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Comparative analysis of variance of several flexible contact lens materials to gas permeability at normal atmospheric pressure relative to state of hydration

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Abstract

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COMPARATIVE ANALYSIS OF VARIANCE OF SEVERAL FLEXIBLE CONTACT LENS MATERIALS TO GAS PERMEABILITY AT NORMAL ATMOSPHERIC PRESSURE RELATIVE TO STATE OF HYDRATION

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and

Frederick W. Martin

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STATEMENT OF PURPOSE

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To comparatively measure the permeability characteristics of various flexible contact lens materials in their commercially available manufacturer form. Specifically, to compare the rates of permeability of naturally occuring gaseous mixture at normal atmospheric pressure and room temperature, and to test the following hypothesis.

1. All lens materials tested have the same rate of permeability.

2. The lenses have the same permeability to mixed gases in the fully hydrated state as they do at five and/or fifteen minutes after exposure to a non-aqueous environment.

3. There is no interaction between specific lens materials and state of hydration, such that some unique combination has differing permeability characteristics from any other combination.

Further, to relate our research to work done by others in the field.

LITERATURE SURVEY

LITERATURE SURVEY

Recent popularity and clinical testing of hydrophilic contact lenses has created a need for basic information on the lens permeability of essential gases and metabolites critical for corneal homeostasis. Contact lens permeability is perhaps one of the most underestimated but important phases of contact lens fabrication, which until recently has been ignored.

Most of the hydrophilic contact lenses are larger than the cornea, and the lens is fixed at its periphery on the corneal limbus or the perilimbal conjunctiva. Polse and Mandell have shown that the human cornea needs from 11 to 19 mm. Hg. oxygen tension under the contact lens to maintain normal thickness and corneal metabolism. A well fitting firm lens (P.M.M.A.) provides 20 mm. Hg. oxygen tension due to tear flow oxygen exchange. A conventionally thick firm lens is impermeable.[7] Fatt has shown that the oxygen uptake rate (consumption) of the cornea decreases directly proportional to the decrease in oxygen tension at the corneal surface.[3] Under these conditions, therefore, tear exchange under the flexible lens is not as effective as in hard contact lenses. Therefore, we have a problem. How does oxygen get to the cornea of an eye fit with a flexible contact lens? Many authors surveyed originally thought that the hydrogel lenses allowed enough oxygen to be permeated through to satisfy the corneas' needs.[1,4,11] Later research has proved them wrong. Since edema does not pose as great a problem with flexible lens wears as compared with hard lens wearers; another avenue for oxygen uptake must be occuring. Typical hydrogel contact lenses supply, through their permeability, about 50% of the oxygen needed for maintaining satisfactory corneal integrity.[9] The other 50% of the needed oxygen is now thought to be supplied by the pumping action of the lids as the patient blinks and the lens is flexed in an anterior-posterior direction. Hill has shown that hydrogel lenses, such as Bausch & Lombs' Soflens, do interfere with normal oxygen uptake rates the same as P.M.M.A. materials.[5] Hill concludes that the fitting of hydrophilic plastic lenses will depend as vitally on adequate tear exchange by lid and eye movements as is the case for conventional plastic lenses, and that "insignificant" oxygen diffuses across these lenses to meet normal epithelial needs. The one exception seems to be the silicone lens, which early reports state as being sufficiently oxygen permeable to supply all of the corneas' needs.[11] Interestingly enough, while the silicone lens has the greatest oxygen permeability, the Bausch & Lomb Soflens has the lowest oxygen permeability of the commercially available flexible lenses. Edelhauser, Fatt, and Mandell agree that there is considerable variation in the oxygen permeability of the available commercial flexible lenses.[3,8,9] In general, the lenses with the highest water content have the best oxygen permeability.

Morrison and Edelhauser did extensive permeability testing and their work appears at this time to be the most authoritative.[9] They report all the various commercial soft lenses being more than adequately permeable to sodium ions as well as to chloride ions. Calcium ion permeability is adequate with all lenses as well, with the exception of the Bausch and Lomb Soflens which has a somewhat lower than desirable calcium permeability factor. This fact, coupled with Bausch & Lombs' low oxygen permeability and lower water uptake, makes a serious drawback for that lens.

