

IN BRIEF

- An alternative method of dry mouth lubrication.
- A novel intra-oral lubricating device.
- Water, saliva substitute and sugar free chewing gum compared with the device.
- The majority of the subjects preferred the device especially at night time.

Patient preferences in a preliminary study comparing an intra-oral lubricating device with the usual dry mouth lubricating methods

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Objective: To compare an intra-oral device to relieve oral dryness with the other methods of lubricating the mouth at night.

Design: Multidisciplinary single blind randomised cross over study.

Setting: The subjects were drawn from patients attending a dry mouth clinic.

Materials and methods: Thirty-four dentate subjects attended on five occasions at intervals of 4 weeks. At the first visit the teeth were scaled and impressions were recorded. The device was fitted either on the second or the fourth visit. At all visits samples were taken of the resting and stimulated saliva for volumetric analysis and the dry mouth score recorded. Data were collected from the lubrication timings and the questionnaire.

Results: Ten water, nine saliva substitute and ten sugar-free chewing gum lubricators completed the study. There were 27 female and two male subjects with an average age of 62 years. Nine out of 10 of those lubricating with chewing gum preferred wearing the device ($P = 0.037$). After the device wearing period the subjects' self assessment of mouth dryness ($P = 0.056$), speech ($P = 0.009$) and swallowing ($P = 0.031$) were more favourable when compared with the alternative lubrication with 66% preferring the intra-oral device to their alternative method of lubrication.

Conclusions: The majority of the subjects preferred wearing the device at night compared with their normal method of lubrication. Subjects' perception of dryness, speech and swallowing became closer to the clinician's assessment after wearing the device.

The number of complaints by patients who have xerostomia is on the increase, especially amongst the elderly.¹ This paper describes one method of assisting patients who have this condition.

A dry mouth can result from several causes, dehydration –

a reduction in liquid intake, medication – anti-depressants and many other medicines, systemic disease – diabetes and autoimmune conditions such as Sjogren's syndrome and radiotherapy to the head and neck regions. A subject's feeling of a dry mouth is not an objective indicator of xerostomia. A recent study¹ showed that only 65% of the attendees at a dry mouth clinic had objective evidence of xerostomia. Of this group who had salivary gland hypofunction the causes were: Sjogren's Syndrome 40%, iatrogenic 22%, idiopathic 19%, psychogenic 14%, and other reasons 5%. The treatment of a dry mouth relies mainly on providing symptomatic relief because in the majority of instances the condition cannot be eliminated.

Conventional methods of lubricating the mouth do not provide a person experiencing dryness with adequate moisture² and dry mouth sufferers tend to choose a lubrication method which is most appropriate at the time. At night time the xerostomia is at its worst because as well as the inherent dryness the salivary gland flow rates fall, thus compounding the problem. Dry mouth sufferers will have a disturbed sleep by lubricating through the night with liquid (usually sips of water). A study of thirty patients who were regular attenders at the Guy's Hospital Sjogren's Syndrome clinic indicated that the most common method of lubrication was water (60%), sugar free chewing gum (27%)³ and saliva substitute (13%) in spray or gel form.⁴ Water is easily dispersed in the mouth and does not provide a lasting lubrication effect. Sugar free chewing gum stimulates the salivary glands and is recommended by xerostomia clinics. Stimulation by medication has been described using pilocarpine but the side effects can be unpleasant.⁵ Both methods assume that there is sufficient residual salivary gland present.

The ideal situation may be to provide the dry mouth sufferer with an intra-oral reservoir which contains saliva substitute, takes up minimal space and slowly releases the lubricant onto the dry oral tissues. The delivery of lubricant into the oral cavity from a hollow prosthesis has been a recognised method for two decades. In effect the prosthesis is a hollow denture. Small orifices of about 2 mm diameter in the reservoir are used to fill it and subsequently to allow delivery of the lubricant into the mouth. Several researchers⁶⁻⁹ have designed reservoirs using complete dentures for radiotherapy patients, the longest period of wear being 30 months. The criticisms of the reservoir dentures are: a) too bulky,

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b) inadequate delivery time and c) contamination of the reservoir chamber.

In a pilot study in 1993 two different designs of complete denture reservoirs were worn by eight patients with a dry mouth.⁴ The lubricants used in the prostheses were Saliva Orthana (Saliva Orthana (Nycomed [UK] Ltd, Nycomed House, 2111 Coventry Road, Sheldon, Birmingham B26 3GA)) and K-Y Jelly (K-Y Jelly (Johnson & Johnson Medical Ltd, Coronation Road, Ascot, Berkshire SL5 9EY)). The patients used personal preference in determining which lubricant they used.

