



Efficacy of a Multipurpose Solution Subscriber Delivery Program on Improving Patient Compliance with Contact Lens Care in Japan

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Abstract

Purpose: To evaluate the efficacy of an option program Care plus, which semiannually delivers standardized volumes of Multipurpose Solution (MPS), on improving patient compliance with practitioner-recommended Contact Lens (CL) care.

Methods: A questionnaire survey was conducted in five eye clinics in Japan. Three hundred ninety-eight potential subjects who already belonged to a subscriber membership system replacing 2-Week Frequent Replacement (2WFR) CLs were identified in a national database; 200 patients were members who had elected the Care plus option (Care plus group) and 198 were those who did not (non-option group).

Results: Age- and gender-matched each 50 patients were randomly selected from two test groups. Wearers in the Care plus group showed greater compliance with practitioner instructions to use one bottle of MPS/month than those in the non-option group (53.1% vs. 27.9%; $P < 0.05$). Some patients in the non-option group used their one-month MPS bottle for up to three months vs. none in the Care plus group ($P < 0.01$). Of the non-option group, 35.3% wearers reported rinsing their storage cases in tap water vs. 11% ($P < 0.05$) among their Care plus counterparts. Care plus patients replaced their storage cases each month at higher rates (45.8% vs. 19.0%; $P < 0.01$).

Conclusions: Compliance with practitioner-recommended CL care was significantly better in patients who elected to participate in the Care plus program of automated MPS care product replacement than in patients who did not choose. These results demonstrate that this strategy may be useful in improving patient compliance with lens care in worldwide populations.

Keywords: 2-week frequent replacement soft contact lenses; Multipurpose solution (MPS); Compliance; Membership system

Introduction

In recent years, the increase of Contact Lens (CL)-related Microbial Keratitis (MK) has become a worldwide public health problem [1,2]. It is well understood that microbial contamination of CLs occurs when CLs are handled, and lack of cleaning or delayed replacement of CL storage cases results in case contamination with formation of a bacterial or amoebic biofilm [3-5]. Microorganisms which multiply in such contaminated storage cases are then transferred to the CLs, and can invade the ocular surface at the time of lens wear [6]. Despite explicit patient instructions at the time of CL dispensing, patients continue to be noncompliant with practitioner-recommended guidelines for optimum lens care [7-9]. In the study of risk factors for MK in daily wear CL users [10], an odds ratio of risk factors has been reported showing that poor storage case hygiene was estimated as a 6.4x increased risk for MK, and that infrequent storage case replacement also increased risk by 5.4x. If lens users clean their lenses by rubbing and rinsing with an appropriate volume of a Multipurpose Solution (MPS); however, it is possible to reduce the quantity of microbial bioburden [11,12]. By contrast, noncompliant wearers reduce the amount of MPS used, resulting in extended use of one bottle of MPS for 2 months or 3 months beyond the recommended one-month expiration date established by manufacturers in Japan. Such noncompliant behavior also further reduces the

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efficacy of rinse on reduction of contaminating microbial agents. In addition, there is also a concern for microbial contamination at the bottle lip or within the MPS container itself by long-term, post-expiration date usage [13,14].