Spinel reports that molecules of substances such as water, urea, glucose and sodium chloride, as well as sodium fluorescein and carbon dioxide are small enough to diffuse into and out of the interconnecting spaces in the matrix, thus permeable.[11] However, other substances with larger sized molecules, such as proteins, viruses and bacteria, cannot penetrate the lens structure. Spinell also reports that some substances have an affinity for the polymer matrix of the flexible lens.[11] Particularly, the -OH group of the contact lens polymer is believed to bond with the ionic or polar components of preservatives such as benzalkonium chloride. Fluorescein also has an affinity for the polymer of the hydrophilic lens. The literature lists two consequences of this affinity; first, discoloration of the lens, leading to such effects as lowered VA, discomfort, etc., and second, such discoloration gives misleading cornea/lens relationship evaluation.[11]

The permeability characteristics of soft contact lenses are undoubtedly important to the effects of the lenses on corneal physiology. The permeability may also be influential in determining the acceptable handling, sterility, and durability characteristics of these lenses.[9] An interesting point seems to be that the various lens' permeabilities confirm the observed hydrophilic properties of these hydrogel lenses. Permeability characteristics of a particular lens may be affected by the lens thickness and the state of hydration.[2] The diffusion rate of a particular substance through a lens is not only influenced by the molecular weight, but probably invokes the ionic charge of the molecule and other unknown factors. As far as the authors of this study could discover, the actual pore size of the various soft lens materials has not yet been accurately determined. The authors of this paper were also unable to find a "comparative" study of permeability characteristics of various hydrogel lens materials to gas mixtures.

APPARATUS AND MATERIALS

APPARATUS AND MATERIALS USED

The following represent the major components used in this study.

1. Flexible Contact Lenses (commercially available):

   a. Bausch & Lomb Soflens
   b. Ophthalmos Contact Lenses
   c. N & N Flexible Lenses

2. Rigid Contact Lenses (P.M.M.A.)

3. Sealants:

   a. Petroleum based stopcock grease
   b. Mercury
   c. Stopcocks

4. Plexiglass 'contact lens seat'

5. Open end manometer (plastic tubed)

6. Calibration rod (mms.)

PROCEDURES AND METHODS

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A major portion of this study involved the fabrication of the apparatus. It was found that the most suitable apparatus for such a "comparative" study was a plexiglass "contact lens seat", combined with an open end manometer.

Five mm. plastic tubing was used in the manometer. Both ends of the manometer were left open. The manometer had the contact lens seat separating each end.

The contact lens seat was lathed from a 2.5 inch plexiglass rod. The housing consists of an upper portion which funnels the gas mixture to the contact lens, which is mounted on a lathed seat, located in the lower portion of the housing. Under the lens was lathed an "inverted" funnel tract, which lead to the start of the open end manometer. A calibration rod was mounted adjacent to the distal end of the manometer, calibrated in mms.

Two controls were utilized. A stopcock was used in the proximal portion of the manometer. This was used in order to test for any leakage of gas through the contact lens housing. Conventional P.M.M.A. lenses were used as a second control. Since conventionally thick P.M.M.A. lenses are gas impermeable, any leakage through the housing and the stopcock was surveyed. No leakage from either control was seen to occur.

The lenses were placed in the seat, in the lower housing portion. Two sealing procedures were used. The first involved the use of a mercury seal. This was found to be unsatisfactory. It was found that the best seal was the use of O-rings and stopcock grease, combined with securing the upper and lower portions of the housing together with machine bolts. No leakage was seen to occur.

On release of the stopcock, gas was allowed to enter the proximal portion of the manometer through the upper portion of the gas funneling housing and in contact with the lens. Any gas which the lens allowed to permeate was passed down the inverted funneling tract in the lower housing portion through the manometer and displaced the manometer water equilibrium level, and the displacement was noted on the calibration rod.

Five 3-minute trials of each lens at three states of hydration was made. A two-way analysis of variance with interaction at the .99 confidence level was performed on the data.

DATA

DATA

The following data represent mm displacement in an open end manometer at normal atmospheric pressure and room temperature over a trial period of three minutes.

Control: Five trials on PMMA lenses, all showing no permeability.

Part I: Lens in a Hydrated State, immediately after removal from an aqueous environment.

	N and N	Bausch & Lomb	Ophthalmos
1.	12.1	9.5	8.2
2.	12.3	10.2	7.9
3.	11.6	9.3	9.0
4.	11.1	9.3	8.7
5.	12.7	10.1	8.0

Part II: Lens Exposed Five Minutes from a Hydrated State.

