al. [28]

have determined that the aqueous tear film thickness is reduced by approximately one third during hydrogel lens wear, and this may make lipid diffusion more likely and promote tear film instability, in accordance with the model of Holly [13].

In summary, rupture of the pre-corneal tear film has been shown to occur more commonly in parameniscal

Table 2
Prelens tear film breakup: distribution of rupture sites for the ten subjects

Subject no.	% Central corneal area* (Ac)	% Total parameniscal area* (Am)	No. of central corneal breaks (Bc)	Total no. of parameniscal breaks (Bm)	Density of central rupture sites Bc/Ac	Density of parameniscal rupture sites Bm/Am
1	0.506	0.494	19	29	37.5	58.7
2	0.676	0.324	53	4	78.4	12.3
3	0.552	0.448	20	28	36.2	62.5
4	0.581	0.419	20	38	34.4	90.7
5	0.499	0.501	33	37	66.1	73.9
6	0.601	0.399	35	22	58.2	55.1
7	0.602	0.398	11	36	18.3	90.5
8	0.608	0.392	44	22	72.4	56.1
9	0.624	0.376	32	30	51.3	79.8
10	0.625	0.375	39	7	62.4	18.7
Average	0.588	0.412	31	25	51.5	59.8
SD	0.055	0.055	13	12	19.3	26.8

zones than in regions overlying the central cornea. Whilst this finding is consistent with the predictions of the meniscus model for tear film stability, it is possible that environmental variables influencing tear film tensile strength also played a prominent role in tear film rupture in some subjects. In contrast with the pre-corneal tear film findings, a predilection for parameniscal tear film breakup was not observed when the Etafilcon A hydrogel contact lenses were worn. This result differed from that previously reported for the Polymacon material.

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