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Comparative assessment of the comfort of two soft contact lenses

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Abstract

Background: Perception of lens comfort is a critical factor and predictor of whether or not an individual will be able to successfully achieve refractive correction with contact lenses. Recent advances in lens materials raise the question of which materials are the best to prescribe. It is important to have some basis on which to compare the various materials in regards to comfort in addition to standard lab bench tests such as Dk and hydration percentage.

Methods: The purpose of this study was to compare Brand A, a silicone hydrogel lens, with Brand B, a conventional hydrogel lens, in regards to wearer comfort. Twenty-nine subjects were randomly assigned to wear either Brand A or Brand B for four weeks and then the other brand for four weeks. Twenty-six subjects successfully completed the study. Subjects returned for follow-up visits at two and four week intervals after the initial fitting of each brand. Comfort was rated by acquiring subjective reports regarding comfortable wearing time and by marking an analogue comfort scale. Subjects also kept a home journal for recording comfort levels.

Results: Statistical analysis showed virtually no difference in the subjects' responses between the left and right eyes. As such only the data for the right eye was fully analyzed. The order in which the lenses were assigned was determined to not have a significant effect in the results; consequently, data was analyzed by brand without concern for an order effect. A slight decrease in comfort was noted for both brands from the two week reporting time to the 4 week reporting time.

Conclusion: The data showed no significant difference between the brands in either subject comfort response or subjective hours of comfortable wear. It can be inferred that both Brand A and Brand B performed equally well in the perceived wearer comfort. This suggests that current silicone hydrogel lenses are as effective at maintaining sufficient lens hydration as conventional hydrogel lenses thereby providing an equally effective level of comfort longevity.

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Keywords

silicone hydrogel, conventional hydrogel, comfort, dehydration, dry eye, analogue comfort scale

Subject Categories

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Comparative Assessment of the Comfort of Two Soft Contact Lenses

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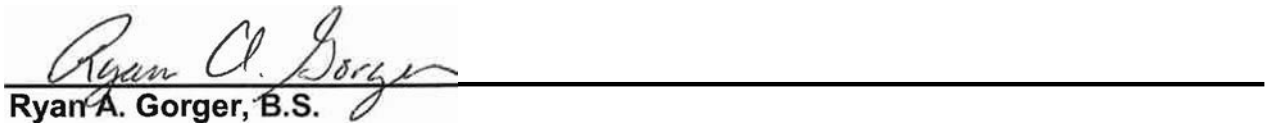

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Key Words: Silicone hydrogel, conventional hydrogel, comfort, dehydration, dry eye, analogue comfort scale

Comfort is one of the top criteria among successful contact lens wearers, while discomfort remains one of the key reasons for discontinuing contact lens use. Of the 25.5 million people in the United States who wear contact lenses, an astonishing 14 million people have stopped wearing contact lenses, most as a direct result of lens discomfort. This indicates that approximately 10% of the 140 million U. S. citizens requiring vision correction are contact lens drop-outs.' Research has also shown that 20% to 50% of contact lens wearers experience discomfort from dryness during contact lens use.[2] Lens dehydration may be one contributing cause of lens dryness. Factors contributing to dehydration-related discomfort include lid-lens interaction resulting from changes in lens surface wetting ability, changes in lens fit, or formation of surface epithelial irregularities due to corneal desiccation. It is well understood that patients who replace their contact lenses at more frequent intervals report less incidence of dryness-related symptoms. Another contribution to the comfort of contact lenses on the eye relates to the oxygen transmission through the contact lens.[3]

Trends in the contact lens industry have shifted from primarily focusing on acuity to targeting the development of lenses that provide both longevity in optimal comfort and crisp vision. Through recent technological advances, the first generation silicone hydrogel lenses were introduced to consumers. These first generation lenses include CIBA's Focus Night & Day and Bausch & Lomb's PureVision lenses. But adversarial researchers have historically attacked their success by arguing that while these first generation silicone hydrogel lenses allow the eye to breathe due to their high Dk, they do not allow sufficient hydration of the lens, which results in decreased comfort longevity thereby defying one of the goals of the contact lens. Despite their ability to

virtually eliminate lens-induced hypoxia, corneal swelling, microcysts, neovascularization, and various mechanical complications, the excitement over these first generation silicone hydrogel lenses has waned, and some eye care providers have expressed a reluctance to explore their full potential.[4]

