

Results of French multicenter trial on Focus NIGHT & DAY

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Abstract

Patients around the world who require vision correction have shown high interest in continuous wear contact lenses. Manufacturers have responded by developing innovative materials that meet the physiological and mechanical requirements for this demand. CIBA Vision Corporation launched the first high Dk fluorosilicone soft contact lens in Mexico in 1998 and has conducted several observational trials in clinical practice settings in many countries.

The purpose of this trial was to report results from clinical practices in France. Six practitioners in France enrolled 134 subjects in this 4 month, open-label, multi-center, prospective, randomized, cross-over trial. Subjects were randomized to be dispensed either Focus NIGHT & DAY [FND] (CIBA Vision Corporation, Duluth, GA, USA) or Acuvue [AV] Vistacon, Inc., Jacksonville, FL, USA) and then crossed-over to the alternative lens after either 3 months' experience with FND or 1 month's experience with AV. Clinical and subjective data were collected at scheduled follow-up visits.

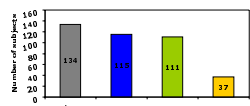
After 1 month of wear, FND was rated better for all aspects of comfort and overall average symptoms than AV. Wearers were satisfied with both lenses and lens features were comparable through 1 month. Preference was higher for FND after crossing over either from or to AV. Eighty-six percent of FND and 85% of AV wearers reported that they usually slept 7 nights per week in their lenses. Seventy-seven percent of FND and 21% of AV wearers reported 22 to 31 nights of continuous wear.

Both lenses gave similar performance for visual acuity. Biomicroscopy signs averaged below grade 1 [trace] with more signs for FND averaging lower than for AV. Biomicroscopy signs generally improved when subjects changed from AV to FND. Deposits remained below grade 1 and wetting was nearly perfect throughout the study. Over 90% of fits for both lenses were acceptable or optimal.

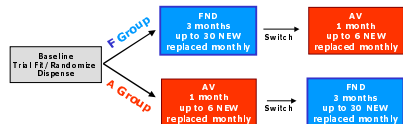
The high subjective satisfaction, good clinical performance and the high Dk characteristics of the FND lens provides practitioners an alternative to low Dk contact lenses. The FND lens delivered subjective and clinical performance that makes it a strong addition to vision correction options for continuous wear.

Methods

- Six practitioners in France enrolled 134 subjects:
 - 63% females and 37% males.
 - Average age 31.6 years.
 - 86% were current contact lens wearers:
 - 32% reported EW.
 - 13.0 hours/day average wearing time among the daily wear (DW) subjects.

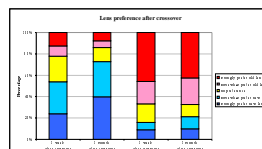
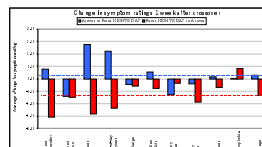
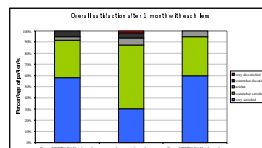
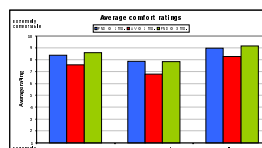


- 4 month open-label, multi-center, prospective, randomized, cross-over design:
 - Subjects were trial fitted with both lens types to insure that they could be successfully dispensed and then randomized to the sequence in which they would wear the lenses.
 - Subjective & clinical data collected at 6 visits:
 - FND: Baseline, 1 week, 1 month, 3 months.
 - AV: Baseline, 1 week, 1 month.



Subjective results

- **Comfort**
 - Wearers rated the Focus NIGHT & DAY lens higher than the Acuvue lens for all aspects of comfort after each lens had been worn for 1 month and the differences were statistically significant (Student's t-test, $p < 0.05$).
 - Focus NIGHT & DAY maintained its high comfort ratings and showed improvement in overall comfort and end-of-day comfort while the other measures of comfort remained stable as patients continued to wear Focus NIGHT & DAY through 3 months.
- **Satisfaction**
 - Over 90% of active wearers were satisfied with Focus NIGHT & DAY through 1 month. This increased to 95% being satisfied through 3 months of wear.
 - Satisfaction with Acuvue was also good with 87% expressing satisfaction through 1 month of wear.
 - The difference in distribution of overall satisfaction between Focus NIGHT & DAY and Acuvue at 1 month was statistically significant (Chi square test, $p < 0.05$).



