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Topical anaesthetic use prior to rigid gas permeable contact lens fitting

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ABSTRACT

Purpose: To investigate effect of topical anaesthetic (TA) during gas permeable (GP) contact lens (CL) fitting on subjective and objective measures of patient anxiety.
Methods: 47 subjects (mean ± sd age = 26.9 ± 4.9 years; soft CL wearers, 18, neophytes, 29). Each subject randomly assigned to Group A or B, and attended on two occasions, one week apart. First visit: subject received bilaterally either a single drop of TA (0.5% proxymetacaine) (Group A) or placebo (0.9% saline) (Group B) prior to GP CL application. No drops were instilled at second visit. Each visit mimicked a GP CL fitting. At each visit, patient anxiety was assessed either subjectively (visual analogue scale (VAS)) or objectively (skin conductance (SC)), as well as anterior ocular health.
Results: Visit 1: GP CL trial produced small increases in hyperaemia and corneal staining, but no difference associated with TA use. Visit 2: increases in staining and hyperaemia were observed, but hyperaemic responses significantly less than at Visit 1, for both groups. Corneal staining also less, but not statistically significant. VAS scores indicated subjects who received TA during Visit 1 were significantly less anxious at Visit 2. Visit 2: comfort slightly reduced for subjects who received TA at Visit 1, and significantly increased for subjects who received placebo. Use of TA reduced anxiety during lens adaptation period compared with subjects receiving placebo.
Conclusions: TA use during GP CL fitting has potential patient benefits: improved first-time GP CL wear comfort, reduced anxiety during adaptation, reduced anxiety prior to subsequent GP CL wear.

The decline in rigid gas permeable (GP) contact lens (CL) prescribing is well documented [1]. In a previous study, we showed that the initial wearing discomfort with GP CLs discourages practitioners from recommending this lens type to patients [2]. Topical anaesthetic (TA) use in rigid gas permeable fitting results in enhanced initial patient comfort [3], and may also reduce patient anxiety about initial lens comfort [3]. If initial comfort is improved with TA, particularly in patients perceived to have high ocular touch sensitivity or are anxious, practitioners may feel encouraged to consider GP CLs as a potential option [4]. However, the use of topical anaesthetic to aid GP CL fitting, is not common practice in the United Kingdom and practitioner opinion is divided on the acceptability of TA during GP CL fitting without evidence on the safety and benefit of TA use.

Anxiety is the adaptive response to a threat, for example, in response to a clinical procedure [5]. Anxiety is known to influence patient success with CL [6,7]. It has been suggested that patients may not try CL because they are anxious about having them placed on their eyes [7]. Anxiety levels appear to vary between individuals and both internal and external forces may influence anxiety levels. Spielberger [8] suggested that 'trait' anxiety refers to a person prone to anxiety, i.e. it is a fixed personality trait, while 'state' anxiety is a transient anxiety experience [8].

Use of TA makes the first GP CL experience more comfortable, but this raises questions over whether this makes the next visit, without TA, a worse experience, and therefore misleads a patient. Literature shows that use of TA results in less patient dropouts following the fitting phase [3], however an insight into patient experience over the fitting phase would be advantageous.

This study investigated the effects of TA use, during GP CL fitting, on the ocular surface to assess its safety of use; on subjective and objective measures of patient anxiety; and of previous TA use on the second patient experience with GP CL.

1. Methods

A prospective, randomised, double-masked cohort study was conducted involving two visits, scheduled with one week between visits.

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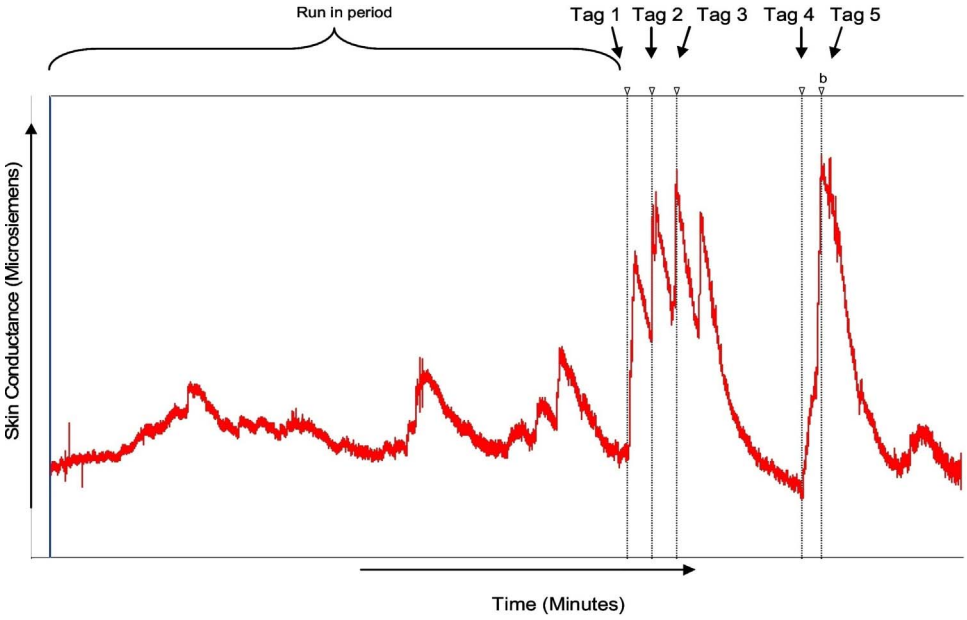

Fig. 1. Example of raw skin conductance trace, showing marker tags. Tag 1: Examiner says: "I'm going to put a drop into yours eyes now"; Tag 2: Examiner says: "I'm now going to insert the lenses to your eyes"; Tag 3: Completion of lens insertion; Tag 4: Examiner says: "I'm now going to remove the lenses from your eyes"; Tag 5: Completion of lens removal.

