Subjective Assessment of a New Mouthwash for Relieving Oral Dryness

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Abstract

A novel, easy-to-use mouthwash that moisturizes the mouth and can counteract oral dryness has recently been shown to be effective. However, users’ subjective assessments of the usability of the mouthwash have yet to be evaluated. Thus, a questionnaire was administered to users of the experimental mouthwash to evaluate its usability. The subjects were 74 persons (59 men; mean age 43.5 ± 21.26 years), who were divided into two groups by age: young subjects, 45 persons (45 men; mean age 24.9 ± 4.7 years); and elderly subjects, 29 persons (14 men; mean age 64.4 ± 7.8 years). The mouthwash was a commercially available product to which a salivation promotion component (kelp extract) and moisturizing components (betaine, sodium hyaluronate) were added. The questionnaire comprising 9 items was administered before and after use of the mouthwash. The questionnaire asked patients to use appropriate scales to rate oral dryness, saliva characteristics, halitosis, intraoral pain, sore throat, unpleasantness of the mouthwash, usability and taste of the mouthwash, and desire to use it in the future. The results showed significant improvements in oral dryness, sore throat, saliva characteristics, and halitosis after use of the mouthwash in both young and elderly persons. In addition, many generally affirmative views of the usability of the experimental mouthwash were obtained. Thus, there was a uniform evaluation across the generations that use of the experimental mouthwash is effective. The results of the questionnaire suggest that this novel mouthwash for oral dryness can be used by people of all generations.

Keywords:
oral dryness, mouthwash, questionnaire survey, halitosis, elderly people

Introduction

Decreased secretion of saliva results in a feeling of oral dryness and is known to cause a range of intraoral disorders, such as candidiasis, inflammation of the tongue, taste disorder, and multiple dental caries (1–3). Oral dryness is frequently experienced by elderly people (4, 5), but there have been reports that, recently, not only elderly people, but also increasing numbers of young people are complaining of oral dryness as a result of excessive stress or depression brought on by a lack of skills to cope with psychological alterations or changes in their environment (6, 7). Oral dryness may thus be considered a disease that is not limited to any one generation.

For this reason, we previously developed an easy-to-use mouthwash suitable for all generations that not only moisturized the mouth but was also a countermeasure against oral dryness, and we reported its potential effectiveness (8). However, the users’ subjective assessments of the usability of the mouthwash should not be ignored. In the present study, a questionnaire was administered to users of the experimental mouthwash in order to evaluate its usability.

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Please evaluate the following items using the scales.

| Item                                      | Rating                |
|-------------------------------------------|-----------------------|
| Sensation of oral dryness                 |                       |
| Saliva with dry sensation                 |                       |
| Halitosis                                 |                       |
| Intraoral pain                            |                       |
| Throat pain                               |                       |

0 = Very bad; 1 = Bad; 2 = Neither good nor bad; 3 = Good; 4 = Very good

Usability of the mouthwash

Taste of the mouthwash

0 = no; 1 = yes

Discomfort or unpleasantness after using the mouthwash

0 = don’t want to use it; 1 = don’t want to use it very much; 2 = don’t know; 3 = want to use it; 4 = definitely want to use it

Do you want to use this mouthwash in the future?

**Fig. 1. Mouthwash questionnaire**

**Methods**

**Subjects**

The subjects were 74 persons (59 men, 11 women, mean age 43.5 ± 21.26 years), who were divided into young subjects and elderly subjects according to the age classifications of the Ministry of Health, Labour and Welfare. The young subjects were 45 persons (45 men, mean age 24.9 ± 4.7 years) comprising outpatients attending the Sleep Clinic of Nihon University School of Dentistry at Matsudo Hospital and students at Nihon University School of Dentistry at Matsudo. The elderly subjects were 29 persons (14 men, 15 women, mean age 64.4 ± 7.8 years) using a care facility for elderly persons, either as residents or on a daycare basis. The subjects were given an explanation of the objectives of the study in accordance with the Helsinki Declaration, and their informed consent was obtained. The study was approved by the Ethics Committee of Nihon University School of Dentistry at Matsudo (approval EC14-040). Exclusion criteria were persons who had oral soft tissue diseases, treatment history of salivary gland diseases within 6 months or currently under treatment.

**Mouthwash**

The mouthwash used in the present experiment (experimental mouthwash) was a mouthwash that is already commercially available (Mondahmin® non-alcohol, Earth Chemical Co., Ltd., Tokyo, Japan) to which a salivation promotion component (kelp extract) and moisturizing components (betaine, sodium hyaluronate) were added (8).

