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ORIGINAL ARTICLE

Impact of wearing an intra-oral lubricating device on oral health in dry mouth patients

PM Frost, PJ Shirlaw, SJ Challacombe, L Fernandes-Naglik, JD Walter, M Ide

GKT Dental Institute, King's College, London, UK

OBJECTIVE: To establish whether an intra-oral lubricating device for dry mouth alters the oral environment.
DESIGN: A single-blind randomized cross-over study.
METHOD: Twenty-nine dentate subjects from the Sjogren's syndrome clinic attended on five occasions at 4-week intervals. They were randomized, having the device fitted on either the second or the fourth visit for the experimental period, whilst using their preferred method of lubrication throughout the rest of the study. The preferred methods of lubrication were either water (group 1, $n = 10$) or saliva substitute (group 2, $n = 9$) or sugar-free chewing gum (group 3, $n = 10$). At each visit microbiological, unstimulated and stimulated saliva samples were collected. Dry mouth score, speech test and periodontal indices were recorded.
RESULTS: The water lubrication group (1) had a resting salivary flow greater than lubrication groups (2 and 3) by post-ANOVA contrasts ($P < 0.001$). The postdevice data also demonstrated a salivary flow greater than lubrication group (3) by post-ANOVA contrasts ($P < 0.05$). The epithelial cell count using the Spearman correlation was high, possibly reflecting increased viscosity of the saliva ($P = 0.044$). The speech test indicated that the experimental subjects had difficulty in speaking ($P = 0.001$). This was slightly easier postdevice wear. *Streptococcus mutans* ($P = 0.009$) and *Lactobacillus* ($P = 0.058$) increased in the saliva after wearing the device. Salivary flow rate, *Candida albicans*, oral dryness, speaking and periodontal indices were unchanged.
CONCLUSIONS: The oral environment was altered by wearing a lubricating device with an increase in the numbers of *Strep. mutans* and *Lactobacillus*. Clinical dryness and speech test correlated with the mean whole salivary flow suggesting a screening method for xerostomia.
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Correspondence: Peter M Frost, 178 Peckham Rye, London SE22 9QA, UK. Tel: +44 (0)20 8693 4001, Fax: +44 (0)20 8693 4001, E-mail: pfdrymouth@aol.com
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Introduction

Saliva has an important role in oral health providing physical and immunological protection, and it acts as a reservoir of ions which aid remineralization of the calcified tissues (Edgar and O'Mullane, 1996). Lubrication with saliva is an important part of keeping the mouth healthy. Saliva allows clearance of sugars and by the action of muco-glyco proteins harmful micro-organisms are aggregated and swallowed (Lenander-Lumikari and Loimaranta, 2000). Mucus aids the lubrication of oral tissues and secretory immunoglobulins protect against micro-organisms. The salivary pellicle protects the mucosa by means of lubrication and the mineralized tissues by providing a physical barrier (Edgar and O'Mullane, 1996). Bicarbonate, protein and phosphate levels of saliva increase with stimulated flow and provide effective buffering, preventing rapid change in the pH (Mandell, 1987). Digestion, taste and water balance are all assisted by salivary flow. Homeostasis of water balance is maintained via osmo-receptors. With dehydration, saliva and urine production is reduced and thirst induces drinking. Conversely, xerostomia will have a negative effect on the oral health (Edgar and O'Mullane, 1996). A dry mouth can be caused by a variety of reasons: dehydration, mouth breathing, medication (Sreebuy *et al*, 1989) chemo- and radiotherapy and salivary hypofunction related to Sjogren's syndrome. Not only is the quantity of saliva diminished in xerostomia but also the quality (Greenspan, 1996). A compromised oral environment allows an increase in micro-organisms, notably *Candida albicans*, *Streptococcus mutans* and *Staphylococcus aureus* (Bahn, 1971). Oral candidiasis results in erythematous patches on the hard or soft palate and the dorsal surface of the tongue. Angular cheilitis presents as fissuring of the commissures and is associated with *Candida* or sometimes with *Staph. aureus*. The dentate dry mouth sufferer will be

susceptible to an increase in oral micro-organisms which will inflame the gingival tissues and predispose to caries (Greenspan, 1996). A study by Almstahl *et al* (2003) of five hyposalivation groups showed an increase in levels of micro-organisms in the saliva when compared with a group with normal salivation. The hyposalivation groups included those who had radiation therapy, primary Sjogren's syndrome, medication, of unknown aetiology and a neuroleptic group, of these the primary Sjogren's group had the most micro-organisms. The changes in microflora appeared to be strongly related to the reason for hyposalivation rather than the degree of reduction in salivary secretion rate.

