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ORIGINAL ARTICLE

Clinical Trial of a Patient-Operated Microwave Care System for Hydrogel Contact Lenses

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ABSTRACT: The clinical effects of a patient-operated system of microwave disinfection for soft contact lenses were assessed in a prospective pilot trial involving 103 patients who were drawn from five optometric practices. Fifty-six subjects used the test system for 1 month, and 13 subjects continued use for a total of 3 months. Both test and control subjects were examined for clinical signs using slitlamp tests. After 1 month, the incidence of all signs reported in the microwave group was not significantly greater than in the control group ($p = 0.267$), and the same was true after 3 months ($p = 0.214$). There was a significantly greater incidence of edema in the 1-month test group and of staining in the control group. UV spectroscopic examination of worn lenses from test subjects exhibiting significant signs did not show a higher level of deposition than on lenses worn by control subjects ($p = 0.397$). (Optom Vis Sci 2001;78:605–609)

Key Words: patient trials, hydrogel contact lenses, microwave, disinfection

Investigation of microwave irradiation as a means of disinfecting hydrogel (soft) contact lenses has been reported since the mid-1980s. Researchers using ordinary domestic microwave ovens have reported impressive microbiological results, in which tests on batches of 10 to 20 lenses have reduced the relevant Food and Drug Administration (FDA) challenge microorganisms from 10^4 to10^6 colony-forming units (cfu/ml) to 0 cfu/ml within 2 min.[1–3] This encourages further development of microwave treatment systems for patient use because this standard of disinfection is termed complete, in contrast to the partial disinfection required by FDA standards,[4] which is only properly achieved after the patient has rubbed and rinsed the lenses.[5, 6] In addition to this much higher standard of disinfection, tests on a wide variety of lenses from all four FDA lens material groups do not reveal any significant clinical alterations in the materials or prescriptions of soft lenses tested *in vitro*.[7–9]

Most prior research has focused on the application of microwaving to the professional environment, for example, for use with batches of trial lenses. However, far less work with patients wearing microwave-disinfected lenses has been reported.[6, 10] This prior work has not involved extensive or detailed clinical trials, but has shown encouraging initial results. The present clinical testing formed part of a larger study of a daily care regimen, for patients to clean and then disinfect their lenses using their own microwave ovens. In designing this pilot system, Communité Européen (CE) regulatory requirements were fully investigated, and extensive testing was performed in the following areas: the effects of heating by microwave irradiation on solutions and materials,[a] microbiological effects,[11] and the effects on lens parameters.[11, 12] With respect to disinfection, this investigation found that for lens pairs challenged with *Acanthamoeba castellanii*, *Candida albicans*, *Pseudomonas aeruginosa*, and *Staphylococcus aureus*, a 60-s microwave irradiation in a 750 W oven, followed by a 10-min cooling, resulted in reduction from 10^4 cfu/ml to 0 cfu/ml for all 40 samples tested. In a test following FDA protocols for proving of contact lens heat disinfectors, 10 lens pairs challenged with *Enterococcus faecalis* were irradiated at medium power only, in a 750 W oven for 120 s, resulting in a reduction from 10^7 cfu/ml to 0 cfu/ml in all 20 samples.[11] Regarding the effects on lens properties, the investigation found that repeated irradiation of 10 common brands of hydrogel lenses for a number of cycles equalling the recommended number of wear days did not reveal any clinically significant changes in lens parameters. A pilot system was then designed that allowed patients to treat their lenses in their own microwave ovens on a daily basis—a more developed version of this system was reviewed in 1998.[13, 14] The pilot system was used in a prospective assessment of whether patients following this microwave regimen would present with significantly more clinical signs than patients using other care regimens.

[a] Tests on solution composition and stability were conducted by the Quality Control Laboratory, Nottingham City Hospital, UK.