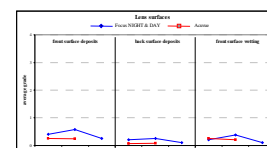
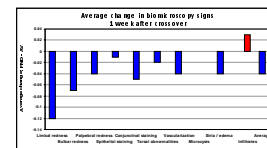
- **Wearer-reported symptoms**
 - The overall average symptom rating through 1 month of wear was better for Focus NIGHT&DAY than for Acuvue. Statistically significant differences favoring Focus NIGHT & DAY were found for lens discomfort, dryness, and end-of-day dryness (Student's t-test, $p < 0.05$).
 - The average change in wearer symptom ratings within 1 week of crossover improved when wearers crossed from Acuvue to Focus NIGHT&DAY and declined when wearers crossed from Focus NIGHT&DAY to Acuvue.
- **Wearer preference**
 - About 55% of wearers preferred Focus NIGHT & DAY within a week of changing from Acuvue. After a month, preference for Focus NIGHT & DAY increased to about 75%.
 - When wearers changed from Focus NIGHT & DAY to Acuvue, preference for the Acuvue lens was about 15% within 1 week and 20% after a month.
 - The preference for Focus NIGHT & DAY remained high after crossing over to Acuvue with about 65% of wearers expressing preference for Focus NIGHT & DAY after 1 week and after 1 month in the Acuvue lens.

Subjective discussion / conclusion

The high Dk Focus NIGHT & DAY lens was accepted very well by wearers when compared against the low Dk Acuvue lens. Wearers reported that all aspects of comfort were high during their first month of experience with Focus NIGHT & DAY and they reported that all aspects of comfort remained high through 3 months of wearing the lenses. Wearers also reported fewer symptoms, particularly those that have been indicated as having major impact on continuation of contact lens wear. Combining the comfort results with those of the symptom ratings supports the results for satisfaction and preference. Patients were more satisfied with and preferred the lens in which they were most comfortable and had fewer symptoms of discomfort, dryness, and end-of-day dryness.

Clinical results

- **Visual acuity**
 - Both lenses gave similar performances for Snellen visual acuity. No statistically significant differences were found in the distribution of VA measurements between Focus NIGHT & DAY and Acuvue at baseline, 1 week and 1 month ($p = 0.623, 0.57, \text{ and } 0.19$, respectively, Chi square test). Focus NIGHT & DAY continued to deliver consistent VA performance through 3 months.
- **Biomicroscopy**
 - Signs for Focus NIGHT & DAY were more often better than for Acuvue, with 6 of 10 signs and 9 of 10 signs averaging lower at 1 week and 1 month, respectively. A statistically significant difference favoring Focus NIGHT & DAY was found for limbal redness at 1 week.
 - Grades for 8 of 10 signs were worse for AV within 1 week of crossover. There was no average change in microcyst grade and the grade for infiltrates was slightly higher with FND within a week of crossover. On average, the change for all 10 biomicroscopy signs evaluated degraded -0.04 with the Acuvue lens.
- **Lens surfaces**
 - Front surface deposits and back surface debris averaged well below grade 1, or very slight, for both lenses throughout the study.
 - Front surface wetting performance also averaged nearly perfect throughout the study.
 - Statistically significant differences were found for front surface deposits at 1 week and 1 month and back surface debris at 1 month.
- **Fit**
 - Fit performance for both lenses was very good with high percentages of fits being evaluated as *optimal*. Overall, more than 90% of fits for both lenses were evaluated as acceptable or optimal. There were no statistically significant differences between the distribution of fits.
- **Adverse events**
 - Sterile corneal infiltrates
 - FND: 4 subjects. None stopped the trial and are still wearing FND:
 - Grade 0.5 to 3.
 - Small and non central infiltrates.
 - Superficial, no staining.
 - 1 HIV+ subject stopped the study.
 - AV:
 - 2 subjects - grades 1 and 2.
 - 1 CLPU for FND small, non central



Clinical discussion / conclusion

Clinical results in this study show that the Focus NIGHT & DAY lens delivered good visual acuity, maintained low deposits, wet well, fit well, and had excellent physiologic performance through 3 months. Adverse events were seen with both lenses and they were easily managed. 85% of Acuvue wearers also reported that they were wearing the lower Dk lens for 7 nights and 21% reported they were wearing it for 22 to 31 nights. Focus NIGHT & DAY offers a high Dk alternative for wearers who want continuous wear. The clinical results from this study in France add to the growing experience of good performance of the Focus NIGHT & DAY lens.