Clinical investigation plan

C20-691
(EX-MKTG-121)

The comparative clinical performance of two daily disposable toric contact lenses

A multi-centre study

A clinical evaluation for
CooperVision Inc.

Principal Investigator
Philip Morgan

May 2021

Contents

Study summary

This open-label, randomised, bilateral, crossover multi-centre study will compare the clinical performance and subjective acceptance of the MyDay Toric and DAILIES TOTAL1 Toric daily disposable soft toric contact lenses, when used on a daily wear, daily disposable basis. Up to 55 subjects will be enrolled and will wear each lens brand for one week in random sequence. The following will be assessed throughout the study: ocular physiology, lens fit, lens surface, visual acuity and subjective response. A study summary is shown in Table 1.

V s t	Procedures
In t a	Informed consent taken Exp anat on of study procedures and sub ect nstruct ons Ocu ar, med ca and contact ens h stor es [redacted] B om croscopy F tt ng of study ens pa r 1 (from f tt ng bank) [redacted] Lens f t F tt ng of study ens pa r 2 (from f tt ng bank) [redacted] Lens f t Order study enses
D spens ng 1	Changes to genera and ocu ar hea th and med cat ons B om croscopy F tt ng of study ens pa r 1 [redacted] Lens f t Sub ect ve scores Issue study enses
Fo ow-up 1 / D spens ng 2 (6-11 days from D sp 1)	Changes to genera and ocu ar hea th and med cat ons [redacted] Subject ve scores Retr eva of unused enses [redacted] Lens f t Removal of enses B om croscopy F tt ng of study ens pa r 2 [redacted] Lens f t Sub ect ve scores Issue second study enses
Fo ow-up 2 (6-11 days from D sp 2)	Changes to genera and ocu ar hea th and med cat ons [redacted] Sub ect ve scores Retr eva of unused enses [redacted] Lens f t Removal of enses [redacted] Payment processed

Table 1: Study summary.

Section 1. Overview

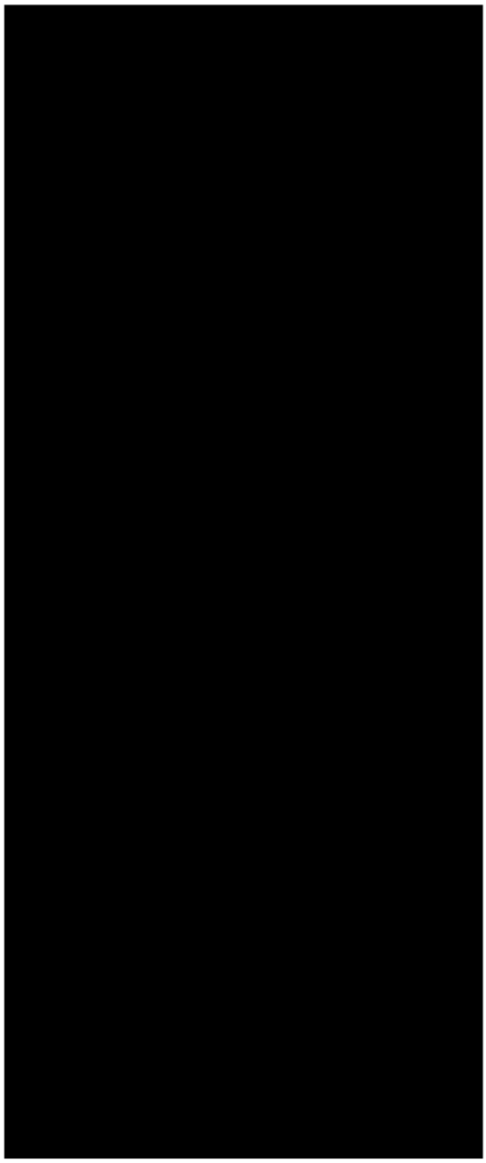
1.1 Background

This project seeks to compare the clinical performance of the MyDay Toric (CooperVision Inc.) and DAILIES Total1 Toric (Alcon Inc.) daily disposable soft toric contact lenses.