METHODS

Subjects

This prospective multicenter study involved 103 patients drawn from five optical practices: four in the UK and one in Holland. Suitable patients were defined as those who had records of successful lens wear for at least 6 months, showed no significant clinical signs in a preliminary slitlamp examination, and were able to give their informed consent to participate. The test group comprised 56 subjects, and 47 subjects were in the control group. Because the patient regimen of heat disinfecting soft lenses has been a well-established practice in the past, test subjects were to switch from their existing systems and use the microwave system over a 1-month period. Further assessment was then to be made of subjects volunteering to continue with the microwave system for an additional 2 months. The 3-month trial involved 20 subjects drawn from two participating centers, comprising 13 test subjects and 7 control subjects.

The selection of test group subjects was random; subjects were drawn from the appointment books of the participating practices and were scheduled for 6-month follow-up examinations. The control group was similarly randomized; it was comprised of subjects who used their normal system, attended their scheduled follow-up examinations in the same period, and were examined by the same examiners used for the test group. Data from the control group was then to provide a baseline for the average incidence of clinical signs detected in the soft lens patients of each practice over the trial period. No exclusion was to be made regarding the types or brands of soft lenses that could be used, nor was any test subject to be excluded on the basis of the care regimen they had formerly used. Test 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. Due to the way their appointment schedules developed over the trial period, three examiners could not provide data for as many control subjects as test subjects, which led to the test group being larger than the control group.

Examination of Subjects

After discussion with optometrists from all five centers, a protocol was developed. The protocol required that participating practices use slitlamp examination to discover any clinically significant signs presented by trial subjects. A six-point scale was used to harmonize the grading methods used in the various practices, which mostly used the nomenclature insignificant, significant, and severe. The number values 0 to 1 were assigned to insignificant, 2 to 3 to significant, and 4 to 5 to severe. For this pilot assessment, in which baseline data from the control group was to be provided from the examiner's practice records, the examiners were briefed to follow their usual practice grading process. Clinical signs selected for examination were those identified in standard textbooks familiar to the examiners[15] and routinely investigated by all five practices in their fitting of hydrogel lenses. Because microwaving is a form of heat treatment, particular attention was given to those signs that would indicate any effects that might arise from lens deposition or compromises in lens fit. Staining, neovascularization, injection, eyelid response, and edema were collectively identified as diseases likely to be caused by deposition or poor lens fit. Examiners were required to provide detailed patient reports in the case of adverse reactions (grades 4 to 5) and also to note any remarkable subject symptoms.

Participating centers were required to use masking in the examination of all subjects, although the very mechanics of the microwave system made it impractical to mask the subjects to which system they were using. The results from each center were to be passed for processing directly to an independent monitor who was an optometrist at one of the participating centers. He would then collate the raw data received for analysis and discussion with the trial organisers.

Microwave Disinfecting System and Lenses

As illustrated in Fig. 1, the microwave disinfecting system tested comprised of a set of containers and a solution to be treated in the patient's own microwave oven. The containers included a barrel-type storage case to hold lenses immersed in solution and a thermoplastic vessel into which the storage case was placed during irradiation. Patients rubbed and rinsed their lenses using the solution, placed them in the storage case, and screwed on the lens cap. The fit of the lens cap was tight enough to prevent fluids from leaking into or out of the storage case at normal atmospheric pressure. Patients then filled the well of the outer vessel with 30 ml of solution, placed the storage case in the well, and put the whole unit in their microwave oven to irradiate for 1 to 2 min, depending on the power rating of the oven. Guarantee and visible indication of complete operation were given by a siphoning effect, whereby the storage case was only one-half filled with solution before irradiation and then after irradiation, the case was wholly filled by back siphoning because steam condensed to form a partial vacuum inside the case. Testing of the kit, using Thermax B heat strips inside five storage cases over five heating cycles showed that siphoning could only occur if the temperature of the solution in the case had been held at 100°C for at least 10 s.