Many studies documenting noncompliant behaviors of CL wearers with practitioner-recommended guidelines continue to be reported worldwide. Previous reports demonstrate that compliant cooperation of CL wearers is poor, and that a large proportion of wearers remain noncompliant despite awareness of potentially increased sight-threatening risk for MK [15-19]. An Internet survey study of CL wearers who use their lenses with satisfaction in Japan revealed that there were many noncompliant wearers and that the choice of CLs by wearers seemed to be price driven rather than being safety focused [20]. A recent study documenting a subscriber-based membership system of 2-week frequent replacement (2WFR) soft CLs further demonstrated that the percentage of compliant wearers who replaced their lenses within the recommended period of lens use was significantly improved ($P<0.01$) as compared with nonmember counterparts, who used their lenses longer than recommended [21]. The rate of incidence of allergic conjunctivitis was also found to be higher in nonmembers as compared with members in this study [21]. Unfortunately, when compliance with post-dispensing practitioner-recommended care guidelines after initial dispensing was compared between members and nonmembers, compliance was still found to be equally poor in both groups [22]. Taken together, these results demonstrate that a lens replacement-only subscriber system that did not include lens care products did not increase post-fitting care compliance. The MELS (Menicon Eye Life Support) program, which was introduced domestically in Japan by Menicon (Nagoya, Japan) in 2001, is a subscription membership system of CLs requiring a first-time admission subscription and a continued monthly fixed fee. In a 2-week frequent replacement program of the MELS membership system, CLs needed for 3 months are usually supplied quarterly, and if the lenses are lost, broken, or spoiled, new lenses are supplied. It is also possible to shorten the manufacturer's recommended replacement cycle by the decision of an eye care professional (ECP; an ophthalmologist in Japan) if more frequent lens replacement is beneficial (allergy, deposits easily, etc.). In addition, members can receive the same service country-wide through a national network in Japan, and the CL data of members is traceable at the time of a domestic travel or change in residency; the details of this system have been described elsewhere [21]. Furthermore since 2006, the MELS program has provided an additional option, Care plus, which automatically delivers 6 bottles of MPS (MeniCare Soft Aquamore, Polyhexamethylene Biguanide (PHMB)-based, 300 mL, Menicon) with 6 storage cases every 6 months directly to members by mail for an additional fixed monthly fee. The present study was initiated to examine the hypothesis that patients electing to participate in the Care plus option might demonstrate increased rates of compliance with practitioner-recommended lens care instructions. To test this hypothesis, questionnaires were sent to the MELS members who elected or did not choose the additional Care plus option.

Methods

Subjects

This national study was conducted at 5 eye clinics in Japan. Subjects were 2WFR wearers of silicone hydrogel CL (2week Menicon Premio, Premio toric, asmoFilcon A, water content 40%, oxygen permeability 129×10^{-11} (cm²/sec)·(mL O₂/(mL × mmHg)) who had

elected to choose the MELS lens replacement program. A total of 398 potential patients, who were 200 Care plus members (Care plus group) and 198 non-option members (non-option group), were randomly identified using a national database of MELS members maintained by Menicon. Occasional users of CLs and wearers who used other CL(s) besides 2WFR CLs were excluded at the time of database identification. Between December 2014 and February 2015, patients received a written postal mail survey, which explained the study design, privacy protection, nonprofit status, participation of their own free will, and usage of data only for research according to the Code of Ethics of the World Medical Association (Declaration of Helsinki). Each participating patient provided written consent to enter the study, and was asked to answer an unsigned questionnaire shown in Appendix 1 which was referred to previous methods with modifications [20-23]. Patients who completed the questionnaire received 1 prepaid card (1,000 Japanese Yen - approximately 9US\$) as a reward.

Statistics

Statistical data analysis was conducted using Fisher exact test, Chi-square test or Mc-Nemar test. Differences of $P<0.05$ were taken as significant.

Results

Age- and gender-matched subjects

Patient consent to this study was obtained from 184 subjects who were 127 Care plus option members and 57 non-option members (46.2% responses), and all consented-patients completed the questionnaire. Wearers who used hydrogen peroxide care products or who wore their lenses less than 5 days per week were excluded. Because of large difference in the number of potential patients in the two groups, 50 subjects from each group were semi-randomly selected as an age- and gender-matched cohort with 35 females (70%) and 15 males (30%) corresponding to the general population of CL wearers by a blind operator only for questionnaire reports. Age distribution of both groups was 8% in age range 10-19, 40% in 20-29, 28% in 30-39, 16% in 40-49 and 8% in 50-59. There were no statistical significant differences in gender ratio among age distribution between two groups ($P>0.05$, Fisher exact test). All patients were daily wearers. Patients in the Care plus group ($n=50$) were 44 each day wearers (88%), 5 wearers of 6 days/week (10%), and 1 wearer of 5 days/week (2%). Patients in the non-option group ($n=50$) were 43 each day wearers (86%), 4 wearers of 6 days/week (8%), and 3 wearers of 5 days/week (6%), which did not differ significantly from wearers in the Care plus group ($P=0.57$, Chi-square test).

