

EFFECTS OF MICROWAVE DISINFECTION ON HYDROGEL CONTACT LENSES

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ABSTRACT

In the recent literature, several authors have experimented with new hydrogel lens disinfection systems using conventional microwave ovens. These studies evaluated disinfection effectiveness, comfort, fitting characteristics, and effects on physical parameters of a limited number of lenses. This laboratory experiment was designed to investigate the potential of protein deposition during microwave disinfection. Matched groups of lenses from three of the four FDA categories of hydrogel lenses were exposed to simulated human "tear" solutions then disinfected by microwaves or traditional heat. No significant difference was found in deposit formation between microwave and heat groups. The study also reports pre- and post-experiment results of diameter, base curve, and refractive power for four brands of lenses not previously studied in regards to microwaves. No changes in diameter, base curve, and refractive power were found. A review of microwave disinfection is presented, and because microwaves have many potential qualities it is suggested that further study be done on these new systems.

Key words: Contact Lens, Disinfection, Microwaves.

INTRODUCTION

Hydrogel contact lenses, the most common type of contact lens prescribed today (1), tend to absorb pathogenic microorganisms because of the chemical nature of the lens materials and care systems. Unfortunately, failure of the patient to comply with disinfection can lead to ocular complications such as infectious ulcers, keratitis, toxic reactions, giant papillary conjunctivitis, and lens damage to name a few (2,3,4). A significant portion of daily wear patients fail to comply with disinfection techniques. Gruber (5) revealed that 48% in a sample of 100 patients did not disinfect their lenses each day. In a study by Collins and Carney (6), 74 of 100 patients were noncompliant in one or more of the following requirements of lens care: 33% were not following appropriate cleaning instructions, 28% did not keep their contact lens cases clean, 20% failed to use the daily cleaner as prescribed, 20% were not rinsing lenses properly, and 18% were not replacing the disinfection solution as instructed.

Patients do not comply for many reasons, but a contributing factor is that current disinfection systems take more time and/or money than patients are willing to invest. Certain patients require specific care systems because of lens type, tear film chemistry, deposits, or higher risk of infection. Each disinfection system has advantages and disadvantages. An ideal disinfection system would possess the following characteristics:

effective elimination of microorganisms, the ability to be used on a wide variety of lens types, low deposit formation, harmless to lens parameters or fitting characteristics, good comfort, inexpensive, convenience, a short disinfection time, simple instructions, and easy to learn (table 1). To promote compliance new disinfection systems are sought after. Therefore, research in hydrogel contact lens disinfection continues in the effort to develop systems with as many of the characteristics of an ideal system as possible.

CURRENT DISINFECTION SYSTEMS

Lens disinfection has gone through several stages of evolution since the introduction of hydrogel contact lenses. The advantages and disadvantages of current systems are listed in table 2. The first FDA approved system was a heat system. Heat systems utilize thermal disinfection by means of small portable heat units. The patient cleans the lenses with a cleaning solution, rinses with saline, then places the lenses in the unit with saline. The advantages of heat disinfection include: low cost, simple to use, and effective kill. The disadvantages are: necessity of electricity, higher rate of protein deposits, limitation of lens type to only low water content lenses, and length of time to disinfect (20 to 40 minutes). Chemical disinfection utilizes solutions with chemicals effective in eliminating pathological microorganisms. The steps and

instructions vary with each system and solutions involved. Some chemical systems are complicated in that separate solutions are necessary for cleaning, rinsing, and disinfecting. Other systems provide solutions that combine two or more of these steps. Examples of chemical disinfectants include: thimerisol, chlorohexidine, polyquad, and dymed. The advantages of chemical disinfection are convenience for travel, wide compatibility among lens types, and lower deposit formation. However, chemical disinfection does not provide protection against as many microorganisms as heat (2). Further, combination solutions are generally less effective than single function solutions (7). Chemical disinfection is also lengthy in time (usually four hours), higher in risk for toxic sensitivity reactions, and more expensive. Hydrogen peroxide disinfection is a chemical method but is often discussed separately. Its mechanism of disinfection is by free radical oxidation. Patients clean their lenses with a cleaner, disinfect, then neutralize the disinfection solution (though specific steps may vary). Hydrogen peroxide is very effective in elimination of microorganisms, is convenient for travel, is low in protein deposits, and is compatible with many lenses. On the other hand, hydrogen peroxide is the more expensive (8). It requires from one to six hours, and more patient instruction is necessary. In addition, discomfort has been a problem often due to patients not neutralizing properly, and there are reports of stinging discomfort even with fully neutralized solutions (9,10).

It is apparent, therefore, that no current system represents an ideal disinfection system, so research continues to develop systems with more characteristics common to an ideal system. Further, a characteristic that neither heat, chemical, or hydrogen peroxide systems possess is a very short disinfection time.

MICROWAVE DISINFECTION

The newest phase in the evolution of disinfection systems is microwave disinfection. Several authors in the recent literature have experimented with the use of standard microwave ovens as an alternative method for hydrogel contact lens disinfection (11,12,13,14). Whether microwave disinfection is accomplished by thermal or nonthermal mechanism remains unclear (11,12,13,14), and the present discussion will not attempt to evaluate that question. Rather, this paper shall concentrate on the applications of microwaves. The proposed advantages of microwave disinfection is effective elimination of microorganisms, low cost of materials and solutions, simplicity and ease of patient learning, and speed of disinfection. The number of studies is limited and a call for more research has been made.

Harris et al. (11) demonstrated that microwave disinfection was effective on samples of bacteria. Lenses inoculated with three common bacteria affecting contact lens wearers were disinfected at several durations. None of the bacteria survived

a ninety second exposure. In an earlier study, Rohrer et al. (12) demonstrated successful kill of bacteria, viruses, and fungi with exposure times between 45 seconds and eight minutes. They also disinfected two lenses 101 times and reported no changes in one lens under inspection of scanning electron microscopy and no changes in the refractive power of the other lens by overrefraction. Boltz and Bhoola (13) examined the effect of microwave disinfection on fitting characteristics and comfort of hydrogel contact lenses. Their results showed no differences in fitting characteristics of the lenses that completed the disinfection process unharmed. Patients did report decreased comfort from wearing microwaved lenses compared to a combined group of heat and hydrogen peroxide disinfected lenses. This difference was significant at the $p < 0.10$ level.

