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Randomized-controlled trial: effect of a reservoir biteguard on quality of life in xerostomia

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BACKGROUND: To assess the effect of a reservoir biteguard for artificial saliva on the oral health-related quality of life of patients with xerostomia.
METHODS: Double-blind randomized placebo-controlled trial among 86 adults with xerostomia. Study group received the trial biteguard. Control group received a conventional biteguard. Outcomes were number of impacts and total scores as recorded by oral impacts on daily performances (OIDP).
RESULTS: At 1-month follow up 84 people remained in the trial. The median number of impacts in the study and control groups was 3 and 4 respectively. The median total score was 6 and 12 respectively. In ANCOVA receipt of the reservoir biteguard reduced the number of impacts recorded by OIDP but there was no difference in the total score.
CONCLUSIONS: Reservoir biteguards improved the quality of life of people with xerostomia by reducing the number of impacts on daily life.
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Introduction

Dry mouth (xerostomia) is a chronic condition affecting one quarter of adults and 40% of elderly people (1). The commonest cause of xerostomia, in developed countries, is the side-effects of therapeutic drugs. Over 400 prescribed drugs cause xerostomia, particularly anti-depressants, antihypertensives and antihistamines. Few alternative drugs are available and appropriate, and many of these have other side-effects. Xerostomia and hyposalivation are also seen as sequellae of damage to salivary glands in autoimmune and other systemic diseases (rheumatoid arthritis, Sjogren's syndrome, system lupus erythematosis), and as a consequence of head and neck radiation for treatment of head and neck cancer. Symptoms of dryness include cracked lips and unquenchable thirst. Severe cases can present with soreness and a burning sensation, and reduced ability to speak, chew, swallow, taste and sleep (2). Persistent dryness can lead to oral mucosal disease, and an increased risk in caries and gingivitis (3).

In the absence of a cure for xerostomia management is primarily palliative. The main lines of treatment include saliva stimulants such as chewing gum and medications and saliva substitutes. Substitutes relieve oral dryness, but have a short 'retention time' in the mouth so have to be re-applied at frequent intervals, which can be inconvenient.

Slow release devices that incorporate reservoirs for artificial saliva have been developed for edentulous patients. Reservoir biteguards, which are cheaper and simple to make, are suitable for dentate and partially dentate individuals (4). They are custom made, and sit over the lower teeth. The device is fabricated from a double layer of clear polyvinyl acetate, incorporating bilateral buccal reservoirs, with small holes in the buccal aspect, and a slit on the lingual aspect. The reservoirs are filled using a monojet syringe, and the substitute saliva leaks through the holes to bathe the cheeks and through the inner slit to the teeth and gums. Patients can increase the escape rate by sucking in their cheeks to depress the outer wall of the reservoir or by pressing on their face over the biteguard. The dimensions of the buccal reservoirs are determined by the shape and size of the mouth, the tension of the soft tissues, depth of the sulcus and the number of missing teeth.

Traditionally, clinicians have assessed health using clinical measurements, rather than considering the subjective experience of the symptoms of disease, or the relief afforded by treatment. Cohen and Jago argued that indicators of oral health would be improved by the addition of a social impact dimension to encompass broader implications of oral conditions; as the underlying aim of dental treatment is to improve quality of life as well as improve oral health (5). For conditions where

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the emphasis is on comfort rather than cure, there is a strong case for appraising interventions using 'quality of Life' measures (6), not just the deviation from biomedical norms of form and function (7).

Oral health-related quality of life (OHQoL) may be particularly useful in the assessment of xerostomia where treatment is often titrated against patients' symptoms rather than objective assessments of the underlying disease. Therefore, the aim of this study was to assess the effect of the reservoir biteguard acting as slow release devices for artificial saliva on the OHQoL of patients with xerostomia.

Materials and methods

The study population was composed of patients with symptomatic xerostomia with one or more symptoms from the European screening questionnaire (8). The European questionnaire was used for initial screening of recruits to the study as the questions have been validated against objective measures of hyposalivation and the questionnaire is widely accepted. The questionnaire is appropriate for use with the source population, as the many of symptomatic patients would be expected to have secondary Sjogren's syndrome. Inclusion criteria included whole unstimulated salivary flow of < 0.2 ml/min, which would encompass patients with symptomatic xerostomia and secondary Sjogren's syndrome, and no clinical evidence of candidiasis on visual examination. Whole unstimulated salivary flow rates were measured by a single clinician (EJG) by asking patients to dribble into a pre-weighed glass vial for 5 min. This sample was also cultured for *Candida* spp. to confirm the clinical diagnosis before entry into the trial.