**Questionnaire**

The questionnaire comprised 9 items and was administered before and after use of the experimental mouthwash (Fig. 1). The questionnaire items were oral dryness status, saliva characteristics, halitosis, intraoral pain, and sore throat, which were evaluated on three-point scales; unpleasantness of the experimental mouthwash, which was evaluated on a two-point scale; and usability and taste of the experimental mouthwash and desire to use it in the future, which were evaluated on five-point scales. In addition, this questionnaire survey was conducted simultaneously with previous report (8).

**Statistics**

The results of questionnaire items relating to oral dryness status, saliva characteristics, halitosis, intraoral pain, and sore throat before and after use of the experimental mouthwash were analyzed by two-way mixed ANOVA.
using SPSS ver. 21 (IBM Japan, Tokyo, Japan). The significance level was set at 5%.

**Results**

Questionnaires were collected from all 74 subjects. For the presence of sensation of oral dryness, among the young subjects before use of the experimental mouthwash, 3 subjects (7%) responded 0 (no), 7 (15%) responded 1 (sometimes), and 35 (78%) responded 2 (yes) (Table 1). After use of the experimental mouthwash, 0 subjects (0%) responded 0, 0 (0%) responded 1, and 45 (100%) responded 2 (Table 1). Analysis of the responses before and after use of the experimental mouthwash score showed a significant increase after use ($P < 0.05$) (Table 1). Among the elderly subjects before use of the experimental mouthwash, 1 subject (3%) responded 0, 2 (7%) responded 1, and 26 (90%) responded 2 (Table 1). After use of the experimental mouthwash, 0 subjects (0%) responded 0, 0 (0%) responded 1, and 29 (100%) responded 2 (Table 1). Analysis of the responses before and after use of the experimental mouthwash showed a significant increase after use ($P < 0.05$) (Table 1).

1. For the presence of feelings of unpleasantness or discomfort with the saliva characteristics, among the young subjects before use of the experimental mouthwash, 3 subjects (7%) responded 0 (no), 6 (13%) responded 1 (sometimes), and 36 (80%) responded 2 (yes) (Table 1). After use of the experimental mouthwash, 0 subjects (0%) responded 0, 1 (2%) responded 1, and 44 (98%) responded 2 (Table 1). Analysis of the responses before and after use of the experimental mouthwash score showed a significant increase after use ($P < 0.05$) (Table 1). Among the elderly subjects before use of the experimental mouthwash, 0 subjects (0%) responded 0, 2 (7%) responded 1, and 27 (93%) responded 2 (Table 1). After use of the experimental mouthwash, 0 subjects (0%) responded 0, 1 (3%) responded 1, and 28 (97%) responded 2 (Table 1). Analysis of the responses before and after use of the experimental mouthwash showed a significant increase after use ($P < 0.05$) (Table 1).

2. For the presence of halitosis among the young subjects before use of the experimental mouthwash, 2 subjects (4%) responded 0 (yes), 4 (9%) responded 1 (sometimes), and 39 (87%) responded 2 (no) (Table 1). After use of the experimental mouthwash, 0 subjects (0%) responded 0, 1

| Oral dryness status | Yes | Sometimes | No |
|---------------------|-----|-----------|----|
| Sensation of oral dryness | | | |
| Young subjects | Before use | 35 | 7 | 3 |
| | After use | 45 | 0 | 0 |
| Elderly subjects | Before use | 26 | 2 | 1 |
| | After use | 29 | 0 | 0 |
| Saliva characteristics feel unpleasant or uncomfortable | | | |
| Young subjects | Before use | 36 | 6 | 3 |
| | After use | 44 | 1 | 0 |
| Elderly subjects | Before use | 27 | 2 | 0 |
| | After use | 28 | 1 | 0 |
| Halitosis | | | |
| Young subjects | Before use | 39 | 4 | 2 |
| | After use | 44 | 1 | 0 |
| Elderly subjects | Before use | 27 | 2 | 0 |
| | After use | 29 | 0 | 0 |
| Intraoral pain | | | |
| Young subjects | Before use | 41 | 4 | 0 |
| | After use | 44 | 1 | 0 |
| Elderly subjects | Before use | 26 | 2 | 1 |
| | After use | 29 | 0 | 0 |
| Throat pain | | | |
| Young subjects | Before use | 41 | 4 | 0 |
| | After use | 44 | 1 | 0 |
| Elderly subjects | Before use | 24 | 3 | 2 |
| | After use | 28 | 0 | 1 |
Table 2. Usability of the mouthwash

| Usability of the mouthwash | Bad | 1 | 2 | 3 | Good |
|----------------------------|-----|---|---|---|------|
| How do you find the usability? | 0 | 1 | 38 | 5 | 1 |
| Young subjects | 0 | 1 | 38 | 5 | 1 |
| Elderly subjects | 0 | 3 | 20 | 5 | 1 |
| How do you find the taste? | 1 | 2 | 35 | 6 | 2 |
| Young subjects | 1 | 2 | 35 | 6 | 2 |
| Elderly subjects | 0 | 3 | 21 | 5 | 0 |
| Do you want to use the mouthwash in the future? | Don’t want to use it | Don’t want to use it very much | Don’t know | Want to use it | Definitely want to use it |
| Young subjects | 1 | 5 | 16 | 21 | 2 |
| Elderly subjects | 1 | 5 | 10 | 10 | 3 |
| Did you feel any discomfort or unpleasantness in your mouth or body after using the mouthwash? | Yes | No |
| Young subjects | 0 | 1 |
| Elderly subjects | 0 | 29 |

