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A clinical evaluation of edge induced conjuctival staining with Acuvue and Seequence disposable lenses

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Abstract

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Subject Categories

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A CLINICAL EVALUATION OF EDGE INDUCED CONJUNCTIVAL STAINING WITH ACUVUE AND SEEQUENCE DISPOSABLE LENSES.

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SIGNATURE PAGE

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ABSTRACT

Disposable extended wear lenses are currently manufactured via two processes. Bausch & Lomb utilizes the conventional spincast method while the Johnson & Johnson lens is produced via a stabilized soft molding process with the lens in a hydrated state. These two processes result in distinctly different lens edge designs. To determine if the differences in lens edge design would result in any signficant conjunctival trauma, sixty subjects were fitted with a Johnson & Johnson lens in one eye and a Bausch & Lomb lens in the other eye. After wearing these lenses for a period of 24 hours, evaluation for staining was performed with sodium fluorescein and a Wratten filter. A Wilcoxon test for nonparametric data showed that the Johnson & Johnson lens was responsible for significantly more conjunctival staining at an alpha level less than .001.

KEY WORDS

Conjunctival staining, disposable contact lenses, extended wear contact lenses, stabilized soft molding, edge flashing, sodium fluorescein staining, Wratten filtering.

INTRODUCTION

Disposable contact lenses are currently attracting a great deal of attention from practitioners as well as patients.[1] Hardly a day goes by in a clinical environment that at least one patient doesn't question the practitioner about the disposable concept. Disposable lenses are catching on in part because previous clinical trials have indicated that disposable lenses are responsible for a reduction in certain problems exaggerated by extended wear. The health related benefits include decreased incidence of GPC,[2,3,4] fewer lens deposits[3,4] and the absence of chemical irritations due to contact lens solutions.[5] Disposable lenses also solve compliance problems related to contact lens disinfection,[6] but practitioner concern has surfaced about compliance related to wearing schedule abuse and stockpiling of supplied lenses. These factors could result in a multiple year supply of lenses if worn on a traditional extended wear schedule.[7] In addition, current disposable extended wear lenses have Dk's which are no better than previous extended wear lenses and the resultant hypoxia continues to cause epithelial microcystic edema[8,9] polymegethism[9] and neovascularization.[6,9]

Several manufacturers are utilizing a new process in the production of the disposable lenses. Of manufacturers currently in national distribution, Johnson & Johnson (manufacturer of the ACUVUE lens) is the only company utilizing a process called stabilized soft molding. This stabilized soft molding process does not allow for the edge of the contact lens to be polished because the lens is manufactured in the hydrated state. Seger and Mutti, reported that this molding process and the inability to polish the edge formed a lens with a sharp junction at the posterior surface and often allowed excess material known as flash to remain attached to the edge.[10] Bausch & Lomb, the manufacturer of the other nationally

distributed disposable lens (SeeQuence) is using the conventional spincast technique which allows polishing of the edge.

A comparison of the edges of the ACUVUE and SeeQuence lenses under 50X magnification reveals startling differences in the molded lens versus the spin cast lens. As can be seen in the photographs in figure1, the spin cast lens presents a much smoother, uniform edge as opposed to that of the molded lens, whose edge is often serrated in appearance. The edges appeared similar to these photographs for all worn and unworn lenses examined, thereby eliminating mishandling as a cause of the dramatic differences between the lens edges.

Along with the edge configuration differences, Seger and Mutti also reported that the molded lenses caused bulbar conjunctival staining in 7 out of the10 patients they examined. This staining involved at least one sector of the eye and in some cases was found to involve 360 degrees of the limbal area.[10] No comparisons with other lens types were reported by Seger and Mutti. It is the purpose of this study to compare the edge induced conjunctival staining produced by the two disposable lenses currently marketed nationally. This will help determine if a molded lens edge presents a greater hazard to the conjunctiva than does a spin cast lens. This study is not designed to analyze the long term clinical implications of conjunctival disruption, but rather to determine if there is a significant difference in conjunctival staining present between the two types of disposable lenses.

For the purposes of statistical analysis the null hypothesis is that there will be no significant difference in the edge induced conjunctival staining between the molded ACUVUE lenses by Johnson & Johnson and the spin cast SeeQuence lenses by Bausch & Lomb.

EXPERIMENTAL DESIGN

SUBJECTS

Sixty subjects were fitted with an ACUVUE disposable lens on one eye and a SeeQuence lens on the other eye. Subjects, who were

obtained on a volunteer basis through Pacific University College of Optometry, included 57 students, 2 professors, 4 relatives of students and 1 layperson. Subjects were included in the study if their eyes were free from anterior segment disease and an acceptable fit was obtained with each contact lens. A fit was deemed acceptable if there was complete limbal coverage and a minimum of 0.25mm but not more than 2.0mm movement in all positions of gaze. There were no subject exclusions with regard to age, race, sex, or previous contact lens experience. Subject refractive error ranged from -6.00 to +1.50. The emmetropes and low hyperopes wore low minus lenses while the myopes had their refractive error appropriately corrected with the contact lenses.