However, studies have shown that up to 97% of patients using soft contact lenses would prefer the use of extended or continuous wear lenses over daily replacement lenses, simply because patients prefer to maintain permanent vision correction from day-to-day and also desire to avoid the daily hassles of insertion and removal.[5] As a result, contact lens manufacturers have continued to improve designs in a search for the ultimate hydrogel contact lens with a focus on improving comfort levels. This ultimate hydrogel contact lens should provide a convenient wearing time schedule without compromising ocular physiology.[6] Various hybrid hydrogel lenses have now been introduced into the marketplace. Examples of these are Brand A and Brand B lenses assessed in this study.

In 1995, Brand B became one of the first of a new class of conventional hydrogels designed to simulate the chemical composition of biological cell membranes. The lens is made of a Group 2 material containing phosphorylcholine, which is present in the cell membranes of red blood cells and other biological tissues. This disposable lens is cast-molded, contains 62% water content, has a refractive index of 1.387, and is approved for daily wear or monthly replacement. It has not been approved for extended wear. Brand B lenses are FDA-approved for use by patients with mild to moderate dry eyes. The crucial elements of this lens are its ability to maintain hydration through a high affinity for water and its ability to withstand accumulation of lens deposits through its electrical neutrality at physiological pH. Its ability to maintain on-eye hydration

permits high oxygen transmissibility, while its resistance to deposit accumulation minimizes clinical developments and facilitates the cleaning of the lens.[7]

In the early 2000's, Brand A was released as a second generation silicone hydrogel lens. The lens has a refractive index of 1.41, a water content of 47%, and is approved for either daily wear or a two-week replacement schedule. It has not been approved for extended wear. It provides UV protection that blocks over 90% of UVA and over 99% of UVB rays. Unlike the first generation silicone hydrogels, the lens has has no surface treatment. The Brand A lens has an internal wetting agent known as, but little else is known about the material composition of the lens.[8] Due to the relatively new nature of this lens, few comparative studies have been conducted. But a previous Brand A vs. Brand B study did not reveal any significant difference in comfort; however, that study relied on descriptors (eg. good, excellent) rather than a continuum of comfort grading. In order to quantify a subject's comfort more direct methods must be utilized to consistently measure the same level of comfort throughout the study.

The purpose of this study was to compare the clinical performance of Brand A with Brand B regarding daily comfort by using visual analogue scales and patient questionnaires.

Materials and Methods

This study was conducted at Pacific University College of Optometry, Forest Grove, Oregon, USA and involved a controlled, single-masked, randomized experiment. Subjects were masked to the identity of the lenses until either the exit visit or disenrollment from the study. The investigators were not masked because the markings on the lenses identified each of the lenses used. The two contact lenses studied were Brand A, FDA group IV with a water content of 58%, and Brand B, FDA group II with water content of 59%. Subjects wore each lens bilaterally in randomized succession for a period of 4 weeks each, with subjects assigned to initially use either lens using a random number generator in Microsoft Excel. Consequently, this was a two-part cross-over study over a 2 month period with an initial baseline analysis and assessments for each lens at 2-week and 4-week intervals.

Comfort was assessed subjectively using differing qualitative and quantitative methods at each 2-week and 4-week visit. Subjects were initially asked to rate the level of overall comfort throughout the previous 2-week period using descriptors of "None, Mild, Moderate, or Severe." A second questionnaire was then utilized where subjects rated overall, initial (comfort after initial insertion of the lens), and end-of-day comfort using a scale of "Excellent, Very Good, Good, Fair, or Poor" regarding the same 2-week period. Average comfortable wearing time in hours per day was also assessed for this period. A final grading system was utilized during each 2-week and 4-week visit where subjects indicated the level of comfort for each eye during the previous 2-week period by drawing a horizontal line across a vertical line of 10 cm length. The top of the vertical line indicated "Extremely comfortable, unnoticeable" lenses, whereas the bottom of the

vertical line denoted "Extremely uncomfortable, impossible to wear" lenses. The vertical line was not numbered, requiring the subjects to estimate the approximate percentage of an acceptable comfort level on an assumed scale of 0 to 100%. Furthermore, all subjects were required to maintain a comfort diary while at home during the 4-week period wearing each of the trialed lenses. Entries in the diaries were completed on days 1-4, day 7, day 14, day 21, and the day prior to the 4-week assessment with that particular lens. Overall comfort, initial comfort, end-of-day comfort, lens handling, dryness, and overall satisfaction where graded on a scale of “0” (extremely unsatisfactory) to "10" (extremely satisfactory). Comfortable wearing time in hours per day was again recorded for each of these days.

