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A study to determine if bacteriostatic agents impregnated in contact lenses can reduce symptoms of contact lens wearers which are not due to lens defects nor to a poor lens design

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Abstract

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Don C. West

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A STUDY TO DETERMINE IF BACTERIOSTATIC AGENTS IMPREGNATED IN CONTACT LENSES CAN REDUCE SYMPTOMS OF CONTACT LENS WEARERS WHICH ARE NOT DUE TO LENS DEFECTS NOR TO A POOR LENS DESIGN.

Presented to the faculty of

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by

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_____

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INTRODUCTION:

Contact lens wearers, after having achieved full-time wear of their lenses, often experience various minor symptoms of discomfort which frequently cannot be attributed to lens defects or to a poor lens design.

The traditional approach for alleviating the difficulties commonly encountered in fitting contact lense's has been a modification in the lens design. On occasion lens modification fails to cope with persistent signs of minor difficulty and the patient obtains and maintains full-time wear of his contact lenses.

Published and unpublished reports contend that patients wearing impregnated lenses are generally "more comfortable" than with their previous lenses.

The plastic which is used in the production of such a lens is "a fully polymerized crosslinked methyl methacrylate in which hexachlorophene and Corobex® are incorporated by a special method of polymerization".[1]

Previous experiments have shown that the impregnated lens is non-irritating and non-toxic to human eyes, and clinically demonstrated to be as well tolerated as ordinary contact lenses.[2]

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1 The lens used in this study was the Aseptoplast lens manufactured by the Plastic Contact Lens Company.

2 Anon., W/J Aseptoplast Contact Lenses, Plastic Contact Lens Publishing Company.

The antimicrobial activity on the lens surface was tested against the pathogens most frequently encountered in the eye; Escherichia coli, Psuedomonas aeruginosa, Diplococcus pneumoniae, Staphylococcus aureus, and Streptococcus hemolyticus. A definite bacteriostatic activity was demonstrated against all the organisms tested. After three months of exposure to the organisms, there was no dimunition in the antimicrobial effect.

It is the intention of this study to determine if the impregnated substance used may alter cases of discomfort or reduce the subjective symptoms.

PROCEDURE:

The subjects were chosen from the Pacific University Optometric Clinic files at random on the basis of corneal astigmatism of 1.50 diopters or less.

Form letters were sent to 50 patients meeting the criteria of the study. Patients responding to this letter were examined in the clinic and data gathered to determine the source of difficulty and the condition and design of the lens. In addition to habitual visual acuities being recorded through their contact lenses, each examination consisted of a biomicroscopic examination, fluorescein pattern, and a refraction to best visual acuity with the contact lenses in place. The presence and severity of injection, mucus deposits, tearing and blink rate were noted objectively.

Thirteen subjects were selected and one lens duplicating the design of the habitual as nearly as possible was given. The sampling was divided in half; seven receiving the impregnated lens on the dominant eye, the other six on the non-dominant eye. The subjects were unaware of the fact that they were receiving only one new lens.

At the time of the initial dispensing, each subject was given a daily recording form to be filled out at the end of a day's wearing time for a period of three weeks.

PLEASE FILL IN THIS CHART AT THE END OF EACH DAY

LESS = L SAME = S MORE = M

SYMPTOMS	Sunday		Monday		Tues.		Wed.		Thur.		Friday		Sat.	
	R	L	R	L	R	L	R	L	R	L	R	L	R	L
Burning, Stinging														
Eyes Watering														
Blinking														
Bloodshot Eyes														
Mattering														
Blurred Vision														
Itching														
General Comfort														
Does lens slip off cornea?														
Number of hours of wear														
How often, if at all, did you remove your lenses because of discomfort?														

REMARKS:

WEEKLY OBJECTIVE EXAM

OBJ. SYMPTOMS	1st WK.	2nd WK.	3rd WK.	4th WK.	5th WK.
Injection					
Tearing					
Blink Rate					
Mattering					

REMARKS:

A. Patients' Name _____

B.

The subjects returned at one-week intervals for an objective evaluation to note any possible problems that the subjects might have. At the end of the three week period, the original lenses were exchanged for the impregnated lenses and an inquiry was made to determine their preference. All of the subjects stated that they had no preference.