The study by Harris provided an excellent foundation for the development of this study. Harris was the first to use a wet microwave disinfection system- that is, the lenses remain hydrated in solution. The other two studies dehydrated the lenses during each disinfection. If time and simplicity are major advantages to microwave disinfection, maintaining the lenses in solution infers that a wet system would be best. Harris's study utilized lenses from each of the four FDA lens categories and showed successful kill for three common bacteria on each lens type. Although Harris does not recommend a minimal exposure time, his data support approximately ninety seconds in a standard microwave oven as an effective duration for killing

bacteria. The study by Rohrer supports effective disinfection in a dry system, but the sample of lens types is clearly too small to claim that microwave disinfection is harmless to hydrogel contact lenses. Boltz and Bhoola investigated more lens types in a dry system. They used two lenses each of three water contents or a total of six lenses. Their lenses included Bausch and Lomb U4 (FDA group 1), B&L 70 (FDA group 2), and Vistamarc (FDA group 4). They disinfected each lens 20 times. In the results, the two Vistamarc lenses (medium water ionic), were damaged, but the Bausch and Lomb lenses (low and high water nonionic) did not reveal any changes in fitting characteristics. Unfortunately, Boltz and Bhoola did not report any pre- and post- disinfection measurements on lens parameters, so any conclusions on whether microwave disinfection harms the lenses themselves is only inferred by their results on fitting characteristics.

A fourth study by Ajello et al. (14) investigated microwave effects on lens parameters. This study reported pre- and post-disinfection measurements on diameter, basecurve, stress, strain, elongation, refractive index, and water content. Samples were taken from each of the four FDA lens categories. They used wet disinfection with the criteria being that lens solution reached 95 degree Celsius for minimum exposure times. The lens solutions were not allowed to boil. When compared to lenses disinfected by heat, there was no significant differences in the physical properties of the lenses.

Thus far, experimental non FDA approved disinfection

systems using microwaves have been investigated with several methods. Microwave disinfection has been reported to destroy bacteria in wet and dry systems, and destroy viruses and fungi in dry systems. It has also been shown to be harmless to lens parameters and fitting characteristics on a limited number of lenses. It has the potential for being a fast, convenient, and easy to learn system. The effects of microwave disinfection on deposit formation has yet to be studied.

The present study analyzes potential for deposit formation on samples of three of the four FDA hydrogel contact lens categories. It is an in vitro study designed to compare deposit formation between groups of lenses subjected to microwave disinfection and heat disinfection. In addition, it reports pre- and post- disinfection measurements of three lens parameters: diameter, base curve, and refractive power. The hypothesis is: do lenses disinfected with microwaves acquire equal deposit formation when compared to lenses disinfected with heat. If deposit formation is significantly greater in the microwave group, doubt is cast on the possible advantages of this disinfection method. Further, the effect on lens parameters is evaluated on several new types of lenses not previously studied.

METHODS

40 new hydrogel contact lenses were acquired for the experiment. 20 lenses were from FDA group 1 category and 10 lenses each from groups 2 and 3. These included: Aquaflex Super Thin, Hydron Spincast, DuraSoft 4, and DuraSoft 2. The lenses were divided into groups A, B, C, and D for analysis (table 3). Each lens was measured for diameter, base curve, and refractive power. Diameter was measured with a 10X lupe, base curve was measured with a HydroVue Soft Lens Analyzer model 100, and refractive power was measured by lensometry. Powers of lenses ranged from +3.25 to -6.25. Base curves ranged from 8.2 to 9.1, and diameters ranged from 13.2 to 14.5.

A solution comprised of a 0.91 unpreserved saline solution with 0.018 lysozyme, 0.040 albumin, and 0.028 globulin was used to simulate protein types and concentrations in human tear film (2,15). A 10X solution had 10 times the concentration of all proteins. One 10X solution was mixed at the beginning of the experiment and all solutions were derived from this original solution. This insured that all lenses within groups were exposed to equivalent "tear" solutions. Although human tear film composition is more complex, these compounds are the most significant ones responsible for protein deposit problems in hydrogel contact lens care (2). Other compounds such as mucus and calcium have been considered as problems for deposits, but

this study will be limited to proteins as proteins are implicated as a leading cause of deposit formation (16). All lenses in groups A and C were subjected to individual vials of the original 10X solution. Lenses in groups B and D were subjected to individual vials of normal solution. The solution was mixed the first day of the experiment, and the experiment went for six consecutive days. Groups A and B underwent microwave disinfection, and groups C and D underwent heat disinfection.

The lenses were shaken and soaked in the artificial "tear" solution for equal amounts of time then disinfected. Heat disinfection was done in open vials with about five milliliters of unpreserved saline in a Bausch and Lomb Soflens Professional Aseptor. Microwave disinfection was performed similar to the method used by Harris. Glass vials with plastic screw tops were filled with about five milliliters of unpreserved sterile saline. One single hole 1/16th of an inch was drilled in each of the plastic tops to permit steam to escape. All twenty lenses were disinfected together in a standard 2450 MHz Magic Chef microwave oven for ninety seconds on the high setting. Most lens solutions were brought to boiling, and most lenses remained hydrated although some were dehydrated when they stuck on the vial lid due to the turbulence of the boiling solution. All groups went through the "tear" solution and disinfection cycle 22 times.

Following the 22 cycles, the lenses were rinsed with unpreserved saline. The groups were then inspected, graded as to deposit formation, and photographed under phase contrast

microscopy. The grading system was an arbitrary 0, 1, 2, 3, or 4. Grade 0 represented the same appearance as a control lens not exposed to any solutions aside from being rinsed once with unpreserved saline. Grade 4 represented a lens coated entirely with proteins. Grades 1, 2, and 3 represented progressive amounts of deposition between grades 0 and 4. Photographs are provided as samples of the grades 0-4 in figures 0-4 respectively. The observer doing the grading did not know if the lens being graded was from group A, B, C, or D and the lenses were presented to him randomly.

RESULTS

Of the 40 lenses beginning the study, 34 lenses completed the procedures without being damaged. Six lenses were damaged most likely by handling and their respective groups are listed in table 4. Comparison of pre- and post- experiment measurements of diameter, base curve, and refractive power revealed no differences beyond those attributable to measurement error.

Results of deposit formation are reported in table 5. Histogram displays are presented in figures 5 and 6. The 10X concentrations, groups A and C, were not analyzed statistically because of the low sample sizes. Comparisons within lens type are inconclusive, but one may look for a tendency between microwave disinfection and heat. There is not an obvious trend. Groups B and D, the normal concentration groups, were evaluated

by one way analysis of variance and no significant difference was found between microwave disinfection and heat.

One way ANOVA summary:

<u>Source</u>	<u>df</u>	<u>F</u>	<u>p</u>
Between groups	7	1.428	0.246
Within groups	<u>21</u>		
Total	28		

Independent t tests did not reveal any significant differences of deposits within lens types between microwave and heat groups with one exception. Aquaflex lenses had significantly lower deposit formation in the microwave group compared to the heat group ($p < 0.05$). One way analysis of variance performed on microwave groups revealed no significant trend of deposit formation with lens type or water content.

One way ANOVA summary microwave group:

<u>Source</u>	<u>df</u>	<u>F</u>	<u>p</u>
Between lenses	3	2.602	0.105
Within lenses	<u>11</u>		
Total	14		

The same procedure also revealed no trend in the heat groups.