The ocular health and development of dry eye symptoms was monitored during the use of each lens. For the purpose of this study, the definition of "dry eye" remained consistent with that established by the National Eye Institute/Industry Workshop, "a disorder of the tear film arising from excessive tear evaporation or from an aqueous tear deficiency (non-Sjogren's) that causes damage to the interpalpebral ocular surface and is associated with symptoms of ocular discomfort".[9] Additionally, all enrolled subjects were limited to current soft contact lens wearers, and no subjects with pre-existing systemic/ocular illness or ocular irritation that would preclude contact lens fitting were enrolled in this study. To help minimize contact lens care product induced complications during the study, subjects were provided with Ciba Vision AOSept Clear Care storage and disinfectant solution for use throughout the study. This care system was also assumed to be least likely to affect lens wearing comfort because of its lack of persistent chemical preservatives. Additionally, only non-presewed rewetting drops

were allowed when required to exclude the possibility of a reaction to any preservative agents.

Subjects were identified using a six-digit code composed of a site number, an enrollment number, and the initial letters of the subject's first and surnames. Subjects satisfied the inclusion criteria if the following conditions were met:

a. Must be of legal age (at least 18 years old).
b. Must sign a Written Informed Consent.
c. Must be an existing daily, weekly, or monthly replacement soft contact lens wearer for at least 4 weeks prior to the study.
d. Must have a typical maximum comfortable wearing time of 10 hours with habitual contact lenses.
e. Require spherical distance correction between +4.00D and -6.00D in both eyes.
f. Must have an astigmatism correction less than 1.00D in both eyes.
g. Must be spherically correctable to a visual acuity of 20130 or better in each eye.
h. Must have normal eyes with no evidence of abnormality or disease. A "normal eye" is defined as one having:
    i. No amblyopia.
    ii. No evidence of lid abnormality or infection (e.g. entropionlectropion, chalazia, recurrent styes, etc.)
    iii. No clinically significant slit lamp findings (e.g. corneal infiltrates or other slit lamp findings Grade 3 or above: corneal edema, corneal staining, tarsal abnormalities, conjunctival injection.
    iv. No other active ocular disease (e.g. glaucoma, history of recurrent corneal erosions, or other corneal, conjunctival, lid, or intraocular infection or inflammation of an allergic, bacterial, or viral etiology.)
    v. No congenital or surgical aphakia.

Similarly, a subject was rendered ineligible for inclusion in the study if any of the following exclusion criteria was met:

a. Existing wearer of Brand A or Brand B.
b. RGP or PMMA wearer within 4 weeks prior to enrollment of the study.
c. Requires concurrent ocular medication.
d. Any systemic illness affecting contact lens wear or the medical treatment of which would affect vision or successful contact lens wear.
e. Eye injury or surgery within eight weeks prior to enrollment of the study.
f. Abnormal lacrimal secretions.
g. Pre-existing ocular irritation that would preclude contact lens fitting.
h. Keratoconus or other corneal irregularity.
i. Pregnancy, lactating, or planning a pregnancy at the time of enrollment.
j. Participation in any concurrent clinical trials.

Results

A. Subjects:

A total of 29 subjects were enrolled in the study. (See Table I) There were 13 males and 16 females ranging in ages from 18 to 56, with an average age of 27.4 for all enrolled subjects. However, two subjects were discontinued from the study following non-contact lens related complications and one subject was discontinued following subject non-compliance with the expected experimental protocol.

B. Statistics Analyzed:

Of particular interest in this study were the subjective ratings of comfort at the two and four week visits, as well as the subject's reporting of hours of comfortable wear. (See Table 2)

C. Comfort Scores:

As it was apparent the comfort ratings for right and left eyes were virtually identical, it was decided to analyze the comfort scores for the right eye (OD) only. Figure 1 displays the median and range of OD comfort scores at each visit for the two types of lenses tested. Figure 2 displays mean and confidence intervals for the same data.