1.2 Personnel

This work will be managed by Eurolens Research, The University of Manchester, under the general direction of Philip Morgan PhD MCOptom FAAO FBCLA. The Principal Investigator for the work is Philip Morgan. Approximately 19 subjects will be enrolled by Eurolens Research. Subjects will also be seen at a minimum of three external optometric practices, who will enrol approximately 36 subjects between them.

In addition to the university, the investigators are all UK-based optometrists registered to practice optometry with the General Optical Council:



1.3 Study objectives

This study aims to compare the clinical performance of the MyDay Toric and DAILIES Total1 Toric daily disposable toric contact lenses.

1.4 Study outcome measures

The primary outcome measure for this study is subjective handling on lens removal. Secondary measures are lens fit parameters and biomicroscopy scores [redacted]

1.5 Study design

This will be a multi-centre, randomised, open-label, crossover, bilateral study, controlled by cross-comparison. Up to 55 subjects will use each lens type for a week in random sequence. Follow-up visits for each lens will be performed after one week of wear. Lenses will be worn on a daily wear, daily disposable wear schedule.

1.6 Statistical considerations

The principal hypothesis to be tested in this work is that handling on lens removal scores for the two lenses are the same. Secondary hypotheses are that [redacted] lens fit parameters and biomicroscopy scores are also the same.

[redacted] such, these will be compared using linear regression models or other parametric methods. Subjective preferences will be compared using chi-squared tests. Lens fit data are expected to be ordinal data and assessed with non-parametric approaches. Deviations from this statistical plan will be discussed in the final report. Deviations may be necessary due to differences between the actual data distribution compared with the anticipated data distribution.

1.6.1 Power analysis

Power analysis using data from a previous study for subjective scores for lens removal on a 0-10 scale indicated that 50 subjects are required to complete the study to provide 90% power, assuming a standard deviation of 1.5 units for intra-subject differences and a meaningful difference of 0.7 units[1]. To allow for discontinuations, up to 55 subjects will be enrolled.

[1] Based on the work of Papas et a . (2011).

1.7 Risk analysis

This study is considered to be a non-significant risk study based on United States Food and Drug administration (FDA) and International Standards Organization (ISO) guidelines due to the daily wear nature of the study. With the potential benefit of this study, the work is considered to be ethically justifiable. Ethical approval will be sought from the University of Manchester Senate Committee on the Ethics of Research on Human Beings (hereafter referred to as Manchester UREC). The work where practical will be conducted in accordance with the ICH Good Clinical Practice Guidelines and the international standard BS EN ISO 14155:2011 'Clinical investigation of medical devices for human subjects'.

Section 2. Resources

2.1 Subject selection

In this work, up to 55 subjects will be enrolled at multiple sites, with the aim of 50 subjects completing the study.

2.1.1 Subject withdrawal and replacement

This study includes four clinical visits. Once the study consent form is signed, the subject is considered to be enrolled on the study. Subjects who have signed the consent form, but who have not completed the initial visit will usually be replaced. All subject data will be included in the final analyses unless there are strong grounds for exclusion; such grounds will be detailed in the final report.

2.1.2 Subject recruitment

Subjects will be recruited by one or more of following means:

1. Posting study details on The University of Manchester's 'Research Volunteers' website.
2. Correspondence to existing wearers on the Eurolens Research database of subjects.
3. Advertising through a variety of media via a format separately approved by Manchester UREC.
4. Advertisement at external sites.
5. Contacting existing patients at external sites.

2.1.3 Inclusion criteria

Subjects will only be eligible for the study if:

1. They are aged between 18 and 40 years and have capacity to volunteer.
2. They understand their rights as a research subject and are willing and able to sign a Statement of Informed Consent.
3. They are willing and able to follow the protocol.
4. They currently wear soft contact lenses or have done so in the past two years.
5. They have a spherical component of their contact lens prescription between Plano to - 6.00DS (inclusive).
6. They have a cylindrical component of their contact lens prescription between -0.75DC and -2.50DC (inclusive).
7. They can be satisfactorily fitted with the study lens types.
8. At dispensing, they can attain at least 6/12 distance high contrast visual acuity in each eye with the study lenses within the available power range.

9. They are willing to comply with the wear schedule (at least five days per week and for at least eight hours per day).
10. They own a wearable pair of spectacles.
11. They agree not to participate in other clinical research while enrolled on this study.