Saliva can be stimulated by using sialogogues such as pilocarpine hydrochloride which stimulates residual gland function, but there are side-effects that limit its use (Guchelaar *et al*, 1997). Cevimeline is a new cholinergic agonist that binds selectively to muscarinic M_3 receptors in salivary glands. It has some advantages over pilocarpine (Ninomiya *et al*, 1998) being as longer lasting with fewer side-effects. Sugar-free chewing gum and saliva stimulants are other methods of stimulating saliva flow (Bjornstrom *et al*, 1990), but when the salivary function becomes further compromised saliva substitutes fulfil a role (Epstein and Stevenson-Moore, 1992). There are many substitutes on the market but the more recent lactoperoxidase gels, toothpastes, mouthwashes and chewing gums attempt to mimic saliva by introducing substances present in natural saliva (Regelink *et al*, 1998).

A method of delivering saliva substitute over a longer period of time is the use of intra-oral reservoirs (Sinclair *et al*, 1996; Frost *et al*, 1997, 2002). Some authors have found them unsuccessful (Al-Hashimi, 2001) but in our experience patients have found them very acceptable especially at night-time when salivary flow diminishes.

The risk factors in a patient with salivary hypofunction need to be monitored, especially when a foreign body, such as a prosthesis that may harbour micro-organisms, is introduced into the mouth (Bahn, 1971). There is evidence that a denture can increase the number of micro-organisms in a dry mouth (Marsh *et al*, 1992).

Aims

The aim of this study was to establish whether the wearing of an intra-oral lubrication device for dry mouth subjects would alter the oral environment, both in terms of changes in the indices used to monitor oral health and the subjective opinion of wearers. A single-blind randomized cross-over study investigated the effect of an intra-oral lubrication device on the oral environment in dry mouth subjects.

Subjects and method

Ethical approval was received from the Guy's and St Thomas' Hospital Trust ethical committee. Thirty-four subjects from the Sjogren's syndrome clinic in the Department of Oral Medicine and Pathology at Guy's Dental Hospital were recruited. Twenty-nine subjects took part in the study. There were 27 female and two male subjects and their average age was 62 years (range 30–83) reflecting the population group of this clinic and similar oral medicine clinics (Johnnson *et al*, 2001). Subjects registered their main lubrication method, subsequently referred to as the 'preferred' treatment, in a preliminary questionnaire. The preferences were: sips of water (group 1) ($n = 10$); saliva substitute gel (group 2) ($n = 9$); and sugar-free chewing gum (group 3) ($n = 10$).

The subjects attended for five visits each at intervals of 4 weeks (Table 1). During the non-experimental period they used their preferred method of lubrication. At the second visit, the lubrication device (Figure 1) containing saliva substitute gel was fitted (Frost *et al*, 2002) in half the subjects (group A), according to random allocation. The other half (group B) continued with their original preferred method of lubrication. At the third visit group A returned to lubricating with their preferred method, commencing a wash-out or postdevice period. The other half of the population (group B) continued lubricating with their preferred method. At the fourth visit, group B (who had not worn the device in the second period) commenced the experimental period. Group A continued using their preferred lubrication method. At the fifth visit the study was completed.

The examination and sampling sequence

At each visit the following sequence was followed:

1. Questionnaire completion

During the course of the study the subjects kept a diary in which their type of lubrication and timings were noted. At each visit this data was totalled and averaged out and entered onto the questionnaire sheet. The

Table 1 Study programme brief treatment protocol

Visit 1	*Visit 2*	*Visit 3*	*Visit 4*	*Visit 5*
OM, Perio, Imps, SP Continue with preferred method	OM, Perio Group A: fit device Group B: continue with preferred method	OM, Perio Washout with preferred method	OM, Perio Group B: fit device Group A: continue with preferred method	OM, Perio
Q1	Q2	Q3	Q4	Q5

OM, oral medicine measurements and saliva sampling; Perio, periodontal measurements; Imps, alginate impressions; SP, scale and polish; Q = questionnaire.

