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A clinical evaluation of edge induced conjuctival staining with NewVues and SeeQuence disposable lenses

Brett N. Hagen
Pacific University

Penny P. Vizina
Pacific University

Terry C. Patrick
Pacific University

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Abstract

Results from a previous study indicated that the Johnson & Johnson ACUVUE® disposable lens caused more conjunctival staining than the Bausch & Lomb SEEQUENCE™ lens.l The current study was performed in the same manner as the previous study to determine if the third type of disposable lens, the Ciba NewVues®, induced a significantly different amount of conjunctival staining from the Bausch & Lomb SEEQUENCE™ lens. Sixty subjects wore a SEEQUENCEn lens on one eye, and a NewVues lens on the other. Prior to dispensing the lenses, subjects were screened by two investigators to insure no conjunctival staining was present and that lens fits were acceptable. After 24 hours, a different investigator, who did not know which lens was worn on which eye, evaluated all subjects to determine the grade of conjunctival staining and the percentage of involvement for each quadrant. Weighted averages for each quadrant and lens type were computed from the grade and percentage of involvement. These weighted averages were used in a Wilcoxin signed-rank test to determine if there was a significant difference in conjunctival staining between lens types, and in a Friedman 4-way analysis to determine if any quadrants were significantly more affected than others. These analyses determined that the NewVues lens caused less conjunctival staining than the SEEQUENCE™ lens ($p<0.05$) and that the inferior quadrant was more affected than other quadrants ($p<0.05$).

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A CLINICAL EVALUATION OF EDGE INDUCED CONJUNCTIVAL STAINING WITH NewVues® AND SEEQUENCE™ DISPOSABLE LENSES.

BY

BRETT N. HAGEN
PENNY P. VIZINA
&
TERRY C. PATRICK, O.D.

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SIGNATURE PAGE

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Brett N. Hagen

Penny P. Vizina

Terry C. Patrick

Dr. Nada J. Lingel

ABOUT THE AUTHORS:

Brett Hagen is a 1987 graduate of Pacific Lutheran University with a Bachelor of Arts degree in Biology. Present memberships include AOSA, AOA Contact Lens Section, COVD, and Washington Optometric Association. Anticipated date of graduation is 1991 from Pacific University College of Optometry.

Penny P. Vizina is a 1986 graduate of Gustavus Adolphus College with a Bachelor of Arts degree in Biology. Present memberships include AOSA. Anticipated date of graduation is 1991 from Pacific University College of Optometry.

Terry C. Patrick is a 1990 graduate of Pacific University College of Optometry with a Doctor of Optometry and a 1988 graduate of Pacific University with a degree in Visual Science. Dr. Patrick now resides and practices in the state of Colorado.

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ABSTRACT

Results from a previous study indicated that the Johnson & Johnson ACUVUE® disposable lens caused more conjunctival staining than the Bausch & Lomb SEEQUENCE™ lens.[1] The current study was performed in the same manner as the previous study to determine if the third type of disposable lens, the Ciba NewVues®, induced a significantly different amount of conjunctival staining from the Bausch & Lomb SEEQUENCE™ lens. Sixty subjects wore a SEEQUENCE™ lens on one eye, and a NewVues lens on the other. Prior to dispensing the lenses, subjects were screened by two investigators to insure no conjunctival staining was present and that lens fits were acceptable. After 24 hours, a different investigator, who did not know which lens was worn on which eye, evaluated all subjects to determine the grade of conjunctival staining and the percentage of involvement for each quadrant. Weighted averages for each quadrant and lens type were computed from the grade and percentage of involvement. These weighted averages were used in a Wilcoxin signed-rank test to determine if there was a significant difference in conjunctival staining between lens types, and in a Friedman 4-way analysis to determine if any quadrants were significantly more affected than others. These analyses determined that the NewVues lens caused less conjunctival staining than the SEEQUENCE™ lens ($p<0.05$) and that the inferior quadrant was more affected than other quadrants ($p<0.05$).

KEY WORDS

Conjunctival staining, disposable contact lenses, extended wear contact lenses, sodium fluorescein staining.