A summary of subject characteristics can be seen below:

SUBJECT PROFILE

SEX	NUMBER	PERCENTAGE
Male	41	68.3
Female	19	31.7
Total	60	

AGE	NUMBER	PERCENTAGE
21-25	34	56.7
26-30	10	16.7
31-35	11	18.3
35-39	05	08.3
Total	60	

PREVIOUS CL EXPERIENCE	NUMBER	PERCENTAGE
None	12	20.0
RGP & PMMA	05	08.3
SCL	37	61.7
RGP & SCL	06	10.0
Total	60	

REFRACTIVE ERROR	NUMBER EYES	PERCENTAGE
Myopia	52	86.7
Hyperopia	05	08.3
Emmetropia	03	05.0
Total	60	

PROCEDURE

All contact lens wear was discontinued for a period of not less than 48 hours and a careful ocular health exam was administered prior to fitting the disposable contact lenses. To establish baseline staining the corneal and conjunctival tissues were evaluated via a Mentor Biomicroscope, sodium flourescein dye, cobalt blue filter, and a Wratten (Kodak No. 12) filter. This filter, which is utilized by placing it in front of the objective of the slit lamp, rather than in front of the light source, serves as a barrier filter to allow only the yellow/green light that is being emitted from the sodium fluorescein into the oculars. The use of this method of fluorescence enhancement is well documented in the literature as a means of increasing the accuracy of fluorescein stain grading.[11,12,13]

For evaluation and statistical purposes, the eye was divided into four quadrants, superior (#1), temporal (#2), inferior (#3) and nasal (#4). Each quadrant was graded for conjunctival staining using the 0-4 scale shown below.

GRADE*	PUNCTATE STAINING
0	None
1	Minimal - up to 100
2	Moderate - hundreds
3	Severe - thousands
4	Maximal - wide spread confluence

*0.5 steps were used when appropriate

In addition to the description of staining, grades were photographically documented in preliminary trials and agreed upon by the investigators prior to the start of the study. These photographs were then used for determining the grades of staining during the study. During the preliminary trials it was found that the sodium fluorescein had a tendency to diffuse into the surrounding conjunctival tissue rapidly, so evaluation was performed on one eye at a time within the first minutes following instillation of the dye. Any subjects exhibiting a baseline staining of more than grade1/2, unequal staining between eyes, or corneal staining were eliminated from the study.

After the tissue health had been evaluated, the subjects' eyes were washed with Bausch and Lomb EYEWASH ™ to remove the sodium flourescein. At this time a contact lens of each edge design was applied to the subjects' eyes and each lens was evaluated for acceptable centering and movement. If acceptable movement and centration were not found the subject was eliminated from the study. The project was designed so that the subject and the investigator performing the staining evaluation did not know which lens type was in which eye.

Following a wearing time of no less than 24 hours the lenses were again evaluated for centering and movement by the investigators who had dispensed the lenses the previous day. The lenses were then removed and sodium fluorescein stain was instilled into one eye at a time and the conjunctiva and cornea were evaluated. Grading of any staining present was performed utilizing the photographic scale with each quadrant assigned a severity between 0-4. The percentage of involvement in each quadrant and the grade of any corneal staining were also noted. Although not in the original design of the study, subject preference was elicited after subjects began volunteering a preference.

MATERIALS

Parameters of the lenses used were:[14]

JOHNSON AND JOHNSON ACUVUE (etafilcon A) LENS PARAMETERS*

Water Content:	58%
Dk	28 x 10-11
Base Curve:	8.8mm
Diameter:	14.00mm
Center Thickness:	0.07mm
Power Ranges:	-0.50D to -6.00D (in 0.25D increments)

BAUSCH AND LOMB SEEQUENCE (polymacon) LENS PARAMETERS*

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

*Measurements are from -3.00D lens

DATA ANALYSIS

A weighted average of conjunctival staining was determined for each quadrant and each eye. The weighted average for each quadrant was calculated by multiplying the percentage area of staining by the grade of stain. Weighted averages for the entire eye were then found by summing the weighted average of each quadrant and dividing by four. A Wilcoxon signed-rank test for nonparametric data was performed on these weighted averages to

determine if there was a significant difference between lens types. A Friedman 4-way analysis was used to determine if there was a significant difference of weighted average between quadrants of the same eye to evaluate if one area was more affected than the other.

RESULTS

Of the 64 subjects who were screened, 61 were fitted with the lenses and 60 finished the 24 hour wearing schedule and were evaluated. Three subjects were not used due to an unacceptable fit and one failed to return for the post-wear evaluation.

A total of 240 quadrants were graded for severity of staining and percentage of conjunctival involvement for each type of lens. Of the 240 quadrants evaluated some degree of conjunctival staining was observed in 93.3% of them with the ACUVUE lenses and 90.8% of them with SeeQuence lenses. (figure 2) The percentage of area involvement and the grade of staining varied dramatically between the two lenses. The means of the weighted averages for all quadrants and eyes are shown in figure 3 and represented graphically in figure 4. The weighted averages of staining in the ACUVUE lenses had a mean of .851 compared to .379 for the SeeQuence lenses. A Wilcoxon signed-rank test on the weighted averages yielded a Z score of 4.458. This indicates that the null hypothesis must be rejected due to a significant difference in the staining between the two lens types at an alpha level less than 0.001. In every quadrant the mean grade of staining and the mean percentage of quadrant involvement was higher with the ACUVUE lenses as compared to the SeeQuence lenses. Although both grade and percentage of area involved contributed to the differences in weighted averages, it appears that the grade of staining rather than the percentage of staining was the largest contributor. See figure 5.