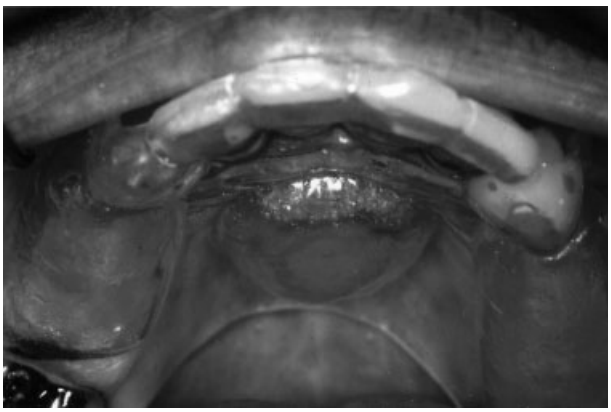

Figure 1 The ethyl vinyl acetate (EVA) device

questionnaire included enquiries regarding the ability to speak, chew and swallow (Frost *et al*, 2002). The subjects were also asked whether they preferred using the lubricating device at night compared with their previous method of lubrication. Participants were asked not to lubricate their mouths for up to an hour before each visit, which was at the same time on the same weekday to avoid diurnal variation.

2. Dry mouth score
Subjects were examined intra-orally by either of two examiners who had been calibrated in their use of a 1–10 scale (Table 2) where 'well lubricated' would be 1 and 'very dry' 10. The following products were used during the course of the study:

1. *Saliva substitute gel*: Oralbalance, active ingredients: lactoperoxidase, glucose oxidase and xylitol (Biotene; Anglian Pharma Sales and Marketing Ltd, Titmore Court, Titmore Green, Hitchin, Hertfordshire, UK).
2. *Sugar-free chewing gum*: Orbit (The Wrigley Company, Plymouth, Devon, UK).

3. Whole mouth unstimulated salivary flow
The 10-min unstimulated salivary flow was measured by expectoration into a receiver. Those subjects who had very dry mouths had flow rates of <0.01 ml min^{-1} and could not produce a specimen in 10 min.

Table 2 Clinical dryness scale

Criteria and scoring method
Add 1 point for each feature to a maximum of 10
1. Mirror sticks to buccal mucosa
2. Mirror sticks to tongue
3. Debris on palate
4. No saliva pooling on floor of mouth
5. Cervical caries
6. Altered gingival architecture
7. Glassy appearance to oral mucosa
8. Saliva frothy
9. Tongue marginally depapillated
10. Tongue highly fissured
11. Tongue lobulated
12. Tongue atrophic
13. Debris on denture

4. Bacteriological sample
Five millilitres of normal saline rinse for 20 s for microbiological analysis. The microbiological samples were analysed for: *Strep. mutans*, *Lactobacillus* and *C. albicans*, as described below. This was accompanied by an epithelial cell count, which is described in the Microbiological protocol section. The relationship between whole saliva flow and epithelial cell count at baseline was measured by using the Spearman correlation coefficient.

5. Parotid stimulated flow
Ten-minute stimulated flow was measured via a Lashley cup placed over Stenson's duct using 5% citric acid, one drop dripping onto the tongue every minute.

6. Speech test
A speech test was undertaken to assess the impact of dryness on speaking. The phoneme sequence 'PUTTICA' was repeated as many times as possible by the subject during a 2-min period and recorded. The three syllables represent three different lip and tongue positions, which was counted by an observer using a mechanical counter which registered each sequence when pressed (Table 3). A parallel study was undertaken with a control group, the members matched by gender and age but with normal salivary flow. Both studies excluded subjects who had respiratory problems which may have caused distress. This validation exercise showed the Puttica scores 116 *vs* 171 ($P < 0.001$) where the experimental group (xerostomia) scored lower than the control group.

7. Periodontal measurements
Periodontal data was recorded for pocket depth, plaque (Silness and Loe, 1964) and bleeding (Loe and Silness, 1963) indices as in tables. As the results did not show any change before and after the intervention of wearing the device the data are not reported in this paper.

Microbiological protocol
Counts of *mutans*-group streptococci, lactobacilli and candida species were obtained by plating the saliva/rinse samples on TYCSB, Rogosa and Sabouraud's agars respectively using standard methods (Murray *et al*, 1999). The identity of *mutans*-group streptococci isolates was confirmed by tests for mannitol and sorbitol fermentation, arginine hydrolysis and production of dextrans.

Epithelial cells count in saliva and assessment of their viability was undertaken according to the method of Manford and Patterson (1979). The sample of saliva clumps and aggregates of bacteria was dispersed efficiently and 1 vol of 0.4% trypan blue in saline was added to the sample. All the epithelial cells were counted using a Fuchs Rosenthal cell counter as used in haematology. The epithelial count was calculated as the number of counted cells $\times 1000 \times 2 =$ number of cells per ml numerated. The results were expressed as a percentage of living cells.