After a week the subjects completed a questionnaire. The results indicated that the average time worn was between 4–12 hours a day and the subjective feeling of mouth dryness before and after wearing the denture improved on a 6-point scale from very dry to normal in all cases. The results were the same for both lubricants. These complete denture lubricating reservoirs therefore were worn longer by the patients than in any comparable study, were less bulky and delivered the lubricant over a longer period of time without replenishment. The patients were regularly reviewed and were still wearing the reservoir dentures after 3 years.

The dentate dry mouth sufferers, whose numbers exceed the edentulous, offer a challenge for the prosthetist to provide an intra-oral reservoir that does not impede the patients' speech. The only previously recorded dentate study using a reservoir was a patient who wore an acrylic palatal reservoir retained by cribs.⁷ In a parallel development at another institution recently an Ethyl Vinyl Acetate (EVA) resin bite guard was developed to deliver K-Y jelly.⁹ The reservoir areas were on the buccal surface of the mandibular device and the lubricant was released onto the buccal mucosal surfaces. The patients tolerated the device well and reported improved oral function.

The aim of our pilot study was to see whether an oral lubricating device could be designed for dentate patients with a dry mouth. A device similar to a mouth guard was designed. Soft vacuum-formed splints constructed from EVA resin (EVA resin (Erkoflex)) Erkodent, Erich Kopp GmbH, Siemensstrasse 3, D – 72285 Pfalzgrafenweiler, Germany)) have been used for many years, for example as protection in contact sports, a night guard for bruxists and as a method of delivery of chlorhexidine and fluoride gels in the management of caries.¹¹

To form a reservoir using this principle a vacuum formed layer of EVA resin is laid down over a cast of the dental arch. Another layer is vacuum formed over the first layer with a water dispersible medium such as plaster and pumice sandwiched between the two layers to create a blister. On removal of the dispersible medium a reservoir area of between 5 and 6 ml is formed (Fig. 1). Three patients wore the flexible device over a period of 1 year initially. The devices interfered with speech so they were worn less fre-



Fig. 1 A lubricating device in place in the mouth showing the palatal reservoir

quently in the day. The lubricant was K-Y jelly and was delivered through two 2 mm-diameter holes.

A prospective cross over study was devised to test the new flexible device in dentate xerostomia subjects against the usual methods of lubricating the dry mouth. All subjects had attended the Guy's Hospital Sjogren's clinic and most of them fulfilled the criteria of the European Community Study Group on the classification of Sjogren's syndrome (SS).¹² Conventional methods of dry mouth lubrication are water, saliva substitute and sugar-free chewing gum. In the pilot study there was good compliance from the three subjects who wore the flexible device and they derived most benefit from night-time wear. The aim of this study therefore was to compare an intra-oral device to relieve dryness with other methods of lubricating the mouth at night.

METHOD

A multidisciplinary single blind randomised cross-over study compared the effectiveness of an intra-oral lubricating device, containing saliva substitute, worn at night with the three most common methods of lubricating the dry mouth. This study was given approval by the Guy's and St Thomas' Hospital Trust Ethical Committee.

Selection

Thirty-four subjects were recruited from the Sjogren's Syndrome clinic at GKT Dental Institute, Guys Campus. The criteria for inclusion were: to be dentate or partially dentate, to have attended the clinic and demonstrated some or all of the criteria of the European Community Study Group on the classification of SS. Those patients not fulfilling the criteria to Sjogren's were assigned an alternative diagnosis. All the subjects in this category complained of a dry mouth. Twenty-nine subjects completed the study, of these 27 were female and 2 male and their average age was 62 years (range 30–83 years). It is well known that in dry mouth clinics females predominate, the gender balance of 7% men reflects this distribution.

Dry mouth sub-groups

Fourteen primary SS and 5 diagnosed as secondary SS subjects entered the study. Five subjects had SOX¹³ a sub-group which features sialadenitis, osteo-arthritis and xerostomia. The remaining five subjects had non-specific xerostomia, related to mouth breathing (one subject), medication (one subject) and the three others had an unknown cause for their dryness.

Description of subject's dental arches

Of the 13 fully dentate subjects, there was no space for a reservoir other than in the vault of the palate (Fig. 1). In the partially dentate group there were five who had bilateral saddles in the mandible and 11 who had a variety of distal extension and bounded saddles in the maxilla. The reservoirs were incorporated into the saddle areas and only one device was made for each subject.