2.1.4 Exclusion criteria

Subjects will not be eligible to take part in the study if:

1. They have an ocular disorder which would normally contra-indicate contact lens wear.
2. They have a systemic disorder, which would normally contra-indicate contact lens wear.
3. They are using any topical medication such as eye drops or ointment.
4. They are aphakic.
5. They have had corneal refractive surgery.
6. They have any corneal distortion resulting from previous hard or rigid lens wear or have keratoconus.
7. They are pregnant or breastfeeding.
8. They have any ocular abnormality which would, in the opinion of the investigator, normally contraindicate contact lens wear.
9. They have eye or health conditions including immunosuppressive or infectious diseases, which would, in the opinion of the investigator, contraindicate contact lens wear or pose a risk to study personnel; or a history of anaphylaxis or severe allergic reaction.
10. They are currently wearing one of the study contact lenses.
11. They have taken part in any other contact lens or care solution clinical trial or research, within two weeks prior to starting this study.

2.2 Subject discontinuation

In general, subjects should be discontinued at any time, if it is in their best interests, as judged by the investigator. Reasons for this may include clinical signs of grade 3 or more, lack of motivation, discomfort, repeated refusal to follow instructions or the use of non-study products such as solutions or lenses. Subjects will be discontinued if a serious adverse event occurs or if they miss two or more planned consecutive visits. Subjects who fail to satisfy all the inclusion and exclusion criteria will be discontinued and replaced. Subjects may choose to leave the study at their own request. All discontinuations will be carefully recorded.

2.3 Safety parameters, adverse events and concurrent illnesses

The key safety parameters are the serious and significant ocular adverse events listed in [redacted] (adverse events are classified as 'serious', 'significant' or 'non-significant'). Clinical assessment is made at the study visit(s) for these parameters. The presence of an adverse event will be reported on the case report forms and those described as 'serious' or 'significant' will be detailed in the final report. Similarly, any concurrent illness that is likely to impact on the relevance and quality of the captured data will be noted on the case report form.

2.3.1 Investigator obligations

At all times the investigator will act in the best interest of the subject. Referral or treatment of an adverse event or other clinical finding should be initiated in the best clinical judgement of the investigator, irrespective of the participation in the clinical study.

2.3.2 Reporting obligations

In the case of a 'serious' or 'significant' adverse event, the investigator will notify Eurolens Research as soon as possible. The Principal Investigator will notify the Sponsor Contact Person as soon as possible following notification of the event. Manchester UREC and any regulatory authorities will be informed as required.

2.4 Study termination

If it becomes necessary to terminate the study earlier than planned, the Sponsor Contact Person will notify the Principal Investigator who will end the study with the cooperation of all sites. Manchester UREC will be informed. If the Principal Investigator becomes aware of any reason to terminate the study earlier than planned (e.g. reported unusual ocular findings or subject symptoms), the Principal Investigator will notify the Sponsor Contact Person to discuss the matter,

2.5 Protocol deviations

Any deviations from this protocol will be recorded and reported to the Sponsor Contact Person as appropriate. Manchester UREC will be informed as necessary.

2.5.1 Protocol amendments

Any amendments will be agreed between the Sponsor Contact Person and the Principal Investigator with the cooperation of all sites. Amendments will be recorded, identified and distributed. Approval from Manchester UREC will be obtained as necessary.

2.6 Study resources

Study products will be stored according to the manufacturer's product instructions.

2.6.1 Lenses

Details of the study lens are provided in Table 2. All lens types are CE marked. Initial lens selection will be as indicated by the manufacturer fitting guidelines.

	MyDay tor c		DAILIES Tota 1 Tor c
Manufacturer	CooperV s on Inc		A con
Mater a	Stenf con A		De ef con A
EWC (%)	54%		Core Water Content (%) 33%; Surface Water Content (%) > 80%
BOZR (mm)	8.6		Lens parameters to be conf rmed
D ameter (mm)	14.5		
Spher ca powers (D)	P ano to -6.00		
Cy ndr ca powers (D)	-0.75; -1.25, -1.75:	-2.25	
Axes (degrees)	10°,20°, 70°,80°, 90°,100°, 110°,160°,170°,180°	10°,20°,90°, 160°,170°,18 0°	

Table 2: Study lenses.

