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Impact of thermo-mechanical skin treatment on refraction and keratometry in patients with dry eye disease and the implications for cataract surgery

Marta Blanco-Vázquez [a], Raquel Gil-Cazorla [b,c,*], Ankur Barua [c,d], Mukesh Taneja [e], Ludger Hanneken [f], Sunil Shah [b,c,d,e]

[a] Ocular Surface Group, Institute of Applied Ophthalmobiology (IOBA), University of Valladolid, Valladolid, Spain
[b] College of Health & Life Sciences, Aston University, Birmingham, United Kingdom
[c] Midland Eye, Solihull, United Kingdom
[d] Birmingham and Midland Eye Centre, City Hospital, Birmingham, United Kingdom
[e] Khmer Sight Foundation, Phnom Penh, Cambodia
[f] Vallmedic Vision, Andorra

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ABSTRACT

Purpose: To determine the changes in keratometry measurements and refraction in patients having the thermo-mechanical periorbital skin treatment, Tixel®, to treat dry eye disease (DED).
Methods: A multi-centre, prospective, non-masked study was conducted. DED patients were recruited in 3 international centres and were evaluated in 5 visits separated by an interval of 2 weeks except for the last visit which took place after 18 weeks from visit 1. The same clinical examination was performed at all visits: OSDI questionnaire, tear stability, keratometry, best corrected visual acuity and refraction. Tixel® treatment was applied at the first 3 visits.
Results: 89 participants (24 males/65 females; mean age: 55.0 ± 14.2 years) were included: 20 presented moderate DED symptoms and 69 severe DED symptoms. Significant differences were found for the spherocylindrical refraction (vector analysis) between visit 1 and visits 2 and 3. Following cumulative analysis, 11.86 % and 16.94 % of participants had more than 0.5 dioptre (D) change in mean keratometry and keratometric astigmatism, respectively, at 3 months post-treatment. A total of 5.40 % had a sphere and cylinder change greater than 0.50D and 16.21 % had the axis changed more than 10 degrees (vector analysis). These changes were particularly significant in patients with severe DED symptoms.
Conclusions: Keratometry readings and refraction can change following thermo-mechanical skin treatment for DED, especially in those patients with severe DED symptoms. This should be considered as potential errors in intraocular lens calculations may be induced.

1. Introduction

An accurate intraocular lens (IOL) calculation is critical for satisfactory postoperative refractive and visual outcomes in patients who undergo cataract surgery and clear lens extraction [1–3]. A precise measurement of the anterior corneal curvature is a key element for IOL calculations [1].

The tear film has an important role in maintaining an optimal refractive surface to provide an adequate visual performance [4–6], and disruption of the tear film leads to unreliable keratometry readings [7]. Disruption of the tear film causes instability which is a fundamental element in the vicious circle of dry eye disease (DED) [8].

DED is a multifactorial condition in which tear film instability, hyperosmolarity, inflammation and neurosensory anomalies play a key role in its pathophysiology [8]. Its prevalence ranges from 5 % to 50 %, increasing with age [9]. It has important socio-economic implications and negatively affects people's quality of life [9].

There are a wide variety of treatments available to improve tear stability and/or corneal surface integrity in DED patients [10–14]. Recently, the treatment of periorbital wrinkles with Tixel® (Novoxel, Netanya, Israel) has been reported to have a positive effect on the signs and symptoms of patients suffering from DED [15–18]. However, the

Abbreviations: **D**, dioptres; **DED**, dry eye disease; **IOL**, intraocular lens; **NIBUT**, non-invasive tear film break up time; **OSDI**, Ocular Surface Disease Index.

* Corresponding author at: School of Optometry, Aston University, Aston Triangle, B4 7ET Birmingham, United Kingdom.
E-mail address: r.gil-cazorla@aston.ac.uk (R. Gil-Cazorla).

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effect of Tixel® treatment on keratometry readings and refraction has not yet been studied. Therefore, the aim of this study is to determine the effect of the novel thermo-mechanical action-based periorbital fractional skin treatment, Tixel®, on keratometry readings and refraction in patients suffering from DED.

2. Patients and methods

This was a multi-centre, prospective, non-masked study approved by the respective Institutional Human Ethics Committees. This study was in compliance with the Tenets of the Declaration of Helsinki and the Good Clinical Practices. The nature of the research was explained to the participants and a signed informed consent was obtained prior to start the study procedures.

2.1. Participants and study visits

Volunteer participants were recruited in 3 international centres (Midland Eye, UK; Vallmedic Vision, Andorra; and Khmer Sight Foundation, Cambodia). Inclusion and exclusion criteria are compiled in Table 1.