The Friedman 4-way analysis was used to determine significance in staining between quadrants in the same eye. It yielded a Chi-r-square value corrected for ties of 24.05 for the ACUVUE lenses and 35.30 for the SeeQuence lenses. Both of these values indicate a significant difference between quadrants with an alpha level less than 0.001. Descriptive statistics showed the

inferior quadrant had a greater percentage of area involvement and a higher grade of staining in both the ACUVUE and SeeQuence lenses. See figure 6.

Some corneal fluorescein staining was noted. Of particular interest was corneal dehydration staining. This staining was noted in 16.7% of the ACUVUE eyes and 21.7% of the SeeQuence eyes. Grades of corneal staining varied between 0 and 3 for both the ACUVUE lens and the SeeQuence lens. The mean in those eyes showing corneal staining was 1.40 with the ACUVUE and 1.62 with the SeeQuence lens. See figure 7.

51 of the subjects involved were asked which lens they preferred. Of the 51 subjects asked, the ACUVUE lens was preferred 37.2% of the time while the SeeQuence lens was preferred 31.4%. There was no discernable preference between the two lenses 31.4% of the time. See figure 8.

DISCUSSION

Our analysis showed the ACUVUE lens caused significantly more edge induced conjunctival staining than the SeeQuence lens. The inferior quadrant manifested the largest area involvement and highest grades of staining for both lens types. This staining was located between the limbus and 2mm beyond the limbus, implicating the edge of the lenses as the likely cause. The investigator conducting the evaluation of the staining was able to accurately predict the lens identity approximately 80% of the time after observing and grading both eyes. This was possible because the ACUVUE lenses seemed to give a more characteristic circumscribed arc staining compared to the more localized sectorial staining seen with the SeeQuence lenses. This arcuate pattern was apparent even in subjects presenting with minor staining. Several grades of the

more circumscribed staining patterns of the ACUVUE staining are depicted in the photographs in figure 9.

It was our clinical impression that subjective preference was not related to the presence or absence of conjunctival staining. Several subjects with as much as grade 3 staining reported they preferred that lens over the eye which displayed less conjunctival staining. Surprisingly, even corneal dehydration staining seemed to be a poor predictor of comfort with only 5 subjects out of 20 with unilateral corneal staining reporting a decrease in comfort of the affected eye.

During preliminary trial it was found that within minutes after insertion, the fluorescein stain diffused rapidly into the surrounding conjunctival tissue and made the staining less distinct. To fully appreciate the staining which is present, evaluation should take place on one eye at a time immediately after sodium fluorescein instillation. Although it is not necessary for detection of the edge induced conjunctival staining, the Kodak Wratten #12 filter also enhances the ability to see the staining. When performing the evaluation, care must be exercised not to mistake lens removal stains, which appear in the inferior quadrant as large round diffuse stains below the normal position of the lens edge, from true edge staining.

Trials performed to establish our staining grades with photographs, revealed that eyes evaluated early in the morning displayed much less staining than the same eyes with the same lenses in a late afternoon or evening evaluation. Some authors have attributed this to less lens movement with sleep, which causes less edge induced conjunctival disruption.[10] It was our clinical impression however, that the amount of lens movement was not a good predictor of quantity or grade of conjunctival staining. Perhaps, eyes that are susceptible to edge induced staining will stain with any amount of movement. It is important to note that all lenses dispensed in this study exhibited at least 0.25 millimeter of movement, therefore we cannot comment on staining in non-moving lenses.