(2%) responded 1, and 44 (98%) responded 2 (Table 1). Analysis of the responses before and after use of the experimental mouthwash score showed a significant increase after use (P < 0.05) (Table 1). Among the elderly subjects before use of the experimental mouthwash, 0 subjects (0%) responded 0, 2 (7%) responded 1, and 27 (93%) responded 2 (Table 1). After use of the experimental mouthwash, 0 subjects (0%) responded 0, 0 (0%) responded 1, and 29 (100%) responded 2 (Table 1). Analysis of the responses before and after use of the experimental mouthwash score showed a significant increase after use (P < 0.05) (Table 1).

3. For the presence of intraoral pain, among the young subjects before use of the experimental mouthwash, 0 subjects (0%) responded 0 (yes), 4 (9%) responded 1 (sometimes), and 41 (91%) responded 2 (no) (Table 1). After use of the experimental mouthwash, 0 subjects (0%) responded 0, 0 (0%) responded 1, and 44 (97%) responded 2 (Table 1). Analysis of the responses before and after use of the experimental mouthwash score showed a significant increase after use (P < 0.05) (Table 1). Among the elderly subjects before use of the experimental mouthwash, 1 subject (3%) responded 0, 2 (7%) responded 1, and 26 (90%) responded 2 (Table 1).

After use of the experimental mouthwash, 0 subjects (0%) responded 0, 0 (0%) responded 1, and 29 (100%) responded 2 (Table 1). Analysis of the responses before and after use of the experimental mouthwash score showed a significant increase after use (P < 0.05) (Table 1).

4. For the presence of sore throat, among the young subjects before use of the experimental mouthwash, 0 subjects (0%) responded 0 (yes), 4 (9%) responded 1 (sometimes), and 41 (91%) responded 2 (no) (Table 1). After use of the experimental mouthwash, 0 subjects (0%) responded 0, 1 (2%) responded 1, and 44 (98%) responded 2 (Table 1). Analysis of the responses before and after use of the experimental mouthwash score showed a significant increase after use (P < 0.05) (Table 1). Among the elderly subjects before use of the experimental mouthwash, 2 subjects (7%) responded 0, 3 (10%) responded 1, and 24 (83%) responded 2 (Table 1). After use of the experimental mouthwash, 1 subject (3%) responded 0, 0 (0%) responded 1, and 28 (97%) responded 2 (Table 1). Analysis of the responses before and after use of the experimental mouthwash score showed a significant increase after use (P < 0.05) (Table 1).
5. For the usability of the experimental mouthwash, among the young subjects, 1 subject (2%) responded 4 (very good), 5 (11%) responded 3 (good), 38 (84%) responded 2 (neither good nor bad), 1 (2%) responded 1 (bad), and 0 (0%) responded 0 (very bad) (Table 2). Among the elderly subjects, 1 subject (3%) responded 4, 5 (17%) responded 3, 20 (69%) responded 2, 3 (10%) responded 1, and 0 (0%) responded 0 (Table 2).

6. For the taste of the experimental mouthwash, among the young subjects, 2 subjects (4%) responded 4 (very good), 6 (13%) responded 3 (good), 35 (77%) responded 2 (neither good nor bad), 2 (4%) responded 1 (bad), and 1 (2%) responded 0 (very bad) (Table 2). Among the elderly subjects, 0 subjects (0%) responded 4, 5 (17%) responded 3, 21 (73%) responded 2, 3 (10%) responded 1, and 0 (0%) responded 0 (Table 2).

7. For the question of whether there were any unpleasant feelings or discomfort after use of the experimental mouthwash, among the young subjects, 0 subjects (0%) responded 0 (yes) and 45 (100%) responded 1 (no) (Table 2). Among the elderly subjects, 0 subjects (0%) responded 0 and 29 (100%) responded 1 (Table 2).