The study consisted of 5 visits separated by an interval of 2 weeks +/- 5 days except for the last visit which took place after 18 weeks (from the first visit). The same clinical examination was performed at all visits, and Tixel® treatment was applied at the first 3 visits (Fig. 1).

2.2. Clinical examination

A detailed medical history was performed. Ocular Surface Disease Index (OSDI) questionnaire (range: 0–100) was used to assess DED symptoms and classify patients in: 0–12 absence of symptoms; 13–22: mild symptoms; 23–32: moderate symptoms; and 33–100: severe symptoms [19,20]. Average non-invasive break up time (NIBUT) was measured to evaluate tear stability using the equipment available at each centre: Oculus® Keratograph 5 M (Oculus®, Arlington, WA, USA) at the UK centre, Sirius (CSO Costruzione Strumenti Oftalmici, Florence, Italy) at the Andorra centre and IDRA plus (SBM Sistemi, Turin, Italy) at the Cambodia centre. A detailed slit-lamp examination was performed to detect any eye alterations or anomalies. Keratometry was obtained by corneal topography using the same devices as for NIBUT measurement, except at the Cambodia centre where the Aladdin (Topcon, Tokyo, Japan) was used. Best corrected visual acuity was measured using a LogMAR visual acuity chart. Subjective refraction was carried out and the spherocylindrical refraction of each patient was decomposed into power vector coordinates (M, J_0, J_{45}) and the length of this vector (B), following the method described by Thibos [21], where:

$$M(\textit{spherical equivalent of the given refractive error}) = Sphere + Cylinder/2$$

The result of removing the spherical power is an astigmatic component that can be represented as the sum of 2 Jackson crossed cylinder lenses, one with power J_0 at axis $\alpha = 0^\circ$ and the other with power J_{45} at axis $\alpha = 45^\circ$, where:

$$J_0 = (-Cylinder/2) \times \cos(2\alpha)$$

$$J_{45} = (-Cylinder/2) \times \sin(2\alpha)$$

The length of this vector, B, which represents the overall blurring strength of a spherocylindrical lens or refractive error, is calculated as follows:

$$B = \sqrt{M^2 + J_0^2 + J_{45}^2}$$

Once the statistical analyses were performed, data were converted back in spherocylindrical refraction to be presented in tables and figures.

2.3. Tixel® treatment procedure

Tixel® is a thermo-mechanical system developed for skin fractional treatment. A thermal component called “tip” protrudes and contacts briefly and directly with the skin creating a matrix of either ablative micropores or non-ablative coagulative sites. The surface of the tip is 0.3 cm^2 and consist of an array of 6 x 4 metallic pyramids (24 in total) that is maintained at 400 °C during treatment. The contact duration (milliseconds), the protrusion (the extent of thermal matching, in microns) and the type of contact (single or double) are determined by the user [22]. The following parameters were set for this study: single contact/shot, contact duration of 8 ms and a protrusion of 400 μm.

The area to be treated was previously cleaned according to the

Table 1
Inclusion and exclusion criteria.

Inclusion criteria
Age over 18 years
Mild to moderate periorbital wrinkles
OSDI score ≥ 23
NIBUT ≤ 10 s
No other eye or skin or immune problems
Exclusion criteria
Pregnancy and/or breastfeeding
Lesions in the periorbital area
Acute conjunctivitis or severe blepharitis
Other concomitant anterior eye disease
Exposure to outdoors/sunbed tanning during the last 4 weeks
Unwillingness to follow the Tixel® aftercare instructions after each Tixel® treatment
Active Herpes simplex or tendency for Herpes Simplex in the periorbital area
Skin cancer, malignant sites and/or advanced premalignant lesions or moles in the treatment area
An impaired immune system condition or use of immunosuppressive medication
Collagen disorders, keloid formation and/or abnormal wound healing
Previous invasive/ablative procedures in the areas to be treated within 3 months prior to Tixel® treatment
Use of any medications (including via topical application except artificial tears), herbal treatment (oral or topic), food supplements or vitamins, which may cause fragile skin or impaired skin healing during the last 3 months
Use of oral Isotretinoin (Accutane® or Roaccutane®) within 3 months prior to treatment or less
History of bleeding coagulopathies or use of anticoagulants
Tattoos or permanent makeup in the treated area
Burned skin, blistered skin, irritated skin, or sensitive skin in any of the areas to be treated
Thread lifting of the area to be treated in the last 3 months

NIBUT = Non-invasive tear film break up time; OSDI = Ocular Surface Disease Index.