Table 3 Mean (standard deviation) of dryness indicators for subjects after 4 weeks using their normal lubricator (control) and after 4 weeks using the device together with *P* values for analysis of variance between groups

	Whole saliva flow rate (ml min^{-1})		*Speech index (PUTTICA words/2 min)*		*Clinical dryness (range 1–10)*	
Lubrication group	*Post-preferred method period*	*Post-device period*	*Post-preferred method period*	*Post-device period*	*Post-preferred method period*	*Post-device period*
Water	0.31 (0.11) ($n = 7$)	0.31 (0.19) ($n = 7$)	112 (56) ($n = 9$)	142 (50) ($n = 8$)	5.5 (3.1) ($n = 8$)	6.4 (2.3) ($n = 9$)
Saliva substitute	0.12 (0.07) ($n = 7$)	0.21 (0.16) ($n = 7$)	116 (39) ($n = 10$)	149 (51) ($n = 9$)	6.7 (2.7) ($n = 10$)	6.5 (2.0) ($n = 10$)
Sugar-free chewing gum	0.06 (0.04) ($n = 9$)	0.09 (0.06) ($n = 8$)	119 (47) ($n = 10$)	126 (43) ($n = 10$)	5.7 (2.6) ($n = 10$)	5.7 (3.0) ($n = 10$)
All patients	0.15 (0.13) ($n = 23$)	0.20* (0.16) ($n = 22$)	116 (49) ($n = 29$)	139** (47) ($n = 27$)	6.0 (2.7) ($n = 28$)	6.2 (2.4) ($n = 29$)

Post-device mean significantly different from postpreferred method mean (*$P = 0.003$, **$P = 0.001$).

Prosthetic procedures

At the end of the first visit the teeth were scaled and polished and alginate impressions were taken for working casts. The casts were used for designing and fabricating the ethyl vinyl acetate (EVA) lubricating device (Frost *et al*, 2002) (Figure 1). Subsequently, on either the second or the fourth visit the device was fitted and the subject was instructed in its use. The subject's satisfaction score was noted at the next visit when completing the questionnaire (Frost *et al*, 2002).

Results

In Table 3 the mean of the dryness indicators for the subjects wearing the device after 4 weeks is shown. Also included are the clinical dryness scores, mean whole salivary flow rates and mean speech index. For the whole salivary resting flow rates, the water lubricators possessed near normal mean salivary flows (0.31 ml min^{-1}) whereas the sugar-free chewing gum lubricators (0.06 ml min^{-1}) had a low mean resting salivary flow. The speech test and clinical dryness results were similar for all three groups. The postdevice whole saliva resting flow rate increased slightly as did the speech index scores ($P = 0.003$). The clinical dryness scores and mean salivary flow rates after wearing the device were unchanged. Subjects showed an improved speech ability in the postdevice period compared with the predevice period by estimated Puttica scores 116 ± *vs* 139 ± ($P = 0.001$).

Data from the microbiological results are shown in Table 4. There was a statistically significant increase in numbers of *Strep. mutans* ($P = 0.009$) and an increase in levels of *Lactobacillus* species which approached significance ($P = 0.058$) after wearing the device. There was a statistically significant negative correlation (−0.434, $P = 0.044$) between the whole saliva flow rate and epithelial cell count at baseline using the Spearman coefficient. The salivary flow rates, *C. albicans* levels and clinical measure of oral dryness did not change after wearing the device. The results of the questionnaire data (Frost *et al*, 2002) showed that there were changes between all variables whilst wearing the device which either approached or reached clinical significance. The subjects' self-assessment of mouth dryness ($P = 0.056$), speech ($P = 0.009$) and swallowing ($P = 0.03$) was more favourable when compared with the preferred lubricant. Overall 66% of the subjects favoured wearing the device compared with their preferred method of lubrication.

Discussion

Referring to Table 3, the normal unstimulated whole saliva flow rate in the population is about 0.3 ml min^{-1} and if this rate falls by 50% symptoms of dryness are noticed by patients (Dawes, 1987). The mean whole flow rate for the water lubricator group was near normal at 0.31 ml min^{-1}. However the other two groups, saliva substitute and sugar-free chewing gum lubricators were 0.07 and 0.04 ml min^{-1}, respectively, both below the dryness threshold of 0.15 ml min^{-1} (Dawes, 1987). These latter groups exhibited xerostomia but the water lubricators showed near normal whole salivary flow rates. During the registration of their preferred method of lubrication it is interesting to note that 60% used water, 27% sugar-free chewing gum and 13% saliva substitute. It appears that although all subjects had been told of the various lubrication methods during their time attending the clinic the majority reverted back to water. It may be that those subjects who were perceived to have the driest mouths were able to derive more benefit from the chewing gum and the saliva substitute.