One way ANOVA summary heat group:

<u>Source</u>	<u>df</u>	<u>F</u>	<u>p</u>
Between lenses	3	0.468	0.711
Within lenses	<u>10</u>		
Total	13		

DISCUSSION

The results of this study are encouraging for the development of a microwave disinfection system, but they must be viewed with caution. At this time, microwave disinfection is only an experimental procedure and not an FDA approved system.

The results of this study serve to expand the data of effects on lens types and begin investigation of protein deposition. Four previously unstudied lens types, Aquaflex Superthin, Hydron Spin Cast, DuraSoft 2 and DuraSoft 4, were subjected to wet microwave disinfection, and the microwaves do not appear to have affected the lens parameters.

As an in vitro experiment, the study has several limitations. Although diameter, base curve, and refractive power did not appear to have been changed, this does not infer that lens material went unchanged nor that fitting characteristics went unchanged. Further, because of hydrogel lens flexibility, measurement of diameter and base curve by 10X lupe and soft lens analyzer respectively has less than desired accuracy. On the other hand, refractive power measurements are accurate and repeatable, so the data do suggest that microwave disinfection of these four lens types will not change dioptric power.

The experiment successfully created protein deposits similar to what is seen on lenses worn by a human subject, but one cannot extrapolate the data to suggest that an in vivo experiment would provide the same results. A contact lens on a human eye is subject to tear film with protein, mucus, cell debris, electrolytes, bacteria etc. It would also be subject to compression and movement by the eyelids. The ideal experiment would utilize human subjects prone to deposit formation. Each subject would wear lenses of the same type, and the lens of one eye would receive microwave disinfection and the other heat. For

this study, however, it was felt that not enough work has been done to establish the safety of microwave disinfection for human subjects. Thus, the present study represents a good alternative to investigate the question of deposit formation. The findings here suggest that on the above four lens types a wet microwave disinfection system does not lead to greater deposition of proteins than heat.

To review, this study and those cited support further investigation of microwave disinfection. A wet microwave system has the advantage of being fast, easy to learn and perform each day, and inexpensive for anyone owning a microwave oven. Of the lenses currently studied (table 6), most do not appear to be harmed by a microwave process. The exception is the two Vistamarc lenses (high water ionic), in Boltz and Bhoola's study. Microwaves seem to be very effective against microorganisms, and the results here are encouraging in regards to protein deposition. Presently, no major disadvantages have been established. Therefore, the potential advantages to a wet microwave disinfection system make pursuing it worthwhile (table 7).

Development of a microwave disinfection system requires several areas to be more thoroughly investigated. Possibly the greatest obstacle is the variability of patient use. Every microwave oven may be different. Ovens may have hot and cold spots, rotating platforms, different energy outputs, uncalibrated timers, etc. To insure that each patient's lenses receive a

standard minimum exposure time to a certain energy level, considerable research will have to be done concerning the many ovens in use and developing criteria for disinfection at home. One method might be to use a color indicator in solution to signal complete disinfection. In other areas, effectiveness against all likely contaminants must be demonstrated. Specifically, viruses and fungi have not been studied in a wet microwave disinfection system. Expanded study of more lens types is necessary. If certain lens types are not acceptable for microwave disinfection, then proper limitations should be set for its use. As soon as a system is considered safe, clinical studies can evaluate a larger scope of comfort, fitting characteristics, and deposit formation.

CONCLUSION

The data presented do not establish significant disadvantages for microwave disinfection of hydrogel contact lenses. Hydrogel contact lenses of several brands and FDA groups were exposed to microwave disinfection and there appeared to be no harm to diameter, base curve, or refractive power. The same lenses during exposure and disinfection to an artificial "tear" solution of proteins, did not show greater deposition than a matched group of lenses receiving traditional heat disinfection. Previous studies on microwave disinfection have been reviewed and

combined data presented. At this time, a wet microwave disinfection system of a limited number lenses has been shown to be promising. The potential advantages of microwaves (table 7) suggest that such a system is worthy of further investigation.

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Table 1

CHARACTERISTICS OF AN IDEAL HYDROGEL CONTACT LENS DISINFECTION SYSTEM:
=====

1. Effective disinfection of bacteria, fungi, and viruses dangerous to hydrogel contact lens wearers.
2. Compatible with a wide variety of lenses.
3. Low deposit formation.
4. Harmless to lens parameters and fitting characteristics.
5. Good patient comfort.
6. Inexpensive.
7. Convenient.
8. Short disinfection time.
9. Easy to learn and use.

Table 2

ADVANTAGES AND DISADVANTAGES OF CURRENT DISINFECTION SYSTEMS

	ADVANTAGES	DISADVANTAGES
HEAT	Effective Kill Inexpensive Little Instruction	Deposit Formation Requires Electricity Limited Compatability Time of Disinfection
CHEMICAL	Convient Less Deposit Formation Wide Compatability	Expensive Toxic Reactions Less Effective Time of Disinfection
HYDROGEN PEROXIDE	Convient Less Deposit Formation Effective Kill Wide Compatability	Expensive More Patient Instruction Time of Disinfection Discomfort

Table 3

EXPERIMENTAL GROUPS CITED (in numbers of lenses)

FDA Category	Group A	Group B	Group C	Group D
	[10X] Microwave	[Normal] Microwave	[10X] Heat	[Normal] Heat
1. Aquaflex	1	4	1	4
1. Hydron	1	4	1	4
2. DuraSoft 4	1	4	1	4
3. DuraSoft 2	1	4	1	4

[10X]= protein concentration 10 times normal tear solution.
 [Normal]= normal protein concentration of tear solution.

FDA Category 1: Low Water Nonionic
 FDA Category 2: High Water Nonionic
 FDA Category 3: Low Water Ionic

Table 4

LENSES DAMAGED

Group	Lens
=====	
A	DuraSoft 4
B	Hydron
B	DuraSoft 4
C	Aquaflex
C	Hydron
D	Hydron

Table 5

PROTEIN DEPOSIT FORMATION (in grades)

(Grade 0= no deposits, Grade 4= entire lens protein coated)

Group A (10X Microwave)

Lens	Grade
DuraSoft 2	3.0
DuraSoft 4	3.5
Hydron	3.0
Aquaflex	1.0

Group B (Normal Microwave)

Lens	Grade	Grade	Grade	Grade	Mean
DuraSoft 2	*	2.0	2.0	2.0	2.0
DuraSoft 4	1.0	0.0	1.0	2.0	1.0
Hydron	0.0	2.0	2.5	2.0	1.625
Aquaflex	1.0	1.0	0.0	0.0	<u>0.5</u> 1.28

Group C (10X Heat)

Lens	Grade
DuraSoft 2	1.0
DuraSoft 4	3.0
Hydron	2.0
Aquaflex	*

Group D (Normal Heat)

Lens	Grade	Grade	Grade	Grade	Mean
DuraSoft 2	2.0	3.0	3.0	1.0	2.25
DuraSoft 4	2.0	1.0	2.0	*	1.66
Hydron	2.0	3.5	0.0	0.0	1.375
Aquaflex	2.0	*	2.0	2.0	<u>2.0</u> 1.82

* Unable to perform.