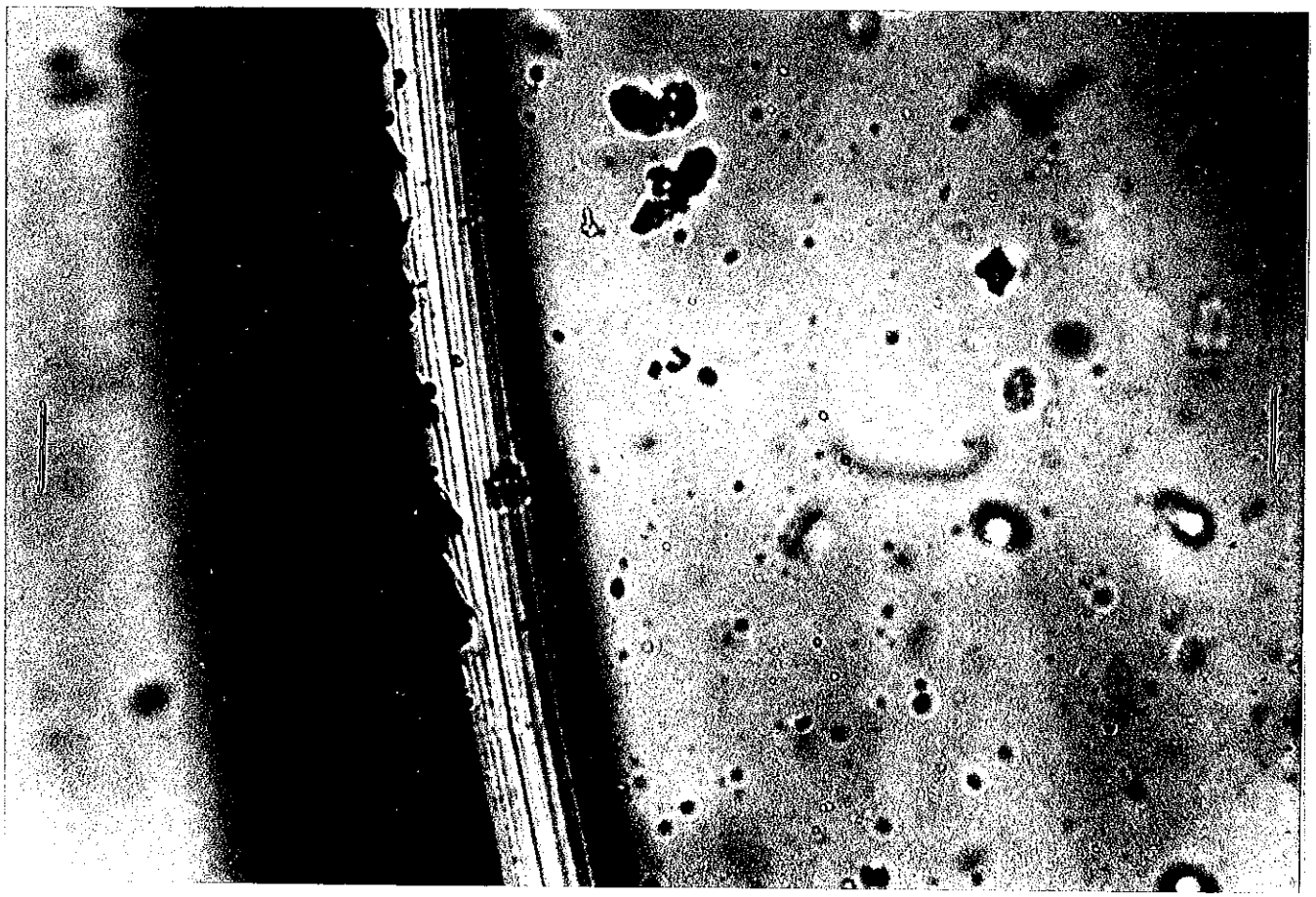
CONCLUSION

While the disposable lens has been shown to improve certain aspects of extended wear such as GPC[3] and acuity[15], it is certainly not a panacea for extended contact lens wear because of such problems as hypoxic related changes[6,9], patient compliance concerns and conjunctival disruption. This study does not indicate a need to discontinue the use of molded lenses or any other disposable lens. It does point out the importance of regular and thorough follow-up care for disposable contact lens wearers. This follow-up care should include lens removal and sodium fluorescein evaluation for all patients because subjective comfort does not seem to be an indicator of conjunctival staining. Special attention should be given to the inferior conjunctival area under the lower lid in those subjects wearing a molded lens such as the ACUVUE. The results of this study also suggest that contact lens manufacturers should further investigate the outcome of the stabilized soft molding process.

In view of the fact that conjunctival staining does exist with disposable lenses, and since there is a significant difference in the staining with a molded lens, further research is needed to determine what effects chronic conjunctival irritation will have on the extended wear patient. The literature is sparse on these effects, although increased GPC and conjunctival thickening have been noted.[16]

FIGURE 1.