Table 4 Median (interquartile range) for microbiological variables at baseline and post-treatment for periods using device and preferred treatment

	Device with salivary substrate		*Preferred treatment*	
Micro-organisms	*Baseline*	*Post-treatment*	*Baseline*	*Post-treatment*
Streptococci ($\times 10^3$)	20 [2.6–115]	145[a] [0.6–707]	30 [0.3–78]	175 [93–120]
Lactobacillus ($\times 10^3$)	64 [6.4–178]	163 [4.7–595]	48 [0.3–525]	61 [4.6–445]

[a]Post-treatment median for device significantly different from baseline ($P = 0.009$) and that for preferred treatment ($P = 0.032$).

The speech test mean values were remarkably consistent amongst the three groups in (Table 3) but the postdevice data indicated an improvement in the speech rate. Whether this is due to an improved lubrication is difficult to assess. The improved speaking could be because of subjects becoming more skilled in this test by the fifth occasion. The average 'Puttica' scores in the postdevice period were 139 and 116 in the predevice period. This represented a statistically significant difference ($P < 0.001$) indicating a relationship between a dry mouth and difficulty in speaking quickly over a period of 2 min. This test combined with the dry mouth scoring (Table 3), may be useful for simple dry mouth screening purposes. The clinical dryness scores were similar in all three groups with a slightly higher dryness with the salivary substitute group. This may not be important because the dry mouth scoring is recorded in whole numbers and is subjective. The devices were introduced at the second or the fourth visit and were assessed at the third and fifth visit. The effect of wearing the device had little impact on the clinical dryness assessed visually and by the flow rate but may have had a slight effect on the speech index.

The increase in micro-organisms in all groups after wearing the device was not surprising. Research performed on patients wearing dentures has shown that the number of micro-organisms in the mouth increases when a prosthesis is introduced but it does not have clinical significance unless the patients are over 80 years of age when the numbers increase in third and fifth visit. The effect of wearing the device had little clinical impact (Marsh *et al*, 1992).

The saliva substitute gel used with the device may have acted as a substrate which encouraged the micro-organisms to increase. Lenander-Lumikari *et al* (1993) found that a lactoperoxidase system form of Biotene toothpaste did not show antibacterial effects against *Strep. mutans* and lactobacilli either in whole saliva or in dental plaque. However this increase in micro-organisms in our study was not reflected by a change in the periodontal and other clinical indices, it is possible that the study did not continue long enough to show a change. *Candida albicans* levels in our study were unchanged both before and after wearing the device. The presence and effects of candidiasis are usually severe with patients who have Sjogren's syndrome (Greenspan, 1996). The correlation between the epithelial cell count and whole salivary flow rate is another indicator of xerostomia, where more squames and debris are present. The epithelial cell count analysis was originally introduced into the study to assist another method of testing the pathogenic activity of the *Strep. mutans* and *Lactobacillus*.

The device could also be used as a delivery system for chlorhexidine gel by direct application to the fitting surface and the patient could use this at intervals depending on their risk status for caries (Kidd, 1991) in addition to using it as carrier for a lubricant. Patient preferences for the device compared with the three lubricating methods were also assessed (Frost *et al*, 2002). The majority of the subjects preferred wearing the device compared with their normal method of lubrication and their perception of dryness, speech and swallowing became closer to normal in the postdevice period after they had worn the device compared with the preferred treatment period. Longer term monitoring is required to see whether there are harmful effects from wearing the lubricating device. Many of the Sjogren's syndrome patients attending the clinic have a regime of antifungal and chlorhexidine mouthwashes for 1 week in four, to keep the candida and micro-organism levels within normal limits and therefore any increase in the micro-organisms when wearing the device might not be clinically significant with this regime.

The cross-over element of the study allowed a comparison between the subjects who received the device at their second visit (group A) with those who received it at the fourth visit (group B) (Frost *et al*, 2002). For those who wore the device first, five of 12 preferred its lubricating effect and for those who wore it second, 14 preferred the device to three who did not. This variation cannot be explained. There was otherwise little difference between the data collected before the intervention of the device and subsequent to it being worn, other than the increase in micro-organisms.

Conclusions

There was a significant increase in salivary *Strep. mutans* levels on wearing the device. The other clinical indices of oral health were not changed after using the device. Further studies would be required to show whether the device was harmful to the gingivae or dental hard tissues on long-term use. A positive correlation was found between the clinical dryness score and the mean whole salivary flow rate for those lubricating with water. The clinical dry mouth scoring system, speech test and mean whole mouth salivary flow correlate and may be useful in screening for xerostomia. The intra-oral lubricating device would seem to be a useful method of lubricating the dry mouth at night-time.

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