CANADIAN OPTOMETRIC CONTACT LENS SOCIETY — La SOCIETE OPTOMETRIQUE CANADIENNE des LENTILLES CORNEENNES

The Effect Of Freeze/Thaw Conditions On Hydrogel Lens Posterior Apical Radius And Surface Quality

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Abstract

Twenty-six hydrogel lenses of identical parameters were subjected to twenty-five freeze/thaw cycles and periodically checked for base curve sagittal depth and surface quality. A matched group of lenses served as an untreated control. The results indicated the treatment group gave more stable measurements than the control group. No surface defects were apparent after twenty-five cycles. It may well be that the freeze/thaw cycle relieves the internal stress created by machining a complex polymer. We are confident that hydrogel lenses of simple HEMA formulations when subject to freeze/thaw conditions, are unharmed.

Abrégé

On a soumis 26 lentilles hydrogel de même composition et de même paramètres à 25 cycles de gel/dégel. A intervalles régulières on a vérifié les rayons de courbure et la qualité des surfaces. Un nombre égal de lentilles semblables ont servi de control sans subir les cycles de gel/dégel. Le groupe expérimental a manifesté plus de stabilité dans ces deux paramètres que le groupe de control. Il est possible que le cycle gel/dégel dissipe les contraintes internes résultantes des procédés d'usinage dans la fabrication. L'auteur est confiant que les lentilles hydrogel s'en tirent indemnes d'un cycle gel/dégel.

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Introduction

The literature on hydrogels describes the effect of temperature variation on these materials.[1,2] Many articles on the outcome of temperature change on hydrophilic lenses concentrate on the result of increasing the temperature of the environment.[3,4] Rarely have clinicians or researchers published the aftermath of severely reduced temperatures, on hydrogel lenses.[5] There is a legitimate concern for reduced temperatures, for many practitioners have received soft lenses in a frozen state. Since manufacturers, distributors, and clinicians exist in climates subjected to freezing temperatures, often for protracted periods; it is entirely possible for a lens to pass through one or more cycles of freeze-thaw in transit from someone's inventory to the consumer. We therefore asked the question "What happens to a pristine lens immersed in a saline filled vial when subject to a series of freeze-thaw cycles?"

Does the freezing of the free and bound water within the lens cause a permanent change in the lens parameters?

Does the expansion and contraction of water when passed through the freeze/thaw cycle, affect the surface integrity?

Method and Materials

Fifty-two soft lenses, all of the same material and having the same label values were taken from our experimental lens inventory. All lenses were manufactured by machining by the same operator. This operator was also responsible for hydration and measurement of the lenses. The lenses were divided into two groups (treatment and control), and were remeasured prior to treatment by a different operator using identical equipment. Two lens parameters were selected for analysis. Base curve was selected since our measurement equipment is considered very precise and highly reliable. The base curve was measured using the Panametric ultrasonic transducer (as modified by American Optical) and temperature control within 2° centigrade* was insured during the measurement task. The other parameter evaluated was surface quality. It was felt that repeated expansion and contraction of the polymer could create surface defects visible at low magnification. Therefore, an American Optical Microstar steremicroscope was used at 15X magnification to inspect the lens for surface defects.

The freezing was accomplished in a standard household freezer (approximately -3° centigrade) for twenty-four hours. The lens was kept in a vial in 5 ml of saline. Following the freeze cycle the lens was stored at room temperature for twenty-four hours and then recycled. After five complete cycles the lenses were remeasured. On the same day the control lenses which had been standing untouched at room temperature were also remeasured. When measurement was completed the lens

*Cell temperature for ultrasonic measurement was maintained at 23° centigrade ± 1°.

was returned to its vial and fresh saline added. After analysis of the data the lenses were returned for five more cycles (a total of ten), and the measurement technique repeated. The lenses were once again returned to the freeze/thaw environment for fifteen more cycles (total of 25). A final analysis was then made.