2.6.1.1 Use of lenses

Both lens types will be worn on a daily wear, daily disposable basis (i.e. removed at end of day and discarded). Lenses should be worn for a minimum of eight hours per day, five days per week. The lenses are also to be worn for a minimum of two hours before attending the follow-up visits.

2.6.2 Care regimen

No care system will be used on this study.

2.6.3 Inventory control

Both lens types will be sourced by the respective sites based on their existing accounts and relationships with the two product manufacturers. All worn lenses will be discarded. Lenses of interest such as Product Quality Complaints (PCQ) which have been stored during the study, will be discarded on completion of the study report, unless advised otherwise by the Industrial Contact Person. Unworn lenses will be retained by the sites for use as they see fit. All used study products must be documented (Lot number; Expiry date etc.) in the study paperwork or case record form (CRF).

2.6.4 Clinical equipment

Clinical equipment is regularly maintained and calibrated as required. Standard operating procedures and international standards are used where appropriate.

2.7 Study control

This study is controlled by cross-comparison. Bias will be minimised by randomising the order of assessment.

2.8 Documentation

Documents related to this work that require archiving will be kept by Eurolens Research for a period of 20 years after completion of the final report. The Sponsor company's permission will be sought before the documents are destroyed.

2.9 Data collection and analysis

a) At Eurolens Research, data collected in this work will be recorded on a custom-developed database and an established data trail. Data handling will include export of the study information from the clinical database into spreadsheet format for manipulation, followed by export into a statistical package for analysis. Most clinical data will be entered directly onto the electronic case report form and are considered to be source data.

b) External sites will record study data on paper CRFs, which will be sent to Eurolens Research for data input and analysis. Paper CRFs are considered source data for the external sites. Personal identifiable information will not leave individual sites.

2.10 Study completion

The clinical phase of the study will be considered as complete when all subjects have attended their last visit.

2.11 Confidentiality

All matters related to this work will remain confidential within Eurolens Research, the external sites, the funding company and any regulatory authority (e.g. Manchester UREC). All sites will take reasonable steps to ensure that specific lens-related information is not passed on to study participants unless this is required for clinical management of an adverse event. Personal subject information will not be made available. To cater for this, subjects will only be referred by their unique identity number in the study report. The data activities of Eurolens Research are registered with the data protection officer at The University of Manchester.

2.12 Study monitoring

In order to provide quality control and quality assurance as part of this work, the study monitor will:

1. Liaise closely with the Principal Investigator.
2. Monitor and ensure the safety of the subjects.
3. Ensure that the investigation is being conducted according to the protocol.
4. Monitor and review (or oversee review of) the study records to ensure accuracy.
5. Document their observations and make them available to relevant authorised parties (e.g. Manchester UREC).

6. Implement the Eurolens Research clinical monitoring standard operating procedure.

2.13 Clinical trial registration

This study will be registered with clinicaltrials.gov in accordance with section 801 of the Food and Drug Administration (FDA) Act which mandates the registration of certain clinical trials of drugs and medical devices.

Section 3. Subject management

3.1 Visit scheduling

Subjects will be required to attend four visits – an initial visit, a dispensing visit and two follow-up visits, after one week of contact lens wear in each lens type. Acceptable date ranges are shown in Table 3.

V s t	Target	A owab e range
In t a	N/A	N/A
D spens ng 1	N/A	N/A
Fo ow-up 1/D spens ng 2	7 days from D spens ng 1	6-11 days from D spens ng 1
Fo ow-up 2	7 days from D spens ng 2	6-11 days from D spens ng 2

Table 3: Visits and allowable ranges.

3.1.1 Unscheduled visits

Subjects who attend at their own volition, (or as instructed to do so by the investigator) rather than for a scheduled study visit, will be examined and the visit will be classified as 'unscheduled'. Data collected at these visits will be recorded on the CRFs.

Should a subject attend for their initial visit and be ineligible for the study owing to a reason which the investigator believes to be transient (for instance slit lamp signs higher than those acceptable according to inclusion/exclusion criteria), a repeat first visit can be conducted a short time later. This visit may involve some or all of the scheduled initial visit procedures, with the exception of the consent process, which would not be repeated.