1.1. Subjects

Forty-seven healthy, volunteer, subjects from staff and students within Cardiff University completed the study, m 20, f 27, mean ± sd age = 26.9 ± 4.9 years (range 18–45). Twenty-nine subjects were neophyte and 18 had experience of or were current soft CL wearers. Subjects were excluded if they had worn GP CL before, suffered from any ocular condition including dry eye or any systemic condition known to affect the tear film or cornea, were taking any medication known to affect the tear film or cornea, or were pregnant or breast-feeding. Ethical permission for the study was obtained from the School of Optometry and Vision Sciences Ethical Committee and signed informed consent was obtained from all subjects. All procedures conformed to the tenets of the Declaration of the Helsinki.

1.2. Study groups

Subjects were randomly assigned to two groups (A or B) and either received a single drop of TA (A) or saline placebo (B) prior to GP CL application at the first visit, in both eyes, respectively. Group A (n = 25) had a mean ± sd age of 27.1 ± 4.6 years, m 11, f 14. Group B (n = 22) had a mean ± sd age of 26.6 ± 5.2 years, m 9, f 13.

1.3. State and trait anxiety questionnaire

The Spielberger State-Trait Inventory (STAI) [9] incorporates two 20-item question sets measuring state and trait anxiety. The items are generic and the STAI has been used to measure anxiety in many healthcare studies [10–12]. The full STAI is lengthy and has been shortened to two 6-item scales [9,13,14]. Each item has four possible responses, with each response giving a score, and the anxiety result is found by summing the response scores. The shortened State-Trait scales were completed by all subjects prior to drop instillation and GP insertion.

1.4. Visual analogue scale

An anxiety visual analogue scale (VAS) was completed prior to GP CL application to indicate subject anxiety [15–17,35]. Subjects were asked to mark their answer on the VAS to the question "How anxious do you feel about having contact lenses on your eyes today?", between the two extremes of "Not at all anxious" and 'Very anxious'. A comfort VAS was completed after GP fitting to indicate how comfortable the lenses had been on the eyes in response to the question "How did the contact lenses feel on your eyes today?", between the two extremes of 'Not at all comfortable' and 'Very comfortable'.

1.5. Skin conductance recording procedure

Skin conductance (SC) shows the emotional state reflected by changes in the sympathetic nervous system as a result of stress or arousal. Sympathetic activation causes release of acetylcholine, which acts on the muscarinic receptors leading to sweat production and a skin conductance increase [18]. SC has been used as a tool for monitoring post-operative pain in medicine [19]. It has been found to be better than alternative objective methods, e.g. heart rate, blood pressure and electroencephalograph (EEG), at detecting pain [18].

Skin conductance was measured by attaching 2 silver-silver chloride electrodes (coated with electrode gel) to the pads of the index and middle finger of the subject's left hand. Signals from the electrodes were amplified (×2000) and low pass filtered (0–35 Hz) using a physiological amplifier (Biopac MP30) connected to a laptop PC (Toshiba Satellite Pro 4200) running Biopac Student Lab Pro software (version 3.65, BIOPAC Systems Inc, Goleta, CA). All subjects washed their hands with a liquid soap prior to having the electrodes attached to improve the quality of contact. A period of 10 min was allowed to elapse before data collection to ensure the skin had fully absorbed the gel. The subject was asked to keep their hand still, resting on their left leg throughout the consultation. Conversation during the consultation was controlled and the same explanations and reassurance were given to all participants.

SC response occurs with a latency of 1–3 s following a stimulus, making it difficult to directly link a response to a particular event [23]. For this reason, tags were helpful in marking periods of interest. Specific phrases were used by the examiner at key points during the consultation, and simultaneously the examiner added a tag to the trace (Fig. 1). Tags were also added to the SC trace to identify completion of a particular task during the consultation. When subjects returned for the second visit, Tag 1 was omitted and only Tags 2–5 were inserted onto the SC trace.

Tag 1 Examiner says, "I'm going to put a drop into your eyes now"

Tag 2 Examiner says, "I'm now going to insert the lenses to your eyes"

Tag 3 Completion of lens insertion

Table 1
CCLRU grading measurements for Group A (TA) and Group B (placebo) at each visit.