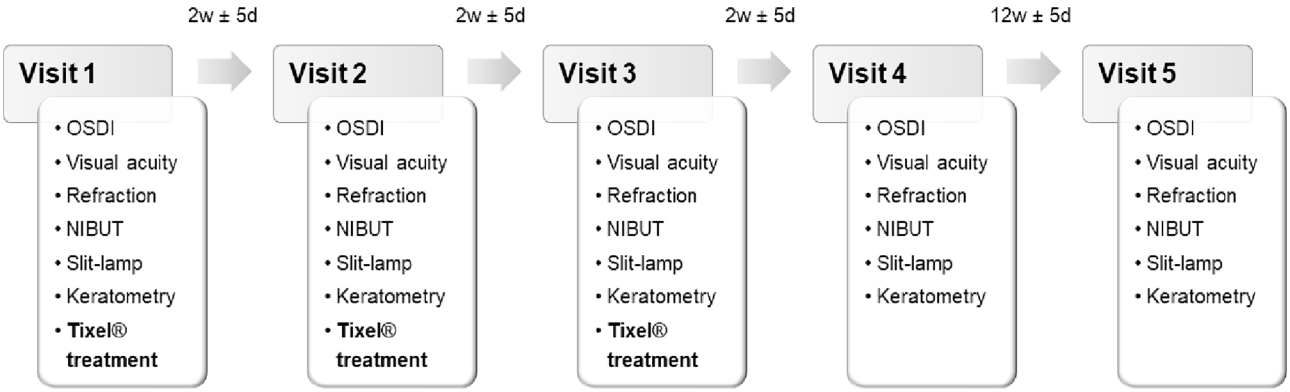

Fig. 1. Clinical procedures performed at each visit. d: days; NIBUT: Non-Invasive Tear Film Break-Up Time; OSDI: Ocular Surface Disease Index; w: weeks.

manufacturer's protocol. A total of 40 shots were applied in the periorbital area in both eyes, 10 shots to each of the upper and lower eyelids (Fig. 2).

2.4. Statistical analysis

Statistical analyses were performed using SPSS Statistics for Windows, Version 24.0 (IBM Corp., Armonk, NY, USA). Sample size was calculated using the G*Power software, Version 3.1.9.4. A small effect size (partial eta squared = 0.02), a statistical significance level of 5 % ($\alpha = 0.05$), a statistical power of 90 % and a correlation among repeated measures of 0.5 were assumed. A total of 77 participants were determined. To allow for dropouts the sample was inflated by 15 % to total sample size of 89 participants.

Both eyes were evaluated, but only right eyes were included for statistical analysis. Categorical variables were presented with percentages. Continuous variables were reported with mean values and standard deviation. The hypothesis of normality was tested for continuous variables using the Kolmogorov-Smirnov test. Then, an overall comparison was conducted among the five study visits using the Friedman test. In addition, comparisons were performed between visit 1 and subsequent visits (visits 2, 3, 4 and 5) using the paired-samples *t*-test or the Wilcoxon test, depending on whether they were normally or non-normally distributed, respectively. P-values ≤ 0.05 were considered statistically significant.

In addition, changes in dioptres (D) of mean keratometry and keratometric astigmatism between visit 1 and post-treatment visit 5 were analysed descriptively considering all patients as a whole, as well as patients with moderate (OSDI score $\geq$ 23 and <33) and severe DED (OSDI score $\geq$ 33) symptoms separately. Changes in refractive errors between visit 1 and visit 5 were calculated using the power vector coordinates (M, J_0, J_{45}) as follows:

$$P_{visit\ 1} = (M, J_0, J_{45})$$

$$P_{visit\ 4\ or\ 5} = (M', J_0', J_{45}')$$

$$P_{change} = P_{visit\ 4\ or\ 5} - P_{visit\ 1} = (M' - M, J_0' - J_0, J_{45}' - J_{45})$$

where P is power vectors.

Then, the change power vector (P_{change} in the above formula) was converted back to spherocylindrical refraction. [23].

3. Results

A total of 89 participants (24 (27 %) males, 65 (73 %) females; mean age: 55.0 ± 14.2 years, range: 23–86 years) were included of whom 20 presented moderate DED symptoms and 69 severe DED symptoms. A statistically significant decrease in OSDI score and an increase in NIBUT were shown after Tixel® treatment in each visit ($p < 0.001$).