EYES WITH ASEPTOPLAST COMPARED TO EYES WITH REGULAR CONTACT LENSES

SYMPTOM		TOTAL		PERCENTAGE		WEIGHTED SCALE		t SCORE
		A	R	A	R	A	R	
BURNING, STINGING	LESS	5	8	5.5	8.8	-.055	+.011	.342
	SAME	76	76	83.5	83.5			.000
	MORE	10	7	11.0	7.69			.237
WATERING	LESS	12	17	13.1	18.4			.396
	SAME	75	72	82.5	79.1	+.088	+.164	.180
	MORE	4	2	4.4	2.2			.270
BLINKING	LESS	5	4	5.5	4.4			.090
	SAME	81	83	89.0	91.3	.000	.000	.252
	MORE	5	4	5.5	4.4			.090
INJECTION	LESS	5	6	5.5	6.6			.108
	SAME	72	75	79.1	82.5	-.099	-.044	.270
	MORE	14	10	15.2	11.0			.288
MATTERING	LESS	32	25	35.2	27.5			.396
	SAME	51	62	56.0	68.1	+.264	+.231	.648
	MORE	8	4	8.8	4.4			.396
BLURRED VISION	LESS	35	25	38.5	27.5			.538
	SAME	52	57	57.1	62.6	+.341	+.176	.324
	MORE	4	9	4.4	9.9			.576
ITCHING	LESS	14	19	15.2	20.9			.396
	SAME	69	66	76.0	72.6	+.066	+.143	.144
	MORE	8	6	8.8	6.6			.183
GENERAL COMFORT	LESS	9	9	9.9	9.9			.000
	SAME	59	57	64.9	62.6	+.154	+.176	.090
	MORE	23	25	25.3	27.5			.162
LENS SLIP OFF CORNEA	LESS	0	0	0.0	0.0			.000
	SAME	91	91	100.0	100.0	.000	.000	.000
	MORE	0	0	0.0	0.0			.000

KEY: A= Eye with Aseptoplast Contact Lens
R= Eye with Regular Contact Lens

COMPARISON OF DOMINANT EYES WITH ASEPTOPLAST LENSES
TO DOMINANT EYES WITH REGULAR LENSES

SYMPTOM		TOTAL		PERCENTAGE		WEIGHTED SCALE		t SCORE
		DW	DWO	DW	DWO	DW	DWO	
BURNING, STINGING	LESS	3	6	7.1	12.3			.305
	SAME	38	38	90.0	77.6	+.048	+.021	.585
	MORE	1	5	2.4	10.2			.610
WATERING	LESS	13	6	31.0	12.2			.788
	SAME	29	42	69.0	85.7	+.31	+.102	.763
	MORE	0	1	0	2.0			.546
BLINKING	LESS	6	1	14.2	2.0			.839
	SAME	34	46	81.0	93.9	+.095	-.021	.750
	MORE	2	2	4.8	4.1			.382
INJECTION	LESS	5	1	11.9	2.0			.725
	SAME	30	42	71.4	85.7	-.048	-.102	.712
	MORE	7	6	16.6	12.2			.019
MATTERING	LESS	15	15	36.7	30.6			.204
	SAME	24	31	57.2	63.3	+.285	+.245	.242
	MORE	3	3	7.1	6.1			.228
BLURRED VISION	LESS	15	14	36.7	28.6			.28
	SAME	26	31	62.0	63.3	+.335	+.245	.101
	MORE	1	4	2.4	8.2			.560
ITCHING	LESS	0	20	0	40.8			2.420 *
	SAME	38	27	90.0	55.2	-.095	+.360	1.450
	MORE	4	2	9.5	4.1			.330
GENERAL COMFORT	LESS	5	7	11.9	14.3			.178
	SAME	32	28	76.1	57.1	+.167	+.143	.942
	MORE	12	14	12.0	28.6			.749
LENS SLIP OFF CORNEA	LESS	0	0	0	0			0
	SAME	42	49	100	100	0	0	0
	MORE	0	0	0	0			0

KEY: DW = Dominant eyes with Aseptoplast lenses
DWO = Dominant eyes with regular contact lenses
* = Significant to the 5% level of confidence