Table 6

CONTACT LENSES STUDIED WITH RESPECT TO MICROWAVE DISINFECTION

Lens	FDA Group	Effects	System	Investigator
B & L U4	1	None	Dehydrated	Boltz & Bhoola
B & L 70	2	None	Dehydrated	Boltz & Bhoola
Vistamarc	4	Ripped	Dehydrated	Boltz & Bhoola
Aquaflex	*	None	Dehydrated	Rohrer
CIBA Soft	1	None	Hydrated	Ajello
Permafex	2	None	Hydrated	Ajello
Soft Mate	3	None	Hydrated	Ajello
Nue Vue	4	None	Hydrated	Ajello
Aquaflex Superthin	1	None	Hydrated	This study
Hydron Spin Cast	1	None	Hydrated	This study
DuraSoft 4	2	None	Hydrated	This study
DuraSoft 2	3	None	Hydrated	This study

* Reported as 42.5%

Table 7

POTENTIAL ADVANTAGES AND DISADVANTAGES OF MICROWAVE DISINFECTION

ADVANTAGES	DISADVANTAGES
=====	=====
Effective Kill*	Requires Electricity
Convenient	Requires Microwave Oven
Time of Disinfection	Discomfort*
Little Instruction	
Inexpensive	
Compatibility*	
Deposit Formation*	

* Limited data available.

Figure Legends:

Figure 0. Grade 0 protein deposits under phase contrast microscopy.

Figure 1. Grade 1 protein deposits under phase contrast microscopy.

Figure 2. Grade 2 protein deposits under phase contrast microscopy.

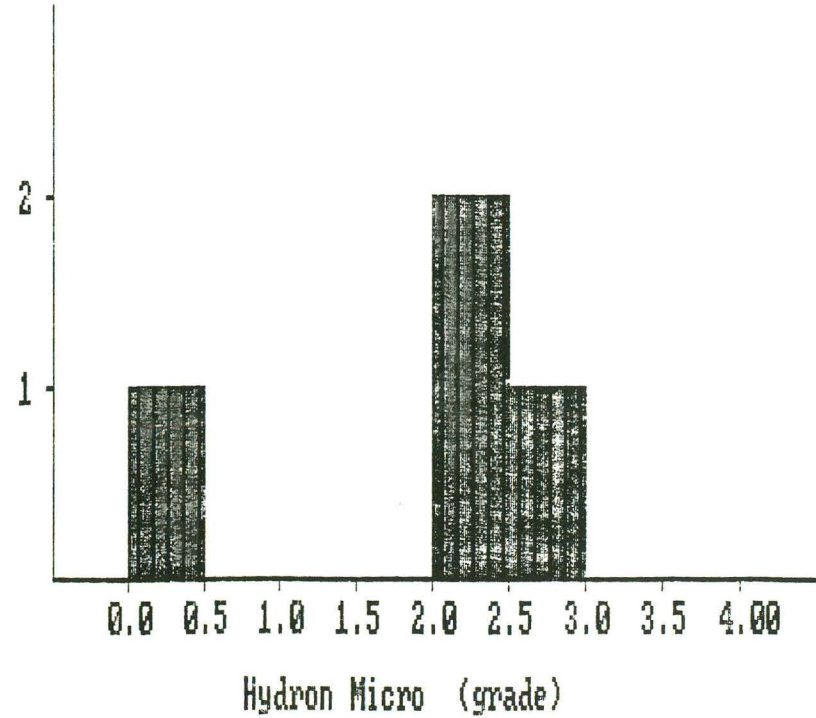
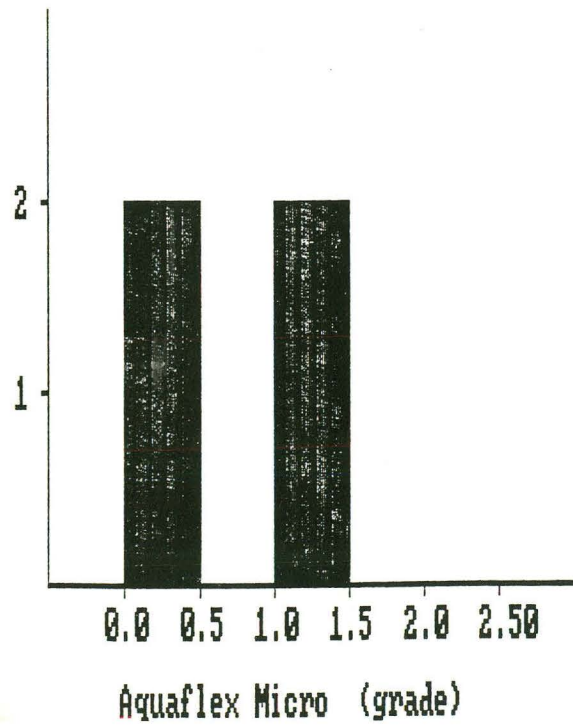
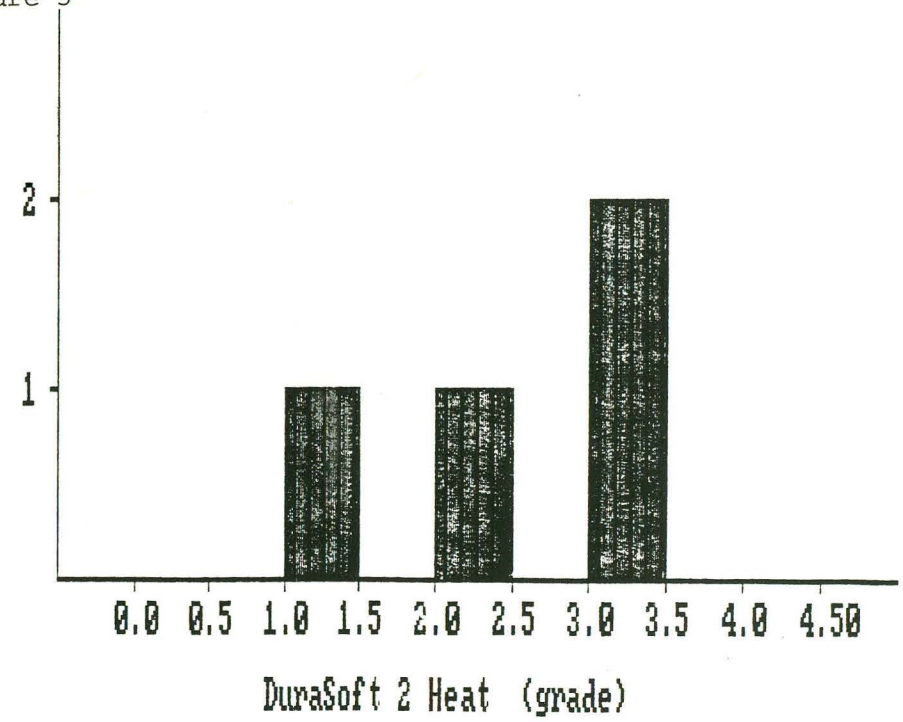
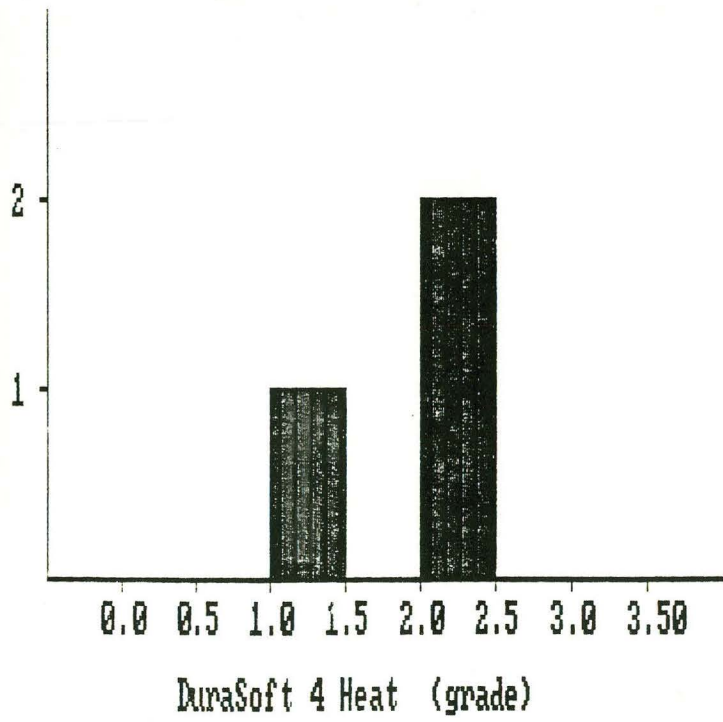
Figure 3. Grade 3 protein deposits under phase contrast microscopy.