INTRODUCTION

Disposable lenses are currently gaining popularity among patients and practitioners.[2] Patients have found the lenses convenient and comfortable while providing excellent vision.[2] Previous studies have indicated that the use of disposable lenses reduces the incidence of the problems exaggerated by extended wear. The problems which are decreased include the incidence of GPC[3,4,5] lens deposits[4,5] and chemical irritation due to contact lens disinfection.[6] Despite these benefits, many practitioners have expressed concern over lens reproducibility due to the processes by which the lenses are made and compliance problems.[7]

At present, three methods are used to produce disposable contact lenses: stabilized soft molding, traditional spin casting and cast molding. The stabilized soft molding process does not allow for edge finishing and as such may cause problems in patient comfort and ocular health. Spin casting and the cast molding each allow for edge finishing and may provide a more tolerable and less traumatizing lens. Seger and Mutti found that the inability to polish the edge in the soft molding process forms a lens with a sharp junction at the posterior surface and often allows excess material to remain attached to the edge.[8] In a more recent study, Lowther examined the soft molded ACUVUE® lens and detected defects in 22.5% of the lenses. Of this 22.5%, all but 3.1% were edge defects. In the same study, Lowther found only 2.5% of the spin casted SEEQUENCE™ lens had such defects.[9]

This study was designed as a follow-up to one comparing the edge induced conjunctival staining of the Johnson and Johnson ACUVUE® lens to that of the Bausch and Lomb SEEQUENCE™ lens. This prior study found that the soft molded

ACUVUE® lens induced significantly more staining than the SEEQUENCE™ lens.[1] It is hypothesized that the difference was due to the different processes by which the lenses are made.

Since the time of the first study by Devries, Lingel, Patrick and Spitzer, a new disposable lens has entered the market, the NewVues® lens manufactured by Ciba. This lens is manufactured by the cast molding process that allows for a polished edge, similar to spin casting. It has gained a very positive rating for product performance from investigators and patients.[2] Photographs of the edges of both lenses show a relatively smooth edge. For completeness and comparability, this study will compare the conjunctival staining found with the Bausch and Lomb SEEQUENCE™ disposable lens to that of the Ciba NewVues® disposable lens using the same design as the initial study by Devries, Lingel, Patrick and Spitzer.[1]

METHODS

SUBJECTS

Subjects were obtained by advertising through the Pacific University College of Optometry. Candidates currently wearing contact lenses were required to discontinue lens wear at least 24 hours prior to their screening/fitting appointment. Criteria for acceptance into the study included: anterior segments free from pathology, no more than 1/2+ sodium fluorescein staining of corneas and conjunctiva, and a comprehensive exam conducted by a Pacific University College of Optometry clinic no more than two years prior to the start of the study.

A summary of subject characteristics can be seen below:

SUBJECT PROFILE

SEX	NUMBER	PERCENTAGE
Male	37	61.7
Female	23	38.3
Total	60	

AGE	NUMBER	PERCENTAGE
21-25	42	70.0
26-30	10	16.7
31-35	5	8.3
35-39	2	3.3
41-45	1	1.7
Total	60	

PREVIOUS CL EXPERIENCE	NUMBER	PERCENTAGE
None	13	21.7
RGP & PMMA	9	15.0
RGP & SCL	7	11.7
SOFT	31	51.7
Total	60	

REFRACTIVE ERROR	NUMBER EYES	PERCENTAGE
Myopia	106	88.3
Hyperopia	4	3.3
Emmetropia	10	8.3
Total	120	

EXPERIMENTAL DESIGN

When evaluating the amount of pre-fit staining, the eye was divided into four quadrants: superior, inferior, nasal, and temporal. One investigator graded the amount of staining based on a 0-4+ photographic scale established by Devries, et al, with grade 0 representing no staining and grade 4+ being the heaviest amount of staining.[1] The amount of staining per quadrant (0 to 100%) was also recorded. Any candidate with grade 1/2 or greater staining was not included in the study.

