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Recommended Citation

Fujisaki, James C. and Mishima, Todd D., "Overnight corneal swelling responses: A comparison of CIBA NewVues vs. Vistakon Acuvue Plus" (1991). *College of Optometry*. 926.
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Overnight corneal swelling responses: A comparison of CIBA NewVues vs. Vistakon Acuvue Plus

Abstract

Two recently marketed disposable soft contact lenses, the CIBA NewVue and the Vistakon Acuvue Plus, were compared for overnight corneal swelling response. After seven hours of sleep, the mean percent central corneal swelling of our fifteen subjects were $7.41\% \pm 3.84$ for the CIBA New Vue and $9.28\% \pm 5.69$ for the Vistakon Acuvue Plus. There was no statistically significant difference between the mean percent corneal swelling induced by these two contact lenses (p

Degree Type

Thesis

Degree Name

Master of Science in Vision Science

Committee Chair

Mark A. Williams, O.D.

Keywords

Corneal swelling, CIBA NewVues, Vistakon Acuvues, disposable contact lenses

Subject Categories

Optometry

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OVERNIGHT CORNEAL SWELLING RESPONSES:
A COMPARISON OF
CIBA NEWVUES VS. VISTAKON ACUVUE PLUS

By

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A thesis submitted to the faculty of the
College of Optometry
Pacific University
Forest Grove, Oregon
for the degree of
Doctor of Optometry
May, 1991

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ABSTRACT

Two recently marketed disposable soft contact lenses, the CIBA NewVue and the Vistakon Acuvue Plus, were compared for overnight corneal swelling response. After seven hours of sleep, the mean percent central corneal swelling of our fifteen subjects were $7.41\% \pm 3.84$ for the CIBA NewVue and $9.28\% \pm 5.69$ for the Vistakon Acuvue Plus. There was no statistically significant difference between the mean percent corneal swelling induced by these two contact lenses ($p < 0.01$ paired t-test). Additionally, no statistically significant difference in mean percent central corneal deswelling between the CIBA NewVue ($3.79\% \pm 4.47$) and the Vistakon Acuvue Plus ($4.89\% \pm 5.58$) was detected one hour after awakening and lens removal. These findings suggest that central corneal edema induced by these two disposable contact lenses is clinically equivalent under extended wear conditions for the lens powers tested in this study (+3.00D).

KEY WORDS

Corneal swelling, CIBA NewVues, Vistakon Acuvues, disposable contact lenses.

INTRODUCTION

The decrease in oxygen permeability levels caused by extended contact lens wear is directly linked to corneal edema^{1,2,3,4,5} and can lead to problems such as corneal neovascularization, loss of corneal transparency, a decrease in visual acuity, a decrease in contrast sensitivity, and increased susceptibility to corneal infections. ^{6,7,8} Fabricating contact lenses to achieve better oxygen transmissibility has, therefore, been a critical issue, particularly when considering materials for extended wear.

During the mid-1980's disposable contact lenses were introduced into the market to try and minimize the problems associated with extended wear contact lenses. Although the use of disposable contact lenses has simplified patient compliance by eliminating cleaning solution and disinfection regimens, and has reduced the extent of protein deposit build-up by frequent lens replacement, there are still problems associated with corneal edema, particularly since the disposable contact lens option is an extended

wear option at this time due to the economic impediment of daily replacement.

Disposable soft contact lenses were first introduced in minus power only. However, CIBA Vision and Vistakon have recently introduced disposable soft contact lenses in plus power. These lenses are the CIBA NewVues and the Vistakon Acuvue Plus.

In this study we measured the changes in central corneal thickness that occurred while patients were wearing these lenses on opposite eyes of biocular subjects, during a single night of sleep, and the decrease in central corneal edema that occurred one hour after awakening and contact lens removal.

METHODS

Fifteen biocular subjects took part in our study. All subjects had either never worn contact lenses before or had not worn soft contact lenses within the past month. At the beginning of this study, all subjects that participated were examined and determined to be free from anterior segment pathology and any other contraindications for contact lens wear. Pachometry was initially performed on both eyes of the subject before contact lens insertion, immediately after seven hours of sleep, and at one hour post lens removal. Pachometry was performed with a Haag-Streit pachometer

(model no. H9001437) with an optical doubling device (with eyepiece), a potentiometer, a fixation device, and with a Diagnostic Concepts slitlamp (model no. 29043) as described previously.⁹ Both the pachometer and the slitlamp were on line with an Apple IIe (enhanced) computer, which utilized a Contact Lens Research Software program (written by Kevin Spreier) specifically developed for pachometry data analysis.¹⁰

An eye patch was used on the contralateral eye during the pachometry recordings in order to facilitate accurate patient fixation. The computer program receives all potentiometer input, controls the fixation device, calibrates each measurement, and computes the mean, standard deviation, and range of the corneal thickness measurements.

For each of the conditions for measurements, a total of seven readings were recorded per eye, with the highest and lowest values being deleted. The remaining five central corneal thickness measurements per eye were then used in the calculations. All measurements per eye fell within a mandatory standard deviation of 0.04 mm to insure operator measurement repeatability. The same procedure for pachometry was followed for all three conditions of measurement for each eye.

Each subject was randomly fitted in a double blind manner with a +3.00D CIBA NewVue (vifilcon A) on one eye and a +3.00D Vistakon Acuvue Plus (etafilcon A) on the other eye. The NewVue (dK 16.0) and the Acuvue Plus (dK 28.0) each has a center thickness of 0.12mm at +3.00D. In this study, each eye was evaluated and determined to have an acceptable contact lens fitting relationship with the initial, randomly assigned contact lens. The subjects were then required to sleep for seven hours before repeating pachometry measurements.