Wearing hours per day

The majority of CL wearing hours per day was 10 h or more but no longer than 16 h (86%: Care plus group ($n=50$) and 78%: non-option group ($n=50$)). The percentage of wearers, who wore their lenses for 12 h or more but no longer than 14 h per day, tended to be lower in the Care plus group (20%) than that in the non-option group (36%, $P=0.12$, Fisher exact test). Wearers, who wore their lenses for 14 h or more but no longer than 16 h per day, tended to be higher in the Care plus group (42%) as compared with the non-option group (24%, $P=0.09$, Fisher exact test).

Napping while lens wearing

The frequency of napping while wearing their lenses in the Care

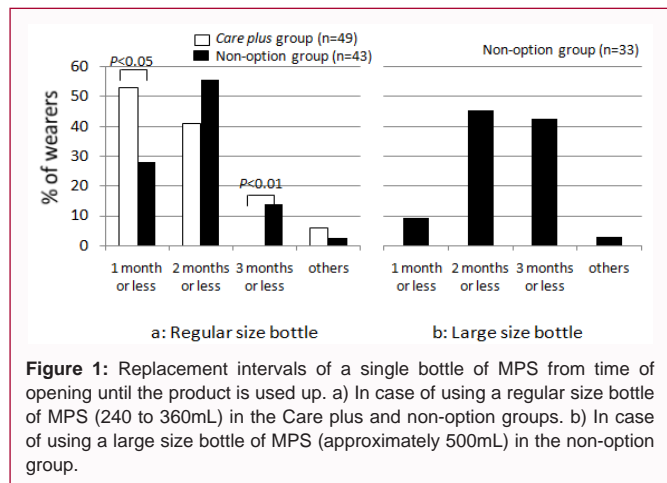


Figure 1: Replacement intervals of a single bottle of MPS from time of opening until the product is used up. a) In case of using a regular size bottle of MPS (240 to 360mL) in the Care plus and non-option groups. b) In case of using a large size bottle of MPS (approximately 500mL) in the non-option group.

plus group (n=50) was “every day” in 6%, “sometimes” in 52%, “not so much” in 34%, and “never” in 8%. By contrast, the frequency of napping in the non-option group (n=50) was “every day”: 8%, “sometimes”: 42%, “not so much”: 34%, and “never”: 16%. The ratio of wearers who never napped with their lenses was not significantly different between the two groups (P=0.36, Chi-square test).

Closed eye wear

The frequency of overnight wear in the Care plus group (n=50) was “sometimes” in 16%, “not so much” in 18%, and “never” in 66%, as compared to the frequency of overnight wear in the non-option group (n=50) “sometimes”: 6%, “not so much”: 30%, and “never”: 64%. The ratio of wearers who sometimes wore their lenses overnight tended to be more in the Care plus group as compare with the non-option group, but was non-significant (P=0.20, Chi-square test).

Compliance with expiration date of lenses

Compliance with expiration date of their lenses (2-week replacement frequency) in the Care plus group (n=50) and the non-option group (n=50) was “I’m always compliant”: 76% and 62%, “I sometimes extended expiration date”: 24% and 32%, and “I always extended expiration date”: 0% and 6%, respectively. There was no significant difference in the ratio of wearers who were “always compliant” with expiration date between the two groups, but tended to be more in the Care plus group as compare with the non-option group (P=0.19, Chi-square test).

Cleaning of CLs

In the Care plus group (n=50), the percentage of wearers who cleaned their CLs by rubbing “each time” and “sometimes” were 76% and 18%, respectively, and the percentage of wearers who did not rub (“no-rub”) were 6%. By contrast, in the non-option group (n=50), the percentage of wearers who cleaned their lenses by rubbing “each time”, “sometimes” and “no-rub” were 74%, 24% and 2%, respectively. There was no significant difference found between both groups (P>0.05, Chi-square test).