Dry mouth scoring and saliva sampling

The subjects attended the clinic on five occasions at 4-weekly intervals. They were scored for their mouth dryness by using a method adopted by this clinic of using a scale of 1–10 where 1 is normal lubrication and 10 is ultimate dryness. Points are added for each clinical sign, such as a mirror sticking to the mucosa, frothy saliva, and an absence of saliva pooling in the floor of the mouth, to a maximum of 10 points.

Samples were taken of their whole salivary flow by expectorating into a 20 ml container for 10 minutes. Stimulated parotid saliva was collected using a Lashley cup placed over the parotid duct on one side connected to a receiver. The gland was stimulated by a 5% solution of citric acid dripped on to the tongue at minute intervals for 10 minutes. Subjects were also required to fill in a questionnaire (Table 1).

Table 1 Dry mouth study questionnaire

Questionnaire number ...	Date.....
Study number	Please write number in order of preference
1) How do you lubricate your mouth ?	
A - sips of water
B - artificial saliva gel
C - non-sugar containing chewing gum
D - other, please write in.....
	Please write number or leave blank
	waking hours Sleeping hours
2) Over the last month how often did you use A during an average day and night ?
3) Over the last month how often did you use B during an average day and night ?
4) Over the last month how often did you use C during an average day and night ?
5) Over the last month how often did you use D during an average day and night ?
	Please write in or leave blank
6) a) Which toothpaste do you use ?
b) Which mouthwash do you use ?
	Please tick one of the boxes in each question
7) How dry is your mouth ?	
very severe severe moderately severe moderate mild normal	
..... 	
8) How difficult is speaking with a dry mouth ?	
extremely difficult moderately moderate slightly normal	
difficult difficult difficult 	
9) How difficult is chewing with a dry mouth ?	
extremely difficult moderately moderate slightly normal	
difficult difficult difficult 	
10) How difficult is swallowing with a dry mouth ?	
extremely difficult moderately moderate slightly normal	
difficult difficult difficult 	
11) Does your mouth feel any different since you entered the trial ?	
Please tick one box	
less comfortable the same more comfortable	
..... 	
12) How often over the last month did you wear the device for an average night and day	
Please write number or leave blank	
waking hours sleeping hours	
13) How easy has the device been to use ?	
Please tick one box	
extremely difficult moderately moderate slightly normal	
difficult difficult difficult 	
14) Would you use the device in preference your normal method ?	
Cross out two	
yes no don't know	
15) Please number from 1-5 in order of preference	
A B C D device	
sips of water saliva substitute chewing gum other 	
..... 	



Lubrication preferences

From the results of a preliminary questionnaire completed at the time of recruitment the subjects' lubrication preferences were determined. The number of subjects for each preference were as follows: water 10, saliva substitute gel 9 and sugar free chewing gum 10. These preferences for the purposes of the study were termed as 'the alternative methods' in order to distinguish them from the device-wearing period. The subjects used their favoured alternative method for four out of the five study periods. The device-wearing period was randomly allocated, subjects either wore it from the second or the fourth visit (Fig. 2). The saliva substitute gel used for the 'alternative method' was the same used by all the subjects in their device wearing period, Oralbalance (Oralbalance, (Biotene, Laclede International sprl., Avenue Joseph Wybran 40, 1070 Brussels, Belgium)). The active ingredients of this product are lactoperoxidase, glucose oxidase and xylitol. At each attendance the subjects were instructed not to lubricate the mouth for up to one hour before the appointments and they attended on the same day at the same time each month to reduce the effect of diurnal variation of the salivary flow.

Construction of the devices

At the first visit the teeth were scaled and polished and alginate impressions were recorded for the construction of the device. The devices were made in exactly the same way as those used for the pilot study. The only change was to alter the apertures by cutting 1 cm long slits in the side of the lubricating chambers to obtain access. The Oralbalance gel which was used in the definitive study is more viscous than the K-Y jelly that was used in the pilot study and requires a larger orifice for releasing the gel (Fig. 3). The slits allow filling and delivery of the lubricant and cleaning using 0.7% sodium hypochlorite solution.

Provision of toothpaste and mouthwash

The foaming agent in ordinary toothpaste, sodium lauryl sulphate (SLS), affects the enzymes within Oralbalance. The enzymes are intended by the manufacturer to partially replace those enzymes of the patient which are deficient due to their reduced salivary flow. To prevent the use of a SLS containing toothpaste the manufacturer provided all subjects with Biotene toothpaste for the periods when they were using Oralbalance as this product contained no foaming agent. Subjects who normally used a mouthwash were provided with Biotene mouthwash as an alternative lest the active agents in their usual mouthwash affected the enzymes in the Oralbalance.