Once determined to be a good candidate, the subject's eyes were rinsed with B&L Eyewash™ to remove the remaining sodium fluorescein. Then one Ciba NewVues® and one B&L SEEQUENCE™ were randomly assigned to each of the patient's eyes and inserted. Fifteen minutes after insertion the lenses were evaluated by a different investigator who accepted the fit if it yielded full limbal coverage and movement of greater than 0.5 mm but less than 2.0 mm on a full blink. These criteria for an acceptable fit were chosen to match the previous study. Myopes were fit with appropriately powered minus lenses while emmetropes and hyperopes were fit with low powered minus lenses. Although plus lenses were available at the time of this study, they were not used in an attempt to keep similar parameters and

conditions as the first study. While Ciba NewVues® were available in two base curves, all subjects were fit successfully with the flatter base curve which is similar to the parameters of the SEEQUENCE™ lens.

After fitting, subjects were asked to wear the lens for 24 to 36 hours and return to the clinic for evaluation. Subjects were instructed not to use rewetting drops or remove the lenses for cleaning during the wearing period if at all possible. These requests were made to try to decrease the variability of lens treatment.

The lens fit was reassessed at the return visit. While not part of the formal statistical analysis, patients were also asked which of the lenses they preferred. After assessment the lenses were removed using care to avoid secondary conjunctival staining from the removal process. The conjunctival grade and percentage involvement of staining was evaluated by an investigator who had not been involved in fitting the lenses. Corneal evaluations for any staining that might have occurred were also performed by this investigator. This individual performed all of the staining evaluation and had participated in the first study which increased continuity between studies.

MATERIALS

Parameters of the lenses used were:

BAUSCH AND LOMB SEEQUENCE™ LENS*[10]

Material:	Polymacon
Water Content:	38.6%
Dk:	8 x 10-11
Base Curve:	Approximately 8.8 mm
Diameter:	14.00 mm
Center Thickness:	0.035 mm
Power Ranges:	-1.00 to -6.00 (in 0.25D increments)

CIBA NewVues® LENS*[10]

Material:	Vifilcon A
Water Content:	55.0%
Dk:	16 x 10-11
Base Curve:	8.4mm, 8.8mm
Diameter:	14.00 mm
Center Thickness:	.12 (+3.00D) .06 (- powers)
Power Ranges:	+4.00 to -6.00 (in 0.25 increments)

*Measurements are from -3.00D lens except where noted

DATA ANALYSIS

The amount of conjunctival staining was multiplied by the severity (grade) of the staining to obtain a weighted average for each quadrant. These weighted averages were then analyzed by a Friedman 4-way analysis to determine if any quadrant stained significantly greater than others. The weighted averages for each quadrant were then added and averaged to create a mean for each of the subject's two lenses. These means were then compared by the Wilcoxin signed-rank test to

determine if one lens caused more conjunctival staining than the other.

To determine whether the investigators could directly compare their results to those obtained in the earlier study by Devries, et al.[1], the data for the B&L SEEQUENCE™ lenses was compared. The analysis for this comparison was performed with the Mann-Whitney U test.

RESULTS

A total of 60 subjects were fit and completed the study out of 67 that were screened. The subjects who were not fit included one subject who presented with excessive conjunctival staining and one with corneal staining secondary to lash ectropian. The five subjects who did not finish the study had removed their lenses prior to the second evaluation. All five were either emmetropes or hyperopes who experienced accommodative discomfort while wearing the lenses.

Out of 240 quadrants which were evaluated, conjunctival edge staining was observed in 35.0% of quadrants with NewVues® lenses and in 43.0% of quadrants with SEEQUENCE™ lenses. The percentage and type of staining was similar in appearance between the two brands of lenses.

The weighted averages of staining in the NewVues® lenses was 0.190 while the weighted average for the Bausch & Lomb SEEQUENCE™ was 0.367. (table 1) A Wilcoxin signed-rank test on these weighted averages yielded a Z score of -1.868. This indicates a significant difference in the staining between the two lenses at an alpha level of <0.05.

The staining of each quadrant of the eye as well as the percent of the quadrant involved is shown in table 2. The weighted means for each quadrant were compared

by Friedman 4-way analysis (Table 3). A Chi-square value corrected for ties of 18.69 for the NewVues® lens and 18.84 for the SEEQUENCE™ lens was achieved. Both values show that staining differed among quadrants for each lens type. By analyzing the descriptive data for the lenses, the inferior quadrant yielded the greatest amounts of staining for both brands of lenses.

The staining caused by the SEEQUENCE™ lens in the previous study[1] and caused by the SEEQUENCE™ lens in this study was compared by the Mann Whitney U test. This was done to determine the degree of similarity between the two results. There was a statistical difference between the amount of staining found with the Seequence lenses at an alpha level <0.05.