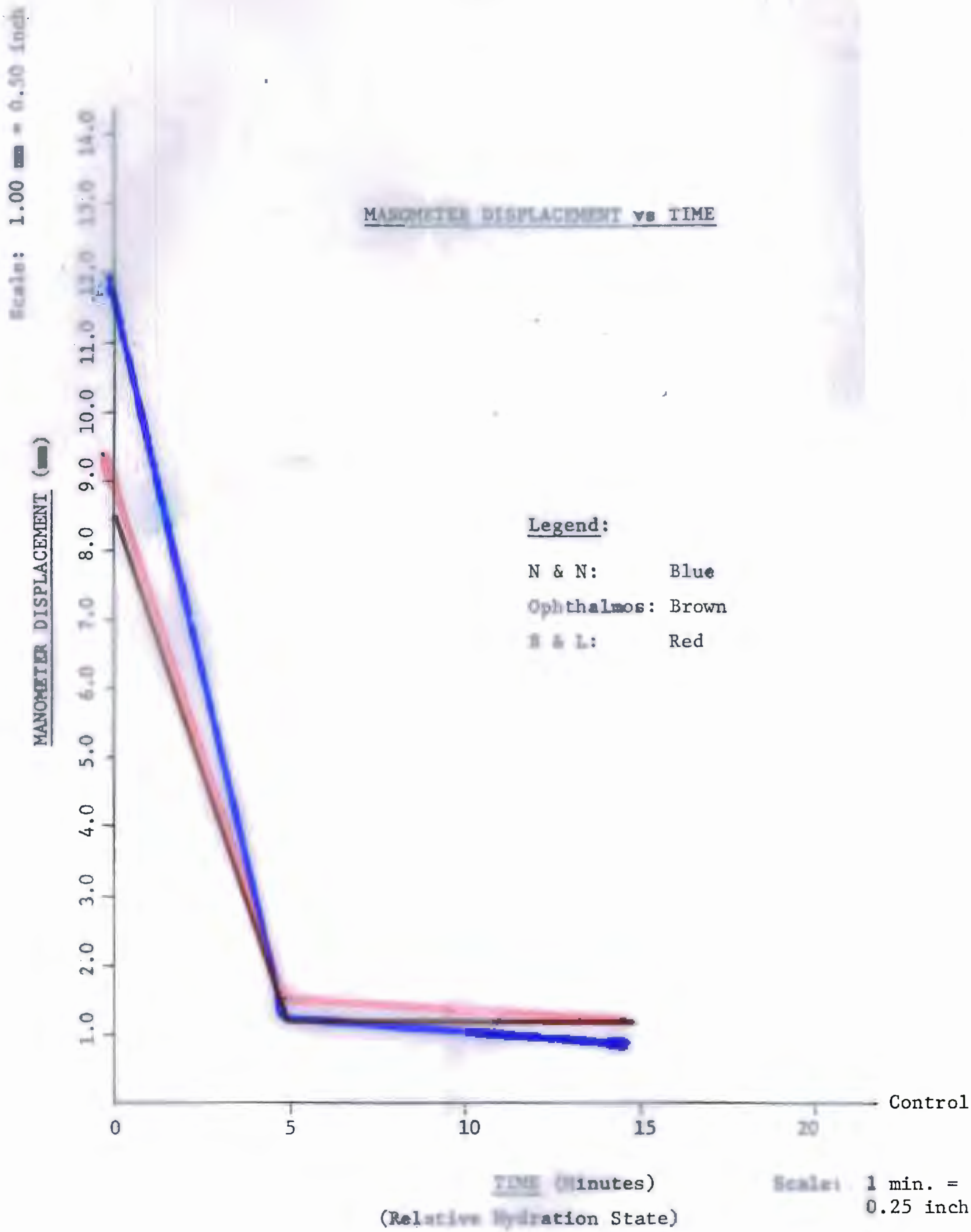
	N and N	Bausch & Lomb	Ophthalmos
1.	1.1	2.0	.9
2.	.8	1.3	.6
3.	1.6	1.1	1.4
4.	1.3	1.5	1.6
5.	1.0	1.7	1.0

DATA (continued)

Part III: Lens Exposed Fifteen Minutes from a Hydrated State.