Results

The lens used was an investigational one made of an approved polymer of 55% water content. Prior experience with this material led us to anticipate a slight steepening of the base curve over time when a lens stood unattended. Figure 1 is a graph of the control group mean sags measured ultrasonically over a period of almost four months. These lenses were subjected to fluctuations in room temperature over a maximum of 2° centigrade. The increasing sag height (change from 0 cycles to 25 cycles is + .036 mm or slightly in excess of 0.1 mm steeper in base curve radius) is as expected.† Note also the increasing variability of the measurements with time (the limit bars of the graph represent one standard deviation). A student "t" test between the 0 cycle mean and 5 cycles mean rejects the null hypothesis ($t = 4.84$: $P > .001$, df = 24) indicating a significant difference between the means. The control lenses of 5 cycles do not appear to be from the same population as the control lenses of 0 cycles. This represents about one month of standing time.

Figure 2 is the same display of the results for the treatment group. In contrast to our control lenses there is a pronounced stability for base curve measurements, and if any trend; one slightly toward a flatter base curve. Variability of measurements seems unaffected and a "t" test between 0 cycles and 5 cycles accepts the null hypothesis that these lenses are from the same population ($t = -0.33$: p = N.S., df = 24) or not significantly different.

†Tests of reliability for this instrument and this polymer allow acceptance of a single reading at the 95% confidence level within a range of ± .015 mm of sag. (AO report J1-1218 L.E. Janoff).

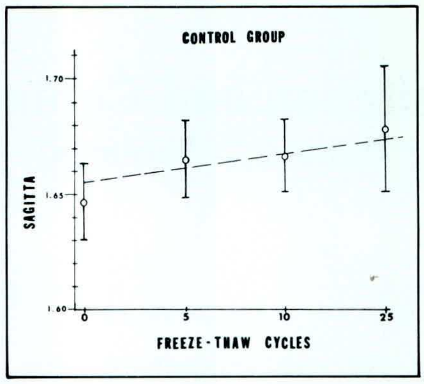

Figure 1: Base Curve Means and Standard Deviations of Untreated Control Lenses Measured at Same Time as Treated Lenses.

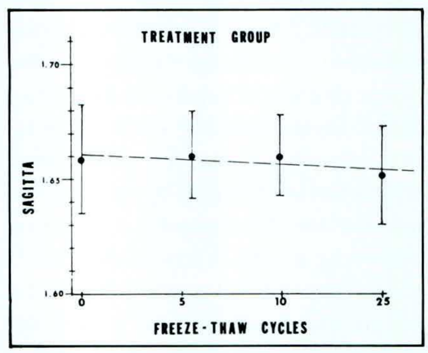

Figure 2: Base Curve Means and Standard Deviations of Freeze/Thaw Treatments for Up to 25 Cycles.

Examination of lenses with the microscope at all stages was unremarkable. One lens from the treatment group showed a surface scratch from handling after ten cycles, and it was no worse after twenty-five cycles.

Discussion

It is quite clear from this investigation that for the hydrophilic polymer tested, twenty-five cycles of freezing and then thawing had no damaging effect upon the lens. No surface defects were visible. Although we did not test all the material properties, the handling quality for treated lenses seemed no different than those of the untreated controls. The lens base curve was essentially unchanged by the twenty-five freeze/thaw cycles. However, for this polymer the stabilization of base curve represented an unusual condition. It is suspected that, simple, HEMA formulations will be unefected by freeze/thaw conditions. It is our new hypothesis that complex copolymers of HEMA will be stabilized by freezing. The expansion and contraction the lens undergoes during the freeze/thaw cycle could relieve internal stress in a lens created by the machining process. Under the usual conditions of gradual hydration without agitation as applied to our control lenses, the slow relief of internal stress results in a shortened base curve radius (and probably a smaller diameter as well).

It is our suspicion that freezing for even a lengthly period has no detrimental effect upon a simple hydrogel of HEMA. Complex HEMA copolymers might benefit from freezing for it may relieve machining stresses quickly and produce a more stable product. Whether this applies to other hydrogels (pyrollidones, acrylamides, etc.) needs to be tested. How other polymer characteristics or lens parameters respond to freezing might also be studied. We at least feel more confident when we say that a HEMA lens the dispenser receives frozen in the vial, can be thawed and used without fear of the consequences. Just let it thaw at room temperature and dispense it with the confidence that it is unadulterated.

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