ACUVUE



SEEQUENCE

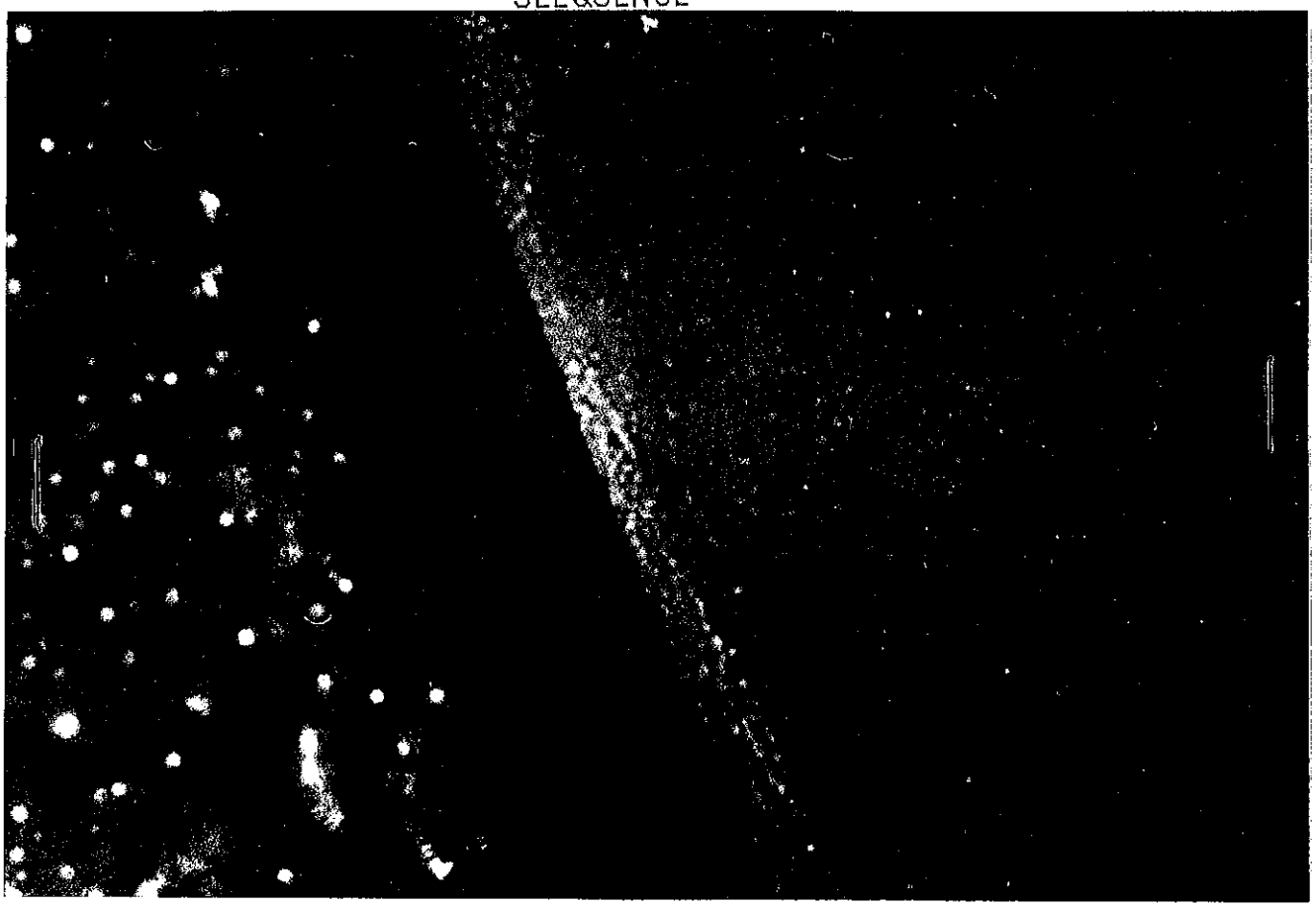


FIGURE 2(Number,% Grade/lens)

GRADE	ACUVUE		SEEQUENCE	
	#	%	#	%
0.0	16	6.7	22	9.2
0.5	85	35.4	132	55.0
1.0	44	18.3	35	14.6
1.5	19	7.9	10	4.2
2.0	33	13.8	14	5.8
2.5	29	12.1	11	4.6
3.0	9	3.8	14	5.8
3.5	0	0.0	0	0.0
4.0	5	2.0	2	0.8
	224/240 = 93.3%		218/240 = 90.8%	

FIGURE 3(Weighted Mean/Eye,)

ACUVUE	Mean	Stand Dev.	Variance
	.851	.636	.404
SEEQUENCE	.375	.465	.216

FIGURE 4. WEIGHTED MEAN INCIDENCE

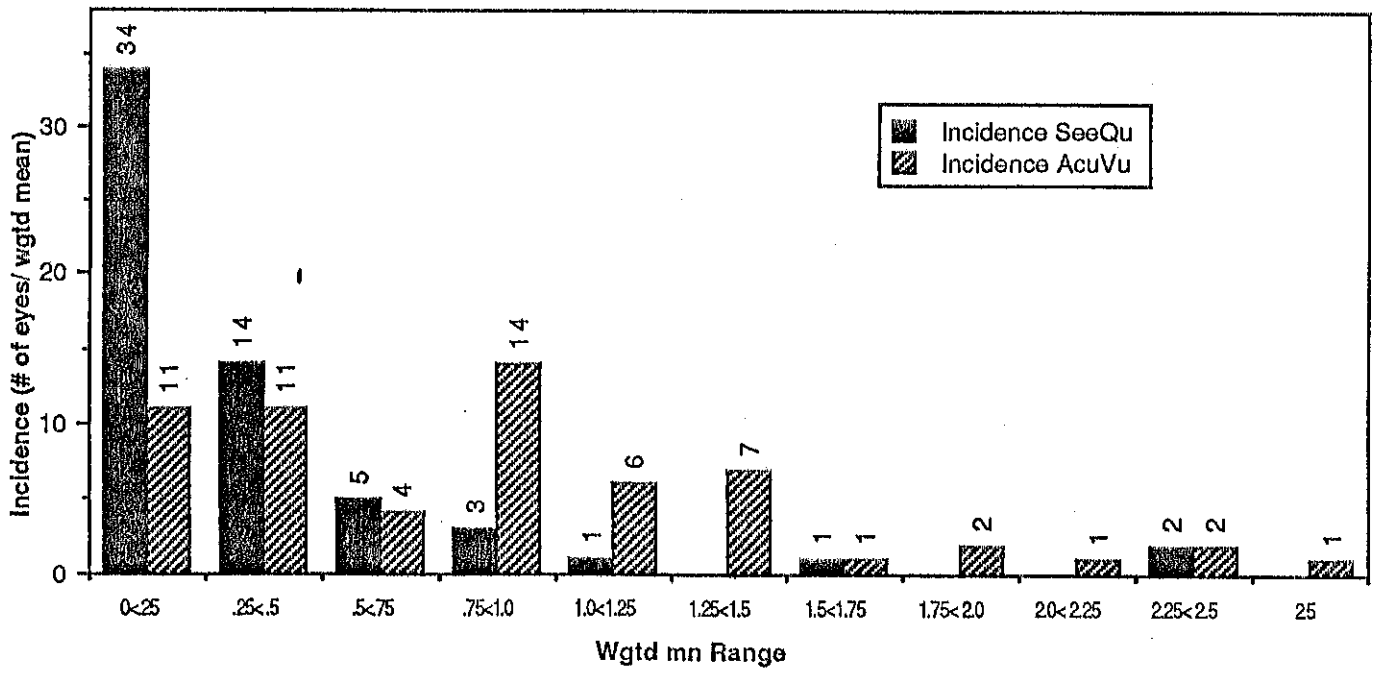


FIGURE 5(Grade staining/quadrant)