Figure 4. Grade 4 protein deposits under phase contrast microscopy.

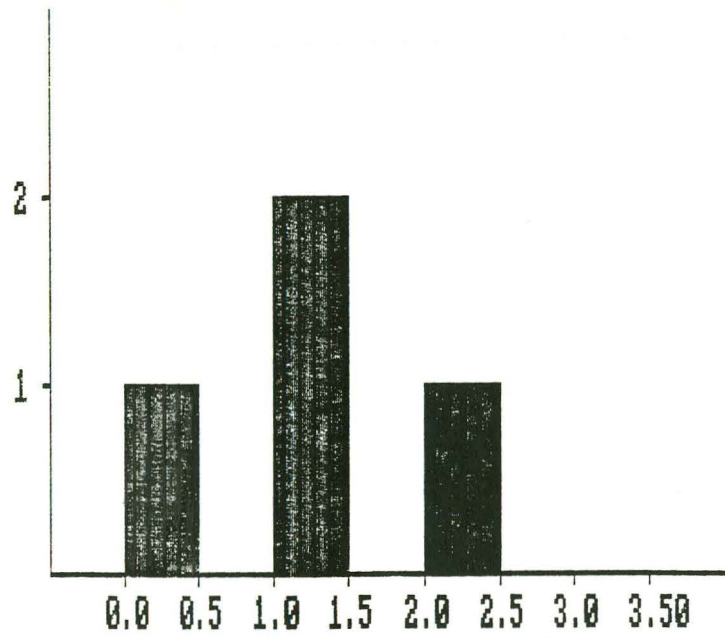
Figure 5. Histograms of the frequency of protein deposit grades for four lenses. Each lens is labeled according to brand and disinfection system.

Figure 6. Histograms of the frequency of protein deposit grades for four lenses. Each lens is labeled according to brand and disinfection system.