Replacement intervals of a care product

Figure 1a shows the replacement intervals of a single regular volume MPS (240 mL to 360 mL) from time of opening until the product was used up in the Care plus group (n=49, one wearer had no answer) and the non-option group (n=43, excluding wearers who did not use regular size bottles). All wearers in the Care plus group used 300 mL bottle MPSs. The average ± standard deviation of MPS volume in the non-option group was 317 mL ± 26 mL (n=26: wearers

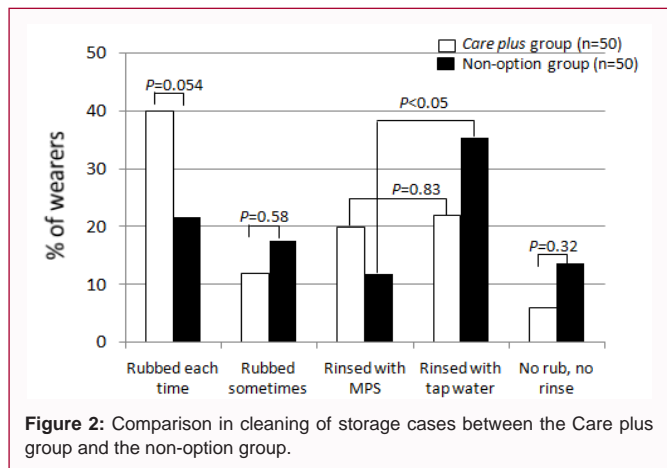


Figure 2: Comparison in cleaning of storage cases between the Care plus group and the non-option group.

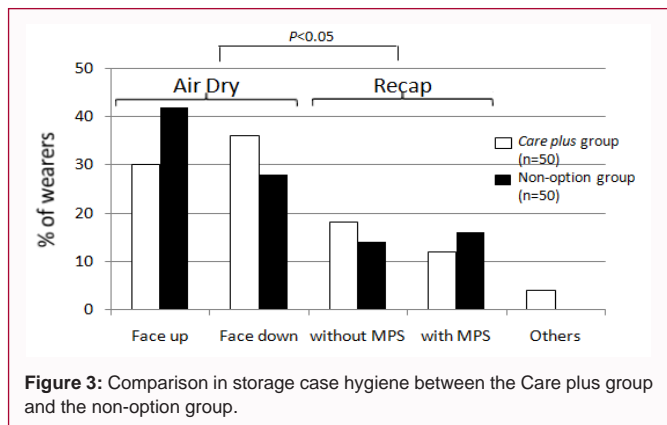


Figure 3: Comparison in storage case hygiene between the Care plus group and the non-option group.

who used 280 mL to 310 mL bottles were 19, and wearers who used 350 mL to 360 mL bottles were 7; wearers who reported the routine use of large-sized bottles of MPS were seven; ten wearers provided no answer about bottle volume). Wearers who used the same bottle of MPS for 1 month or less were significantly more in the Care plus group (26 patients, 53.1%) as compared with the non-option group (12 patients, 27.9%; P<0.05, Fisher exact test). Wearers who extended use for more than 2 months but no longer than 3 months were significantly more in the non-option group (6 patients, 14.0%) as compared with the Care plus group (0 patient, 0%; P<0.01, Fisher exact test).

Figure 1b shows the replacement intervals of a single large volume MPS (approximately 500mL) in the non-option group (n=33, including wearers who also used regular size bottles) from time of opening until the product was used up. Wearers who did not use large size bottles were excluded. Non-option wearers who extended use for more than 2 months but no longer than 3 months were significantly more (14 patients, 42.4%) as compared with those in using regular size bottle (6 patients, 14.0%; P<0.01, Fisher exact test).