DISCUSSION

Both the Ciba NewVues® and the Bausch and Lomb SEEQUENCE™ Lenses yielded diffuse conjunctival edge staining. The staining found with both lenses occurred in an area, from the limbus extending out to 2.0 mm onto the conjunctiva, that was found in direct apposition to the contact lens. This area was free from staining prior to lens insertion. The NewVues® caused less conjunctival staining than SEEQUENCE™ and although the two studies are not directly comparable, the SEEQUENCE™ stained less than the ACUVUE® in the first study. The SEEQUENCE™ data from the present study statistically differs from that of the previous study. The clinical relevance of this is questionable as the two weighted means differed by only .120.[1] One explanation for the statistical difference was a decrease in incidence of insertion and removal staining in the present study. Because the first study reported a pattern of staining thought to be caused by lens removal,

extra care was taken during this study to avoid its occurrence. The fact that NewVues® lenses caused the least conjunctival staining would lead it to be the lens of choice if all other factors were considered equal.

The long term effects of constant conjunctival irritation as would exist in extended wear are not known at this time. While one could certainly postulate some of these effects: conjunctival scarring, auto immune reactions, hypertrophy, etc., long term studies need to be completed for definitive answers.

While not part of the statistical analysis, two other factors were observed and recorded during the study. One of these factors was corneal staining. While both types of lenses caused corneal staining in some cases, the SEEQUENCE™ lens had greater incidence of corneal staining and greater intensity (Table 4). However, it was not the intent of this study to evaluate corneal staining or to determine its relevance.

Lens preference was the other factor recorded. The majority of people had no preference when asked which lens was more comfortable. Of those persons preferring one lens to the other, more felt the SEEQUENCE™ lens was the most comfortable (Table 5).

CONCLUSION

Disposable lenses have continued to gain popularity both with practitioners and patients. As such, it is important that we continue to monitor both the reproducibility of these lenses and their subsequent impact on the eye. This research shows that follow-up care is an important part of the disposable regimen. Such follow-up care should include lens off evaluations with sodium fluorescein to monitor both conjunctival disruption as well as any corneal changes. This conjunctival staining research continues to show that the inferior portion of the

conjunctiva is generally more heavily involved and thus is an area that should be concentrated on during follow up inspections.

Since patient comfort is not a good indicator of type or amount of staining, the practitioner's role becomes even more important. It is important to schedule some follow-up appointments later in the day to check for staining as it has been seen that staining for many patients worsens during waking hours. Patients that stain chronically should be refit until it is proven that long term irritation to the conjunctiva will not induce permanent changes in the patient's future.

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Table 1

WEIGHTED MEAN/EYE

	Mean	Stand Dev.	Variance
NewVues®	.190	.294	.086
SEEQUENCE™	.367	.596	.356

Table 2

GRADE STAINING/QUADRANT

NewVues®	Q1	Q2	Q3	Q4
Weighted Ave.	.175	.458	.608	.379
Stand. Dev.	.581	.804	.912	.516
Variance	.338	.647	.831	.266
SEEQUENCE™				
Weighted Ave.	.342	.717	.825	.554
Stand. Dev.	.805	1.10	1.05	.860
Variance	.648	1.22	1.09	.740

PERCENT OF STAINING/QUADRANT

NewVues®				
% Stain	.048	.163	.272	.133
Stand. Dev.	.133	.272	.375	.239
Variance	.018	.074	.140	.057
SEEQUENCE™				
% Stain	.140	.237	.344	.218
Stand. Dev.	.281	.344	.401	.321
Variance	.079	.119	.161	.103

Table 3

FRIEDMAN 4-WAY ANALYSIS, QUADRANT DIFFERENCES

	NewVues®	**SEEQUENCE™**
Degrees Freedom	3	3
# Samples	4	4
Chi-r^2	10.745	12.185
Chi corrected for ties	18.687	18.843

NewVues®	Q1	Q2	Q3	Q4
Sum Rank	126.0	153.5	172.0	148.5
Mean Rank	2.100	2.558	2.867	2.475
SEEQUENCE™				
Sum Rank	153.5	171.0	153.0	122.5
Mean Rank	2.558	2.850	2.550	2.042