NON-DOMINANT EYES WITH ASEPTOPLAST CONTACTS COMPARED TO NON-DOMINANT EYES WITH REGULAR CONTACT LENSES

SYMPTOM		TOTAL		PERCENTAGE		WEIGHTED SCALE		t SCORE
		NDW	NDWO	NDW	NDWO	NDW	NDWO	
BURNING, STINGING	LESS	2	1	4.1	2.38			.178
	SAME	40	39	81.9	93	-.120	-.024	.662
	MORE	7	2	14.3	4.76			.839
WATERING	LESS	0	13	0.00	13.3			2.21 *
	SAME	46	28	93.9	66.7	-.061	+.285	1.293
	MORE	3	1	6.1	2.38			.318
BLINKING	LESS	1	6	2.0	14.3			.915
	SAME	45	34	49.2	81	-.042	+.095	1.22
	MORE	3	2	6.1	4.76			.076
INJECTION	LESS	1	6	2	14.3			.930
	SAME	41	34	83.9	81	-.122	+.095	.076
	MORE	7	2	14.3	4.76			.636
MATTERING	LESS	10	14	20.4	33.4			.560
	SAME	34	27	69.2	64.3	+.120	+.310	.019
	MORE	5	1	10.2	2.4			.560
BLURRED VISION	LESS	20	12	40.9	28.6			.458
	SAME	25	26	51	62	+.325	+.19	.407
	MORE	4	4	8.2	9.5			.114
ITCHING	LESS	14	0	28.5	0.00			1.299
	SAME	32	38	65.1	90.6	+.245	-.095	1.145
	MORE	3	4	6.1	9.5			.242
GENERAL COMFORT	LESS	7	6	14.3	14.3			.000
	SAME	32	25	65.1	58.9	+.061	+.119	.019
	MORE	10	11	20.4	26.2			.267
LENS SLIP OFF CORNEA	LESS	0	0	.000	.000			.000
	SAME	49	42	100	100	.000	.000	.000
	MORE	0	0	.000	.000			.000

KEY: NDW = NON-DOMINANT EYES WEARING ASEPTOPLAST CONTACT LENSES
NDWO =NON-DOMINANT EYES WEARING REGULAR CONTACT LENSES
* = SIGNIFICANT TO THE 5% LEVEL OF CONFIDENCE

RIGHT EYE WITH ASEPTOPLAST COMPARED TO RIGHT EYE WITH REGULAR CONTACT LENSES

SYMPTOM		TOTAL		PERCENTAGE		WEIGHTED SCALE		t SCORE
		RW	RWO	RW	RWO	RW	RWO	
BURNING, STINGING	LESS	2	8	4.8	19			.864
	SAME	38	32	77.5	76.2	-.142	+.122	.025
	MORE	9	2	18.4	4.27			.788
WATERING	LESS	4	13	8.2	30.9			1.373
	SAME	44	28	89.9	66.7	+.061	+.245	1.042
	MORE	1	1	2	2.3			.051
BLINKING	LESS	4	1	8.2	2.38			.457
	SAME	41	41	83.9	97.6	.000	+.020	.94
	MORE	4	0	8.2	0.00			1.018
INJECTION	LESS	2	2	4.8	4.27			.025
	SAME	36	37	73.5	88.1	-.184	-.020	.712
	MORE	11	3	22.5	7.1			.762
MATTERING	LESS	15	14	30.6	33.4			.127
	SAME	28	28	57.1	66.7	+.184	+.285	.343
	MORE	6	0	12.2	0.00			1.245
BLURRED VISION	LESS	27	7	55.1	16.7			1.513
	SAME	20	29	40.9	69.1	+.51	+.020	1.042
	MORE	2	6	4.8	14.3			.635
ITCHING	LESS	13	6	26.5	14.3			.522
	SAME	30	34	61.2	81	+.142	+.082	.787
	MORE	6	2	12.2	4.27			.508
GENERAL COMFORT	LESS	8	3	16.3	7.2			.534
	SAME	25	30	51.1	71.4	+.163	+.122	.762
	MORE	16	9	32.7	4.7			1.372
LENS SLIP OFF CORNEA	LESS	0	0	.000	.000			.000
	SAME	49	42	100	100	.000	.000	.000
	MORE	0	0	.000	.000			.000