Best corrected visual acuity and keratometric and refractive parameters at each of the study visits are shown in Table 2. Comparing the pre-treatment visit (visit 1) with the following visits (visits 2, 3, 4 and 5), a

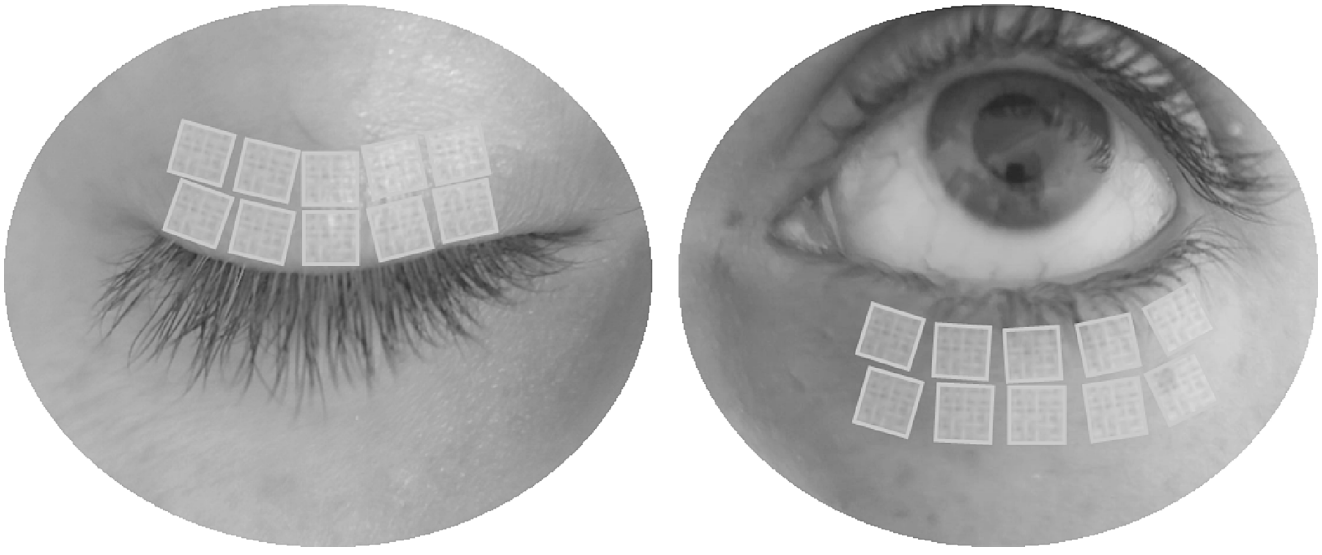

Fig. 2. Graphical representation of the shots applied with Tixel® treatment in the periorbital area.

Table 2
Clinical parameters at each of the study visits.

Parameters	Visit 1 (N = 89)	Visit 2 (N = 87)	Visit 3 (N = 84)	Visit 4 (N = 81)	Visit 5 (N = 62)	P-value[a]
BCVA (logMAR)	0.05 (0.02–0.08)	0.05 (0.02–0.08)	0.04 (0.01–0.06)	0.05 (0.02–0.07)	0.04 (0.01–0.07)	0.14
Mean keratometry (D)	43.45 (43.06–43.84)	43.44 (43.03–43.86)	43.42 (43.01–43.82)	43.38 (42.96–43.80)	43.54 (43.07–44.02)	0.26
Keratometric astigmatism (D)	0.95 (0.79–1.12)	0.99 (0.81–1.18)	0.95 (0.79–1.10)	0.90 (0.76–1.03)	0.87 (0.72–1.02)	0.44
M Refraction	−0.49 (−1.00–0.01)	−0.42 (−0.94–0.10)	−0.43 (−0.97–0.11)	−0.43 (−0.99–0.13)	−0.80 (−1.58–−0.03)	0.70
J_0 Refraction	−0.09 (−0.17–−0.01)	−0.09 (−0.17–−0.01)	−0.10 (−0.18–−0.03)	−0.10 (−0.17–−0.02)	−0.10 (−0.19–−0.01)	0.83
J_{45} Refraction	−0.01 (−0.07–0.06)	−0.01 (−0.08–0.05)	−0.01 (−0.08–0.05)	−0.02 (−0.09–0.05)	0.03 (−0.02–0.09)	0.24
B Refraction	1.43 (1.05–1.82)	1.44 (1.05–1.83)	1.46 (1.05–1.87)	1.45 (1.02–1.88)	1.67 (1.06–2.27)	0.89

Variables are presented as mean (95 % confidence interval). [a]P-values for the comparison of the five study visits. B = overall blurring strength of the spherocylindrical refraction vector; BCVA = best corrected visual acuity; D = dioptres; M, J_0 and J_{45} = power vector coordinates of the spherocylindrical refraction; n = number of participants at each visit; Visit 1 = before Tixel® treatment; Visit 2 = 2 weeks after the first treatment session; Visit 3 = 2 weeks after the second treatment session; Visit 4 = 2 weeks after the last treatment session; Visit 5 = 3 months after the last treatment session.

significant improvement in best corrected visual acuity was only observed between visit 1 and visit 3 (p = 0.04). Mean keratometry was on the borderline of statistical significance between visits 1 and 4 (p = 0.09), with lower values at visit 4. In addition, significant differences were found for the M power vector coordinate between visits 1 and 2 (p = 0.04) and for the overall blurring strength, B, between visits 1 and 3 (p = 0.04).