Consecutive adults attending outpatient rheumatology, liver, pain management, oral medicine, speech and language and Sjogren's syndrome clinics at two London teaching hospitals who met the inclusion criteria were invited to participate. Patients who required hospital transport or were unable to understand and complete the questionnaires were excluded.

The primary outcome measure was the oral impacts on daily performance (OIDP), which is based on Locker's interpretation of the World Health Organisation's model for oral health (7, 9). It is designed to measure disabling and handicapping impacts of oral disease on the person's ability to perform eight daily activities: eating and enjoying food; speaking and pronouncing; cleaning teeth; sleeping and relaxing; smiling, laughing and showing your teeth without embarrassment; maintaining one's usual emotional status; carrying out one's major work or social role and enjoying contact with people.

In its original form the OIDP enquires whether participants have experienced any impact on each of the eight daily activities in the previous 6 months. For each activity affected supplementary questions enquire about the severity and frequency or duration of impacts. OIDP revealed substantial oral impacts and had good reliability and stability in a low dental disease Thai population but observed low levels of oral impacts among elderly people in the UK (10, 11). A modified version of OIDP was used to record only the presence and severity scores. The severity of impacts was reported on a 5-point Likert scale where 4 represented 'very severe' and 0 represented 'none'. The possible range of scores was therefore between 0 and 32. This approach was selected so that a shorter reference period of 4 weeks could be used and has been shown to predict scores using the full version of the instrument (9).

Other data included the participant's age, sex, current or most recent employment status and self-classified ethnic group. Data on the underlying diagnosis and other medical information were collected from participants' medical records. The clinical status of the mouth was assessed using a trained examiner.

After initial examinations, baseline data collection and impressions, participants were pre-randomized into either the study (reservoir biteguard) or the control groups according to study number using sealed envelopes. The envelopes were available only to the technician making the devices. Members of the control group were given a conventional biteguard as a placebo device in case the presence of a biteguard stimulated saliva production. Participants were blinded throughout the trial period, as they were informed that the trial was testing two different biteguards. The examiner was not blinded from this stage because she was fitting the biteguards. However, all the follow-up assessments were questionnaire-based and so the risk of measurement bias was minimized.

All participants, both test and controls were asked to wear the biteguards at night-time and at other times during the day if they preferred. All participants were provided with aqueous gel (KY Jelly, Johnson and Johnson, Maidenhead, UK) and artificial saliva spray (Saliva Orthana, Nycomed, Little Chalfont, UK) for symptomatic relief of their xerostomia for the duration of the study. After 4 weeks participants returned for follow-up OIDP data collection.

The sample size calculation was based on published mean OIDP scores in people whose perception of trouble from oral problems was classed as 'very much' and 'fair' (9). A sample of 85 people was selected to lend a 90% power to detect a difference of the same magnitude for an α of 0.05.

The project was approved by the Research Ethical Committee of King's College Hospital. Written consent was obtained from all participants.

Statistical analysis

Two summary measures were created for OIDP, the number of impacts and the total score. The total score was calculated as the sum of codes for the severity questions.

Analysis was conducted in four stages. Baseline variables were compared between the study and control group to assess the comparability of the two groups. Appropriate bivariate analyses were then used to compare the outcomes in the two groups at follow up.

The primary analyses of the study compared follow-up OIDP data in the two groups using conditional

analysis by adjusting for baseline scores in ANCOVA (12, 13). Data for the number of impacts were square root transformed and the total scores were transformed as root (total score +2) to fulfil the requirements of multiple regression models. Data were analysed on an intention-to-treat basis with the baseline values for the two absent participants entered as the follow-up data.

Finally, in order to explore the possible benefits provided by the biteguard, the number of participants with each impact at baseline but absent at follow up (i.e. decrements), and the number of participants with no impact at baseline but present at follow up (increments) was compared for each impact between the two groups (14). Analyses were conducted using JMP for the Macintosh (Apple, Cupertino, CA, USA).

Results

Of 136 people who were invited to participate, 92 were recruited but six declined to before randomization due to work commitments, as a result of ill health, lack of interest or childcare problems. Thus, 86 participants were randomized into the study and control groups (Fig. 1).