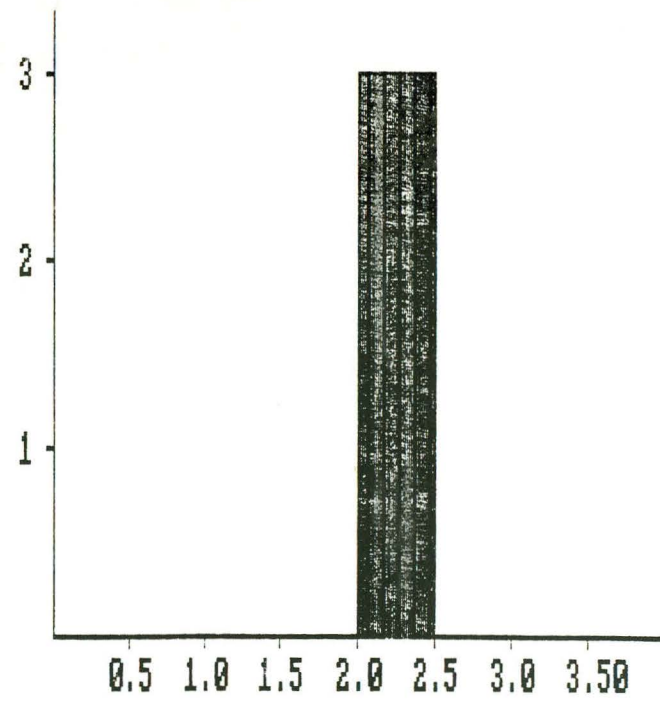
Figure 5



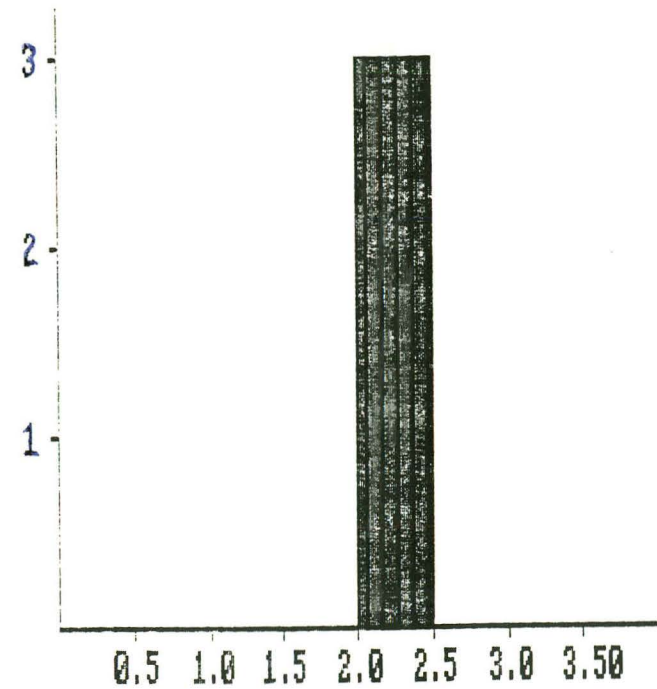
Figure



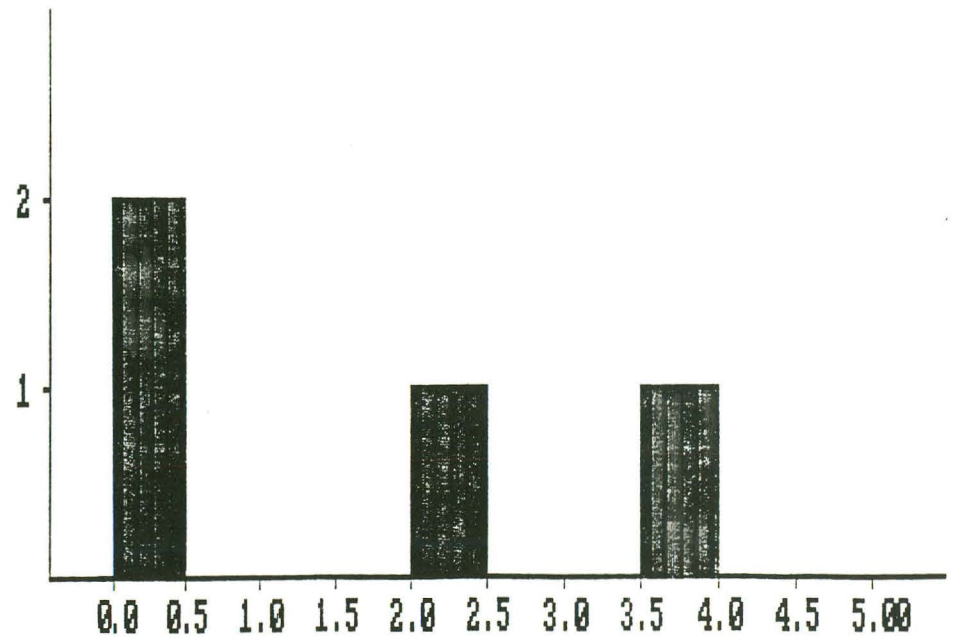
DuraSoft 4 Micro (grade)



DuraSoft 2 Micro (grade)



Aquaflex Heat (grade)



Hydron Heat (grade)

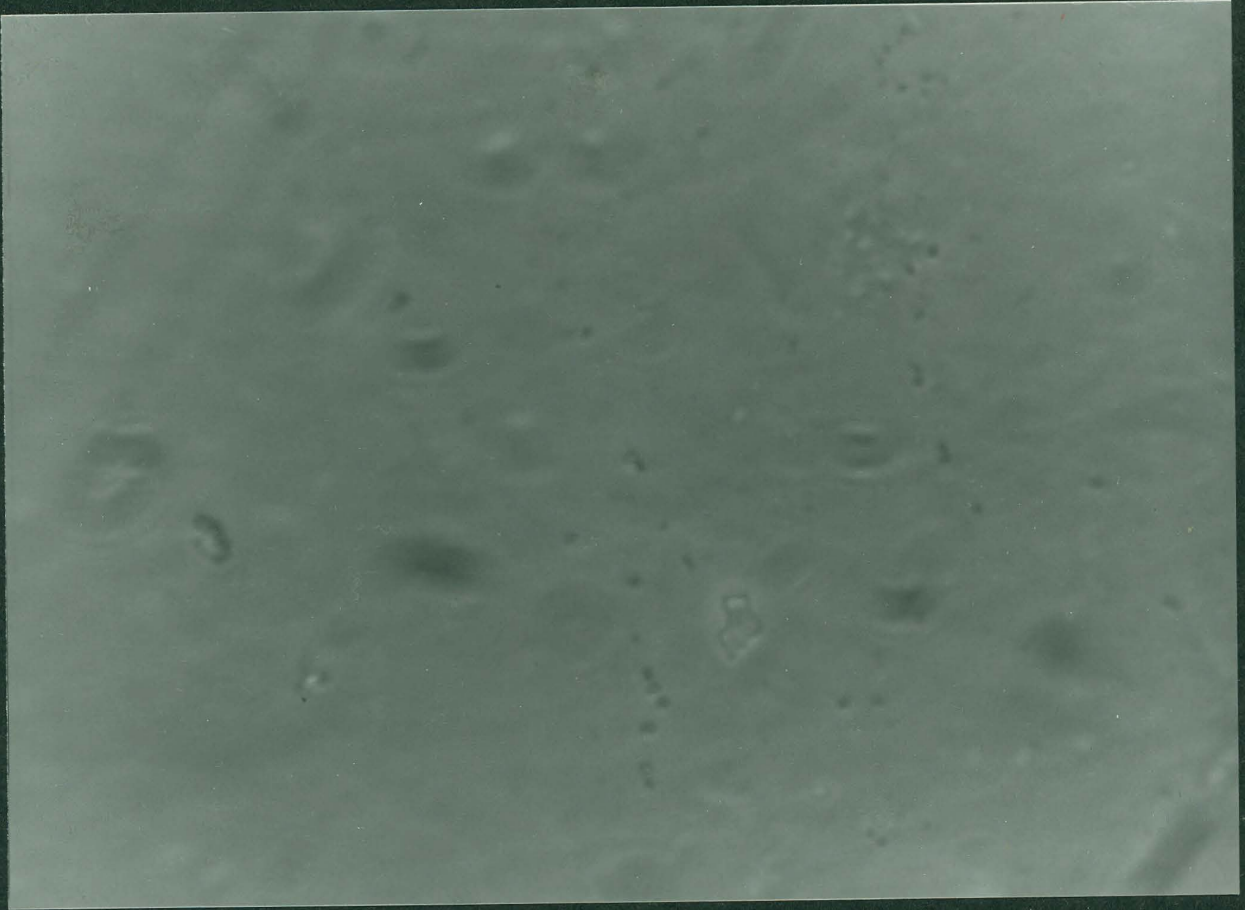


Figure 0. Grade 0 protein deposits under phase contrast microscopy.