ACUVUE	Q1	Q2	Q3	Q4
Weighted Ave.	.603	.652	1.145	.613
Stand. Dev.	.787	.762	1.05	.797
Variance	.62	.581	1.103	.635
SEEQUENCE				
Weighted Ave.	.27	.291	.895	.416
Stand. Dev.	.541	.512	.927	.61
Variance	.292	.262	.86	.372

(% Staining /quadrant)

ACUVUE	Q1	Q2	Q3	Q4
% Stain	.509	.502	.59	.421
Stand Dev.	.378	.346	.341	.314
Var.	.143	.12	.116	.098
SEEQUENCE				
% Stain	.373	.288	.568	.379
Stan Dev.	.372	.269	.359	.309
Var.	.139	.072	.129	.095

FIGURE 6(Friedman 4-way Analysis, Quadrant differences)

	ACUVUE	SEEQUENCE
Degrees Freedom	3	3
# Samples	4	4
Chi_r-Squared	21.365	28.065
Chi corrected for ties	24.051	35.302

ACUVUE	Q1	Q2	Q3	Q4
Sum Rank	132.0	142.5	189.5	136.0
Mean Rank	2.2	2.375	3.158	2.267
SEEQUENCE				
Sum Rank	117.0	138.5	189.5	155.0
Mean Rank	1.95	2.308	3.158	2.583

FIGURE 7(GRADES OF CORNEAL STAINING)

(GRADE)	1	2	3	MEAN
ACUVUE	7	2	1	1.4
SEEQUENCE	7	4	2	1.62

FIGURE 8(LENS PREFERENCE)

PREFERENCE	ACUVUE	SEEQUENCE	NO
# PREFERRED	19	16	16
% OF TOTAL	37.2	31.4	31.4
% W/PREFERENCE	54.3	45.7	----

Descriptive data: AV and B&L

X_1: Wgtd mnA

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.851	.636	.082	.404	74.719	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
.013	2.5	2.487	51.049	67.278	0

X_2: Wgtd mnS

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.379	.463	.06	.215	122.309	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	2.275	2.275	22.729	21.276	0

Quad diffs, AcuVue

Friedman 4 X variables

DF	3
# Samples	4
# Cases	60
Chi_r-Squared	21.365
Chi corrected for ties	24.051
# tied groups	40

1

Friedman 4 X variables

Name:	Σ Rank:	Mean Rank:
Q1 wgtd	132	2.2
Q2 wgtd	142.5	2.375
Q3 wgtd	189.5	3.158
Q4 wgtd	136	2.267

2

Quad diffs, SeeQuence

Friedman 4 X variables

DF	3
# Samples	4
# Cases	60
Chi_r-Squared	28.065
Chi corrected for ties	35.302
# tied groups	51

1

Friedman 4 X variables

Name:	Σ Rank:	Mean Rank:
Q1 wgtd	117	1.95
Q2 wgtd	138.5	2.308
Q3 wgtd	189.5	3.158
Q4 wgtd	155	2.583

2

Wilcoxon weighted means: AV vs. B&L

Wilcoxon signed-rank X_1: Wgtd mnA Y_1: Wgtd mnS

	Number:	Σ Rank:	Mean Rank:
- Ranks	13	251.5	19.346
+ Ranks	43	1344.5	31.267

note 4 cases eliminated for difference = 0.

Z	-4.458
Z corrected for ties	-4.458
# tied groups	6

Quad diffs, AcuVue, descriptive stat, % stain

X_1: Q1%

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.509	.378	.049	.143	74.315	60

Minimum:	Maximum:	Range:	Sum:	Sum Squared:	# Missing:
.1	1	.9	30.55	24.003	0

1

X_2: Q2%

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.502	.346	.045	.12	68.978	60

Minimum:	Maximum:	Range:	Sum:	Sum Squared:	# Missing:
.1	1	.9	30.1	22.165	0

2

X_3: Q3%

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.59	.341	.044	.116	57.769	60

Minimum:	Maximum:	Range:	Sum:	Sum Squared:	# Missing:
.1	1	.9	35.4	27.74	0

3

X_4: Q4%

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.431	.32	.041	.102	74.206	60

Minimum:	Maximum:	Range:	Sum:	Sum Squared:	# Missing:
.1	1	.9	25.85	17.168	0

4

X_5: Q% mn

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.507	.226	.029	.051	44.581	60

Minimum:	Maximum:	Range:	Sum:	Sum Squared:	# Missing:
.1	1	.9	30.417	18.433	0

5

Quad diffs, AcuVue, descriptive stat, grade

X_1: Q1

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
1.017	.934	.121	.873	91.882	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	5	5	61	113.5	0

1

X_2: Q2

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
1.092	.816	.105	.665	74.71	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	4	4	65.5	110.75	0

2

X_3: Q3

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
1.633	1.085	.14	1.177	66.418	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
.5	4	3.5	98	229.5	0