The solution was a pasteurized, nonpreserved, hypotonic saline solution containing 0.67% NaCl w/v that was buffered with a borate system. The disinfection times given by the microbiological testing already mentioned showed an evaporation loss of 2 to 4 ml from the total solution volume in the disinfector apparatus, as tested in a wide variety of microwave ovens, in the range 600 to 1000 W. This required that the saline be hypotonic before treatment so that the evaporation led to a final solution tonicity in the isotonic range, 0.85 to 0.95% NaCl w/v. No preservatives, surfac-

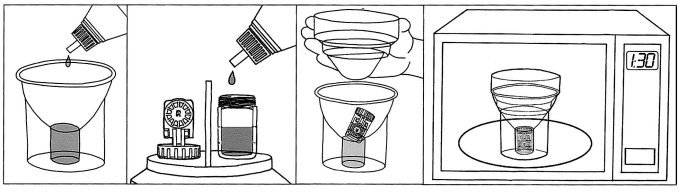

FIGURE 1.
Steps for microwave disinfection: 30 ml of saline poured into disinfector; 7 ml of saline poured into storage case; storage case placed inside disinfector; and loaded disinfector microwaved for 1 to 2 min depending on oven power.

tants, or other chemicals were used in the solution as a precaution against the creation of unforeseen by-products due to heating to 100°C by irradiation. Toxicological tests on the solution by Nottingham City Hospital demonstrated stability in chemical composition and pH following treatment in the manner directed for the trial system.

Subjects were clearly directed by instructions and labeling not to use the saline directly in the eye, but to store, on a strictly daily basis, the treated solution in the outer vessel and use this for rubbing and rinsing lenses. Subjects were advised to insert lenses with solution from the airtight storage case in which they had been treated. These daily supplies of treated solution had been completely disinfected to 0 cfu/ml and were therefore less contaminated by challenge microorganisms than tests have shown bottled multipurpose solution to be within days of opening.[16] The subjects' microwaves used in this trial were allowed to range in power from 600 to 1000 W. Thus, treatment times varied accordingly, from 1 to 2 min at medium power. As described above, patients used a wide range of lenses, from 2-week to annual replacement, the principal types being 50 to 58% water content (w/c) ionic lenses, 38% water content nonionic lenses, and 70 to 74% water content nonionic lenses.

Ultra Violet Spectroscopic Examination of Worn Lenses

The level of lens deposition was further investigated by an independent examination of at least 10 lenses, five taken from the eyes of any test patients exhibiting significant signs and five taken at random from the control group. A further two unworn lenses were controls for the measuring technique. Members of the Eurolens research team at University of Manchester Institute of Science and Technology (UMIST) conducted the randomized, masked examination and reported their technique as follows:

"UV absorbency was determined using a Pye Unicam spectrophotometer, set at wavelength 280 nm, together with a pair of matched quartz 1-cm sample and reference cells. The cells were filled with sterile saline solution, and the contact lenses under test were placed into the cell such that they faced the direction of the UV light path. The absorbency due to the deposited lens was determined by recording the absorbency directly from the UV spectrophotometer display. The measurement was then repeated using the unworn lens to determine the absorbency due to the lens material, and this value was subtracted from the value obtained for the test lens to determine the absorbency due to any protein present."[17]

Analysis of Results

Slitlamp examination results from the test and control groups were grouped by sign. The statistical method used tested 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 97. The threshold for statistical significance in the results of slitlamp examinations was set at the level of $\alpha = 0.05$.

RESULTS

Results of the slitlamp examinations for the test and control groups are shown in Table 1. Four patients withdrew from the trial by failing to present for their scheduled follow-up examinations. A further 14 patients were entered as trial subjects by two subpractices of one of the participating practices, but the examiners at these subpractices did not follow the protocol by starting their subjects with fresh lenses. Therefore, the results from these practices were not included.

There was a significantly greater incidence of edema in the test group and significantly greater incidences of staining at 1 month and injection at 3 months in the control group. Symptoms of

TABLE 1.
Results of slitlamp examinations

Sign	Test Group Grade (%)			Control Group Grade (%)			p Value
	0–1	2–3	4–5	0–1	2–3	4–5	
Edema							
Month 1[a]	95.2	4.8	0.0	100.0	0.0	0.0	0.031
Month 3[b]	100.0	0.0	0.0	100.0	0.0	0.0	1.00
Neovascularization							
Month 1	100.0	0.0	0.0	97.9	2.1	0.0	0.135
Month 3	100.0	0.0	0.0	100.0	0.0	0.0	1.00
Staining							
Month 1	96.2	3.8	0.0	90.4	9.6	0.0	0.037
Month 3	100.0	0.0	0.0	71.4	28.6	0.0	0.004
Injection							
Month 1	84.6	12.5	2.9	87.2	9.6	3.2	0.597
Month 3	100.0	0.0	0.0	78.6	14.3	7.1	0.014
Eyelid							
Month 1	94.2	5.6	0.0	100.0	0.0	0.0	0.073
Month 3	100.0	0.0	0.0	100.0	0.0	0.0	1.00

[a] At the month 1 examination, 104 test eyes and 94 control eyes were examined.
[b] At the month 3 examination, 26 test eyes and 14 control eyes were examined.