Both the Biotene toothpaste and mouthwash were supplied without enzymes by the manufacturer so that the gel, which retained its enzymes, could be properly evaluated.



Fig 3. A dentate device being filled with saliva substitute gel

Lubrication diary

The questionnaire data on lubrication were collected at the end of each 4-week period. Subjects were also required to maintain a diary of lubrication timings (Table 2). An entry was made every time liquid, saliva substitute or chewing gum was used. For those who had a sip of water, for example at 15-minute intervals, this was calibrated as 10 sips per cupful for ease of recording the total amount consumed. Other methods of lubrication included, sugar free pastilles or chews which were counted as other methods of lubrication (Table 1), as were cubes (2 sq. cm) of fruit if they were taken for lubrication and not for nutrition purposes.

Statistical analysis

The scales for dryness and the difficulty with speaking, chewing and swallowing were measured on an ascending 6-point scale. Medians and interquartile ranges were used to summarise the scales in each group. Differences between groups were tested using the Mann-Whitney *U* test. Within-group differences between baseline and post-treatment measures were tested using the Wilcoxon signed-ranks, matched-pairs test.

RESULTS

The mean whole saliva flow rate for the 29 subjects was 0.14 ml/min. This varied from mean values of 0.26 ml/min for the water lubricators to 0.056 mls/min for the chewing gum lubricators. Table 3 shows the results of self-assessed variables from the questionnaire. There were changes between baseline and post treatment for all variables whilst wearing the device which either approached or reached statistical significance. The equivalent differences for the alternative treatment were not statistically significant. Following the device wearing period,

Fig 2. Study programme – brief treatment protocol

Visit 1	Treatment 1	Visit 2	Treatment 2	Visit 3	Treatment 3	Visit 4	Treatment 4	Visit 5
OM		OM		OM		OM		OM
Imps		Randomly allocate				Randomly allocate		
SP		Fit device or lubricate with alternative method		Wash-out from Dev stage to lubrication with Alt		Fit device or –lubricate with alternative method		Wash-out from Dev stage to lubrication with Alt
Q1		Q2		Q3		Q4		Q5

Alt = Alternative method; Dev = Device + Saliva substitute gel; OM = Oral Medicine measurements and sampling; SP = Scale and polish; Imps = Impressions; and Q = Questionnaire

Table 2 Dry mouth study

Diary										
Study No					Starting date					
This is a study diary to assist you in filling in the monthly questionnaires. Key for lubricating method.										
A	– sips of water				write					
B	– saliva substitute				in					
C	– non-sugar containing chewing gum				number					
D	– other – please write in				of					
Dev	– lubricating device – write in number of hours				times					
W = waking hours					S = sleeping hours					
Week 1										
	A		B		C		D		DEV	
	W	S	W	S	W	S	W	S	W	S
	Hours		Hours		Hours		Hours		Hours	
1										
2										
3										
4										
5										
6										
7										
Days										
Totals										
Average										
Comments										
[This is repeated two grids /A4 sheet]										

Table 3 Median (interquartile range) for self assessed dryness variables at baseline and post treatment visits, together with P values for tests comparing values between baseline and post-treatment visits and between the device and alternative treatment at the post treatment visit.

Variable	Device		Alternative treatment		P value for posttreatment difference *
	Baseline	Post-treatment	Baseline	Post-treatment	
Dryness	3 [2-4]	4 [2-4]	3 [2-3.5]	3 [2-4]	0.056
P value for difference †		0.055	0.595		
Speech	3 [2-5]	4 [2-5]	4 [2-5]	2 [2-5]	0.003
P value for difference †		0.017	0.132		
Chew	3 [2-4.5]	2 [2-5.5]	3 [2-5.5]	4 [2-4]	0.152
P value for difference † the dryness parameters		0.051	0.906		
Swallow	2 [2-5]	4 [2-5]	3 [2-5.5]	2.5 [2-4]	0.031
P value for difference †		0.033	0.088		

*Mann - Whitney U test

†Wilcoxon signed ranks, matched pairs test
Statistically significant P values in bold font

the subjects' self assessment of mouth dryness ($P = 0.056$), speech ($P = 0.009$) and swallowing ($P = 0.031$) was more favourable when compared with the alternative methods. The score for chewing remained the same before and after wearing the device.

As part of the random allocation the device was fitted either on the second visit or on the fourth. For those who wore the device first, 5 out of 12 preferred its lubricating effect whilst 7 did not, but for those who wore the device second 14 preferred the device to 3 who did not.