3

X_4: Q4

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
1.183	.93	.12	.864	78.556	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	4	4	71	135	0

4

X_5: Q mn

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
1.232	.589	.076	.347	47.809	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
.167	2.625	2.458	73.917	111.528	0

5

Quad diffs, SeeQuence, descriptive stat

X_1: Q1%

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.373	.372	.048	.139	99.72	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
.1	1	.9	22.4	16.54	0

1

X_2: Q2%

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.288	.269	.035	.072	93.158	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
.1	1	.9	17.3	9.245	0

2

X_3: Q3%

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.568	.359	.046	.129	63.088	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	1	1	34.1	26.965	0

3

X_4: Q4%

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.379	.309	.04	.095	81.372	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
.1	1	.9	22.75	14.243	0

4

X_5: Q% mn

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.402	.193	.025	.037	48.08	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
.1	1	.9	24.137	11.918	0

5

Quad diffs, AcuVue, descriptive stat

X_1: Q1 wgtd

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.603	.787	.102	.62	130.684	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	3	3	36.15	58.357	0

1

X_2: Q2 wgtd

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.652	.762	.098	.581	116.987	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	2.5	2.5	39.1	59.771	0

2

X_3: Q3 wgtd

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
1.145	1.05	.136	1.103	91.718	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
.05	4	3.95	68.7	143.73	0

3

X_4: Q4 wgtd

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.613	.797	.103	.635	129.992	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	3	3	36.775	59.993	0

4

Quad diffs, SeeQuence, descriptive stat

X_6: Q1 wgtd

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.27	.541	.07	.292	200.213	60

Minimum:	Maximum:	Range:	Sum:	Sum Squared:	# Missing:
0	2.5	2.5	16.2	21.615	0

6

X_7: Q2 wgtd

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.291	.512	.066	.262	176.051	60

Minimum:	Maximum:	Range:	Sum:	Sum Squared:	# Missing:
0	2.5	2.5	17.45	20.543	0

7

X_8: Q3 wgtd

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.895	.927	.12	.86	103.641	60

Minimum:	Maximum:	Range:	Sum:	Sum Squared:	# Missing:
0	3	3	53.675	98.734	0

8

X_9: Q4 wgtd

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.416	.61	.079	.372	146.516	60

Minimum:	Maximum:	Range:	Sum:	Sum Squared:	# Missing:
0	2.5	2.5	24.975	32.341	0

9

Quad diffs, SeeQuence, descriptive stat -

X_{11}: Q2

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.817	.695	.09	.483	85.079	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	3	3	49	68.5	0

11

X_{12}: Q3

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
1.392	1.013	.131	1.026	72.792	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	4	4	83.5	176.75	0

12

X_{13}: Q4

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.933	.767	.099	.589	82.207	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	3	3	56	87	0

13

X_{10}: Q1

Mean:	Std. Dev.:	Std. Error:	Variance:	Coef. Var.:	Count:
.675	.65	.084	.422	96.267	60
Minimum:	**Maximum:**	**Range:**	**Sum:**	**Sum Squared:**	**# Missing:**
0	3	3	40.5	52.25	0

10

RESEARCH/THESIS PROJECT APPLICATION

WHICH INSTRUCTIONAL COORDINATING COMMITTEE APPROVED THIS PROJECT?

Clinic - Contact lenses

TODAY'S DATE: 11-15-88 DATE OF APPROVAL: _____

PROJECT TITLE: A Comparison of Disposable Extended Wear Contact Lens edge design.

FACULTY ADVISOR (PRINT): _____

FACULTY ADVISOR (SIGNATURE): _____

TWO SENTENCE PROJECT ABSTRACT: The edge of a contact lens by virtue of its design may induce trauma to the adjacent tissue. A comparison study investigating trauma due to the lens edge design of a molded disposable contact lens, the B & L Sequence, versus a spin cast disposable contact lens, the J & J Acu-vue, will be evaluated by flourescein staining and biomicroscopic evaluation.

STUDENT RESEARCHERS (PLEASE PRINT FULL NAMES):

1. Doug Devries YEAR OF GRADUATION: 1989
2. Terry Patrick YEAR OF GRADUATION: 1990
3. Linda Spitzer YEAR OF GRADUATION: 1990
4. _____ YEAR OF GRADUATION: _____
5. _____ YEAR OF GRADUATION: _____

THIS FORM SHOULD BE IN DR. R. YOLTON'S BOX BY 4:30 FRIDAY MARCH 18, 1988. PLEASE PRINT OR TYPE AND CHECK SPELLING. WHAT YOU WRITE WILL BE DISTRIBUTED AS WRITTEN TO STUDENTS AND FACULTY. THANKS.

A COMPARISON OF DISPOSABLE EXTENDED WEAR CONTACT LENS EDGE DESIGN

Doug Devries
Linda Spitzer
Terry Patrick

PURPOSE AND HISTORY

At present only two disposable extended wear contact lenses are available in the United States, the Bausch and Lomb Sequence and the Johnson and Johnson Acu-Vue. The Acu-Vue is a molded lens and as a result of this production technique has a distinct edge which may prove to be a problem with regards to comfort and ocular health. The Sequence lens on the other hand is a spincast lens and by virtue of this technique has a distinctly smoother edge that should prove to be more comfortable and less traumatizing to the eye.