Cleaning method of storage cases

Figure 2 shows the cleaning method of storage cases after each use (Care plus group: n=50, non-option group: n=50; 1 wearer had 2 answers, answers=51). Compliance with cleaning “each time” was significantly increased in the Care plus group compared to the non-option counterparts (P=0.054, Fisher exact test). Answer to the question “What do you rub with?” was overwhelmingly “with a finger” (100% for the Care plus group versus 85% for the non-option group). In the case of rinse only without rubbing for cleaning storage cases,

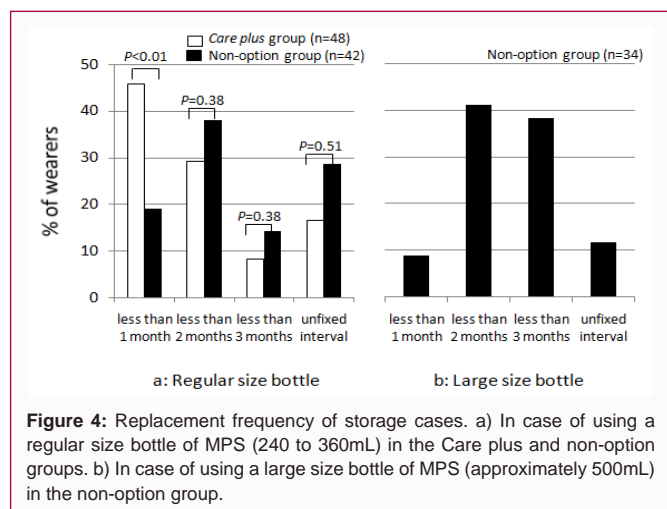


Figure 4: Replacement frequency of storage cases. a) In case of using a regular size bottle of MPS (240 to 360mL) in the Care plus and non-option groups. b) In case of using a large size bottle of MPS (approximately 500mL) in the non-option group.

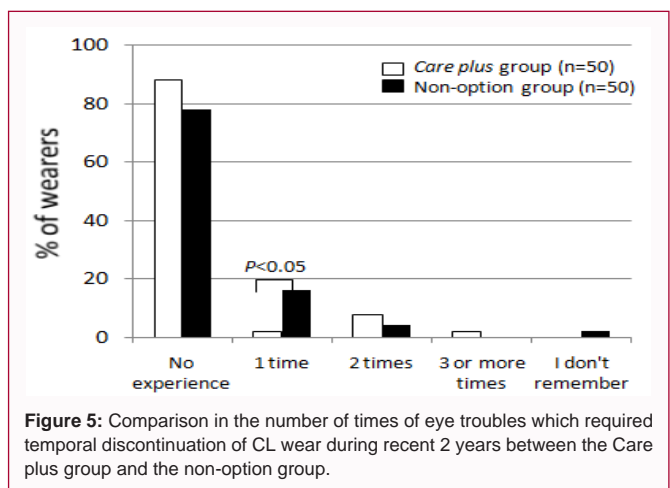


Figure 5: Comparison in the number of times of eye troubles which required temporal discontinuation of CL wear during recent 2 years between the Care plus group and the non-option group.

in the Care plus group, the percentage of wearers who rinsed with an MPS or tap water were 20% and 22%, respectively, and there was no significant difference between both regimens ($P=0.83$, Mc-Nemar test). Conversely, in the non-option group, wearers who rinsed with tap water (35.3%) were significantly higher than wearers who rinsed with an MPS (11.8%; $P<0.05$, Mc-Nemar test).

Storage case hygiene

Figure 3 shows storage case hygiene after each use (Care plus group: $n=50$, non-option group: $n=50$). Regardless of face up or face down storage, the percentage of wearers who air dried their storage cases was 66% in the Care plus group and 70% in the non-option group. Regardless of discarding MPS in wells of a storage case or not, the percentage of wearers who recapped their storage cases was both 30% in the Care plus group and non-option group. Although there was no significant difference in storage case hygiene regimen between both groups ($P>0.05$, Fisher exact test), the percentage of wearers who “air dried” was significantly higher than that of wearers who “recapped” in both groups ($P<0.05$, Fisher exact test). The ratio of wearers who air dried with “face down” rather than “face up” was not significantly different between the Care plus group and non-option group ($P=0.52$, Fisher exact test).