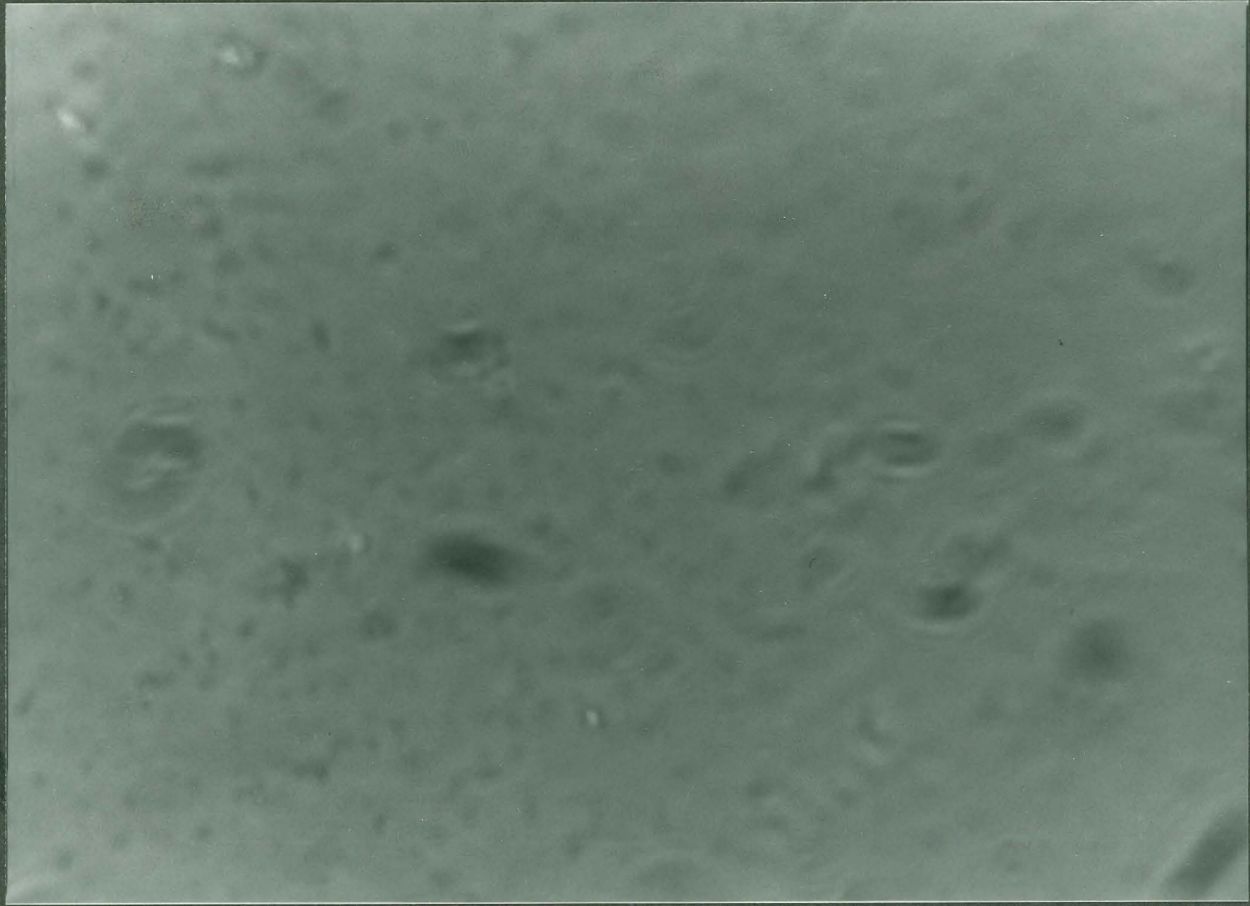


Figure 1. Grade 1 protein deposits under phase contrast microscopy.

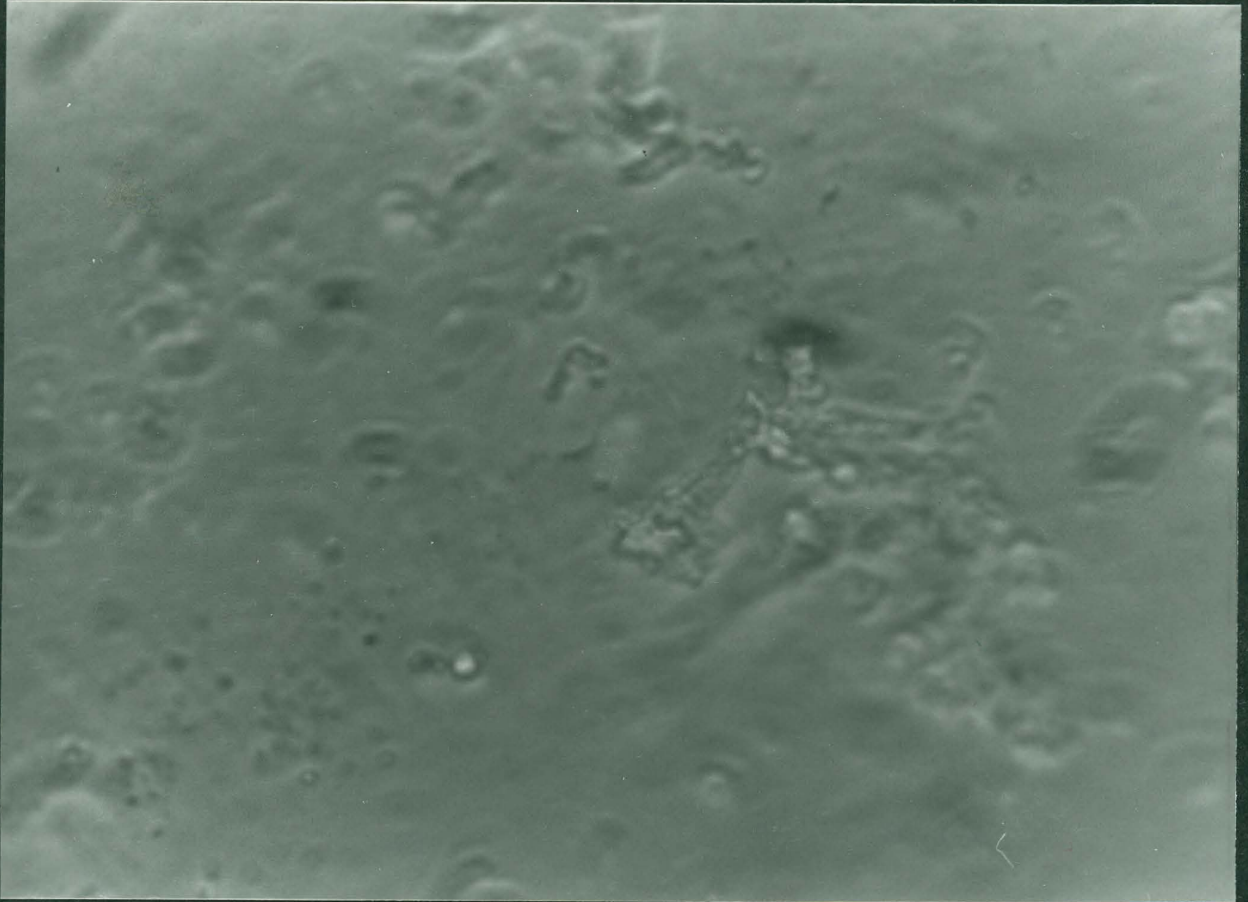


Figure 2. Grade 2 protein deposits under phase contrast microscopy.