Due to the cross-over design of the study, one concern was that there might be an order effect. From Figure 1 and Figure 2 it can be seen that there is no noticeable order effect, since in sequence A (Brand A lenses worn first) there is a trend to prefer the initial lenses, and in sequence B (Brand B lenses worn first) there is no such trend.

As we felt justified in rejecting the assumption of order effect, data from the two sequences were combined to test for difference in OD comfort. Means and confidence intervals are displayed in Figure 3.

A paired t-test was used to test for significance. At the two week interval the Brand A lens scores were not significantly better than the Brand B scores. (Mean difference 8.038, 95%CI = -0.5427 to 16.62. Student's-t Test. p = 0.0.651, t=1.929, DF = 25). There was also no significant difference at the four week interval. (Mean difference 5.231, 95% CI = -2.020 to 12.481. Student's t-Test p = .1498, t= 1.486, DF = 25).

D. Comfortable Wearing Time:

Figure 4 shows the Means and 95% confidence intervals for the hours of comfortable wear for the combined phases. It is clear there were no significant differences between the brands.

Discussion

Our finding that the Brand B lens provides comparable daily comfort to the Brand A lens is consistent with findings of a previous Brand A vs. Brand B study. Our study demonstrated that there was no significant difference in lens preference among subjects. However, the study was restricted to a small number of subjects and was confined to a limited subject base composed primarily of optometry students and their spouses. A larger study incorporating subjects more representative of the general population may have shifted our results towards preference of one lens over the other. Nevertheless, both comfortable wear and comfortable wearing time were shown to be essentially identical for both lenses. Additionally, there was similar, yet minimal, incidence of dry eye symptoms associated with each lens after prolonged wear. But we did not specifically evaluate either the effects of ambient environmental variations (i.e., hot, moderate, cold, etc.) or levels of lens dehydration as they relate to lens comfort, which would have required a larger subject pool to best establish a correlating relationship, should one exist. However, previous studies have not effectively shown a definitive correlation between lens hydration and comfort.[10]

Another surprising piece of anecdotal evidence implied during our study was regarding the effectiveness of conventional hydrogel lenses vs. silicone lenses in providing optimal comfortable wear. According to our study, each lens performed almost identically suggesting that current silicone hydrogel lenses are as effective at maintaining sufficient lens hydration as conventional hydrogel lenses thereby providing an equally effective level of comfort longevity.

Our study also demonstrated that marking the subjective comfort perception on an analogue scale to later be quantified for analysis is a practical and efficient method of gathering perceived comfort data. This may allow for detection of more subtle variations in responses than forcing subjects to pigeon hole their responses into a few broad categories.

Tables and Figures:

Table 1: The following table summarizes the pertinent subject enrollment criteria:

Subject ID	Gender	Age	Refractive Error	Avg. Daily Wear Time Of Previous CL Brands (Hours)	Avg. Comfortable Daily Wear Time of Previous CL Brands (Hours)
02/31/JN	Male	27	OD -1.00-0.25X090 OS -1.00-0.25X068	14	10
02/32/KR	Female	24	OD -4.25DS OS -4.25-0.50X160	10	10
02/33/CJ	Male	25	OD -2.75-0.25X065 OS -2.25DS	11	11
02/34/EM	Female	22	OD -5.25-0.75X178 OS -4.75DS	15	11
02/35/AA	Female	24	OD -3.75DS OS -5.50-0.50X090	12	12
*02/35/SO	Female	24	OD -6.75-0.75X060 OS -7.25-0.75X135	12	10
02/36/JE	Female	24	OD -4.75-0.50X005 OS -5.00-0.50X145	15	10
02/37/EM	Female	26	OD -0.75-0.75X150 OS -1.00DS	10	10
02/38/BB	Male	32	OD -1.00-0.50X100 OS -1.75-0.50X160	14	14
02/39/AW	Male	26	OD -2.00-0.50X100 OS -1.75-0.50X133	16	15
02/40/CG	Female	34	OD -2.75DS OS -5.00-1.00X080	10	8
02141/ML	Male	22	OD -3.00DS OS -3.00DS	10	10
02/42/DM	Male	25	OD -3.25DS OS -3.25DS	14	14
02/43/HH	Female	37	OD -3.25-0.50X090 OS -3.75-0.50X090	12	10
02/44/AW	Male	25	OD -5.00DS OS -4.75DS	15	15
02/45/KL	Female	25	OD -5.25-0.75X018 OS -5.25-0.75X175	10	10
02/46/MS	Female	26	OD -3.75-0.25X175 OS -3.75-0.25X175	12	8
02/47/LR	Female	40	OD -3.75-0.25X040 OS -2.25-1.00X180	13	12
*02/48/SP	Male		OD -3.75DS OS -3.50-0.75X080	16	16
02/49/RH	Female	20	OD -2.50DS OS -2.50DS	12	12
02/50/SO	Female	23	OD -0.75DS OS -0.75DS	8	8