		Pre-GP fitting Mean ± sd	Post-GP fitting Mean ± sd	Difference in grading Pre- and Post-GP wear Mean ± sd (Paired *t*-test)	Difference between Groups A and B Mean ± sd (Ind *t*-test)
Visit 1					
Conjunctival hyperaemia	Group A	1.84 ± 0.28	2.08 ± 0.43	0.25 ± 0.25 ($p < 0.05$)	0.10 ± 0.64 ($p = 0.15$)
	Group B	1.78 ± 0.26	1.93 ± 0.34	0.15 ± 0.16 ($p < 0.05$)	
Limbal hyperaemia	Group A	1.59 ± 0.42	1.91 ± 0.50	0.26 ± 0.56 ($p < 0.05$)	0.01 ± 0.14 ($p = 0.93$)
	Group B	1.52 ± 0.28	1.78 ± 0.40	0.27 ± 0.26 ($p < 0.05$)	
Corneal staining	Group A	0.19 ± 0.27	0.63 ± 0.66	0.44 ± 0.56 ($p < 0.05$)	0.17 ± 0.16 ($p = 0.30$)
	Group B	0.28 ± 0.49	0.55 ± 0.66	0.27 ± 0.54 ($p < 0.05$)	
Visit 2					
Conjunctival hyperaemia	Group A	1.67 ± 0.15	1.78 ± 0.21	0.03 ± 0.36 ($p < 0.05$)	0.01 ± 0.08 ($p = 0.86$)
	Group B	1.73 ± 0.27	1.78 ± 0.31	0.04 ± 0.12 ($p = 0.11$)	
Limbal hyperaemia	Group A	1.51 ± 0.34	1.69 ± 0.26	0.10 ± 0.42 ($p < 0.05$)	0.03 ± 0.10 ($p = 0.73$)
	Group B	1.51 ± 0.29	1.56 ± 0.31	0.07 ± 0.16 ($p = 0.15$)	
Corneal staining	Group A	0.31 ± 0.32	0.68 ± 0.49	0.37 ± 0.37 ($p < 0.05$)	0.25 ± 0.09 ($p < 0.05$)
	Group B	0.32 ± 0.41	0.44 ± 0.44	0.12 ± 0.17 ($p < 0.05$)	

Tag 4 Examiner says, "I'm now going to remove the lenses from your eyes"

Tag 5 Completion of lens removal

Using the tags, information from the trace, such as mean response and maximal response, were determined within these periods of interest. Maximal response was selected as the key result for analysis in the results because this gave the subject's peak arousal or anxiety experienced within each period. Absolute SC values do not facilitate comparison of SC between individuals. Therefore, SC values recorded during the 'run-in period' (from the start of the trace until drop insertion) were averaged and subtracted from subsequent recordings to normalise the data in all subjects.

1.6. Anterior eye assessment

At both visits, the health of the anterior eye was assessed using a slit-lamp. White light assessment allowed grading of conjunctival and limbal hyperaemia, according to the CCLRU grading scale. A sodium fluorescein sterile ophthalmic strip (FS) (Chauvin Pharmaceuticals, Romford, UK) was wetted with non-preserved 0.9% saline (Oxysept Saline; Abbott Medical Optics, High Wycombe, UK) and the FS applied to the inferior tarsal conjunctiva. Tear film fluorescence was enhanced with cobalt blue light, in conjunction with a Wratten Filter (No 12) in front of the objective lens. The corneal integrity was assessed and any corneal staining was recorded diagrammatically, and also graded using the CCLRU grading scale.

At the first visit only, corneal keratometry of both eyes was measured using a 2-position Javal-Schiötz type keratometer (Topcon Corporation, Tokyo, Japan).

1.7. Schedule

Subjects were invited to attend for two GP CL fitting sessions, with a one-week separation between the two visits. The first visit mimicked a first GP CL fitting session when either TA or placebo drops were instilled. The second visit mimicked a second GP CL fitting session and no drops were instilled.

Based on the keratometry measurement, an appropriate GP CL was selected from a fitting set (Quasar, No7 Contact Lenses, Hastings, UK). All lenses had a total diameter of 9.60 mm and back vertex power of −3.00 Dioptres. The required lenses were cleaned and rinsed using Boston Advance 2-step system (Bausch & Lomb, Kingston-upon-Thames, UK). To mimick a CL fitting session, the selected CLs were then applied to both eyes while the patient's eyes were in down-gaze. Once the lenses were settled and tearing had reduced or stopped, the lens fit was assessed. The examiner advised the subject that lenses were to be removed, which was then done by placing mild pressure on the inferior and superior lid margins, and digitally moving the lids together to release the lens. Conjunctival hyperaemia and limbal injection were regraded and corneal staining was noted and graded. Further FS was instilled at this stage only if required, since successive FS instillation is known to increase corneal staining [20].

Group A volunteers received 1 drop of 0.5% proxymetacaine hydrochloride (proparacaine) (Chauvin Pharmaceuticals, Romford, UK) in both eyes. Group B received 1 drop of 0.9% saline (Chauvin Pharmaceuticals, Romford, UK) in both eyes. Coloured tape was used to code the minims to mask both subject and examiner to the drops being administered.

On each visit, patient anterior ocular health, and subjective and objective patient anxiety were measured. Keratometry was undertaken at the first visit only (Keratron Scout topographer (KS-1000), Optikon, Rome, Italy).

1.8. Statistical analysis

Data was analysed using SPSS 16.0 (SPSS Inc., Chicago, USA) and examined for normality by the Shapiro-Wilk test and appropriate statistical tests used [21]. A probability value of < 0.05 was used for statistical significance. Differences between groups were assessed by unpaired *t*-test (parametric) or *U* Test Mann-Whitney (non-parametric data). Internal reliability of the short version state and trait questionnaires was assessed using Cronbach alpha. Post-hoc Wilks' Lambda was used to assess within-group interactions. Interpolation of the C-CLRU grading scale produces an approximate interval scale and it has been argued that parametrical statistical tests may be applied to such data [20], consequently parametric tests have been used predominantly Statistically, no significant difference was found between the eyes and therefore right eye data is presented throughout.