3.1.2 Missed visits

Subjects not attending for a visit will be contacted and encouraged to return for assessment. If two consecutive study visits are missed, the subject will be discontinued. It is expected that study site personnel will attempt all reasonable means of communication in this event, including corresponding with the subject by letter.

3.2 Visit conduct

3.2.1 Pre-enrolment

The subject will receive a study-specific information form outlining the study at least 24 hours before the initial visit.

3.2.2 Initial visit

Subjects should attend wearing their spectacles.

They will then be required to sign an informed consent form prior to enrolment [redacted] A copy of the signed form will be issued to the subject. When the subject has signed the consent form, they are considered to be enrolled on the study.

Subjects will be instructed on the following:

1. Lens handling, application and removal, where necessary.
2. Specific study instructions, such as the importance of not using any other contact lens products.
3. General contact lens information such as the management of red eyes.

[redacted]

2. [redacted]
3. [redacted].
4. Slit lamp biomicroscopy will be carried out for the signs outlined in Table 4. Grades will be scored to the nearest 0.1 unit in the best judgement of the investigator using Efron Grading Scales:
    a. Using the recommended settings for slit width, magnification and filter, examine the anterior eye. Biomicroscopic signs listed in Table 4 should be graded.
    b. Instil sodium fluorescein (using a fluorescein ophthalmic strip wetted with saline) in both eyes and using cobalt blue light and a Wratten 12 filter or similar yellow filter, examine and grade the following: corneal and conjunctival staining.
    c. [redacted].

d. The upper eyelid should then be everted and examined both with cobalt blue light (with the yellow filter in place) and with white light (no filter in place). The grading of upper palpebral conjunctivitis should then be made with the Efron Grading Scales.

C ass f cat on	Pr mary s gns	Secondary s gns
S gns	Conjunct va redness L mba redness Cornea neovascu ar sat on Ep the a m crocysts Cornea oedema Cornea sta n ng Locat on of sta n ng Con unct va sta n ng Pap ary conjunct v t s	B ephar t s Me bom an g and dysfunct on Muc n ba s
Sca e	Efron Grad ng Sca es (scored to nearest 0.1)	Efron Grad ng Sca es (scored to nearest 0.1) (except muc n ba s, where the number s recorded.

Table 4: Biomicroscopic signs. Staining assessed with sodium fluorescein.

5. The investigator will confirm that the subject satisfies all the inclusion and exclusion criteria. Subjects who fail to meet all the criteria at this time will usually be discontinued and replaced unless the reason is considered to be transient in which case a further visit can be scheduled (see 3.1.1 above).
6. Using the fitting set, the first lens pair will be fitted according to the randomisation table [redacted] selecting the closest available lenses for the subject's prescription.
7. The subject or investigator may apply lenses. Orientation of toric markings do not need to be taken into consideration when applying lenses.
8. The lenses will be allowed to settle for 5 minutes.
9. [redacted]
10. [redacted]
11. [redacted]
12. [redacted]

[redacted]

13. Lens fit will be assessed using the following evaluations: horizontal and vertical centration, corneal coverage and movement. Normally, for an acceptable fit, centration and movement will fall within currently accepted clinical criteria [between -1 and +1 on a -2 to +2 grading scale [redacted]
14. [redacted]
15. The first lens pair will be removed and discarded.
16. Using the fitting set, the second lens pair will be fitted according to the randomisation table [redacted] selecting the closest available lenses for the subject's prescription.
17. Procedures are repeated for the second lens pair, as outlined in steps 6 to 15 above.
18. The subject will be discharged, and the study lenses ordered. Subjects are allowed to wear their own lenses until the next visit.

Where possible, for a single subject, the same spherical and cylindrical BVPs should be ordered for the two lens types – the axis ordered may vary for the lenses due to the different stabilisation characteristics of the lenses. However, if the fitting process indicates that a different spherical and/or cylindrical BVP needs to be ordered, this will be permitted.

3.2.3 Dispensing 1 visit

Subjects should attend this visit wearing their spectacles. Subjects attending this visit wearing contact lenses should be rescheduled.