Table 4

GRADES OF CORNEAL STAINING

Grade	1/2	1	2	3
NewVues®	4	5	5	2
SEEQUENCE™	5	7	8	1

Table 5

LENS PREFERENCE

Preference:	NewVues®		SEEQUENCE™	No
# Preferred	19	13	28	
% Of Total	37.2		21.7	46.7
% W/ Preference	59.38		40.62	----

Quad diffs, CIBA descriptive stat

X_1: mean w grade

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.19	.294	.038	.086	154.186	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	1.5	1.5	11.425	7.261	0

Quad diffs, B&L, desciptive stat

X_1: mean w grade

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.367	.596	.077	.356	162.335	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	3.25	3.25	22.037	29.069	0

Friedman 4 X variables

DF	3
# Samples	4
# Cases	60
Chi_r-Squared	10.745
Chi corrected for ties	18.687
# tied groups	54

1

Friedman 4 X variables

Name:	Σ Rank:	Mean Rank:
Q1 wgtd	126	2.1
Q2 wgtd	153.5	2.558
Q3 wgtd	172	2.867
Q4 wgtd	148.5	2.475

2

Friedman 4 X variables

DF	3
# Samples	4
# Cases	60
Chi_r-Squared	12.185
Chi corrected for ties	18.843
# tied groups	47

1

Friedman 4 X variables

Name:	Σ Rank:	Mean Rank:
Q4 wgtd	153.5	2.558
Q3 wgtd	171	2.85
Q2 wgtd	153	2.55
Q1 wgtd	122.5	2.042

2

Wilcoxon weighted means: CIBA vs. B&L

Wilcoxon signed-rank X_1: Ciba Mean Y_1: B&L Mean

	Number:	Σ Rank:	Mean Rank:
- Ranks	35	926.5	26.471
+ Ranks	18	504.5	28.028

note 7 cases eliminated for difference = 0.

Z	-1.868
Z corrected for ties	-1.868
# tied groups	12

Quad diffs, CIBA, descriptive stat, grade

X_1: Q1

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.175	.581	.075	.338	331.97	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	4	4	10.5	21.75	0

1

X_2: Q2

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.458	.804	.104	.647	175.435	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	3	3	27.5	50.75	0

2

X_3: Q3

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.608	.912	.118	.831	149.876	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	4	4	36.5	71.25	0

3

X_4: Q4

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.275	.516	.067	.266	187.657	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	3	3	16.5	20.25	0

4

X_5: Q mn

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.379	.493	.064	.243	130.035	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	2.75	2.75	22.75	22.969	0

5

Quad diffs, CIBA, descriptive stat, % stain

X_1: Q1%

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.048	.133	.017	.018	280.466	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	.6	.6	2.85	1.182	0

1

X_2: Q2%

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.163	.272	.035	.074	166.421	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	1	1	9.8	5.96	0

2

X_3: Q3%

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.272	.375	.048	.14	137.912	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	1	1	16.3	12.71	0

3

X_4: Q4%

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.133	.239	.031	.057	179.335	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	1	1	8	4.44	0

4

X_5: Q% mn

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.154	.172	.022	.03	111.899	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	.75	.75	9.238	3.173	0

5

Quad diffs, CIBA descriptive stat

X_1: Q1 wgtd

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.057	.193	.025	.037	335.762	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	1.2	1.2	3.45	2.397	0

1

X_2: Q2 wgtd

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.228	.532	.069	.283	233.907	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	3	3	13.65	19.812	0

2

X_3: Q3 wgtd

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.363	.584	.075	.341	160.762	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	2.4	2.4	21.8	28.05	0

3

X_4: Q4 wgtd

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.113	.308	.04	.095	271.336	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	2	2	6.8	6.35	0

4

X_1: Q1

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.342	.805	.104	.648	235.648	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	4	4	20.5	45.25	0

1

X_2: Q2

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.717	1.102	.142	1.215	153.803	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	4	4	43	102.5	0

2

X_3: Q3

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.825	1.045	.135	1.092	126.65	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	4	4	49.5	105.25	0

3

X_4: Q4

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.554	.86	.111	.74	155.188	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	4	4	33.25	62.062	0