2. Results

2.1. Physiological effects

At Visit 1, no significant difference was found in baseline ocular surface grading between the two groups (Table 1). Following GP CL application, conjunctival and limbal hyperaemia, and corneal staining was significantly increased in both groups when compared to their baseline measures (Fig. 2). Comparison of grading pre- and post-GP fitting revealed no significant differences between the groups for hyperaemia or corneal staining change. Likewise, comparison of final C-CLRU scores revealed no statistical difference between the groups.

At Visit 2, no significant difference was found in baseline grades for limbal and conjunctival hyperaemia or corneal staining between the groups. Following GP CL application, both groups showed an increase

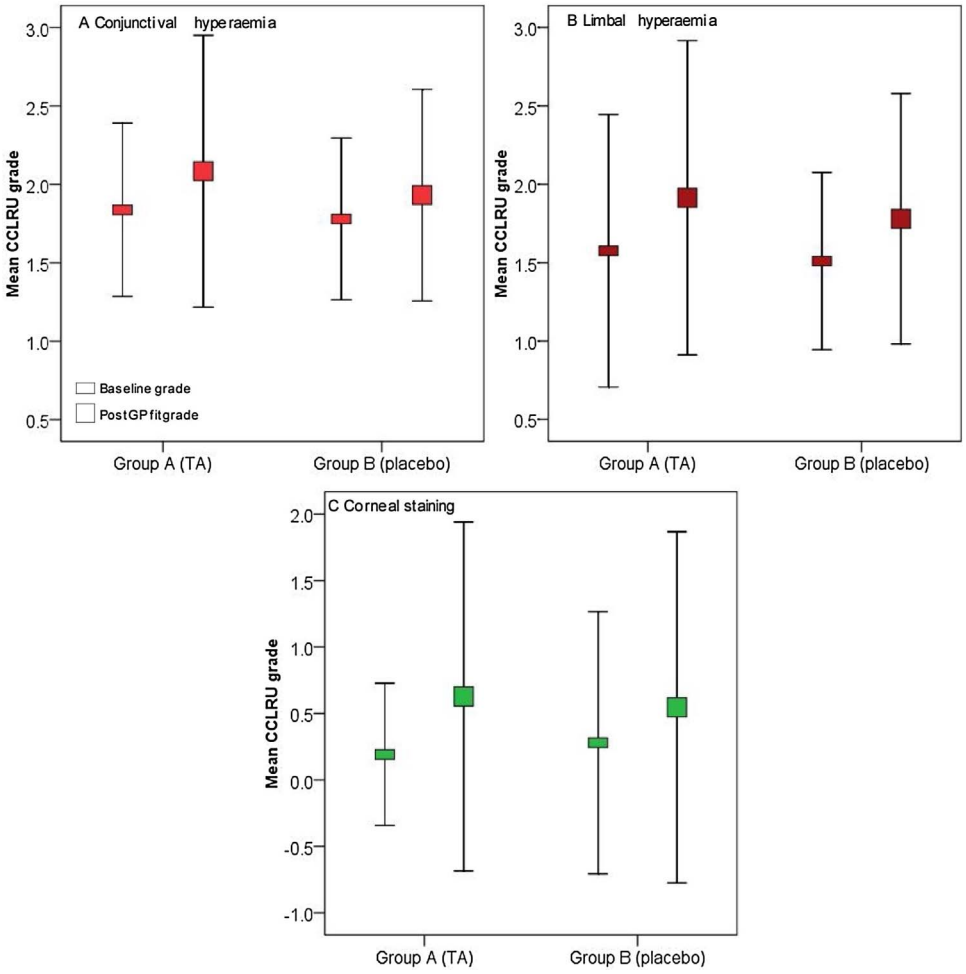

Fig. 2. Error plots showing mean ± sd CCLRU grading scores pre- and post-GP lens fitting at Visit 1. A: Conjunctival hyperaemia, B: Limbal hyperaemia and C: Corneal staining.

in mean hyperaemia and corneal staining scores (Table 1) (Fig. 3). There was a significant increase in hyperaemia and corneal grading scores between the pre- and post-GP CL fitting for Group A. The hyperaemia increase in Group B was not statistically significant when comparing before and after GP grading. Comparison of difference in grade (pre- and post-GP) between groups revealed no significant difference in hyperaemic response between the groups. Following GP CL fitting, corneal staining was significantly increased in both groups, however there was a significantly greater corneal response in Group A compared with Group B (Fig. 4).

2.2. Psychological effects

Internal reliability of the short version state and trait questionnaires was assessed using Cronbach alpha. Cronbach alpha values for state anxiety analysis were: Visit 1, $\alpha = 0.97$; Visit 2, $\alpha = 0.99$, indicating a high degree of consistency, and making comparison of state anxiety results statistically reliable [22].

Inter-group trait scores were similar at Visit 1 and 2 for Group A ($p = 0.97$, Mann-Whitney) and Group B ($p = 0.63$, Mann-Whitney). State anxiety showed no significant difference between groups in baseline anxiety at Visit 1 ($p = 0.56$, Mann-Whitney). No significant change in state anxiety was evident between Visit 1 and 2 for Group A ($p = 0.35$, Mann-Whitney), but Group B had increased state anxiety at Visit 2 ($p < 0.05$, Mann-Whitney) (Fig. 5).