02/51/SF	Male	47	OD -1.75-0.75X100 OS -2.25DS	12	12
02/52/RW	Male	26	OD -2.50-0.75X067 OS -2.00-0.75X088	12	12
02/53/DA	Male	26	OD +4.00-0.25X095 OS +3.75-0.25X020	16	15
02/54/SS	Female	22	OD +3.00DS OS +3.50-0.50X025	14	14
02/55/EG	Female	56	OD -4.00DS OS -3.50DS	14	14
02/56/DH	Female	23	OD +4.00-0.50X100 OS +4.75DS	12	10
02/57/GB	Male	23	OD -0.75DS OS -1.00DS	15	14
**02/58/CN	Male		OD -2.25-0.50X160 OS -2.50-1.00X180	14	14

Total Number of Subjects	**Total Males. vs. Total Females**	**Average Age**	**Average Refractive Error (Equivalent Sphere)**	**Avg. Daily Wear Time Of Previous CL Brands Of All Subjects (Hours)**	**Avg. Comfortable Daily Wear Time of Previous CL Brands Of All Subjects (Hours)**
29	13 Males and 16 Females Completed Study	27.39	-2.25	12.79	11.82

* Discontinued for development of ocular complications.

**Discontinued for non-compliance with experimental protocol.

Table 2: Individual subject's responses for subjective ratings of comfort at the two and four week visits, as well as the subject's reporting of hours of comfortable wear.

Brand A: Group 1

Patient #	OD 2 week	OS 2 week	2wk Comfort Hrs	OD 4 week	OS 4 week	4wk Comfort Hrs
31JN	91	91	13	84	85	13
33CJ	75	86	12	79	91	10
36JC	90	90	12	82	89	14
38BB	69	79	12	91	93	12
41ML	47	48	10	62	61	10
43HH	92	90	12	84	84	11
46MS	74	74	10	59	76	11
50SO	82	84	7	73	74	8
51SF	88	86	12	89	89	12
52RW	73	74	16	78	65	11
54SS	56	81	12	31	52	8
56DH	78	72	12	74	51	9

Brand A: Group 2

Patient #	OD 2 week	OS 2 week	2wk Comfort Hrs	OD 4 week	OS 4 week	4wk Comfort Hrs
32KR	90	90	11	90	89	13
34EM	74	89	14	95	94	14
35AA	93	94	14	96	96	14
37EM	90	91	12	93	92	12
39AW	84	84	13	77	58	11
40CG	98	97	15	94	96	15
42DM	87	87	13	80	82	13
44AW	88	94	13	95	95	13
45KL	76	75	12	92	93	12
47LR	81	75	10	88	89	10
48SP	86	86	16	84	83	16
49RH	86	88	10	87	87	11
53DA	82	85	15	85	84	16
55EG	97	97	14	99	99	15
57GB	83	83	12	89	90	13

Table 2: continued

Brand B: Group ▮

Patient #	OD 2 week	OS 2 week	2wk Comfort Hrs	OD 4 week	OS 4 week	4wk Comfort Hrs
32KR	92	90	15	93	94	13
34EM	72	70	10	90	75	13
35AA	98	98	14	99	99	14
37EM	79	59	8	80	59	8
39AW	68	76	12	84	89	12
40CG	100	100	16	100	100	16
42DM	85	81	14	96	97	14
44AW	94	94	14	98	98	13
45KL	80	73	8	75	75	10
47LR	19	20	6	45	25	5
48SP	90	90	15	90	90	16
49RH	85	83	11	81	82	12
53DA	90	81	17	83	84	15
55EG	100	100	14	97	97	14
57GB	35	34	12	77	77	11