Mean age in the study and control groups was 59.9 (SE: 1.8) and 59.3 (1.8) years respectively. The two groups had had xerostomia for similar periods [means 6.9 years (SE: 1.0) and 5.6 years (1.0) respectively]. The two groups were also similar at baseline with respect to sex, age, ethnicity, employment status, dental attendance and remedies for oral dryness (drinks, sucking sweets, chewing gum and using artificial saliva) (Table 1).

Participants had complex medical histories. For example, in the study and control group Sjogren's syndrome was secondary to rheumatoid arthritis (34.9% and 53.6% respectively), primary biliary cirrhosis (25.6% and 12.2%) and systemic lupus erythematosis (7.0% and 0.0%). Likewise, many participants were using xerostomic medication including antidepressants (35% and 30% in the study and control groups respectively), diuretics (22.5% and 29.7%) and anti-Parkinson drugs (2.6% and 0.0 respectively).

The two groups had similar OHQoL at baseline although the study group had a slightly lower median total OIDP score (Table 2).

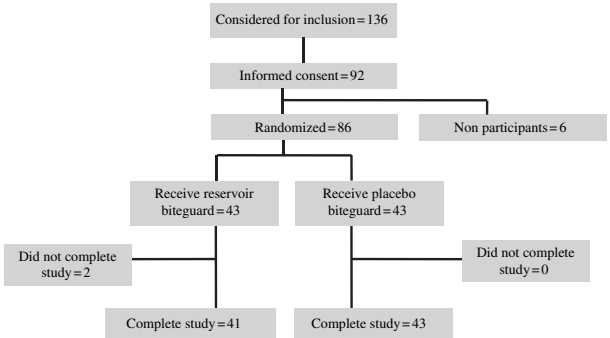

Figure 1 Trial profile: randomized placebo-controlled double-blind trial of reservoir biteguard.

Table 1 Characteristics of participants at baseline in study and control groups

	Control (%) (N = 43)	*Study (%) (N = 43)*
Female	72.1	81.4
White British	48.8	67.4
Retired	60.5	53.5
Regular dental attender	74.4	74.4
Current smoker	13.9	20.9
Symptomatic relief for dryness		
Drinks	90.5	97.7
Sweets	41.9	62.8
Gum	53.5	65.1
Artificial saliva	53.5	27.9
Primary diagnosis		
Rheumatoid arthritis	53.6	34.9
Osteoarthritis	29.3	30.2

After 1 month 84 people remained in the trial. One person left the trial because she was in hospital and another person was lost to follow up because she had a dispute with the hospital authorities regarding treatment in another department. At follow up, similar numbers in the study and control groups had worn the biteguard every night for the whole month (37% and 44% respectively; $P = 0.54$, chi-square test).

At follow up the study group had slightly fewer impacts and lower total OIDP scores although neither difference reached significance (Table 2). When the baseline values for the OIDP data were accounted for in conditional analysis the number of impacts was significantly lower in the study group (Table 3). The OIDP total scores did not differ significantly between the two groups in the ANCOVA.

Table 2 Number of impacts and oral impacts on daily performances (OIDP) total score at baseline and follow up

	Baseline, Median (95% CR)		*Follow up, Median (95% CR)*		
	Study	*Control*	*Study*	*Control*	*P-value (Mann–Whitney U-test)*
Number of impacts	4 (1–8)	4 (1–8)	3 (0–8)	4 (0–8)	0.12
Total score	10 (1–32)	12 (0–32)	6 (0–32)	11 (0–32)	0.19

Table 3 Analysis of covariance models for number of impacts and total oral impacts on daily performances (OIDP) score in randomized-controlled trial of reservoir biteguard

	B (SE)	*P-value*	R^2
Number of impacts[a]			
Group	0.133 (0.065)	0.045	0.411
Baseline number	0.193 (0.028)	0.000	
Total score[b]			
Group	0.116 (0.095)	0.225	0.467
Baseline score	0.086 (0.011)	0.000	

[a]Transformed as root number of impacts.
[b]Transformed as root (total score +2).

Table 4 Relief of impacts and new impacts in randomized-controlled trial of reservoir biteguard

	Study group (%)		*Control group (%)*	
	Increments	*Decrements*	*Increments*	*Decrements*
Eating and enjoying food	7.0	25.6	9.3	7.0
Speaking and pronouncing	2.3	11.6	16.3	14.0
Cleaning teeth	7.0	20.9	7.0	20.9
Sleeping and relaxing	9.3	23.3	7.0	18.6
Smiling, laughing and showing teeth without embarrassment	4.7	13.9	23.3	13.9
Maintaining usual emotional state	11.6	20.9	7.0	11.6
Carrying out major work or social role	7.0	20.9	14.0	18.6
Enjoying contact with people	2.3	20.9	11.7	16.3

Table 4 provides an indication of the nature of the benefits provided by the biteguard. In the study group, more people experienced relief of an impact (decrements) than experienced the onset of an impact (increment) for all eight daily performances in OIDP. In the control group, more participants experienced the onset of an impact than relief for eating and enjoying food, speaking and pronouncing and smiling and laughing. There were also similar number of increments and decrements for maintaining the usual emotional state, carrying out ones social role and enjoying contact with people in the control group.