The following procedures will be performed (any ocular measurement procedures outlined below will be carried out on each eye):

1. [redacted]
2. Any medical or ocular issues since the last visit will be recorded.
3. [redacted]
4. The subject will apply the first randomised pair of lenses. Orientation of toric markings do no need to be taken into consideration.
5. Lenses are allowed to settle for five minutes.
6. Toric lens fit will be assessed as described in Section 3.2.2.
7. [redacted]
8. Lens fit will then be assessed using the following evaluations: horizontal and vertical centration, corneal coverage and movement, using the grading scales in [redacted]
9. [redacted]
10. [redacted]
11. The investigator will confirm that lens fit [redacted] are satisfactory:
    a. In the case of an unacceptable lens fit, proceed to the next randomised lens (on the same day, or as a separate visit).
    b. In the case of unacceptable vision (less than 6/12), if in the opinion of the investigator an alternate lens from within the available power range would improve vision, then new lenses can be ordered and this visit repeated. If an alternate lens is not indicated then proceed to the next randomised lens (on the same day, or as a separate visit).
12. [redacted]

- [redacted]

13. The subject will be issued with 10 pairs of contact lenses for the first study period.
14. The subject will then be discharged and asked to return for the one-week follow-up visit having worn the study lenses for at least two hours. Subjects should be asked to wear their lenses for a minimum of eight hours per day, five days per week.

3.2.4 Follow-up 1/Dispensing 2 visit

Subjects should attend wearing the study lenses which should have been in situ for at least two hours. Subjects who attend without lenses in situ for at least two hours will usually be rescheduled.

The following procedures will be performed (any ocular measurement procedures outlined below will be carried out on each eye):

1. Any medical or ocular issues since the last visit will be recorded.
2. Lens wearing times since the previous visit will be recorded (hours per day, days per week and comfortable hours per day).
3. Lens wearing time on study visit day.
4. The subject will be asked about their agreement with statements related to lens comfort [redacted]
5. [redacted]
6. The subject will be asked to score the following with reference to appropriate [redacted]
   - [redacted]
   - Ease of lens removal
   - [redacted]

7. [redacted]
8. Retrieval of any unused lenses.
9. [redacted]
10. [redacted]
11. Lens fit, toric lens fit, rotational recovery [redacted], as described in section 3.2.2 above.
12. The lenses will then be removed and discarded.
13. [redacted]
14. The second randomised lens pair will be fitted and allowed to settle for five minutes.
15. The subject will apply the second randomised pair of lenses. Orientation of toric markings do no need to be taken into consideration.
16. Lenses are allowed to settle for five minutes.
17. Toric lens fit will be assessed as described in Section 3.2.2.
18. Rotational recovery will be assessed one minute after manually displacing the lens 30 degrees temporally:
    a. [redacted]

d. A timer begins, the subject while seated at the slit lamp is instructed to look straight ahead and to blink normally.
e. After one minute has elapsed, record the location of the lens marker and record the value on the protractor.

19. Lens fit will then be assessed using the following evaluations: horizontal and vertical centration, corneal coverage and movement, using the grading scales in [redacted]
20. Lens deposition and wettability will be graded using the grading scales in [redacted].
21. [redacted]
22. [redacted]
23. [redacted]

15. The subject will be issued with 10 pairs of contact lenses for the second study period.
16. The subject will then be discharged and asked to return for the one-week follow-up visit wearing the study lenses for at least two hours. Subjects should be asked to wear their lenses for a minimum of eight hours per day, five days per week.

3.2.5 Follow-up 2 visit

Subjects should attend wearing the study lenses which should have been in situ for at least two hours. Subjects who attend without lenses in situ for at least two hours will usually be rescheduled.

1. The same procedures as at Follow-up 1 (Section 3.2.4 above) will be carried out.
2. [redacted]
3. At the final visit (or when the subject is discontinued at an earlier visit) arrangements to issue the subject with their payment will be made, although they may have been asked by the investigator to attend a post-study follow-up visit. They should continue to use their lenses and solutions as advised, and seek aftercare for their contact lenses.

3.2.6 Post-study follow-up visit

In the case of a subject who exits the study with significant clinical signs or symptoms, the investigator must undertake to examine the subject at intervals he/she determines to be clinically appropriate until the sign or symptom has resolved or returned to a level that is considered to be clinically acceptable. Details from these visits will be recorded on a post-study follow-up visit form.

