Clinical Evaluation of Two Daily Disposable Lenses in Neophytes

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Introduction

Daily disposable lens wear may be the most trouble-free way of wearing contact lenses, because the wearer has fewer symptoms and adaptive signs and report better subjective vision and overall satisfaction than with any other modality [1]. Additionally, patients wearing daily disposable lenses see most compliant with replacement frequency [2].

Most contact lens-related trials are conducted on experienced patients, yet the neophyte presents unique challenges and opportunities. Neophytes must become adapted to the wearing of 1 of the 3 lens designs and remain lenses, and be willing and able to follow recommendations for lens wear, replacement, and aftercare. An exploratory clinical trial of 4 weeks in duration was conducted to evaluate various aspects of lens wear and fitting of neophytes with two daily disposable contact lenses.

Purpose

The primary objective was to evaluate the performance of two daily disposable lenses in neophytes. The main efficacy variables were subjectivity, comfort, handling, comfortable wearing time, overall satisfaction and purchase intent. Secondary variables were overall fit, centration and interchangeability training time.

Methods

Two daily disposable lenses (Test product: Hufilcon A 60%; water control product: Nairafilcon A 46%; water) were evaluated in a prospective, randomized, parallel-group, open-label, prospective single (subject) clinical trial to compare their performance in neophytes when worn for 4 weeks in daily disposable modality. 51 subjects were enrolled and randomized. 26 were the test product (male 35%, mean age 23±4.6) and 25 the control product (female 68%, male 32%, mean age 23±4.1). 48 subjects completed the trial.

Results

Average training time for insertion and removal was approximately 10 minutes each. The difference was, on average, 2 to 3 minutes between the two lens brands (insertion: test product 15.9±6.1 sec, control product 13.6±5.6 sec, P=0.04; removal test product 10.5±5.5 sec, control product 9.1±3.9 sec, P=0.02). Within the first week, subjects achieved acceptable fit with the study lenses. While most differences were not statistically significant due to the small sample size, subjective ratings of overall comfort, wear, handling and satisfaction as well as comfortable wearing time favored the test product (Hufilcon A) initially and were similar at the remaining visits.

Regarding overall comfort, on average, the Hufilcon A lens was rated significantly better at 1 week (test product 8.2±1; control product 7.7±1.8), better or similar in 2 weeks (test product 8±1.2; control product 7.1±1.6), 4 weeks (test product 8.5±0.9; control product 8.2±0.9), and 8 weeks (test product 8.8±1.0; control product 8.8±1.2; P=0.122). On average, the overall vision with the Hufilcon A lens was rated similar or slightly better at all visits (1 week: test product 8.6±1.4; control product 8.2±1.6; 2 weeks: test product 8.5±1.4; control product 8.1±1.6; 4 weeks: test product 8.9±0.8; control product 8.8±0.9; 8 weeks: test product 8.9±0.9; control product 8.8±0.7). Overall vision, comfort, and subjective ratings of overall comfort, wear, handling and satisfaction as well as comfortable wearing time favored the test product (Hufilcon A) initially and were similar at the remaining visits.

Conclusions

Although the survey via telephone showed that after completion of the trial, the majority of subjects from both groups returned to wearing glasses as their main correction. 16% of the Hufilcon A group and 11% of the Narafilcon A group were contact lenses more often than glasses. All other subjects were willing to continue contact lenses.

References


Acknowledgements

We thank the investigators who took part in the study. The study was supported by CIBA-VISION.

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Regarding front surface wearing, with the exception of an (1%) Grade 1/2/3/4/5 flattening at 1 week and 2 weeks (2% of a call with Hufilcon A, all findings were Grade 0 (None) and 2 (Mild). However, the frequency of Grade 0 findings was substantially higher with Hufilcon A, especially at dispensing and 4 weeks. While the differences did not statistically significant; after 4 weeks, purchase intent was higher with Hufilcon A; there were more subjects who “definitely” or “probably” would purchase Hufilcon A lenses (P=0.127).

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