TABLE 2.
Results of UV spectroscopy examinations of worn lenses

	Worn Test Lenses (N = 6)	Worn Control Lenses (N = 3)	Unworn Control Lenses (N = 3)	p Value
Mean difference	0.191	0.271	0.000	0.397

dryness and lens awareness were reported by eight test subjects. Also reported by six test subjects was a reduction of stinging when solution was put in the eyes. As shown in Table 2, six lenses were returned for measurement of lens deposition from test subjects who had presented with significant signs, along with three lenses from control subjects who had not. No significant difference in the level of deposition was found between the two lens groups.

DISCUSSION

Looking at the total results for the trial, there was not a statistically significant difference in the incidence of clinical signs between the test and control groups. There were statistically significant differences in the incidence of particular signs, which suggest slightly differing clinical performance between microwave and cold disinfection regimens. A possible limitation of the microwave regimen may be indicated by the significantly greater incidence of edema in the test group at 1 month. This, in turn, may relate to the reported symptoms of dryness and lens awareness by test patients. Because the test solution contained none of the wetting or lubrication agents commonly found in conventional care solutions, this may have caused increased lens adhesion, one of the causes of edema.[15] Another cause of edema can be poor lens fit,[15] and heating by microwave irradiation can bring about transient changes in the parameters of certain lens types.[4] It was anecdotally reported that some test subjects had inserted lenses directly after heating, and a future precaution would be to instruct patients not to insert lenses for at least 1 h after treatment.

Use of a nonpreserved saline could be an advantage of the present microwave regimen and may account for the significantly lower incidence of staining in the test group. Punctate staining can be a sign of reactions to solutions,[15] either allergic, as in the case of reactions to preservatives such as PHMB,[18] or toxic, as in the case of irritation caused by inadequate neutralization of hydrogen peroxide.[19] Both of these systems had been formerly used by subjects in the test group, and six test subjects reported a relative absence of solution stinging.

Lens deposition as a result of heating with microwaves does not appear to have been a more important factor in the clinical signs presented. The test lenses submitted for spectroscopy came from subjects showing significant clinical signs and yet did not show significantly greater levels of deposition than control lenses taken from sign-free patients. Furthermore, other indications of deposition, such as eyelid responses, were not significantly different in test and control groups. The small sizes of the 3-month subject groups make it difficult to explain the significantly lower incidence of injection in the 3-month test group without further investigation.

CONCLUSION

Patient use of a daily microwave care regimen over 1 month did not result in a significantly higher incidence of clinical signs overall compared with use of other care regimens such as multipurpose solutions and peroxide ($p = 0.267$). This remained true for a smaller test group of subjects after 3 months ($p = 0.214$). Some statistically significant differences were found in particular signs, with a greater incidence of edema in the microwave group at 1 month ($p = 0.031$) and greater incidences of staining at 1 month and injection at 3 months in the control group. UV spectroscopic examination of worn lenses taken from test group patients presenting significant clinical signs did not show a higher level of lens deposition than lenses worn by sign-free subjects in the control group ($p = 0.397$). In view of the superior disinfecting performance of microwave over cold care systems, the results of this pilot trial should encourage more detailed investigation of the effects and potential clinical value of microwave care regimens.

Participating optometrists were James Pinder, Peter Tomasevic, Albert Steck, Colin Lee, and John Rogers. Spectroscopic analysis of worn lenses was performed by Philip Morgan, James Ma, and Nathan Efron of Eurolens Research at UMIST, UK. Data evaluation was performed by Mike Port, City University, London UK

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