There was no significant difference between Group A and B VAS anxiety scores at Visit 1. At Visit 2, Group A were significantly less anxious about lens application. Group B were marginally more anxious at Visit 2, though this finding was not statistically significant. Comparison of the change in anxiety over the two visits, between groups, was not significant (Table 2) (Fig. 6).

At Visit 1, initial GP VAS comfort scores were higher in Group A compared with Group B, but this difference was not statistically significant. At Visit 2, comfort scores significantly decreased in Group A and increased in Group B (Table 2) (Fig. 7).

2.3. Skin conductance

For Visit 1, a mixed, between-within subjects ANOVA was conducted to assess the impact of two different interventions (effect of drops) on subjects' maximal SC response across three time periods (lens insertion, adaptation to lenses, and lens removal). There was no significant interaction between drop and time (Wilks Lambda, $p = 0.97$). There was no significant main effect for time ($p = 0.97$). The main effect comparing the groups, depending on the type of drop instilled, was not significant ($p = 0.64$). A one-way repeated measures ANOVA was conducted to compare maximal SC responses over time, but no significant effect of time was found (Group A, $p = 0.78$; Group B, $p = 0.98$).

For Visit 2, a mixed, between-within subjects ANOVA found no significant interaction between drop and time (Wilks Lambda, $p = 0.82$), nor was there a significant main effect for time ($p = 0.84$). The main effect comparing the groups, depending on the type of drop instilled, was not significant ($p = 0.18$).

3. Discussion

The findings from this study indicate that TA is beneficial in

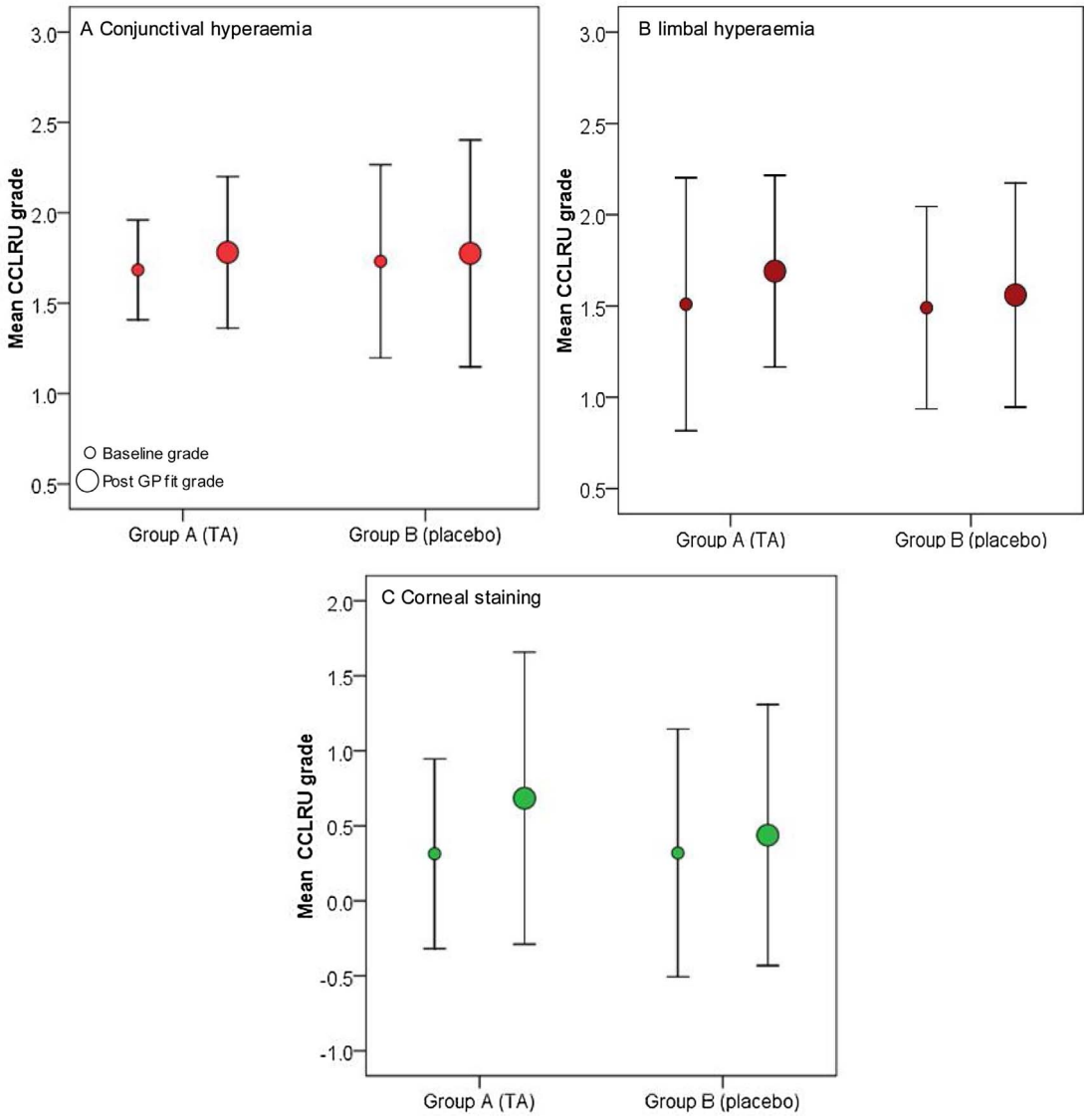

Fig. 3. Error plots showing mean ± sd CCLRU grading scores pre- and post-GP lens fitting at Visit 2; A: Conjunctival hyperaemia, B: Limbal hyperaemia and C: Corneal staining.