Discussion

In this randomized-controlled trial, when compared with a placebo device, the reservoir biteguard reduced the number of adverse impacts on daily life in people with xerostomia but did not reduce the total scores of the OIDP. The benefits provided to participants wearing the reservoir biteguard related to a general relief of adverse impacts on eating, speaking, smiling, carrying out one's major social role and enjoying contact with other people.

It is interesting to note that although the reservoir biteguard was intended for night-time wear changes in the number of impacts on sleeping and relaxing were similar in the study and placebo groups (Table 4). One explanation for this phenomenon could be the additional salivation associated with the presence of both biteguards in the mouth at night. Alternatively, it may be that the additional lubrication and cleansing of the reservoir biteguard afforded a greater level of general comfort to the study group that improved their OHQoL in a variety of ways. Another trial of a reservoir device also found a variety of benefits including reduced mouth dryness and improved speech and swallowing (15).

The apparent lack of effect of the reservoir biteguard on OIDP total score of participants may be related to the mathematical properties of the instrument or the design of this study. The OIDP was intended to record disabilities and handicap (termed 'the ultimate impacts of the mouth on everyday life') (9). For this reason, it is relatively insensitive to the effects of oral conditions (16, 17). Xerostomia can be a debilitating condition. In this study, most participants had tried a variety of remedies for symptomatic relief yet most had scored <12 of 32 for the severity of their problems (Table 2). This feature of the data has two consequences. First, there is limited scope for improvements in participants' OIDP scores. Secondly, analysis of such skewed data may lack power to distinguish between the two groups. The OIDP total score data only met the distributional requirements of the analysis after an unorthodox transformation. This feature of OIDP has been noticed before and may require attention (16, 17).

The short follow-up period of the study may also have limited the apparent benefit of the device. One-month may not have been adequate for participants to become accustomed to the biteguard. However, participants in the trial reported by Frost et al. used the trial device for a similar period (15). The OIDP was designed for use with a 6-month reference period so that respondents could record both the duration and severity of impacts. Whilst the use of only the severity scale simplified the conduct of this study it may have removed useful detail on the experience of participants or may have influenced the mathematical properties of the OIDP (9). Further research is required on the value of different approaches to the use of OHQoL data in evaluative research.

One other factor may have attenuated the relationship between treatment and outcome in this study. 'Quality of life' may be a dynamic construct that changes within individuals (18, 19). People with chronic conditions may adapt to their impairment and disability in a way that masks their perception of the impact of the disability on their daily life. In this case, patients may not recognize or accept that they have an impairment or that it is seen as a disability by another (20). This phenomenon may have affected participants' responses to the questionnaires and warrants further research.

There are few other data with which these findings may be compared. The randomized-controlled trial of a different reservoir device referred to above used a device with a reservoir in the palate, did not use a placebo and used assessments of patients subjective experience that had not been validated (15). That trial associated a range of benefits with the device and thus some comparison of their relative value appears appropriate.

There are few OIDP data from longitudinal studies that may be compared with these findings. Soe (21) conducted a randomized-controlled trial of amalgam

fillings in Myanmar adolescents with low disease experience. Levels of impact on OHQoL were low; nevertheless the total OIDP score detected a treatment effect because of increased impact in the control group. More research of the use of this and other OHQoL measures in longitudinal research is required.

As this study was conducted the European criteria for Sjogren's syndrome have been revised (22). There was no change however, to the three screening questions used to screen for dry mouth and those changes do not impact on the interpretation of this study.

The rigour of randomized-controlled trials provides good evidence of the effectiveness of the intervention within the trial but creates an artificial environment that may not reflect the normal lives of participants. For example, participants may have behaved unusually or repeated administration of questionnaires might change their awareness of the impact of their mouths on their quality of life. For these reasons more research is needed on the benefits of this device. However, this randomized-controlled trial indicates that the reservoir biteguard improved the OHQoL of people with xerostomia by reducing the number of their daily activities that were affected by their dry mouths.

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