Brand B: Group 2

Patient #	OD 2 week	OS 2 week	2wk Comfort Hrs	OD 4 week	OS 4 week	4wk Comfort Hrs
31JN	85	85	13	87	87	13
33CJ	61	87	12	30	82	13
36JC	35	58	10	40	62	8
38BB	84	89	13	88	87	16
41ML	72	70	11	67	66	10
43HH	65	64	10	50	50	7
46MS	63	52	8	61	55	8
50SO	51	50	7	50	51	8
51SF	85	86	12	82	80	12
52RW	52	42	6	51	32	6
54SS	63	75	10	70	75	12
56DH	84	82	12	81	76	12

Figure 1: Median and range of right eye comfort scores at each visit for the two types of lenses tested.

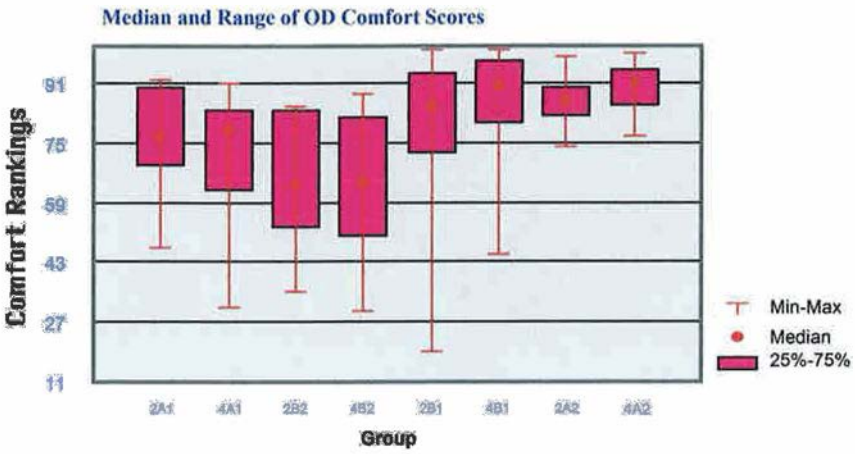


Figure 2: Mean and confidence intervals of right eye comfort scores at each visit for the two types of lenses tested.

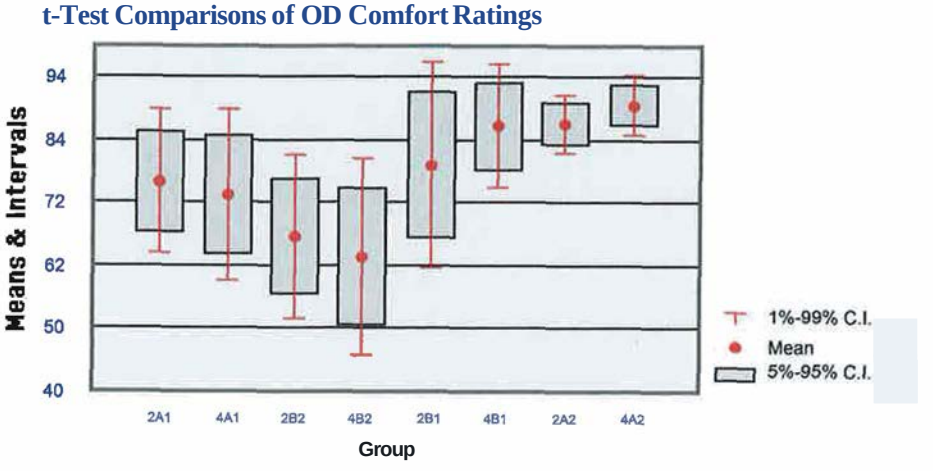
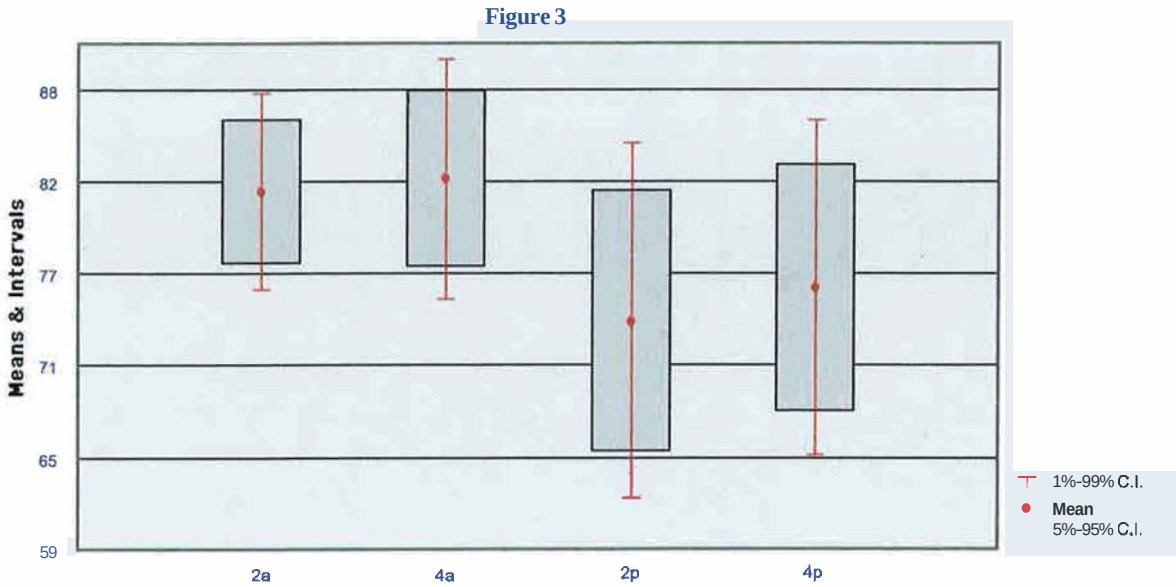