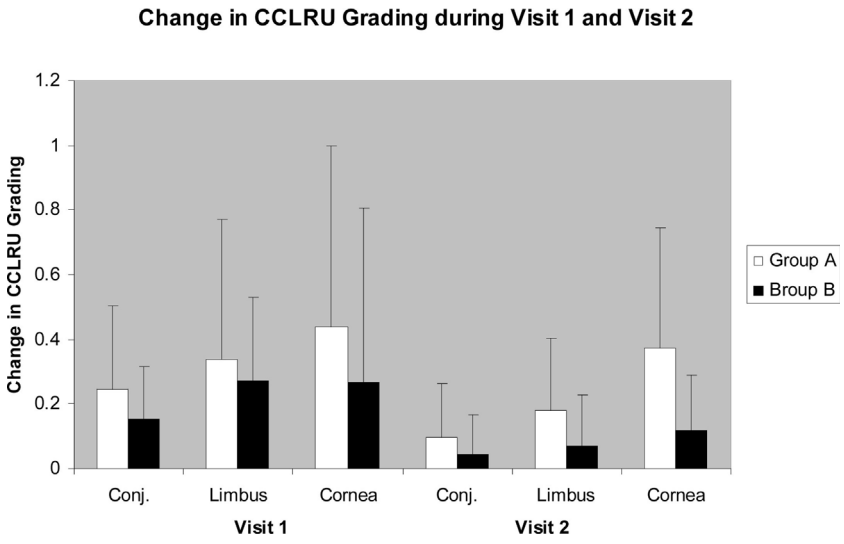

Fig. 4. Mean change in CCLRU grading scores during Visits 1 and 2 for Groups A and B.

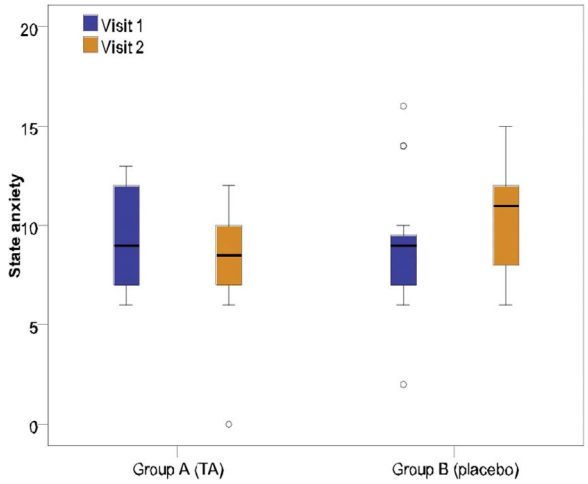

Fig. 5. Box plot of median and range of state anxiety scores (from the shortened 6-item version of the Spielberger State-Trait Inventory (STAI) questionnaire) for Groups A and B at Visits 1 and 2 (whiskers represent the 10th and 90th percentiles).

Table 2
VAS anxiety and comfort results for Groups A and B at each visit.

		Group A (TA drop)	Group B (placebo)	Mann-Whitney Test
Anxiety VAS				
Visit 1 score	Median	13.57	9.29	p = 0.33
(%)	Range	0.00–84.29	0.00–74.29	
Visit 2 score	Median	10.71	17.14	p = 0.31
(%)	Range	0.00–35.71	0.00–55.71	
Wilcoxon Rank test		p < 0.05	p = 0.94	
Comfort VAS				
Visit 1 score	Median	28.57	26.79	p = 0.25
(%)	Range	2.86–100.00	2.86–97.86	
Visit 2 score	Median	22.86	58.57	p = 0.12
(%)	Range	0.00–100.00	0.00–98.57	
Wilcoxon Rank test		p < 0.05	p < 0.05	

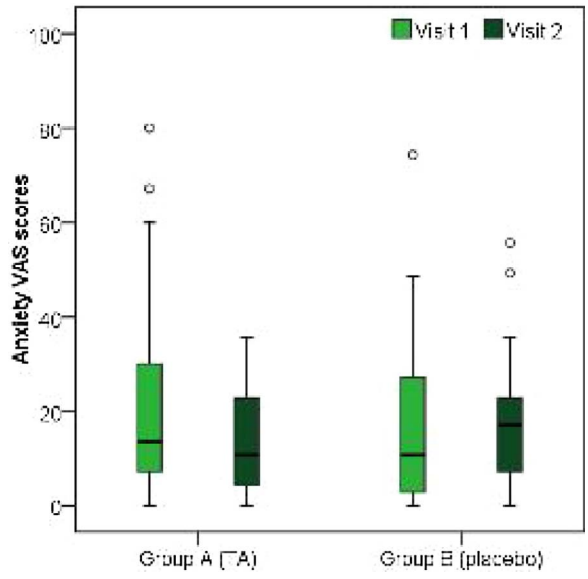

Fig. 6. Box plot of median and range of VAS anxiety scores for Groups A and B prior to GP lens insertion at Visits 1 and 2.

reducing both objective anxiety measurements during adaptation to GP CLs and self-reported anxiety prior to second-time lens insertion, while producing no clinically significant physiological changes. However, this