After seven hours of sleep, one subject was awakened at a time and pachometry was performed by a masked observer under controlled conditions where the patient was not allowed to open the test eye until the contact lens was removed and pachometry measurements were ready to be taken. The eye that was not immediately being tested was briefly patched to insure eye closure during testing of the contralateral eye. One hour after contact lens removal, pachometry measurements were repeated.

Corneal swelling was calculated as a percent change in corneal thickness as compared with baseline thickness readings,
$$\% \text{change} = \frac{(\text{final thickness} - \text{baseline thickness})}{\text{baseline thickness}} \times 100.$$
¹ Corneal deswelling was determined by subtracting the 1 hr. post lens removal mean corneal swelling result from the immediate

post lens removal mean corneal swelling result for each lens.

All statistics were determined by running the program Statview

512+™ designed for the Macintosh computer.

RESULTS

Insert Table 1

Insert Table 2

By comparing immediate post lens removal corneal thickness to baseline pachometry readings, and comparing one hour post lens removal corneal thickness to baseline pachometry readings, central corneal swelling was observed with both lenses (Scheffe F-test @ 90% significance level).

Table 1 lists the mean percent of corneal edema for each lens at immediate post lens removal in the morning and one hour post lens removal. The mean percent change in central corneal thickness of eyes wearing the Vistakon Acuvue Plus lens increased 1.87% and 1.10% more than the eyes wearing the CIBA NewVues as measured immediately after lens removal and one hour after lens removal respectively. The mean difference in percent swelling change

between the two different types of lenses are not statistically significant ($p < 0.01$, paired t-test) either immediately post lens removal or at one hour post lens removal.

Table 2 shows the mean percent of central corneal deswelling occurring 1 hour post lens removal. Statistically this difference of 0.77% is not significantly different ($p < 0.01$, paired t-test).

DISCUSSION

At immediate post contact lens removal after seven hours of sleep, and at one hour post lens removal, corneal swelling was observed with both types of lenses. There was no statistically significant difference in mean percent central corneal swelling produced by the CIBA NewVue and the Vistakon Acuvue Plus under these two conditions. There was also no statistically significant difference in the rate of deswelling of the central cornea between eyes which wore the two different types of lenses, one hour post contact lens removal.

The amount of physiological corneal swelling that occurs during sleep without contact lens wear is 3-4%, and reaches 0% an hour after the eyes open.¹¹ It has been suggested that the minimum desirable oxygen transmissibility for extended wear as its limit for overnight swelling is approximately 8% in order for the cornea to

regain its original thickness.³ Holden et.al. reported that non-disposable soft extended wear lenses cause 10-15% overnight corneal swelling.³ Therefore, the CIBA NewVue and the Vistakon Acuvue Plus would seem to be acceptable alternatives to non-disposable extended wear lenses based solely on the mean overnight central corneal swelling responses observed in our study of 7.41% and 9.28% respectively.

One of the most serious complications with the use of extended wear contact lenses is the development of corneal ulcers. It has recently been shown that patients are at a greater risk of developing bacterial corneal ulcers using contact lenses on an extended wear basis vs. a daily wear basis.^{12,13} It is believed that extended wear lenses cause corneal hypoxia which leads to a breakdown in the corneal epithelial barrier facilitating entry for microorganisms present on the ocular surface as normal flora, from contaminated contact lens solutions, or as opportunistic infections.¹³ Therefore, proper follow-up care, high quality lens materials, patient compliance and patient education are essential in minimizing contact lens-associated infections.

The best alternative to minimize overnight corneal edema in contact lens wearers would obviously be a daily wear schedule.

Many patients, however, will continue to wear contact lenses on an extended wear basis out of convenience. Even though many successfully wear soft contact lenses currently available for extended wear, there is still a need to find materials which have better oxygen-diffusion properties to reduce corneal edema induced by overnight contact lens wear and thereby avoid potential complications.¹⁴ For the present, rigid gas permeable contact lenses have the best oxygen transmission properties, which result in a smaller amount of central corneal swelling than disposable soft contact lenses for extended wear.² For those patients who continue to insist on wearing soft lenses on an extended wear basis, it seems that the CIBA NewVue and the Vistakon Acuvue Plus disposable lenses are clinically equivalent with regard to induced corneal edema for the lens power tested in this study, and they offer the simplicity and convenience of a disposable system.

ACKNOWLEDGEMENTS

The authors would like to thank Drs. Christina Schnider, Nada Lingel and Robert Yolton for their help with this project. We would also like to thank CIBA Vision Corp. and Vistakon Inc. for supplying the lenses for this study, and Beta Sigma Kappa for providing us with a student research grant.

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TABLE 1. Mean Corneal Swelling Results Following 7 hours of Lid Closure

<u>Lens Type</u>	<u>Immediate Post Lens Removal</u>	<u>1 Hr. Post Lens Removal</u>
CIBA NewVue	7.41% ± 3.84	3.79% ± 4.47
Vistakon Acuvue	9.28% ± 5.69	4.89% ± 5.58

TABLE 2. Mean Corneal Deswelling 1 Hr. Post Lens Removal

<u>Lens Type</u>	<u>Deswelling: 1 Hr. Post Lens Removal</u>
CIBA NewVue	3.62%
Vistakon Acuvue Plus	4.39%