	N and N	Bausch & Lomb	Ophthalmos
1.	1.1	1.2	1.3
2.	.6	1.5	.6
3.	1.9	.9	1.2
4.	.9	.8	.9
5.	1.0	1.6	1.3

GRAPHS


MANOMETER DISPLACEMENT vs TIME
Scale: 1.00 mm = 0.50 inch
MANOMETER DISPLACEMENT (mm)
1.0
2.0
3.0
4.0
5.0
6.0
7.0
8.0
9.0
10.0
11.0
12.0
13.0
14.0
Legend:
N & N: Blue
Ophthalmos: Brown
S & L: Red
Control
0
5
10
15
20
TIME (Minutes)
(Relative Hydration State)
Scale: 1 min. = 0.25 inch

ANALYSIS AND RESULTS

ANALYSIS AND RESULTS

Analysis of Variance (Two Way) with Interaction:

Null Hypothesis One: All lens materials tested have the same rate of permeability.

Null Hypothesis Two: The lens materials tested have the same permeability characteristics in the hydrated state as they do five and/or fifteen minutes after exposure to air.

Null Hypothesis Three: Interaction between lens materials and state of hydration does not affect permeability.

Lens Materials (Manufacturer)	= Blocks
State of Hydration (Time)	= Trials
Experimental Trial	= Elements
Level of Confidence	= .99 (α = .01)

BLOCKS

TRIALS	N and N	Bausch & Lomb	Opthalmos
Part I	12.1, 12.3, 11.6, 11.7, 12.7	9.5, 10.2, 9.3, 9.0, 10.1	8.2, 7.9, 9.0, 8.7, 8.0
Part II	1.1, .8, 1.6, 1.3, 1.0	2.0, 1.3, 1.1, 1.5, 1.7	.9, .6, 1.4, 1.6, 1.0
Part III	1.0, .6, 1.9, .9, 1.0	1.2, 1.5, .9, .8, 1.6	1.3, .6, 1.2, .9, 1.3

Formulas used in calculations follow on next page.

Formulas:

$$SST = \sum_{i=1}^{k} \sum_{j=1}^{n} \sum_{n=1}^{r} X_{ijn}^2 - \frac{1}{knr} \cdot T^2...$$

$$SS(Tr) = \frac{1}{nr} \cdot \sum_{i=1}^{k} T_i^2 - \frac{1}{knr} \cdot T^2...$$

$$SSB = \frac{1}{kr} \cdot \sum_{j=1}^{n} T_j^2 - \frac{1}{knr} \cdot T^2...$$

$$SSI = \frac{1}{r} \cdot \sum_{i=1}^{k} \sum_{j=1}^{r} T_{ij}^2 - \frac{1}{knr} \cdot T^2 - SS(Tr) - SSB$$

$$SSE = SST - SS(Tr) - SSB - SSI$$

Source of Variation	Degrees of Freedom	Sum of Squares	Variance	F
Treatments	2	530.595	265.297	47.329
Blocks	2	13.1968	6.598	1.177
Interaction	4	63.6248	15.906	2.837
Error	36	201.794	5.605	
Total	44	809.21		

For: Treatments, $F_{.01} = 5.30$ therefore F is significant.

Blocks, $F_{.01} = 5.30$ therefore F is not significant.

Interaction, $F_{.01} = 3.94$ therefore F is not significant.

Therefore the following Null Hypothesis can/cannot be rejected:

Null Hypothesis One cannot be rejected.

Null Hypothesis Two can be rejected.

Null Hypothesis Three cannot be rejected.

CONCLUSION

CONCLUSION

Of the materials tested we can conclude that although there appear to be differences in permeability by observations of the findings in graphical form, these differences are statistically insignificant at the .99 confidence level. There is a significant difference, however, between these flexible lens materials in the hydrated state and shortly after removal from an aqueous environment. Loss of permeability falls off rapidly as can be seen from analysis of the data graphically. There is no significant interaction between any particular combination of materials and state of hydration affecting permeability.

It is beyond the scope of this study to state definitively that these lens materials permit the transmission of gases at sufficient rates to carry on normal physiological processes for homeostasis of the cornea per se. However, previous work by others coupled with our acceptance of the hypothesis that these materials have the same rate of permeability (to a .99 confidence level) would lend evidence to a hypothesis that none of these materials has clinically significant permeability characteristics.

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