KEY: RW = RIGHT EYE WITH ASEPTOPLAST CONTACT LENS
RWO = RIGHT EYE WITH REGULAR CONTACT LENS

COMPARISON OF LEFT EYES WITH ASEPTOPLAST TO LEFT EYES WITH REGULAR LENSES

SYMPTOM		TOTAL		PERCENTAGE		WEIGHTED SCALE		t SCORE
		OSW	OSWO	OSW	OSWO	OSW	OSWO	
BURNING, STINGING	LESS	1	1	2.4	2.0			0
	SAME	36	44	85.8	89.8	-.095	-.061	.020
	MORE	5	4	11.8	8.2			.254
WATERING	LESS	7	5	16.7	10.2			.356
	SAME	32	43	76.2	87.8	+.096	+.082	.534
	MORE	3	1	7.1	2.0			.305
BLINKING	LESS	1	4	2.4	8.2			.508
	SAME	40	42	94.2	85.8	0	+.020	.508
	MORE	1	3	2.4	6.1			.333
INJECTION	LESS	2	3	4.8	6.1			.127
	SAME	37	39	88.1	89.7	-.024	-.082	.051
	MORE	3	7	7.1	14.2			.458
MATTERING	LESS	16	11	38.0	28.5			.559
	SAME	24	35	57.2	71.4	+.333	+.163	.508
	MORE	2	3	4.8	6.1			.127
BLURRED VISION	LESS	8	18	19.0	36.7			.737
	SAME	31	29	73.9	59.2	+.119	+.327	.534
	MORE	3	2	7.1	4.1			.254
ITCHING	LESS	1	13	2.4	26.5			1.373
	SAME	39	32	92.8	65.3	-.024	+.184	1.283
	MORE	2	4	4.8	8.2			.279
GENERAL COMFORT	LESS	4	8	9.5	16.3			.382
	SAME	34	28	81.0	57.2	0	+.102	.966
	MORE	4	13	9.5	26.5			.864
LENS SLIP OFF CORNEA	LESS	0	0	0	0			0
	SAME	42	49	100	100	0	0	0
	MORE	0	0	0	0			0

KEY: OSW = Eyes with Aseptoplast lenses
OSWO = Eyes with regular contact lenses

COMPARISON OF DOMINANT EYES WITH ASEPTOPLAST AND NON-DOMINANT EYES WITH REGULAR LENSES TO NON-DOMINANT EYES WITH ASEPTOPLAST AND DOMINANT EYES WITH REGULAR LENSES

SYMPTOM		TOTAL		PERCENTAGE		WEIGHTED SCALE		t SCORE
		I	II	I	II	I	II	
BURNING, STINGING	LESS	4	8	4.76	8.2			.469
	SAME	77	78	91.7	79.6	+.012	-.041	.866
	MORE	3	12	3.57	12.2			.794
WATERING	LESS	26	6	30.1	6.1			1.73
	SAME	57	88	67.9	89.8	+.298	+.020	1.445
	MORE	1	4	1.2	4.1			.505
BLINKING	LESS	12	2	14.3	2.04			1.19
	SAME	68	91	81.0	92.9	+.095	-.031	.992
	MORE	4	5	4.76	5.1			.072
INJECTION	LESS	11	1	13.1	1.02			1.37
	SAME	64	83	76.3	84.7	+.024	-.122	.505
	MORE	9	13	10.7	13.3			.271
MATTERING	LESS	29	25	34.6	25.6			.433
	SAME	51	65	60.7	66.3	+.298	+.174	.289
	MORE	4	8	4.8	8.2			.469
BLURRED VISION	LESS	27	34	32.1	34.7			.144
	SAME	52	56	61.9	57.2	+.262	+.265	.181
	MORE	5	8	6.0	8.2			.271
ITCHING	LESS	0	24	0	24.5			2.71*
	SAME	76	59	90.5	60.2	-.095	+.194	1.878
	MORE	8	5	9.5	5.1			.396
GENERAL COMFORT	LESS	11	14	13.1	14.3			.108
	SAME	57	60	67.9	61.3	+.143	+.102	.361
	MORE	23	24	27.4	24.5			.072
LENS SLIP OFF CORNEA	LESS	0	0	0	0			0
	SAME	84	98	100	100	0	0	0
	MORE	0	0	0	0			0