Individual changes in keratometry and refraction were observed, particularly, 11.86 % and 16.94 % of the overall participants the mean keratometry and keratometric astigmatism, respectively, changed more than 0.50 D between visit 1 and visit 5. In participants with moderate DED symptoms, the mean keratometry and keratometric astigmatism changed more than 1 D in 8.33 % and 16.67 % respectively, with no participants with a change between 0.51 and 1 D (Fig. 3). For participants with severe DED symptoms, 12.76 % and 17.02 % had a change of more than 0.50 D in mean keratometry and keratometric astigmatism, respectively.

Regarding spherocylindrical refraction (converted from vector analysis), it was observed that in 5.40 % of the overall participants the sphere and cylinder changed more than 0.50 D between visits 1 and 5, while in 16.21 % of the participants the axis changed more than 10 degrees. For participants with moderate DED symptoms, all had a sphere and cylinder change of less than 0.50 D and an axis change of less than 10 degrees (Fig. 4). For participants with severe DED symptoms, 6.90 % had a sphere and cylinder change greater than 0.50 D and 20.69 % had an axis change higher than 10 degrees.

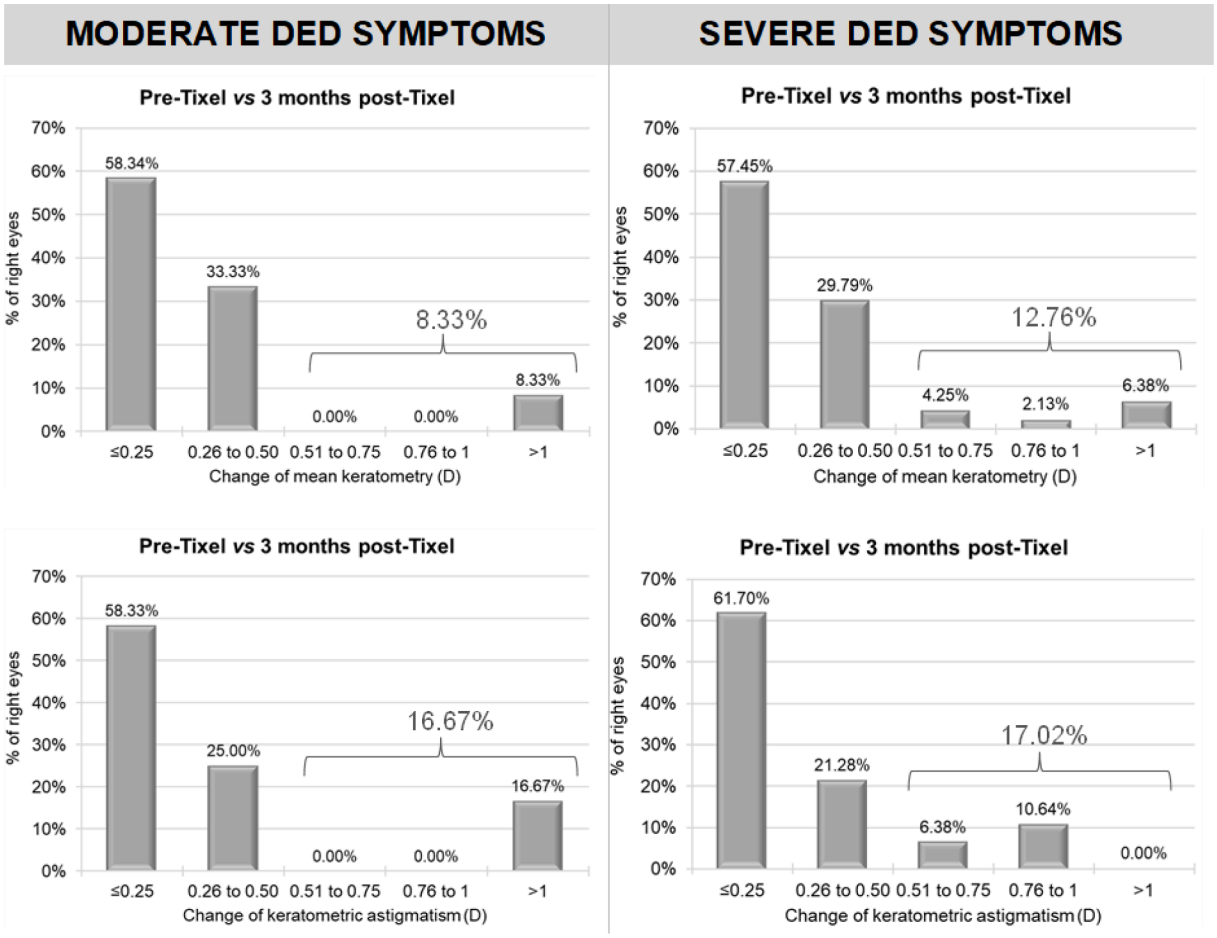

Fig. 3. Changes in dioptres (D) of mean keratometry and keratometric astigmatism between pre-Tixel® visit (visit 1) and 3 months post-Tixel® visit (visit 5) in patients with moderate and severe dry eye disease (DED) symptoms. vs: versus.

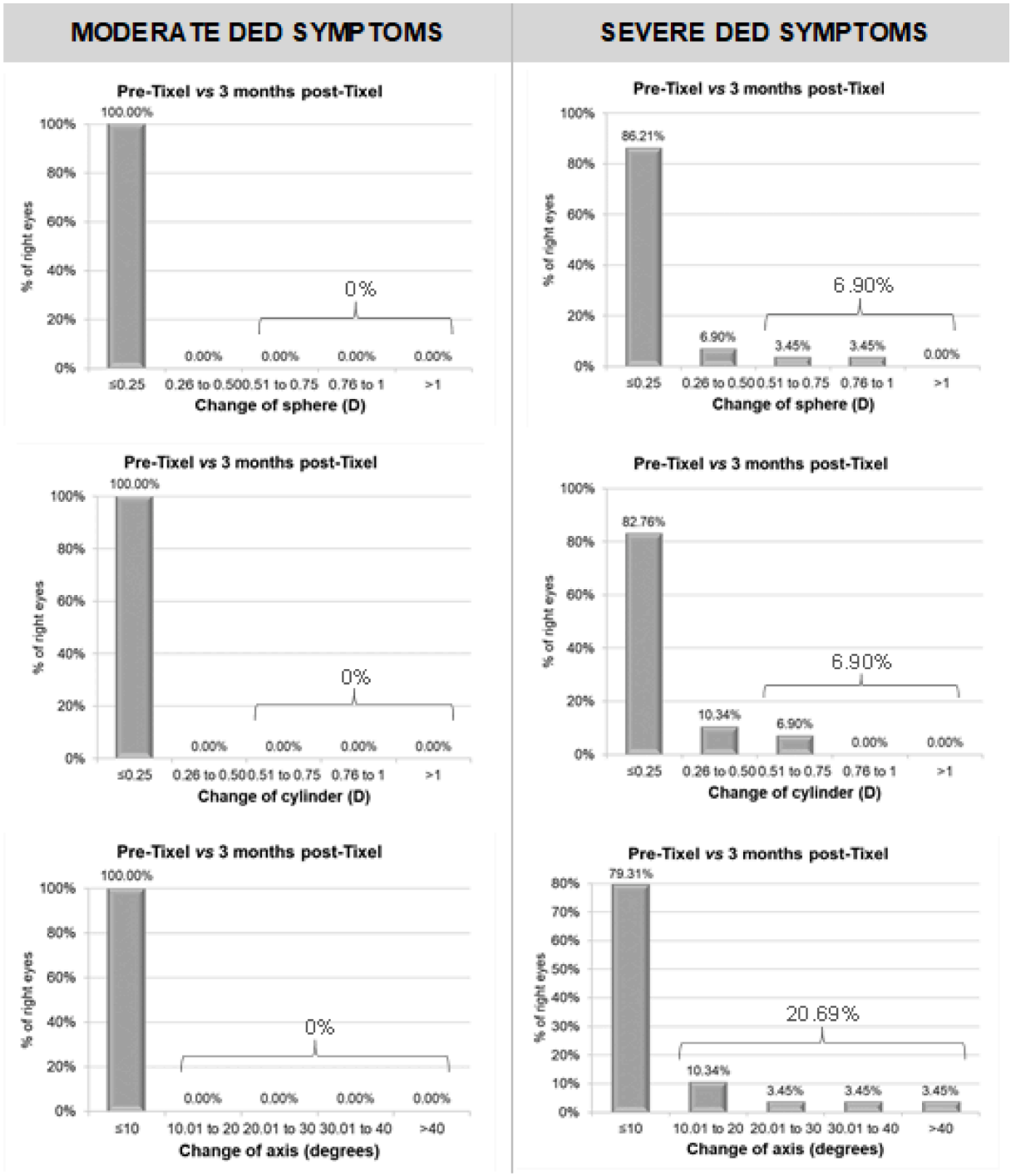

Fig. 4. Changes of sphere, cylinder and axis between pre-Tixel® visit (visit 1) and 3 months post-Tixel® visit (visit 5) in patients with moderate and severe dry eye disease (DED) symptoms. D = dioptres; vs: versus.