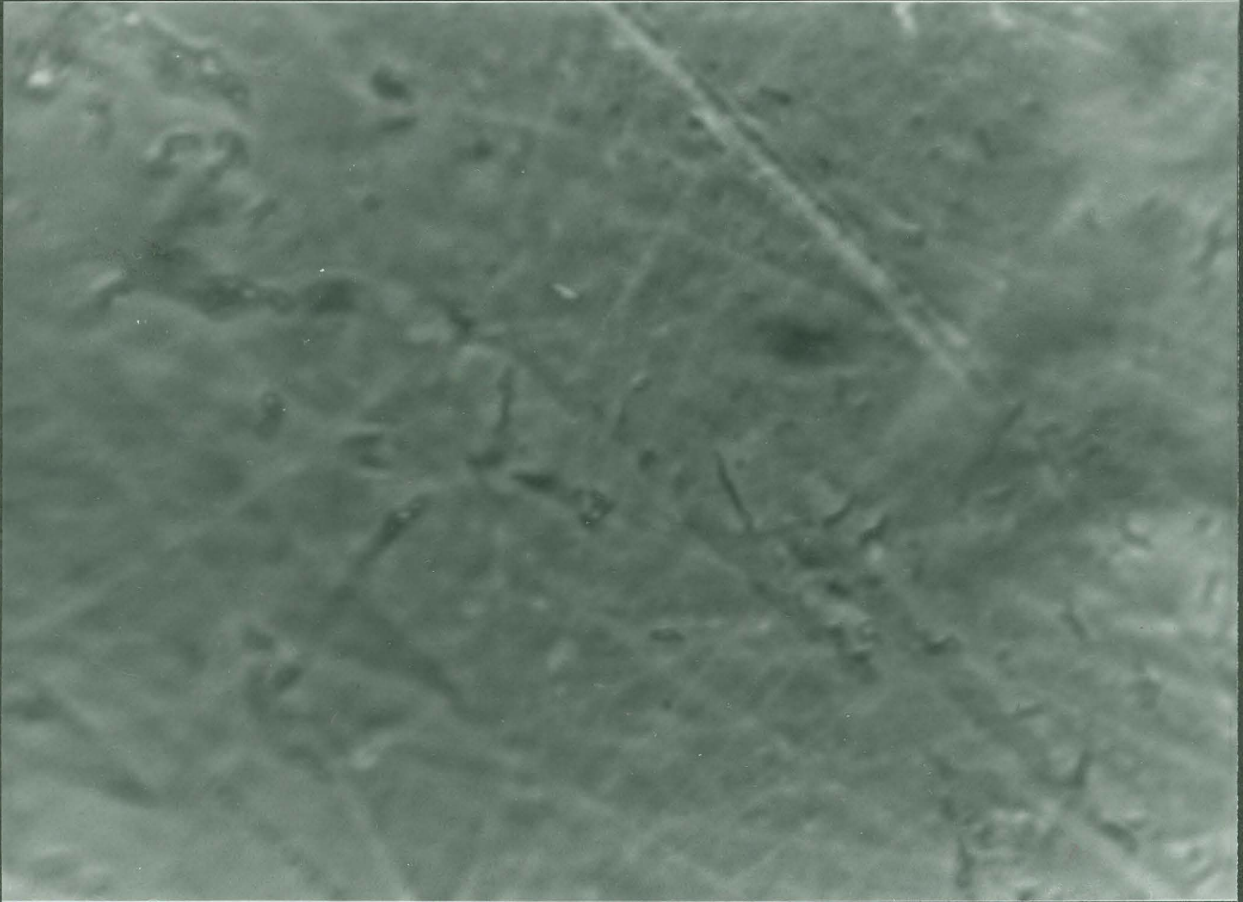


Figure 3. Grade 3 protein deposits under phase contrast microscopy.

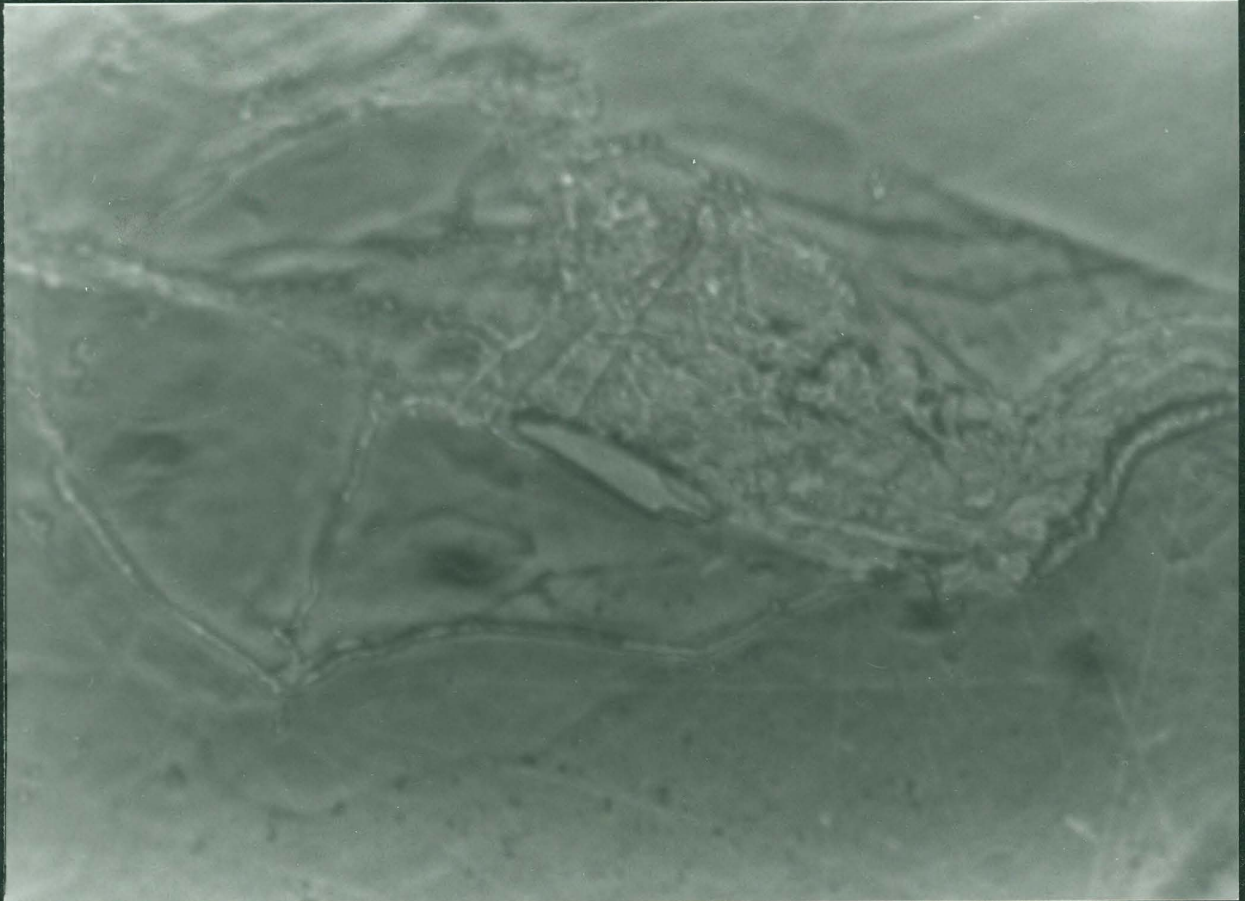


Figure 4. Grade 4 protein deposits under phase contrast microscopy.