Replacement frequency of storage cases

Figure 4a shows the replacement frequency of storage cases for wearers who used a regular volume of MPS (Care plus group: $n=48$, non-option group: $n=42$, excluding wearers who did not use regular size containers). Wearers who replaced their storage cases once a month or less were significantly increased in the Care plus group (45.8%) than in the non-option group (19.0%; $P<0.01$, Fisher exact test); however the percentage of wearers who extended case use for more than 2 months but no longer than 3 months or replaced cases at irregular intervals was not significantly different between two groups ($P=0.38$ and $P=0.51$, respectively; Fisher exact test).

Figure 4b shows the replacement frequency of storage cases for wearers who used a large volume MPS in the non-option group ($n=34$, excluding wearers who did not use large size). Wearers who extended MPS use for more than 2 months but no longer than 3 months were significantly increased (13 patients, 38.2%) as compared with those patients using regular size bottle (6 patients, 14.3%; $P<0.05$, Fisher exact test).

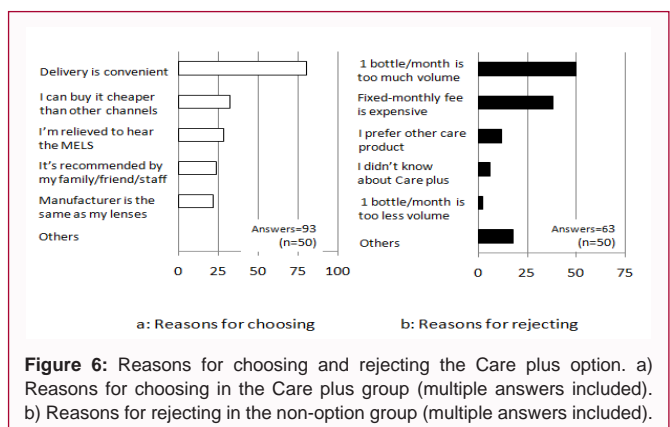


Figure 6: Reasons for choosing and rejecting the Care plus option. a) Reasons for choosing in the Care plus group (multiple answers included). b) Reasons for rejecting in the non-option group (multiple answers included).

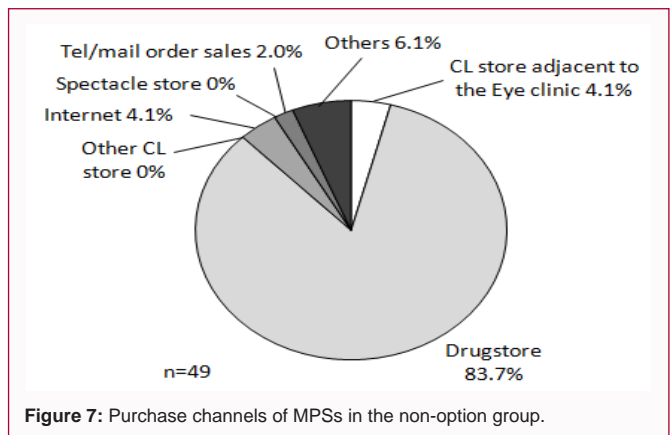


Figure 7: Purchase channels of MPSs in the non-option group.

Summary of compliance

Table 1 shows a short summary of circumstances of patient compliance with guidelines for proper CL use and lens care recommended by ophthalmologists, manufacturers and competent authorities in Japan for the Care plus group and the non-option group. Patient compliance with lens use was almost the same between the two groups. However, overall, compliance with lens care was better in the Care plus wearers than non-option counterparts.

Eye complications

Figure 5 shows the frequency of eye discomfort which resulted in temporal discontinuation of CL wear during a past 2-year period in the Care plus group ($n=50$) and the non-option group ($n=50$). A history of one period of lens discontinuation was significantly

Table 1: Comparison of patient compliance with practitioner recommended guidelines between the Care plus group and the non-option group.