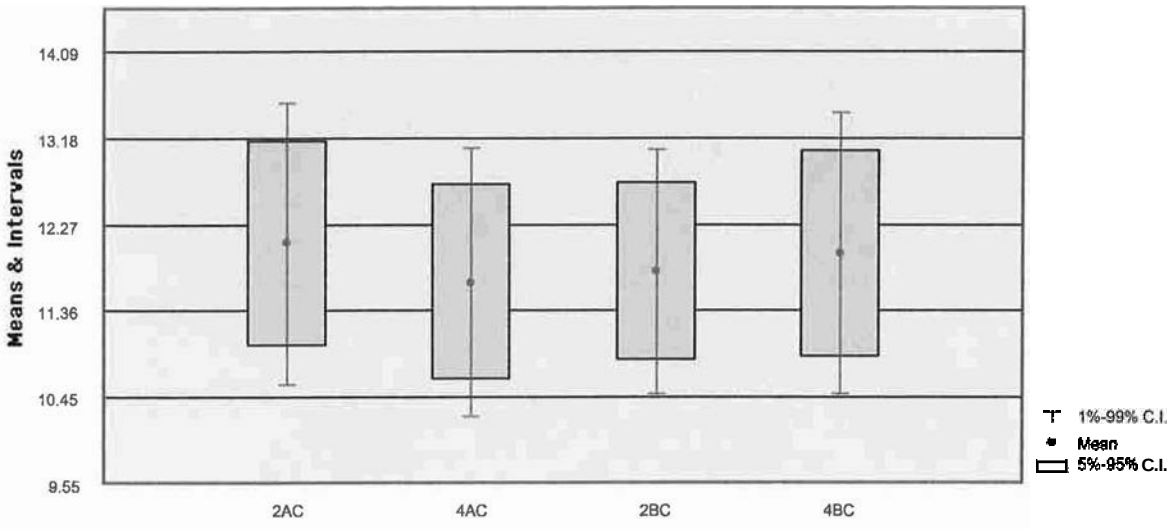
Figure 3: Two sequences were combined to test for difference in OD comfort. Means and confidence intervals



Group: 2A = Lens A at 2 Weeks. 4A = Lens A at 4 weeks, 2B = Lens B at 2 weeks, 4B = Lens B at 4 weeks

Figure 4: Means and 95% confidence intervals for the hours of comfortable wear with the two phases combined

FIGURE 4: COMFORTABLE WEARING TIME



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