Evaluation of Surface Refractive Index Shift of kalifilcon A Lenses Compared to Dailies Total 1, Precision 1 and Biotrue ONEday Lenses

PROTOCOL

STUDY #: ROC2-20-012
B+L IDE #: IR20-03-00
PROJECT NAME: Crystal (R0947)

Sponsor:
Bausch + Lomb Incorporated
1400 North Goodman Street
Rochester, NY 14609

[redacted]

This study is being conducted in accordance with 21 CFR Parts 812, 50, 54 and 56, applicable B+L Standard Operating Procedures, and the Declaration of Helsinki.

Revision Chronology:

Version 1.0 March 31, 2020

[redacted]

OBJECTIVE:

The objective of this insertion study is to evaluate potential surface refractive index shifts and/or surface water content changes of kalifilcon A lenses compared to Dailies Total 1, Precision 1 and Biotrue ONEday lenses.

STUDY DESIGN:

Approximately 20 habitual soft contact lens wearing subjects will be enrolled in this unilateral, randomized, double-masked (subject and investigator masked) repeated measures insertion study. All subjects will be seen for a Screening/Dispensing Visit at which informed consent will be obtained and eligibility will be assessed. If subjects satisfy all eligibility criteria and none of the exclusion criteria, subjects will insert study lenses in random, successive order according to unique randomization schedules that will be provided to each Investigator.

SUBJECTS:

Approximately 20 habitual soft contact lens wearing subjects will be enrolled.

SUBJECT ELIGIBILITY:

Inclusion Criteria:

To be eligible for entry into the study, the subject must:

1. Be 18 years or older and have full legal capacity to volunteer.
2. Have physiologically normal anterior segments not exhibiting clinically significant biomicroscopy findings.
3. Have no active ocular disease or allergic conjunctivitis.
4. Not be using any topical ocular medications.
5. Be willing and able to follow instructions.
6. Have signed a statement of informed consent.

Exclusion Criteria:

The subject is not eligible to participate in the study if the subject is:

1. Participating in a conflicting study in the opinion of the Investigator.
2. Considered by the Investigator to not be a suitable candidate for participation.

SUBJECT DISCONTINUATION:

The Investigator may discontinue a subject during the study for any reason if, in his or her opinion, it is in the best interest of the subject. Reasons for discontinuation include but are not limited to:

- adverse effects
- other ocular complications
- subject non-compliance
- subject request

- subject found to be ineligible during study participation*

***Any subject enrolled in the study, who later is found to have not met any of the eligibility criteria at entry, will be discontinued at the Sponsor's request.**

Subject discontinuations will be documented clearly on the applicable case report form.

TEST ARTICLES:

Test lenses:

T01. kalifilcon A lenses (Bausch + Lomb) [Reformat code: Crystal]

Control lenses:

C01. Dailies Total 1 (Alcon) [Reformat code: DT1]
C02. Precision 1 (Alcon) [Reformat code: Precision 1]
C03. Biotrue ONEday (Bausch + Lomb) [Reformat code: BOD]

All contact lenses will be -3.00D or closest marketed power available.

Masking:

This will be a double masked (subject and investigator) study.

Test Article Accountability:

All test materials will be accounted for on the Clinical Trial Materials Form and Lens/Solution Tracking Form. Subjects must return all remaining study materials to the Investigator at the final study visit, or their exit visit if discontinued prior to this visit.

METHODOLOGY:

Visits 1-4

- Each subject will wear one of the four lens types in a randomly determined order in the study eye for each timepoint of 5, 10 and 15 minutes. A new lens will be inserted for each timepoint.
- The worn lenses for each subject will be measured for surface refractive index on the refractometer.

For subsequent visits, the above procedures will be repeated for the remaining study lens types according to the randomization schedule for a total of 4 visits. Additional visits may be required for scheduling purposes.

RISK ANALYSIS:

The justification for this insertion study is to evaluate potential surface refractive index shifts and/or surface water content changes of kalifilcon A lenses compared to Dailies Total 1, Precision 1 and Biotrue ONEday lenses. All control lenses are FDA approved in the United States.

There are no major risks known to be associated with the products that will be used in this study. The risks involved in this study will be minimized because the subjects will be examined at specified intervals. The risks are further minimized by the study eligibility criteria. The subject population will be restricted to persons who are 18 years of age or older and have full legal capacity to volunteer; no restrictions are made as to gender.

With contact lens wear there may be increased risk of corneal edema (swelling of the cornea) which may temporarily affect vision or comfort, neovascularization (small blood vessels growing into the cornea), giant papillary conjunctivitis (small bumps on the inside of the eyelids), iritis (internal inflammation in the eye), corneal infiltrates (corneal inflammation) and corneal erosion/abrasion or corneal infection, which if untreated may cause ocular problems.

ADVERSE EVENTS:

Adverse effects arising in this study will be handled and reported according to applicable Research Clinic procedures. Subjects who experience an adverse event during study participation will be discontinued from study participation but will be followed by the Investigator until resolution of the adverse event or until the Investigator determines that further improvement is not expected.

STATISTICAL CONSIDERATIONS:

Randomization:

Subjects will be assigned subject numbers sequentially as they are enrolled. Lens types will be presented to subjects in a random order, according to a unique randomization schedule produced prior to study enrollment.

Statistical Analysis:

Continuous data will be summarized using descriptive statistics: n, mean, standard deviation, median, minimum and maximum. Unless otherwise noted, paired t tests will be used to test for differences in means for each of the parametric dependent variables. Differences at the $p \leq 0.05$ level are considered to be statistically significant and difference $p \leq 0.10$ but >0.05 will be considered a statistical trend.

STUDY MONITORING:

The study will be monitored according to applicable Research Clinic procedures.

STUDY TERMINATION:

Should the Investigator and/or study requester wish to terminate the study, applicable Research Clinic procedures will be followed.

PROTOCOL AMENDMENTS:

If there are changes to this study after initial IRB approval which impact subject safety or are significant study design changes, they will be documented in a protocol amendment and submitted for IRB approval prior to implementation.