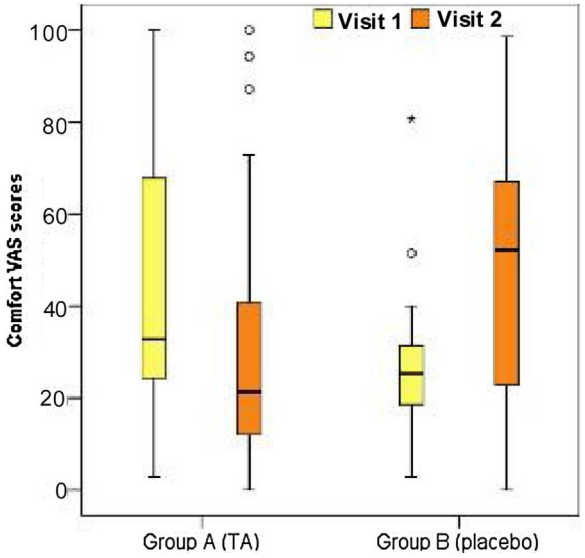

Fig. 7. Box plot of median and range of VAS comfort scores for Groups A and B at Visits 1 and 2.

benefit for subsequent lens wear may produce a falsely raised expectation for future CL wearing comfort.

The use of TA during GP CL fitting has been demonstrated to be a clinically safe practice with potential patient benefits including improved first-time GP CL wear comfort, reduced anxiety during adaptation and reduced anxiety prior to second-time GP CL wear. The use of TA itself did not adversely increase ocular surface hyperaemia or corneal staining response during lens fitting. At the second visit, the ocular redness response to GP CLs was reduced, irrespective of previous drop experience (TA or placebo). Comfort at initial fitting was marginally improved with TA, although it was worse at the dispensing visit. Patients who received TA during fitting had significantly reduced anxiety (VAS) prior to lens collection, suggesting that this practice may minimise CL drop-out rates. The disadvantages of TA use may be the reduced comfort during second-time GP CL wear when no TA is administered.

These findings concur with a previous study which reported reduced drop-out rates in first-time wearers fitted with use of TA at fitting and dispensing visits [4]. A similar study fitted apprehensive patients using TA and reported superior comfort, less alteration to blink rate and less tearing compared with a control group. Furthermore, 50% of subjects felt confident about wearing GP CLs following fitting with TA compared with 20% of control subjects [4]. The study also reported the use of TA to significantly reduce time for GP CL stabilisation on the eye. (GP CL stabilisation time, blink rate or lacrimation were not measured during this investigation). Effect of TA on GP CL stabilisation time might be of interest as the time needed to fit GP CLs is perceived to be greater than that for soft CL fitting. The use of TA to shorten fitting appointments might be a further indication for TA use in GP CL fitting.

3.1. Physiological response

The collective mean (n = 47) baseline bulbar conjunctiva hyperaemia CCLRU grade was 1.81 ± 0.27 units at Visit 1 and 1.70 ± 0.21 units at Visit 2. Murphy et al. (2007) indicated that bulbar conjunctiva hyperaemia grading with the CCLRU normally ranges from 1.3–2.6 units, and a grade of more than 2.6 should be considered abnormal. Most eye care practitioners (ECPs) would accept that slight increases in ocular surface hyperaemia occur when CLs are first applied. Due to inter-subject variability, measurement of change in bulbar conjunctiva hyperaemia is more meaningful than absolute values, with a change of 0.4 units considered as clinically significant [24]. The results here

indicate that the mean increase in hyperaemia grades during the GP CL trial were small (less than one quarter of a CCLRU grade), but statistically significant. Importantly, the study demonstrated that use of TA did not promote a clinically significant increase in hyperaemia in this cohort.

Hyperaemia increase at Visit 2 was statistically more significant in Group A than Group B. A possible explanation for these findings might be that the Group B hyperaemic reaction was conditioned by an improvement in comfort experience at the second exposure to GP lenses. Meanwhile, subjects in Group A, who received TA at Visit 1 experienced a reduced level of ocular comfort at Visit 2, and therefore responded as if they were naïve to GP CLs. An alternative explanation might be that, while baseline hyperaemia grades were greater in Group B than Group A ($p = 0.06$), the mean increase in redness was small and similar ($p < 0.05$) for both groups.

It has been reported that a mean CCLRU corneal staining grade of 0.1 (max 0.5) should be anticipated for non-CL wearers [25]. However, the cohort reported here included both non-CL wearers and soft CL (SCL) wearers. SCL wear alters cell exfoliation and proliferation in the corneal and limbal epithelia resulting in increased staining [26,27]. This study found a mean baseline corneal staining grade of 0.23 ± 0.39 units, which was marginally higher than the Dundas et al. [25] study for non-CL wearers, and marginally less than the mean Grade 0.5 reported in a study of asymptomatic hydrogel CL wearers [28]. Our study found < 0.1 unit difference in mean corneal staining grade (post-GP CL wear) between the placebo and TA group. Although mean change in corneal staining grade was larger in the TA group, this difference was not statistically significant. Similar studies have also reported no significant increase in corneal staining with TA use compared with a control drop [29,30].