4. Discussion

The regularity and integrity of the tear film is essential for maintaining optimal optical quality and visual function, as the tear film is the first refractive surface with which light comes into contact [24]. An optimal tear film is also very important for the acquisition of precise measurements for IOL calculation [7,25–28], and then for satisfactory postoperative outcomes [7,25,26,29].

In DED, the tear film is compromised, so degraded quality of vision is likely to be found in these patients [24]. There are a variety of treatments for DED [10]. Among them, the effect of the thermo-mechanical action-based periorbital fractional skin treatment, Tixel®, on the signs and symptoms of DED patients has recently been reported [15–18]. This study reports on the impact of treatment of DED (in this instance with Tixel® treatment) on the anterior corneal curvature measurements and refraction.

Significant changes in best corrected visual acuity and refraction parameters were found after Tixel® treatment as well as borderline differences in corneal curvature readings. In addition, 11.86 % and 16.94 % of DED patients had their mean keratometry and keratometric astigmatism, respectively, changed more than 0.50 D at 3 months post-treatment. A total of 5.40 % had a sphere and cylinder change greater

than 0.50 D and 16.21 % had an axis change greater than 10 degrees. These changes were particularly significant in patients with severe DED symptoms.

The improvement in visual acuity at 2 weeks after the second Tixel® treatment session found in the present study was minimal (1 letter) but similar to iLUX® and Lipiflow® DED treatments [30]. The improvement in visual acuity following these three treatments, all with thermal action on the meibomian glands, could be explained by the fact that the application of heat promotes the melting of the meibum which facilitates its release into the tear film, and this in turn facilitates lubrication and regeneration and regularisation of the corneal epithelium, improving visual quality [30]. However, this improvement by 1 letter only at one study visit can be considered clinically irrelevant.

Changes in keratometry after Tixel® treatment in DED patients were on the borderline of statistical significance between the pre-treatment visit (visit 1) and the 2-week visit after the last treatment session (visit 4). Statistically significant changes in refraction were found between the pre-treatment visit (visit 1) and the 2-week visits after the first and second treatment session (visits 2 and 3). Previous studies have also reported differences following various treatments for DED. In particular, some authors have reported differences in axial length (0.12 ± 0.57 mm) and keratometry (0.26 ± 0.28 D in steep keratometry and 0.29 ± 0.32 D in flat keratometry values) following Lifitegrast ophthalmic solution 5 % (Xiidra; Novartis, Basel, Switzerland) [31]. Similar results were also reported for axial length (0.02 ± 0.02 mm) and keratometry (0.27 ± 0.14 D in steep keratometry and 0.29 ± 0.16 D in flat keratometry values) after the use of 2 % Rebamipide ophthalmic suspension (Otsuka Pharmaceutical Co., Wexham, UK) [32]. These keratometric changes were greater than those found in the present study after Tixel® treatment (0.09 D maximum change among visits for mean keratometry), which may suggest that the changes in keratometry after Tixel® were slight. These discrepancies may be explained by the different criteria used for inclusion of DED patients or by the different effect of each treatment on keratometry. Changes in refraction after Lifitegrast ophthalmic solution 5 % or 2 % Rebamipide ophthalmic suspension were reported using the spherical equivalent, which provides limited information and is difficult to compare with our results. Therefore, the changes in keratometry and refraction after Tixel® were only between some specific visits and were minimal.

In addition, Matossian showed that keratometry readings and keratometric astigmatism changed at least 0.13 D in 76 % of the 25 eyes of patients with DED associated with meibomian gland dysfunction at 6 weeks ± 2 weeks after Lipiflow® treatment [33]. Röggla et al. evaluated the influence of two artificial tears of high and low viscosity on keratometry in 54 eyes of mild to moderate DED patients and 69 normal eyes of non-DED patients. They showed a change of more than 0.5 D in keratometry performed 30 s after instillation of either high- and low-viscosity eye drops in 34.3 % and 27.8 % of DED, respectively, and in 13.2 % of normal eyes for both eye drops [28]. These percentages were slightly higher than those found after Tixel® treatment in DED patients, probably due to the differences in sample size, in the inclusion criteria for DED patients, and in the treatment itself. However, a considerable percentage of DED patients had a change of more than 0.50 D in keratometry (11.86 % and 16.94 % for the mean keratometry and keratometric astigmatism, respectively), sphere and cylinder and 10 degrees in axis (10.81 %, 13.52 % and 18.92 %, respectively) after Tixel® treatment, being especially significant in participants with severe DED symptoms.