These differences in lens design suggest that when a lens of each design is applied to a subject we may find differences in conjunctival staining and subjective patient comfort. At the current time only one study concerning edge design is available and was not a comparison of two lenses but evaluated the trauma induced only by the Acu-Vue lens. The researchers found that after one hour of wear, and upon sodium flourescein staining, 8/10 subjects exhibited staining where the lens edge had rested.

Based on the differences in lens design, limited research in edge induced trauma from disposable lens edge design and a desire to provide patients with the safest lens for extended wear we feel these differences should be investigated.

METHODS

HYPOTHESIS

Considering molded disposable contact lenses versus spincast disposable lenses and the differences in the resulting edges, the edge which results from the molded process will cause more trauma to the eye than the edge produced from the spincast process when evaluated by sodium flourecein staining and biomicroscopic evaluation.

MEASUREMENT PROCEDURES AND EXPERIMENTAL DESIGN

Measurement of conjunctival staining will be accomplished by staining the eyes of the patient by instilling sodium flourescein into

both eyes and evaluating the amount of staining prior to lens wear with a biomicroscope. After this baseline measurement has been taken, two lenses, one of each design and appropriate fit, will be applied to the patients eyes. They will wear the lenses for one hour. After the lenses have been in place for the prescribed time they will be removed. The patient will again be stained with sodium flourescein and evaluated once again for staining. A scale of 1-4 will be utilized to grade the staining and a value yet to be determined will be assigned for clinical significance.

Approximately 50-60 patients will be involved in this trial. The results will be evaluated statistically via a t-test which should be sufficient for a comparison of the data. We expect to find clinically significant staining in a statistically significant number of eyes wearing the Acu-Vue lens.

We expect to be able to complete the experimental portion of the study within in 3 week time frame beginning in mid November with completion of the project by January 1, 1989.

EVALUATION AND REPORTING OF RESULTS

Upon completion of the experiment and a statistical analysis of the results our advisor and the researchers will evaluate the findings. If they are of a significant nature and warrant publication and scrutiny by interested parties, submission to appropriate journals and symposiums will evaluated.

PACIFIC UNIVERSITY INSTITUTIONAL REVIEW BOARD

PROJECT DISPOSITION FORM

PROJECT TITLE: A clinical evaluation of extended wear disposable contact lenses

PRINCIPAL INVESTIGATOR(S): Doug Devries, Terry Patrick and Linda Spitzer

FACULTY SUPERVISOR(S): Dr. James E. Peterson

The IRB met on 9-12-88 and made the following decision regarding this project.

1. APPROVAL ☑ by mail

This project is approved based on the materials furnished by the principal investigator(s). Copies of all Informed Consent and/or Model Releases must be retained by the principal investigator(s) and upon completion of the project delivered to the Director of Research for permanent storage. Failure to deliver these releases at the completion of the project may cause personal legal liability for the principal investigator(s). Any occurrence of injury (physical, psychological, etc.) to a subject or any significant change in research design must be reported to the Chairperson of the IRB immediately.

2. APPROVAL WITH MODIFICATIONS REQUIRED ☐

The general concept of this project is acceptable as are supporting materials. The IRB requests the following modifications be made and reviewed with the Chairperson of the IRB. If modifications are acceptable, (s)he will sign and date below. The project is then approved and subject to the conditions stated under item 1 above. (Human subjects may not be used until the Chairperson signs below.)

Required Modifications _____

_____

_____

_____

Modifications Accepted _____ Date _____
(Chairperson, IRB)

3. DISAPPROVED ☐

Because of the reasons listed below, the IRB cannot approve of the use of human subjects in this project. The principal investigator(s) may correct the problems and resubmit the project to the IRB or may request to appear in person at an IRB meeting to explain the project more fully.

Reasons for Disapproval _____

_____

_____

_____

Chairperson, IRB J E Peterson Date 9/12/88

PATIENT CONSENT FORM

1. Pacific University College of Optometry

   A. PROJECT TITLE:
   A clinical evaluation of extended wear disposable contact lenses.

   B. PRINCIPAL INVESTIGATORS:

Doug Devries	357-7311
Terry Patrick	357-0174
Linda Spitzer	357-3504

   C. ADVISOR:
   James E. Peterson O.D. 357-6151, ext. 2314

   D. LOCATION:
   Pacific University College of Optometry, Forest Grove, Oregon

   E. DATE:
   Sept 15 1988 to April 1, 1989

2. PROJECT DESCRIPTION:
   This project will compare two different types of disposable extended wear 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 of each type of contact lens in each eye for the manufacturer's recommended period. Fresh lenses will be rotated from eye to eye for purposes of comparison. This will involve a total of four months of lens wear. Periodic visits are required after the lenses are dispensed so that data can be gathered and any visual changes monitored.

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 the loss of an eye. Your close cooperation in the observation of symptoms and the adherence to the wearing schedules are vital to the health of your eye.

4. DESCRIPTION OF BENEFITS:

Use of disposable extended wear lenses may improve your ocular health. All patients who finish the project may receive free of charge, a 6 month to one year's supply of disposable extended wear contact lenses. If disposable contact lens wear is continued, the patient will need regular optometric care which will be at the patients own expense.

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, or 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 TO WITHDRAW:

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.

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REFERENCES

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THESES OPT DeVries D K 1989
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DeVries, Douglas K.

A clinical evaluation of
edge induced conjunctival