4

X_5: Q mn

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.609	.74	.096	.548	121.511	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	3.25	3.25	36.562	54.629	0

5

Quad diffs, B&L, descriptive stat, % stain

X_1: Q1%

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.14	.281	.036	.079	200.397	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	1	1	8.4	5.82	0

1

X_2: Q2%

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.237	.344	.044	.119	145.534	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	1	1	14.2	10.36	0

2

X_3: Q3%

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.344	.401	.052	.161	116.441	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	1	1	20.65	16.583	0

3

X_4: Q4%

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.218	.321	.041	.103	146.967	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	1	1	13.1	8.935	0

4

X_5: Q% mn

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.235	.252	.033	.063	107.273	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	1	1	14.087	7.05	0

5

Quad diffs, B&L, desciptive stat

X_1: Q1 wgtd

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.198	.528	.068	.279	266.191	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	3	3	11.9	18.805	0

1

X_2: Q2 wgtd

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.406	.759	.098	.576	186.958	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	3	3	24.35	43.847	0

2

X_3: Q3 wgtd

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.558	.941	.122	.886	168.749	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	4	4	33.475	70.973	0

3

X_4: Q4 wgtd

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.307	.71	.092	.505	231.337	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	4	4	18.425	35.433	0

4

Descriptive data, B&L 89-90 vs. B&L 90-91

Mann-Whitney U X_1: Column 2 Y_1: Column 1

	Number:	Σ Rank:	Mean Rank:
B&L Early	60	4015	66.917
B&L Late	60	3245	54.083

U	1415
U-prime	2185
Z	-2.021
Z corrected for ties	-2.022
# tied groups	22

Patient Consent Form

1. **Pacific University College of Optometry**

Project Title:

A clinical evaluation of edge induced conjunctival staining with Newvues and Seequence disposable lenses.

Principal Investigators:

Terry Patrick	357-0174
Brett Hagen	645-1034
Penny Vizina	645-2611

Advisor:

Nada J. Lingel, O.D. 357-6151 ext. 2284

Location:

Pacific University College of Optometry, Forest Grove, Oregon.

Date:

February 20, 1990 to May 1, 1990.

2. **Project Description:**

This project will compare two different types of disposable contact lenses that are currently approved by the FDA as extended wear lenses. The lenses will be compared on the basis of patient comfort and clinical ocular signs. Each patient will wear one Ciba NewVues contact lens and one Bausch and Lomb SeeQuence contact lens for 24 hours. Conjunctival staining will be evaluated before and after the lenses are worn.

3. **Description of Risks:**

Associated risks of extended wear lenses are as follows: corneal abrasions, new blood vessel growth in the cornea, and corneal swelling. In the worst case, these injuries could lead to the loss of an eye. Risks are more likely to occur with long-term wear but your close cooperation in the observation of symptoms and the adherence to the wearing schedules are still vital to the health of your eyes.

4. **Advantages of Participation:**

The participant will be able to subjectively evaluate the comfort and performance of extended wear disposable lenses. In this way subjects will gain valuable knowledge for future reference as a clinician.

5. **Compensation and Medical Care:**

If you are injured in this experiment, it is possible that you will not receive compensation or medical care from Pacific University, the experimenters or any other organization associated with the experiment. All reasonable care will be taken to prevent injury.

6. **Alternative Advantages of Subjects:**

The wearing of spectacles, hard contact lenses, or daily wear soft lenses may be more advantageous to you.

7. **Offer to Answer Any Inquiries:**

The investigators will be happy to answer any questions that you may have at any time during the course of the study. If you are not satisfied with any of the answers you have received, please call Dr. A. R. Reinke at 357-6151, ext. 2276.

During your participation in the project you are not a clinic patient for the purposes of the research and all questions should be directed to the researchers and/or the faculty advisor who will be solely responsible for any treatment (except in an emergency).

8. Freedom [illegible]:

You are free to withdraw your consent and to discontinue participation in this project or activity at any time without prejudice to you.

I have read and understood the above. I am 18 years of age or older (or this form is signed for me by a parent or guardian).

_____

Printed Name

_____

Signed

_____

Address

_____

City State Zip Phone

_____

Date

Name and address of a person not living with you who will always know your address.

_____

_____