These changes in keratometry and refraction may be due to variations in the tear film [7,28,29] such as the improvement in tear stability found after Tixel® treatment in this study. The topographers used in this study are based on the reflection of the mires from the corneal surface being sensitive to an unstable tear film [7,29]. An unstable tear film compromises the corneal biometry [29]. In addition, corneal curvature may be affected by damage to the corneal epithelium [29,34]. Also, chronic dry eye and tear deficiency have been associated with corneal changes [34]. This can impact on refraction, as the tear film and the anterior surface of the cornea provide most of the refractive power of the eye [26].

Changes in keratometry and refraction are especially important before a patient with DED undergoes cataract, clear lens extraction or refractive surgery. Firstly, it is crucial a detailed examination of the ocular surface to detect DED patients as a high prevalence has been reported in candidates for cataract and refractive surgery [35–38]. According to the PHACO study more than 80 % of the 143 subjects scheduled to undergo cataract surgery had a tear break-up time (TBUT) $\leq$ 7 s, 76.8 % were positive for fluorescein staining and 46.6 % had a Schirmer score $\leq$ 10 mm [35]. Regarding candidates for refractive surgery, these percentages vary according to studies between 10 % and 50 %, possibly due to the different populations evaluated and the different criteria used to determine DED [36–38]. Once cases of DED have been detected, the ocular surface of these patients should be treated to regularise it prior to surgery for better visual outcomes and patient satisfaction. Several authors have reported that ocular surface optimisation following DED treatments increases the accuracy of pre-surgical measurements and calculations and predicted post-surgical residual refraction [31–33]. In addition, treating the ocular surface in patients with DED prior to surgery reduces the incidence and severity of post-surgical symptoms and signs [39].

In summary, our results demonstrate change of some parameters of anterior corneal curvature and refraction following non-ablative thermo-mechanical skin treatment in DED patients, especially in those with severe DED symptoms. These changes can have a direct impact on the pre-surgical parameters of IOL calculations and refractive surgery. Failure to take these changes into account can result in miscalculation of pre-surgical parameters leading to patient dissatisfaction and additional surgical correction.

However, this study has some limitations. Some patients did not complete some study visits due to the local restrictions during COVID-19 pandemic. Another limitation of the study is the absence of a control group. Tixel® treatment has a thermal mechanism that induces heating sensation in the treated area, making it difficult to add a sham group [17,18].

Furthermore, patients with moderate and severe DED symptoms were included in the present study, and it would be interesting to corroborate these results in patients with mild DED symptoms.

In addition, the measurement of NIBUT and corneal keratometry were performed with the equipment available at each centre, and although there can be differences in the measurements between instruments [40,41], this should not affect the results as the same patients were compared between visits where the same equipment was used at each centre. Finally, although ethnicity/race could have an impact on the ocular surface anatomy [42] and/or DED parameters [43], we did not included it since this would not affect the results of this study as patients were compared within themselves.

In conclusion, anterior corneal curvature readings and refraction can change following non-ablative thermo-mechanical skin treatment for DED, especially in those patients suffering from severe DED symptoms. This should be considered prior to cataract surgery, clear lens extraction or refractive surgery in order to correctly calculate pre-surgical parameters to achieve satisfactory visual outcomes and avoid additional surgical procedures.

CRediT authorship contribution statement

Marta Blanco-Vazquez: Writing-original draft, Formal analysis. **Raquel Gil-Cazorla:** Formal analysis, Writing-reviewing & editing, Supervision. **Ankur Barua:** Data curation, Writing-reviewing & editing. **Mukesh Taneja:** Data curation, Writing-reviewing & editing. **Ludger Hanneken:** Conceptualization, Data curation, Writing-reviewing & editing. **Sunil Shah:** Conceptualization, Data curation, Formal analysis, Writing-reviewing & editing, Supervision, Funding acquisition,

Resoruces.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Study supported by Novoxel® (Israel). MBV was supported by: 1) the Ministry of Science, Innovation and Universities, Government of Spain [grant reference: FPU17/02715]; 2) "Movilidad doctorandos y doctorandas UVa 2021", Spain; 3) "Prácticas Erasmus + 2020–2021", University of Valladolid, Spain; and 4) IMFAHE's Excellence Fellowships 2021; all these grants are unrelated to this study.

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