This result is perhaps surprising given that most optometrists will anecdotally report a reluctance to use TA due to its 'toxic effect' [32,33]. Yet, UK practitioners routinely instil TA prior to clinical techniques such as Goldmann applanation tonometry [24]. Clinicians are aware of the potential risks associated with TA use, but consider that the benefits of producing corneal anaesthesia outweigh them. Indeed, TA is known to be mildly toxic to the corneal epithelium [20]. One study investigating corneal staining reported 17.6% of eyes stained with fluorescein at baseline measurement, but that following TA instillation (oxybuprocaine and tetracaine), 60% of eyes stained with fluorescein [31]. However, it is likely that the preservative (0.01%, benzalkonium chloride) accompanying the TA in that study was responsible for the staining increase. Research has reported that sequential instillation of TA was not responsible for increased epithelial permeability, but the addition of preservatives significantly increases corneal permeability [31]. Preservative-free TA minims (0.5%, proxymetacaine) were used in this study to reduce the risk of ocular surface response associated with preservative. Repeated use of TA can delay wound healing or cause keratitis [31], but only one drop of TA was used in this study.

At Visit 2, the results indicated that corneal staining was increased in all subjects following GP CL insertion, but the mean grade increase was not clinically significant for either Group A or B [34].

3.2. Psychological response

Measured trait anxiety at the start of each visit (although not expected to change between visits) confirmed an even distribution of tendencies toward anxiety in both groups, i.e. there was no skew in either group towards very sensitive individuals. State anxiety refers to the transient or current level of anxiety experienced by the subject. Variations in volunteer personality types and extraneous factors, which might have influenced state anxiety levels, may produce the wide variation observed in results prior to the Visit 1 CL trial. Importantly, both measures of anxiety (state anxiety and VAS) were not significantly different between Groups A and B at Visit 1. Both groups were naïve to GP CLs and masked as to whether they would receive TA or placebo drops.

At Visit 2, subjects who had previously received TA at Visit 1, showed less anxiety when measured with the VAS, but no significant change in state anxiety scoring. It may be that the state score was affected by extraneous stress factors and this masked the reduction in anxiety relating specifically to GP CL insertion. Conversely, the placebo group state anxiety scores showed a significant increase at Visit 2 implying that their negative experience at Visit 1 caused them to feel more anxious in anticipation of GP CL insertion for the second time. However, this was not the case for their anxiety VAS responses, which showed no significant change from Visit 1. This is perhaps because subjects were no longer naïve to GP CLs and knew what to expect (i.e. no fear of the unknown as at Visit 1). Social anxiety research indicates that within a formal encounter people generally want to make a good impression and want to avoid appearing foolish [34]. Therefore, an alternative explanation may be that subjects were too embarrassed to admit to feeling anxious at the prospect of second-time GP CL discomfort experience, a condition more easily expressed on a simple VAS.

During CL fitting, subjects who had received TA appeared less 'aroused' during the adaptation period than the placebo group. This seems a logical finding as Group A subjects were anaesthetised and therefore experienced better comfort, and consequently reduced stress levels. Apart from reduced corneal sensitivity, other factors which may affect stress levels during adaptation to lenses might have included change in vision due to the power of the trial lens (-3.00 Dioptres), acceptability of the CL fit, and individual lid architecture or tightness. However, the effects of these factors should have been equal for both groups.

At Visit 2, SC appeared somewhat heightened in the anaesthetic group because they now experienced the full sensation of the GP CL, whereas Group B had lower SC response since they experienced an improved level of comfort at second exposure to GP CLs. However, statistically there was no difference in the results for the two groups.

Electrodermal activity is the most widely accepted measure of arousal or anxiety, and SC is the best objective measurement of electrodermal activity [36]. Previous research has investigated SC during soft CL fitting and reported characteristic anxiety fluctuations during the consultation. Specifically, heightened stress response during CL insertion and CL removal was reported [37,38]. Visual inspection of each trace produced by subjects in this study found heightened SC response during CL insertion and removal. However, this research was specifically interested in alterations to the SC response due to the use of TA during GP CL fitting. The trends shown in the results indicate that there may be a reduction in anxiety with TA, however the results were not statistically significant. Trends may become significant with increased sample size.

At Visit 2, VAS comfort levels were improved in the group (A) that received TA prior to initial CL fitting, but this was not significantly better than the placebo group (B) ($p = 0.12$). This lack of statistical significance may be because there was a wide variation in comfort scores and the sample size. If the cohort had been larger, it is likely that this trend would have shown statistical significance. It may be that the superior palpebral conjunctiva is less well anaesthetised due to application of the drop to the inferior palpebral conjunctiva. This is supported by the idea that comfort during GP CL wear may be more directly linked to sensitivity of the superior tarsal plate and the position of the CL margin in relation to the superior lid [3].

It is possible that there could be a negative outcome from the use of TA, arising from the decreased comfort experienced by first visit TA subjects, at the second non-TA visit. In this situation, the subject experiences more discomfort, which may promote cessation of GP CL wear. However, the reduced anxiety levels at the second visit for the first visit TA subjects is a strong indication that subjects, although experiencing higher levels of discomfort, are calmer about the whole lens fit process. This tends to support the benefit of TA use in GP CL fitting.

A prospective study with GP CL fitting in healthy subjects under normal clinical conditions would be a useful extension of this study, by allowing the investigation of whether lens fit complexity can have an impact on patient anxiety.

In summary, use of TA in GP CL fitting has been demonstrated to be clinically safe practice that may enhance first GP CL lens experience, especially in anxious patients, reduce anxiety during GP CL adaptation, and reduce anxiety prior to subsequent GP CL wear.

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