KEY: I = Dominant eyes with Aseptoplast and non-dominant eyes with regular contact lenses
II = Non-dominant eyes with Aseptoplast and dominant eyes with regular contact lenses
* = Significant to the 5% level of confidence

DISCUSSION:

The statistical analysis of data obtained from the study was performed by totaling the daily subjective responses of "less", "more" and "same" for each separate symptom. These were then totaled for the first week's wearing time. The total data covered a period of three weeks but only the first week was used in the analysis since all the results tended to be nearly the same for the three week period.

Weighted scale values were assigned the totals by taking the difference of the "less" and "more" totals and dividing this by the total number of responses for that particular symptom. A plus value was arbitrarily assigned to those values in which there were more "less" responses than "more" responses. Likewise minus signs were given those values in which there were more "more" responses than "less" responses. The exception to this was in the condition of general comfort where the opposite situation was used since a response of "more" indicated an increase in general comfort.

Percentages were then calculated for the total weekly scores in each category of "less", "more" and "same" under each symptom. The significance of the difference between the percent for one eye and the percent of the other eye for each symptom were then calculated using the Lawshe and

Baker nomograph to obtain "t" scores.

A "t" score of 2.18 was necessary to show a significant response at the 5% level of confidence with 12 degrees of freedom.

Chi scores were calculated in several instances but yielded less significance in the anaylisis than the "t" scores and were disregarded.

Attempts were made to determine if the reports by patients that these lenses were generally "more comfortable" could be subdivided to show a reduction or elimination of individual symptoms of discomfort. Analysis of the completed results showed only two symptoms as being significant to the 5% level of confidence. The first occurred under the symptom of tearing when comparing the non-dominant eyes with the impregnated lens to the non-dominant eyes with the regular lens. This had a "t" score of 2.42 when one of 2.18 was required. This condition of less watering existed in the eye which had the regular lens and not the impregnated lens. The second condition was that of itching which occurred in two comparisons. The first comparison, which had 12 degrees of freedom, was the dominant eye without the impregnated lens to the dominant eye with the impregnated lens and yielded a "t" score of 2.35 when 2.18 was significant. Again this occurred in the eye with the regular lens. In the second comparison of itching

where a significant "t" score was found, the subjects were so divided that the sum totals of the two eyes for seven of the subjects with the impregnated lens on the dominant eye were compared to the sum totals of the two eyes for the six of the subjects which had the impregnated lens on the non-dominant eyes. In this case there were 25 degrees of freedom and a "t" score of 2.71 was obtained when one of 2.06 was needed. This comparison was made to see if there was any sympathetic effect on the eye wearing the regular lens as a result of the impregnated lens' being on the other eye. The results in this comparison seem to indicate a sympathetic effect to some extent.

POSSIBLE SOURCES OF ERROR:

Attempts were made to duplicate the patient's lens; however, by the nature of the construction, it is evident that this is extremely difficult.

When dealing with studies of this type, a great source of error is encountered when the subjects, as untrained observers, are required to make an evaluation of subjective responses.

By the nature of the study itself, it could very well be that previously unnoticed symptoms came to the subject's attention and/or by the knowledge of the study, they may have expected better results.

It is also possible that some lens defect may have gone unnoticed by the authors which could have affected the results.

Many of the impregnated lenses, were noted as a lighter shade of tint than that of a corresponding shade in regular contact lenses. This allowed some of the subjects to suspect that their two lenses were different.

NEED FOR FURTHER STUDIES:

Further studies along this line are needed to eliminate some of the uncontrolled variables mentioned.

Another proposal would be to increase the mumber of subjects which could increase the significance of the results.

A third approach would be to substitute impregnated lenses for the habitual lenses of a patient already wearing contact lenses without his knowledge of the change.

SUMMARY:

Thirteen full-time wearers of contact lenses were fit with one impregnated lens. The subjects were not informed as to which was the impregnated lens. Daily records as to various subjective responses were kept for each eye. A statistical analysis of these subjective reports showed no significant difference in the symptoms in the eyes with the impregnated lenses.

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