Guidelines			Care plus group	Non-option group	
Classification	Compliance items	Recommendation			
Lens wearing	Wearing hours per day	Up to 16 hours	Good	Very good	
	Napping while lens wearing	Should avoid	Fair	Fair	
	Sleeping while lens wearing	Never	Good	Very good	
	Expiration date (Replacement frequency)	2 weeks	Very good	Good	
Lens cleaning	Rubbing with fingers	Every time	Very good	Very good	
Care product (MPS)	Expiration date after opening	Regular size bottle	1 month	Good	Fair
		Large size bottle	1 month	—	Poor
Storage cases	Cleaning, rinsing	With MPS	Good	Fair	
	Hygiene	Air dry	Good	Good	
	Replacement interval	Regular size bottle	1 month	Good	Fair
		Large size bottle	1 month	—	Poor

increased in the non-option group than that in the Care plus group ($P < 0.05$, Fisher exact test); however, temporary discontinuations more than 1 time were not significantly different between 2 groups ($P = 0.41$, Fisher exact test). There was no patient who had severe eye complications that required hospitalization in either test group.

Reasons for choosing and rejecting the Care plus option

Reasons for choosing the Care plus option are shown in Figure 6a (multiple answers included, $n = 50$, answers = 93). The main reason for choosing participation was “delivery is convenient; it’s troublesome to go and buy it” (80%).

Reasons for rejecting the Care plus option in the non-option group are shown in Figure 6b (multiple answers included, $n = 50$, answers = 63). The main reason given for rejecting participation was “1 bottle of MPS/month is too much volume (I cannot use it up in 1 month)” from 25 patients (50%). There were “I’m using it with my brother(s), sister(s) or family”, “I’m collecting shopping coupon points at a drugstore”, and “I purchase cheaper care products at a drugstore” as other reasons for rejecting from 9 patients (18%).

Purchase channels of care products

Purchase sources of MPSs for the non-option group are shown in Figure 7. Drugstores were overwhelmingly the main purchase channel (83.7%).

Volume of care product

Answers about the volume of an MPS (300 mL/container/month) for the Care plus group members ($n = 50$) were “just a good volume (I use it so that it may be used up)” 42%, “it remains” 36%, and “it’s not enough” 22%. When 1 bottle of MPS/month remained ($n = 49$, one wearer had no answer), patients reported that “I use it just as it is” 83.7%, “I use it so that it may not be remained” 16.3%, and there was no answer of “discard”.

Circumstances after choosing Care plus option

Change of consumption volume of MPS per one time treatment in the Care plus group after choosing the option ($n = 50$) was reported as “no change” (80%), “increased” was 14%, and “decreased” was 6%.

Change of replacement frequency of storage cases in the Care plus group after choosing the option ($n = 50$) was “no change” in 64% and “the frequency decreased” in 6%, but “the frequency increased” was reported in 30%.

Satisfaction of Care plus option

The degree of satisfaction in the Care plus group after choosing the option ($n = 50$) was reported as: “satisfied” 34%, “mostly satisfied” 52%, “can’t say either way” 14%, “a little dissatisfied” 0%, and “dissatisfied” 0%.