3.3 Monitoring subject compliance

Subjects are required to adhere to the instructions provided during this clinical investigation. This will be confirmed at the study visit(s) by verbal questioning of the subject by the investigator.

3.4 Missing, unused and spurious data

The absence of any data will be carefully and critically considered. If appropriate, partial datasets will be included in the final analysis. Any data missing from a subject visit will be outlined in the report by indicating the number of subjects included for each analysis. Data that are unused or considered to be spurious will be detailed and discussed in the report.

Section 4. Study co-ordination

4.1 Document processing

All case report forms will be processed and evaluated by Eurolens Research, who will produce the final report with full statistical analysis. A draft report will be sent to the Sponsor Contact Person in order to make comments and ask for re-drafts. If no comments are received from the Sponsor Contact Person within eight weeks, a final report will be released with a separate document control page (in duplicate), requesting the Sponsor Contact Person to sign both copies, one to keep and the other to be returned to Eurolens Research.

4.2 Disclosure

All matters relating to this clinical study are confidential and should only be disclosed to relevant authorised parties. More precise details relating to disclosure are outlined in the Research Agreement. None of the investigators involved in this work owns equity in the funding company.

4.3 Personnel

Protocol amendment

Study title: The comparative clinical performance of two daily disposable toric contact lenses

The table below lists the changes to be implemented in this work:

<table>
<tr><th>New revision no.</th><th>Section/s to be Amended and details</th></tr>
<tr><td>1</td><td>Both lenses are now available in all axes from 10 to 180 (10 degree steps)

Section 2.6.1 Lenses

Table 2: Study lenses now amended to reflect the change of study lenses.

<table>
<tr><th>Name</th><th>MyDay toric</th><th>DAILIES Total1 for Astigmatism</th></tr>
<tr><td>Manufacturer</td><td>CooperVision Inc</td><td>Alcon</td></tr>
<tr><td>Material</td><td>Stenfilcon A</td><td>Delefilcon A</td></tr>
<tr><td>EWC (%)</td><td>54%</td><td>Core water content 33%, surface water content >80%</td></tr>
<tr><td>BOZR (mm)</td><td>8.6</td><td>8.6</td></tr>
<tr><td>Diameter (mm)</td><td>14.5</td><td>14.5</td></tr>
<tr><td>Spherical powers (DS)</td><td>Plano to -6.00D</td><td>plano to -6.00D</td></tr>
<tr><td>Cylinder powers (DC)</td><td>-0.75, -1.25, -1.75</td><td>n-0.75, -1.25, -1.75</td></tr>
<tr><td>Axes (degrees)</td><td>10-180, 10 degree steps</td><td>10-180, 10 degree steps</td></tr>
</table>
Table 1: Study lenses</td></tr>
<tr><td>2</td><td>Number of subjects
The original protocol stated that up to 55 subjects should be enrolled, as the power calculation is based on 50 subjects completing the study.

As a result of a much higher number of ineligible subjects than expected, up to 65 subjects will now be enrolled. The intended number of subjects to complete remains 50.

As the lens SKU range is now increased, any subject who was originally ineligible owing to the required lens not being available, can now be re-enrolled and, if they wish to reenrol, will be treated as a new subject (i.e. they will reconsent and re-attend the initial visit and so on).
Subjects found ineligible for other reasons will not be re-enrolled.</td></tr>
</table>

Table 2: Changes to protocol C20-691 (version 1.0)

Document approved by:

[redacted]

[redacted]

[redacted]

[redacted]

Protocol amendment

Study title: The comparative clinical performance of two daily disposable toric contact lenses

The table below lists the changes to be implemented in this work:

New revision no.	Section/s to be Amended and details
1	Inclusion criterion 1 originally read 'They are aged between 18 and 40 years old and have capacity to volunteer'. Now amended to 'They are at least 18 years old and have capacity to volunteer'
2	Number of subjects The original protocol stated that up to 55 subjects should be enrolled, as the power calculation is based on 50 subjects completing the study. Protocol amendment 1 increased the maximum number to 65. In order to avoid to falling short of the required number of completed subjects, owing to a high rate of subjects being found ineligible at the initial visit, the maximum number of subjects to be enrolled is increased to 70.

Table 1: Changes to protocol C20-691 (version 1.0)

Document approved by: