ABSTRACT: Purpose. To test the design of a patient care regimen for soft lenses that aims to provide the highest standards of disinfecting through use of domestic microwave cookers, while also providing storage equipment and solution that enable patients to follow a conventional cold disinfecting regimen when traveling. The cleaning efficacy of surfactant agents during microwave treatment was also considered. Methods. The microbiologic performance of the regimen and its disinfecting apparatus was tested according to the Food and Drug Administration (FDA) protocols for contact lens heat disinfectors. Subsequently, a prospective pilot clinical trial of the regimen involving 15 subjects was carried out to the protocols of the FDA and International Standards Organization 11,980:1997. Results. Lenses inoculated with 10^7 colony-forming units (cfu) of Enterococcus faecalis were disinfected to 0 cfu by a 12-s irradiation of a compact disinfecting case that held the lenses suspended in 12 ml saline. A proof of operation indicator performed correctly for all 10 cases tested. No adverse reactions were found in the pilot patient trial, using Renu multipurpose (Bausch & Lomb, Rochester, NY) as the test solution, and no statistically significant difference was found between test and control groups in respect of any sign. However, the greater incidence of edema, palpebral hyperemia, and lens front-surface deposition in the microwave test group may be clinically significant. Conclusions. The design of the test care regimen proved easy for patients to follow in either hot or cold disinfecting mode. The greater incidence of certain signs in the microwave test group suggests the need to continue using a rub and rinse step for the microwave mode and for additional investigation into the choice of an appropriate multipurpose solution formulation for this proposed regimen, preferably one that does not use a block copolymer-type surfactant agent. (Optom Vis Sci 2004;81:471–477)

Key Words: microwave, disinfecting, hydrogel contact lenses, microbiology, patient trials

Market trends indicate that although the use of daily disposable and extended-wear hydrogel lenses continues to grow, a majority of patients in the U.K. are still using monthly and fortnightly replacement brands. Although present patterns of lens wear may be regarded to be in a period of transition, the use of lenses requiring adjunct systems of lens care continues to invite consideration of more efficacious systems, particularly for monthly replacement lenses. The authors have already reported on the efficacy of a patient-operated system of microwave disinfecting of hydrogel lenses using physiologic saline solution. The principal advantage of microwave treatment is that it achieves a complete rather than partial kill of all challenge organism cells in the lens, the daily solution supply, and the storage case. The reliability of heat compared with chemical disinfecting is attested in the form of the international standards for contact lens disinfection. These require a pasteurizing device to prove itself by killing all cells of just a single challenge microorganism, whereas chemical systems need to demonstrate a variety of log reductions in the cell populations of at least six different challenge species. The principal concern about microwave treatment has been its effects on lens polymers properties and on the level of lipid deposition. Subsequent testing of lens parameters suggests that the physical properties of the majority of lens brands are not adversely affected by repeated microwave treatment. As for lens deposition, it has been necessary for patients to rub and rinse lenses before microwave treatment because the treatment is a disinfecting rather than a cleaning one and the saline solution used contains no surfactant agents. This leads to consideration of whether the inclusion of a suitable cleaning agent in the solution may help reduce lens deposition. Another concern about the microwave care regimen is that patients who travel fairly frequently find that they cannot follow it consistently and therefore need to follow a second care regimen when traveling. For purposes of clinical consistency and patient convenience, it would be better to use a common solution rather than a mixture of different kinds. A common solution could then offer a dual mode of use: (1) a hot disinfecting method for best cleaning and disinfecting results; and (2) a cold disinfecting system for acceptable cleaning and disinfecting in sit-
The second option would depend on using a solution that was already proven efficacious as a stand-alone multipurpose solution. For ease of use, it would also be important to ensure that the microwave treatment cases were as compact and portable as those used for chemical systems. Accordingly, the present work set out to investigate how feasible it would be to make these improvements through a redesign of the basic features of previous microwave care regimens. To this end, a standard polyhexamethylene biguanide (PHMB) preserved multipurpose solution was chosen to be the common solution for this dual-mode care regimen, and adaptations were made to an existing form of storage case to permit microwave treatment. Preliminary testing showed that the microwave heating of multipurpose solutions using surfactant agents, mostly block copolymers of the BASF Pluronic family (Mount Olive, NJ), produced vigorous flocculation as the solution temperature came to 100°C. At that temperature, a column of foam rose rapidly above the solution and, in the case of Renu (Bausch & Lomb, Rochester, NY), forced about 4 ml solution out of the vent caps in the selected storage case, even when the microwave was immediately switched off. By contrast, Opti-Free (Alcon, Ft. Worth, TX), which uses sodium citrate as a cleaning agent, produces the least flocculation, forcing only about 0.5 to 1 ml out of the case, whereas use of preserved saline solution led to no such losses. It was then decided to further investigate whether this flocculation could obviate the rub and rinse step, with which at least 30% of patients apparently fail to comply.9

The testing of this design approach comprised three parts: (1) testing of the performance of a vented contact lens case with a seal device that indicates proper disinfesting temperature has been achieved; (2) testing microbiologic performance following the U.S. Food and Drug Administration’s (FDA) recommended protocols;3 and (3) pilot patient trials of the system following FDA and International Standards Organization (ISO) 11,980:1997 recommended protocols.10 Whereas the object of the first two tests was to meet the full standards requirements, the object of the clinical trial was limited only to a pilot test, using fewer patients than required by the standards protocols. All three tests were conducted prospectively, and the patient trials assessed whether patients following the microwave regimen would present with significantly more clinical losses. It was then decided to further investigate how feasible it would be to make these improvements through a redesign of the basic features of previous microwave care regimens. To this end, a standard polyhexamethylene biguanide (PHMB) preserved multipurpose solution was chosen to be the common solution for this dual-mode care regimen, and adaptations were made to an existing form of storage case to permit microwave treatment. Preliminary testing showed that the microwave heating of multipurpose solutions using surfactant agents, mostly block copolymers of the BASF Pluronic family (Mount Olive, NJ), produced vigorous flocculation as the solution temperature came to 100°C. At that temperature, a column of foam rose rapidly above the solution and, in the case of Renu (Bausch & Lomb, Rochester, NY), forced about 4 ml solution out of the vent caps in the selected storage case, even when the microwave was immediately switched off. By contrast, Opti-Free (Alcon, Ft. Worth, TX), which uses sodium citrate as a cleaning agent, produces the least flocculation, forcing only about 0.5 to 1 ml out of the case, whereas use of preserved saline solution led to no such losses. It was then decided to further investigate whether this flocculation could obviate the rub and rinse step, with which at least 30% of patients apparently fail to comply.9

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**METHODS AND EQUIPMENT**

**Storage Case**

The case was an adaptation of a standard barrel case design for use in a peroxide regimen, in which a metal catalyst or tablet is inserted to neutralize the peroxide. The case used is manufactured by Bonasse Enterprises (Taipei, Taiwan), and as illustrated in Fig. 1, the case design is typical in flaring outward toward the cap to create a gap for expanding gases, and the cap of the case is vented by small perforations to allow their escape. A silicone rubber washer, with a central hole that allows the washer to be fitted around the lens carrier stem fixed under the cap. When the cap is screwed onto the case, this washer fits against the walls of the case in such a way as to separate the case into two chambers, one above the seal and one below.

In operation, the lower chamber holds the lenses and solution, and the upper holds ambient air. When the case is irradiated, the pressure of heated water vapor forces the edges of the dividing seal upward, allowing the vapor to escape from the lower to the upper chamber, where it may then be vented in the normal way through the valves and vents in the cap. Once the irradiation has finished, the vapor still trapped in the lower chamber starts to cool and condense. The condensation creates a partial vacuum that draws the edges of the seal far below the line at which it seats itself when screwed on, and down into the lower chamber. The seal then provides a visual indication to the patient that the correct operating temperature had been reached. A failsafe performance indicator is essential to any medical device accreditation for heat disinfector apparatuses.11 This was provided in the present design by a 2-mm-thick circular silicone rubber washer, with a central hole that allows the washer to be fitted around the lens carrier stem fixed under the cap. When the cap is screwed onto the case, this washer fits against the walls of the case in such a way as to separate the case into two chambers, one above the seal and one below.

The patient operating instructions for using this case in a domestic microwave oven were as follows. The patient removes the lenses from the eye and places them into their respective lens carriers without rubbing or rinsing. The patient then fills the case with 10 ml multipurpose solution, places the lenses into the solution, screws on the cap, and places the case into the center of the microwave oven. Patients are instructed to switch the oven on at full power, observe the case through the glass door, and switch off as soon as they see and hear the signs of boiling and flocculation. The time taken to raise the solution temperature to this point depends...
on the power rating of the cooker and is typically 12 s in an 800-W
cooker. The time-temperature curve measured using Thermax B
heat strips (Thermographic Measurements, Flintshire, UK) shows
that because of the slight pressurization in the case, the temperature
reached when there are visible signs of boiling is 104 ± 2°C. A
guaranteed kill of all viable cells normally requires increasing the
solution temperature to 100°C and holding it there for 5 min.12
Three minutes after irradiation, the solution in the case is at a
temperature of 70 ± 2°C, which is sufficient in itself to effect
pasteurization—a reduction in the number of viable cells by two or
more log values9—that is equivalent to the disinfecting standards
required by FDA accreditation for multipurpose solutions.6

Microbiology
Thirteen of the aforementioned storage cases were tested accord-
ing to the protocol set out in the FDA guidance document for
contact lens care products.6 This protocol for heat disinfection of
hydrogel lenses requires that the examiners follow exactly the pa-
tient regimen proposed by the product design and demonstrate a
reduction from 107 colony forming units (cfu) in the test samples
to 0 cfu. Ten cases were randomly selected as test cases, and three
were used as control cases. In addition to testing the microbiologic
effects of the microwave treatment of the cases, testing was also
conducted on the performance of the seals on the 10 test cases to
ensure that they performed as described in the users’ instructions.

Twenty-six hydrogel contact lenses taken from the required
FDA lens classification groups were supplied in sterile vials; 13
lenses were ionic and 13 were nonionic. All lenses were randomized
and numbered and handled blindly by the microbiologic investi-
gator. One investigator prepared the cell cultures, inoculated the
test lenses, and tested all lenses for growth. A second investigator
irradiated the lenses in pairs as per the attached user instructions,
recorded the performance of the case indicators, and passed over
the 13 numbered cases to the first investigator for examination.

To determine whether the irradiation time of 10 to 15 s was
sufficient to meet the required standards, a sterile, phosphate-buff-
ered physiologic saline was used for test and control samples and in
preparation of cell cultures. This maintained microbiologic con-
sistency and permitted comparison with test results from earlier
devices that used much longer irradiation times of 60 to 90 s.
Control samples of Renu multipurpose solution were not used
because the solution is designed to remove cells from lenses prin-
cipally by the mechanical action of rubbing and rinsing, and it only
contains the same concentration of PHMB (0.00005% w/v) as is
used to preserve saline solutions.13 The microorganisms tested
were of the strain Enterococcus faecalis var. Zymogenes NCTC
10,927. As indicated in the standards literature, this species is used
only as a challenge to contact lens heat disinfecting devices, not to
the effects of multipurpose solutions.14

Growth Medium
E. faecalis was grown at 37°C and diluted in tryptone soya broth.
Plate counts were carried out in tryptone soya agar. The cells were
counted using a hemocytometer slide. A freshly grown, pure cul-
ture of the yeast Saccharomyces cerevisiae was harvested, washed,
and resuspended in sterile distilled water. After counting the cells,
the concentration was diluted to 107 cells/ml and killed by heat
treatment of 10 min at 100°C.

An E. faecalis culture was washed and suspended in sterile dis-
tilled water and diluted to a concentration of 107 cells/ml. A via-
bility check was carried out on this culture by conventional micro-
biologic technique. Serial dilution of a small aliquot of each cell
suspension was performed, and estimation of viable cell counts was
made using the pour plate technique by plating out 1.0-ml aliquots
of each dilution from 10−3 to 10−6 in duplicate. At the final
dilution stage, the culture was diluted in the suspension containing
107 killed yeast/ml.

At the start of the test proper, 0.1 ml E. faecalis suspension was
placed in the bottom of the sterile plastic Petri dish. The lens,
concave side up, was then placed in the center of this droplet. An
additional 0.1 ml E. faecalis was then placed in the cup of the lens.
After a 20-min period, the lens was carefully tilted, any extraneous
liquid allowed to drip off, and then placed in the contact lens
holder (lenses in pairs). Following the test protocol, the storage
case proposed for the patient regimen was then placed in the center
of a Panasonic 800-W microwave oven (Matsushita Electric, Se-
causus, NJ) irradiated, and the oven switched off as soon as the
operator observed visible signs of boiling in the case. The mean
treatment time was 12 s.

After treatment, the lens was removed from each case, allowed
to drip dry for a few seconds, and then placed into the prepoured
tryptone soya agar and plate. Then 1 ml of tryptone soya agar was
placed on the upper, exposed surface of the lens. This would allow
detection of any remaining viable bacteria in duplicate using the
pour plate technique. This process was repeated for all 20 lenses in
ionic and nonionic batches. The timing of addition of bacteria to
the lenses was staggered to allow a constant 20 min of contact
between lens and bacterium before the microwave treatment.

The control lenses (three of each type) were treated in similar
fashion except that no microwave treatment was used and the
estimation of final numbers of viable bacteria necessitated serial
dilution of the solution used in the microwave treatment. At the
end of the microwave treatment, the test lens cases were left to
stand and cool for 15 min before opening and removing the lens to
be plated out. Incubation for 48 h at 37°C was sufficient to allow
counting of plates.

Pilot Patient Trials
The pilot patient trial was a prospective single-center study in-
volving 15 patients drawn from one U.K. practice during a
3-month period. The trial protocol was that of ISO 11,980:1997.
Patients were assessed at an initial examination, after 1 week, and at
1, 2, and 3 months.

Subjects
Suitable patients were defined as those who had records of suc-
cessful lens wear for at least 6 months, showed no significant clin-
cal signs in a preliminary slitlamp examination, and were able to
give their informed consent to participate. None of the subjects
were to be users of the Renu multipurpose solution selected for this
test. The test group comprised 10 subjects, and the control group comprised 5. The selection of test and control group subjects was to be random according to patient consent. Patients from both groups were given random number identities, which were masked from the investigator. The same investigator examined both groups using the Efron grading chart for symptoms.

Lenses

Test and control subjects were required to start the trial with fresh lenses to exclude the possibility of irradiating residues of other chemical systems left in their lenses. Patients in both groups continued to use their existing monthly replacement hydrogel lenses. All the patients in this trial were using FDA class 2 lenses (British Approved Name category 4a, 66).

Solutions

The solution used for the patient trials was Renu, a buffered saline preserved with 0.0005% w/v PHMB and containing 1% w/v poloxamine surfactant agent, one of a family of anionic surfactant agents manufactured by BASF. PHMB has already been used in Bausch and Lomb preserved saline solutions that are indicated as safe to use in contact lens heat disinfector units. To assess the effects of heating this multipurpose solution to 100°C, control and test samples of Renu heated to this temperature were taken for spectroscopic analysis. Differences between samples proved beyond the limits of detection because of the small concentrations of chemicals under analysis. No traces of altered solution chemistry were detectable, although a transient phase of slight precipitation was observed when the temperature was held at 100°C. This is believed to be a precipitation of the surfactant agent, which is no longer visible as soon as the temperature decreases below boiling point. Over repeated treatments, small residues of surfactant agent were detectable on the surfaces of the storage cases, similar to those found when the storage case has been repeatedly rinsed with multipurpose solution and left to air dry.

Examination of Subjects

Clinical signs selected for examination were those identified by the protocol of ISO 11,980:1997. This includes assessment of the following: slitlamp examination for signs of epithelial and stromal edema, corneal vascularization, limbal hyperemia, and bulbar and palpebral conjunctival hyperemia. Slitlamp examination was also used to determine the level of deposits on lens front and back surfaces and to determine lens front-surface wettability by checking for patches of nonreflecting surfaces. Other patient assessments included lens wear time and subjective acceptance of vision and comfort, which were reported at each periodic visit. The examiner was required to provide detailed patient reports in the case of adverse reactions (grades 4 or 5) and also to note any other remarkable signs. The raw data from the masked examinations were to be passed directly to the test organizer for unmasking and collation.

Microwave Disinfecting System and Lenses

Patients were issued sealed and numbered identical 3-month packs of Renu, 10 containing the storage case and instructions for microwave use and 5 containing instructions to follow the manufacturer’s directions for the multipurpose solution. Each subject’s identity was then given using the number printed on the sealed pack. The instructions for the microwave regimen accorded with the description given of the storage case design previously, and test patients were directed not to rub and rinse their lenses before microwave treatment. The subjects’ microwaves used in this trial were allowed to range in power from 600 to 1000 W. Thus, treatment times would vary accordingly from 10 to 15 s. Test patients were instructed to repeat the microwave treatment if the indicating seal was not drawn down below the indicating line on the case.

Analysis of Results

Slitlamp examination results from the test and control groups were grouped by sign. The statistical method used was to test the null hypothesis in terms of the two sample proportions by finding the standard score z and thus the two-tailed p value. All calculations were performed using Microsoft Excel 2000 (Redmond, WA). The threshold for statistical significance in the results of slitlamp examinations was set at the level of \( \alpha = 0.05 \).

RESULTS

Microbiology and Storage Case Performance

The seals of all 10 test cases were drawn below the proof of operation indicating line. Solution was lost from all cases by evaporation of liquid and vapor through the vent holes in the cap. On cooling, a volume of 1 to 2 ml was found trapped above the dividing seal in the upper chamber of the case. The mean volume of solution left in the cases was 7 ml. In one case the volume of solution in the lower chamber was about 4 ml. The solution was lost by flocculating out of the vent holes in the cap rather than by evaporation because the microwave was turned off as soon as visible signs of boiling were seen. Because at least 3 ml solution can be recovered from the depression on the top surface of the lens cap, this was taken as further indication that the brief period of boiling had not altered the solution tonicity through losses caused by evaporation.

No cell growth was detected on 18 of the test lenses. Cell growth was detected on the edges of two lenses. Both of the lenses showing growth were treated in the case in which the solution volume had decreased to 4 ml. For the control lenses, the final viable cell count was \( 1.04 \times 10^5 \).

Patient Trials

One control group patient withdrew from the trial by failing to come to her scheduled follow-up examinations. The average wear time was 11.6 h in the test group and 13.5 h in the control group. Table 1 summarizes the total results during 3 months of the slitlamp examinations for the test and control groups. No adverse reactions were reported in either test or control group. No clinical sign observed in either test or control group was graded \( \geq 2 \). The results for visual acuity are shown by reference to the successive line reductions in LogMAR progression from the best corrected initial measurement, for which a loss of two lines is regarded as a severe sign. Lens fit was assessed as a standard part of the slitlamp exam-
ination, with the examiner noting only the anomalies found in lens centration and movement. No reports were noted of significant alterations in lens centration or movement in either the test group or control group. Measurements returned of lens dimensions were incomplete because of time pressures in the examiner’s practice.

The base curve of one pair of lenses in the test group was noted to have flattened by an unspecified amount in month 3, and one of these lenses was graded 3 for lens front-surface deposits. The patient in the test group wearing the lens graded at 3 for front-surface deposition rated subjective acceptance for comfort at 2. Table 2 summarizes the results of the subject acceptance responses, showing the mean overall score and the percentage of all responses falling into the three selected categories. There was no statistical difference between the subject acceptance scores in test and control groups, but all patients in the control group rated acceptance in the highest category, whereas 30% of test patients rated their acceptance in the second category.

**DISCUSSION**

**Storage Case**

The storage case used was an adaptation of an existing case designed for use in a peroxide regimen. The performance of the adapted case was not entirely satisfactory in the microbiologic testing, and the reasons were easily identified in advance of its use for the patient trial. The perforations in the cap seal can align directly

### TABLE 1.
Results of slit lamp examinations over 3 months

<table>
<thead>
<tr>
<th>Clinical signs</th>
<th>Test Group (20 eyes)</th>
<th>Control group (8 eyes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epithelial Edema</td>
<td>0–1; 2–3; 4–5</td>
<td>0–1; 2–3; 4–5</td>
</tr>
<tr>
<td>Stomal Edema</td>
<td>90; 10; 0</td>
<td>100; 0; 0</td>
</tr>
<tr>
<td>Corneal Vascularization</td>
<td>75; 25; 0</td>
<td>100; 0; 0</td>
</tr>
<tr>
<td>Limbal hyperemia</td>
<td>83; 17; 0</td>
<td>81; 19; 0</td>
</tr>
<tr>
<td>Bulbar conjunctival hyperemia</td>
<td>75; 25; 0</td>
<td>75; 25; 0</td>
</tr>
<tr>
<td>Palpebral conjunctival hyperemia</td>
<td>73; 17; 0</td>
<td>93; 7; 0</td>
</tr>
<tr>
<td>TOTAL SIGNS (168 eyes)</td>
<td>78; 22; 0</td>
<td>92; 8; 0</td>
</tr>
<tr>
<td>DEPOSITION</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lens front-surface deposits</td>
<td>58; 32; 0</td>
<td>75; 25; 0</td>
</tr>
<tr>
<td>Lens back-surface deposits</td>
<td>88; 12; 0</td>
<td>88; 12; 0</td>
</tr>
<tr>
<td>Lens front-surface wettability</td>
<td>88; 12; 0</td>
<td>94; 6; 0</td>
</tr>
<tr>
<td>VISUAL ACUITY</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Score (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acceptance</td>
<td>4–5</td>
<td>4–5</td>
</tr>
<tr>
<td>Comfort (p = 0.440)</td>
<td>2–3; 0–1</td>
<td>2–3; 0–1</td>
</tr>
<tr>
<td>Mean score = 77%</td>
<td>70; 30; 0</td>
<td>100; 0; 0</td>
</tr>
<tr>
<td>Vision (p = 0.236)</td>
<td>70; 30; 0</td>
<td>100; 0; 0</td>
</tr>
<tr>
<td>Mean score = 74%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### TABLE 2.
Subject acceptance scores after 3 months

<table>
<thead>
<tr>
<th></th>
<th>Test Group (N = 10)</th>
<th>Control Group (N = 4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Score (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acceptance</td>
<td>4–5; 2–3; 0–1</td>
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with the vent holes, greatly increasing the escape of liquid and vapor; therefore, this alignment needs to be avoided in assembly. This anomaly is likely to account for the failed disinfection in one of the microbiologic test samples.

Microbiologic Testing

The tests demonstrate what is now well established from earlier work, that high concentrations of challenge organisms can be completely killed by the steep thermal curve up to temperatures of $>100^\circ\text{C}$ produced by microwave irradiation of lenses immersed in solution and followed by a cooling period of at least 2 min, during which the lenses are held at temperatures $>70^\circ\text{C}$. The one failed sample demonstrates the need to keep the lenses fully immersed during treatment.

Pilot Clinical Trial

Encouraging findings are the absence of adverse reactions, of signs rated $>2$ on the Efron scale, and that no statistical difference was found between test and control groups in the occurrence of any sign. However, the small sample size necessitates caution in extrapolating from these results. The findings of higher incidences in the test group of stromal edema, palpebral hyperemia, and lens front-surface deposition may be clinically, if not statistically, significant. In previous trials of a microwave regimen involving 103 patients a greater incidence of edema was found, but not of hyperemia, which was actually lower in the test group, whereas lens front-surface deposition was nearly equivalent in both trial groups. The incidence of both signs in this trial may then be connected to the higher incidence of lens front-surface deposition found in the test group of the present trial, in which patients did not follow the rub and rinse step undertaken in the previous trial, using only a physiologic saline solution.

The results for front-surface deposition indicate that the presence of a surfactant agent in the microwave solution does not obviate need for a rub and rinse step. Contrarily, surfactants of the block copolymer type may actually contribute to the problem of deposition in a microwave system. Residues of surfactant agent were found on the clear plastic storage cases that had been repeatedly irradiated, demonstrating that the coating can build up in the absence of the mechanical action of rubbing and rinsing. Because the concentration of surfactant is considerably greater in Renu than in comparable solutions, this may have been more significant in the absence of the mechanical action of rubbing and rinsing. Because the concentration of surfactant is considerably greater in Renu than in comparable solutions, this may have been more significant in terms of coating the lens and of possible toxic effects, which are unlikely to be connected with the tiny concentration of 0.00005 w/v of PHMB already used to preserve saline solutions used for heat disinfecting. Because the examiner did not observe significant alterations in lens fit, it would appear that a higher level of deposition could have been the main causal factor for the higher incidence of edema and hyperemia in the test group.

It is notable that the only recorded compromise in lens fit was made for a pair of lenses showing the greatest observed level of deposition. It is well known that heat disinfecting tends to harden lens deposits, which can lead to a range of lens-wearing complications. The role of deposition is further indicated by the lower subjective rating of vision in the test group, in which two patients reported a slight clouding of vision, even though the constancy of visual acuity was measured nearly the same in both groups. These results suggest that multipurpose solutions using a block copolymer surfactant are not suitable candidates for the sought-after common solution of a dual-mode regimen. Better candidates may be those containing anticoagulant and chelating agents such as sodium citrate, which is stable in an aqueous medium when heated to $100^\circ\text{C}$. More preliminary investigation of the effects of solutions containing such cleaning agents needs to be conducted in vitro before any future patient trial of a dual-mode microwave regimen.

CONCLUSION

Microbiologic testing of a dual-mode care regimen for hydrogel lenses demonstrates that a short microwave treatment mode of 10 to 15 s is effective in killing all challenge organisms attached to the lens when following the standard FDA testing protocol for heat disinfecting units using only physiologic saline. The microwave mode of treatment is enabled by making simple adaptations to an existing type of barrel storage case and using a multipurpose solution, which gives the patient the opportunity to use the same equipment to follow a normal cold disinfecting regimen in situations when they do not have access to a microwave oven. The design of this case made for a more portable system that was still capable of giving the necessary visual indication that correct operating temperature has been reached. A pilot clinical trial of the microwave treatment mode did not reveal a statistically significant higher incidence of any clinical signs or of clinical signs overall when compared with patients using the same multipurpose solution in a normal cold disinfection regimen ($p = 0.394$). However, the presence of a surfactant agent in the common solution may have produced clinically significant differences between test and control groups, in which there was a greater incidence of stromal edema, palpebral conjunctival hyperemia, and lens front-surface lens deposition in the microwave test group. These findings suggest that the inclusion of a block copolymer‐type surfactant in the solution is not efficacious and does not obviate the need for a rub and rinse step in the microwave mode of treatment. In view of the continuing widespread use of monthly and fortnightly hydrogel lenses, the superior disinfecting performance of microwave over cold care systems encourages a continued search for more appropriate solution formulations that could be used for microwave and cold care regimens.

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REFERENCES

Microwave treatment of contact lens cases contaminated with acanthamoeba. Cornea 2001;20:467–70.


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