Discussion

A subscription membership system of CLs may simply be useful for identifying a cohort of patients who want to be more compliant and assisting them to do so. Shimamoto et al. [21] reported that the average duration of use of a single 2WFR lens was significantly longer in nonmembers, who did not belong to a membership system of CL replacement, than in members ($P < 0.001$). The percentage of wearers who replaced their 2WFR lenses within the recommended 15.4 days/lens wear was significantly increased by monthly fixed fee based-automatic lens replacement as compared with nonmembers ($P < 0.001$) [21], because any unexpected additional economical expense of CLs was prevented by membership in the system. Member wearers in the study reported here also showed good compliance with practitioner-recommended proper lens wearing including wearing hours per day, sleeping while lens wearing, and expiration date, but excluding napping while lens wearing as summarized in Table 1. It was thought that noncompliant reason would be “no harm in napping while lens wearing” as compared with “sleeping while lens wearing”, because patients have been informed by practitioners and manufacturers that the oxygen permeability of silicone hydrogel lenses is higher than that of hydrogel lenses. Patients have also been instructed worldwide to use rub and rinse cleaning of soft CLs; however, Morgan et al. [17] reported that the percentage of wearers who rubbed their CLs correctly has varied between 10% and 40%. In this questionnaire survey, Japanese wearers reported excellent compliance, cleaning their CLs by rubbing each time more than 70% in both the Care plus and non-option groups. Overall compliance with CL use (wearing and cleaning) was better in subscription member wearers as compared with general nonmember wearers. Unfortunately, Ariwaka et al. [22], however, reported that compliance with lens care regimens was not similarly improved by subscription membership of lens replacement alone. That is, it can be said that patient compliance with lens care in a subscription membership system of CLs is the same as that in general wearers who does not choose a CL membership. In this questionnaire survey study, patient compliance with lens care was compared between subscription members who elected

to participate in an additional monthly fixed fee based-option care delivery program Care plus and who did not choose the option. As summarized in Table 1, overall compliance with lens care was better in the Care plus option wearers than in non-option members who have the same care compliance behavior as general nonmember wearers. The hypothesis that patients electing to participate in the Care plus option might demonstrate increased rates of compliance with practitioner-recommended lens care instructions was proven. Wu et al. [24] reported that the recommended guidelines to patients for post-dispensing lens care differ among manufacturers, competent authorities and practitioners, and that wearers were often confused by this inconsistency. In the United States and Europe, recommended period for an expiration date for use of MPS after opening (discard dates) varies between 90 days and 6 months. Recommendations for replacement frequency of storage cases vary from one month to 6 months. Because biocontamination of lens storage cases directly promotes increased risk for MK, many studies have concentrated on case replacement, while neglecting compliance with overall use of care solutions. In some cases, a new storage case is supplied with a fresh bottle of MPS care solutions; however, larger bottles purchased for cost savings result in prolonged lens case use, which significantly increases risk for MK. The use of large volume bottles also directly increases the risk for finger-touch contamination of the bottle rim, as well as risk for direct microbial inspiration when flushing lenses or storage cases. Such contamination has been reported by Inaba et al. [13] and Yamasaki et al. [14] showing microbial adherence to the inside of the upper wall of the MPS level. Accordingly, in Japan, a manufacturer's recommended expiration date for an opened container of MPS is one month after opening. In the study reported here, participants were queried on the basis of one month expiration and each month replacement with a fresh storage case. Previous our Internet survey study of CL wearers in Japan revealed that the choice of CLs by wearers seemed to be price driven rather than being safety focused [20]. An important concomitant finding of the study by Ariwaka et al. [22] was also that choice of lens care products was a price driven decision. The current questionnaire study was undertaken to examine whether adding the elected benefit of convenience and potential cost savings of MPS care solutions automatically supplied to patients in one-month use bottle with a new storage case would increase compliance with their post-fitting lens care. And, indeed, significant behavioral increased compliance was observed for monthly solution volume use as well as monthly replacement with new storage cases. Importantly, patients who elected the Care plus option also used less tap water rinsing, and patients in both groups reported less wet closure of lens cases versus recommended air drying. Tilia et al. [7] have reported that use of tap water to rinse storage cases resulted in higher levels of storage contamination with bacteria; and, Wu et al. [25] have shown that wetly-recapped storage cases resulted in very low level of biofilm removal. Taken together, these results demonstrate that an elective choice of planned lens replacement coupled to automatic MPS renewal and a one-month solution size supplied with a new storage case, represents a significant new paradigm in promoting practitioner-recommended post-fitting care compliance. Addition studies will be needed in other global populations to confirm the observed Japanese behavior.

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