8. For the question of whether subjects would like to continue using the experimental mouthwash in the future, among the young subjects, 2 subjects (4%) responded 4 (definitely want to use it), 21 (47%) responded 3 (want to use it), 16 (36%) responded 2 (don’t know), 5 (11%) responded 1 (don’t want to use it very much), and 1 (2%) responded 0 (don’t want to use it) (Table 2). Among the elderly subjects, 3 subjects (10%) responded 4, 10 (35%) responded 3, 10 (35%) responded 2, 5 (17%) responded 1, and 1 (3%) responded 0 (Table 2).

Discussion
The results of the questionnaire on oral dryness status and usability administered before and after use of the experimental mouthwash showed significant improvement in oral dryness status, sore throat, saliva characteristics, and halitosis after use of the mouthwash in both the young and the elderly. In addition, many generally affirmative views of the usability of the experimental mouthwash were obtained. From the foregoing, it may be said that there was a uniform evaluation across the different generations that use of the experimental mouthwash is effective.

Items relating to oral dryness status
In questionnaire items relating to oral dryness status, in both generations there was a significant reduction in sensation of oral dryness after use of the experimental mouthwash. This may be regarded as a clear indication of the effectiveness of the mouthwash. In addition, saliva characteristics, halitosis, and intraoral and pharyngeal pain also improved in both generations after use of the experimental mouthwash. López-Jorne et al. (9) used a mouthwash containing betaine to treat subjects complaining of oral dryness, and they used a questionnaire on oral dryness to survey the subjects before and after treatment. They found significant improvement in oral dryness status, and they therefore concluded that the mouthwash was useful. At the same time, Alpóz et al. (10) used Buccotherm™ spray (Buccotherm®, Castéра-Verduzan, FRANCE) on subjects complaining of oral dryness, and they administered a questionnaire survey before and after use of the spray. They reported significant improvements in the oral dryness status and oral mucosa pain of the subjects, and stated that the oral spray is useful. Looking at the present survey results, which also show significant improvements in oral dryness status and associated symptoms, the subjective assessment suggests that the experimental mouthwash may be useful as a measure against oral dryness.

In addition, while significant improvement was seen after use of the experimental mouthwash, there were no significant differences between young and elderly subjects. The mouthwash may therefore be regarded as effective for both generations.

Items relating to usability
For the usability of the experimental mouthwash, 97% of young subjects and 90% of elderly subjects gave positive responses. However, 10% of elderly subjects gave somewhat negative assessments, and this may have been because usability also included the washing actions of gargling and spitting out, which were perhaps unfamiliar to the elderly subjects, as well as the characteristics of the mouthwash itself. Nonetheless, even when this is taken into account, it is probably true to say that the present mouthwash can be used easily by all generations. Needless to say, the fact that use of the mouthwash is simple, involving no more than gargling, is particularly advantageous for elderly people.

In addition, for the taste of the experimental mouthwash, 94% of young subjects and 90% of elderly subjects
responded positively. This mouthwash has a lychee flavor, and after use, there were no subjects who complained of discomfort or unpleasantness. In a study by Shiroma et al. (11), 323 subjects aged 18-74 years who complained of oral dryness used a moisturizing mouthwash for oral dryness and were surveyed by a questionnaire. The results showed that positive responses regarding usability and taste were obtained from over 80% of subjects, and the authors concluded that the mouthwash was useful for managing oral dryness. In the present study, positive responses were received from 90% or over of subjects from both generations, suggesting the possibility that the experimental mouthwash can be used as a measure against oral dryness by all generations, with no resistance concerning usability or taste. Further, concerning continued use of the mouthwash in the future, 13% of young people and 21% of elderly people responded that they did not want to continue to use it. The experimental mouthwash may thus be considered to be generally accepted by all generations as a mouthwash that can be used on a long-term basis. At the same time, 49% of young subjects and 55% of elderly subjects responded either that they did not know whether they wanted to continue to use the mouthwash or not, or that they did not want to use it. Thus, approximately half of the subjects wanted to use the experimental mouthwash. Takenaka (12) carried out a questionnaire survey of general subjects and reported that approximately half of the subjects had experience using a mouthwash, which is a similar trend to the present study. However, Takenaka also reported that, of those with experience using a mouthwash, approximately half had ceased using it, and the most common reason given for this is that the subjects no longer saw the need for the mouthwash. The present results were probably obtained because few of the subjects in the present study originally complained of oral dryness, and therefore few subjects felt the need to improve oral dryness.

The present study has yielded a generally favorable evaluation of the experimental mouthwash. However, subjects were instructed to brush their teeth, but no intraoral examination was done in this experiment. Therefore, plaque and calculus remain in the oral cavity of the subject, which may increase the viscosity of the saliva (13). Also, there is a need to examine long-term use to see how the effects can be judged and whether users become habituated to the stimulus or grow weary of it. We therefore intend to carry out a more detailed study in the future.

Conclusion

The results of the questionnaire suggest that the novel mouthwash for oral dryness can be used by people of all generations.

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