Table 4 demonstrates that for the maxillary dentate arch, 62% preferred the device and for the partially dentate subjects 60% preferred the device in the mandibular arch and 73% in the maxillary arch. Overall 19 subjects (66%) preferred the intra-oral device to their alternative method of lubrication. Seventy-four per cent of those preferring the device had it fitted on the fourth visit.

Nine out of ten of those lubricating with chewing gum preferred the device ($P = 0.037$) whereas subjects using other methods

showed no particular preference (Table 5). There was no difference in terms of the fully dentate compared with the partially dentate subjects in terms of device preference.

DISCUSSION

The mean whole mouth salivary flow rate for this group of subjects with xerostomia was 0.14 ml/min. This compares with a reported figure of 0.15 ml/min,² which is the accepted dryness threshold found by halving the average unstimulated whole saliva rate of 0.3 ml/min. Dry mouth lubrication studies often rely on subjective assessments,¹⁴ however, in this study the subjects' self scoring was averaged out over five visits and the measurements of salivary flow and clinical dryness were available for correlation. The subjects had a feeling of well being regarding the improvement in speech and swallowing and their dry mouths felt more moist after they had worn the device (Table 4). By not having to lubricate with the usual methods in the night it might seem that nocturnal wear would create less disturbance of sleep. However questioning the

Table 4. Patient preferences vs dental arch used for device

Type of arch	Completely dentate		Partially dentate		Partially dentate	
	Maxillary arch		Mandibular arch		Maxillary arch	
Number of devices	13		5		11	
Preference for wearing the device	Yes 8	No 5	Yes 3	No 2	Yes 8	No 3

Table 5 Patient preferences according to lubrication method. Average mean whole saliva flow rates in brackets

Water lubricators (0.26 mls/min) Preferred device		Saliva substitute lubricators (0.087 mls/min) Preferred device		Sugar free chewing gum lubricators (0.056 mls/min) Preferred device	
Yes	No	Yes	No	Yes	No
6	4	4	5	9	1

subjects on choices for eating indicated that they chose moist, soft food for preference. Anything dry had to be washed down with copious amounts of water, despite the fact that the subjects chewing score was unchanged after wearing the device. The presence of the device, even if unfilled, may cause stimulation of the subjects' salivary glands. It has been found that amongst the elderly that their resting saliva is reduced when compared with younger age groups but that the stimulated salivary flow is at normal limits for all age groups.¹⁵

Regarding the preference of subjects according to their habitual lubrication method (Table 5) it was interesting that 90% of the chewing gum lubricators also preferred wearing the device. This suggested that subjects who tolerate chewing gum found that wearing the device was easier than in the other lubrication groups, the other groups were nearly equally divided between those who did and did not like the device. Another finding is that the chewing gum lubricators had the driest mouths and the water lubricators the most moist (Table 5). The positioning of the reservoirs in the device did not make as much impact as anticipated. The maxillary device in the partially dentate was slightly favoured with 73% preferences compared with the maxillary device in the completely dentate (62%) and the partially dentate mandibular device (60%). The reason for this may be because the partially dentate device had reservoirs in the saddles and the palate thus increasing the lubricant capacity. The majority of the subjects wore partial dentures so it was a case of exchanging the denture for the device. One would anticipate that someone who was already wearing a denture would find it easier to wear the device. This correlation was not clear-cut; having a palatal reservoir did not appear to be a hindrance for the completely dentate.

The bite guard device⁸ could be compared with the device used in this study but it is difficult to speculate whether the bite guard design is better than the device in our study, since no comparative studies have been carried out. Another advantage of a 'bubble' type of reservoir construction was that the stone casts on which they are made can be stored and replacement devices can be produced conveniently. All subjects kept their devices and were free to wear them as and when they wished after the study period was over. It is the principal author's experience that the device's life can exceed 2 years, so that it may provide the dry mouth sufferer with an alternative economic method of lubrication.

CONCLUSIONS

The majority of the dry mouth sufferers preferred wearing the intra-oral device compared with their normal method of lubrication. This was especially so at night when the mouth was at its driest. Subjects' perception of dryness, speech and swallowing became closer to normal after they had worn the device, compared with the alternative methods.

The authors would like to thank: Dr Ron Wilson for the advice on research methodology and the statistical analysis. Mr Rowland Gardner, Technical Instructor, for the development and provision of the lubricating devices. Sources of support: Shirley Glasstone Hughes Memorial Prize Fund for the major funding. Laclede International sprl for supplying Biotene dry mouth products and assisting with some expenses. E. M. Natt for providing the ErkoFlex EVA thermo forming blanks. Wrigley's for providing the Orbit sugar free chewing gum.

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