Clin Oral Invest (2005) 9: 148–153
DOI 10.1007/s00784-005-0302-y

ORIGINAL ARTICLE

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A preliminary report on patient acceptance of a novel intra-oral lubricating device for the management of radiotherapy-related xerostomia

Received: 11 August 2004 / Accepted: 14 January 2005 / Published online: 14 May 2005

Abstract Management of radiotherapy-related xerostomia is difficult. Saliva substitutes are helpful but the effects are short-lived. The purpose of the study was to develop a prototype intra-oral lubricating device for the management of radiotherapy-related xerostomia and to evaluate patient acceptance. An intra-oral lubricating device was fabricated that incorporated a reservoir in the palatal vault and permitted slow release of saliva substitute by the patient. Preliminary clinical testing was done in five patients with radiotherapy-related xerostomia. A measure incorporating seven questions was used to explore patient acceptance. The device was simple to fabricate using materials available in a technical laboratory. All patients were able to wear the device for at least 4 h per day throughout the test period. The device was considered easy to use and clean. Some impairment of speech and chewing was noted although this appeared to be related to the bulkiness of the reservoir. General oral comfort was improved due to the lubricating effect. The bulk of the reservoir was reduced as a consequence of patient feedback. The design addressed key problems associated with previous lubricating systems. Patient reports on oral functioning with the device in situ provided pivotal information on the device's utility.

Keywords Xerostomia · Radiotherapy · Management · Lubricating device · Patient satisfaction

Introduction

The production and secretion of saliva is essential for optimum oral health and function [1]. Key roles of saliva include lubrication during swallowing and speech, provision of a mucous barrier, bacterial control and buffer capacity.

Radiotherapy to the head and neck region induces major, often irreversible, salivary gland damage that leads to dramatic quantitative and qualitative changes in residual saliva [2, 3]. Intractable dental caries, persistent fungal infections and speech and swallowing problems are some of the sequelae of the resulting xerostomia [4]. Management of radiotherapy-induced xerostomia is problematic. Systemic medication and local approaches can be used to stimulate salivary production and secretion provided there is residual gland function [1, 5]. Often, however, saliva production is permanently impaired and symptomatic management of xerostomia is required [4, 6]. Carboxymethylcellulose, K-Y jelly (Johnson and Johnson Medical Ltd, Berkshire, UK) and Oral Balance gel (Laclede Inc., Rancho Dominguez, CA, USA) are commonly-used saliva substitutes. Oral Balance gel, in particular, appears to be effective in the symptomatic relief of xerostomia and has no known side-effects [4, 7]. However, like other saliva substitutes its lubricant effect is short-lived because it is rapidly swallowed. To overcome this problem, intra-oral devices with reservoirs have been developed that permit the slow release of lubricant onto the dry oral tissues [5, 8]. However, some design features, notably precise control of saliva substitute flow, have proved problematic, especially when viscous material is employed. Such features have precluded more widespread use and hindered compliance, especially in dentate individuals where the retentive components also extend onto the occlusal surfaces of the teeth [5].

The aim of this study was to evaluate patient acceptance of a prototype intra-oral lubricating device for the management of radiotherapy-related xerostomia.

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Materials and methods

Subjects

Five southern Chinese people, four males and one female, with a mean age of 61.2 years (SD 11.6), participated in

this preliminary study. They were attendees at a Dry Mouth Clinic in the Prince Philip Dental Hospital, Hong Kong for periodic review of their oral condition. All had received conventional radiotherapy to the head and neck region at least ten years previously for the management of nasopharyngeal carcinoma. All were disease-free at the time of the study. None of them were using saliva substitutes other than water or systemic medication for the management of xerostomia. The study was approved by the Faculty of Dentistry Ethics Committee, The University of Hong Kong.

Lubricating device

The design made use of the palate as the reservoir for the saliva substitute. Oral Balance gel (Laclede Inc., Rancho Dominguez, CA, USA) was considered the saliva substitute of choice. It is a viscous material that does not readily flow under atmospheric pressure. To overcome this, an elastic diaphragm (Hygienic Dental Dam; Coltène Whaledent Dentalvertriebs GmbH, Konstanz, Germany) was incorporated into the reservoir to provide positive pressure on the gel so that it flowed from the reservoir. An "on-demand" system was incorporated into the design so that the subject could release some gel when desired. This was done by using a ball valve located at the opening into the oral cavity. Slight tongue pressure on the ball released a small bolus of gel.

Fabrication

The device comprised three parts: a base plate (Probate Hot; Ivoclar Vivadent AG, Schaan, Liechtenstein), a cover with a ball-valve system and an elastic diaphragm (Fig. 1).

Base plate

1. Maxillary and mandibular irreversible hydrocolloid impressions (Aroma Fine DF III; GC Corp, Tokyo, Japan) were made, a maxillo-mandibular jaw record was taken as necessary, and the casts mounted on a semi-adjustable articulator.
2. The maxillary cast was surveyed and the location and extent of the reservoir outlined on the cast. The base plate was then designed to incorporate optimum support, retention, stability and hygiene features.
3. The base plate was waxed-up, clasp assemblies incorporated, and it was then processed into clear heat-cured acrylic resin (Probase Hot; Ivoclar Vivadent AG, Schaan, Liechtenstein) (Fig. 2).
4. A vent hole (1 mm diameter) was made in the central part of the base plate.

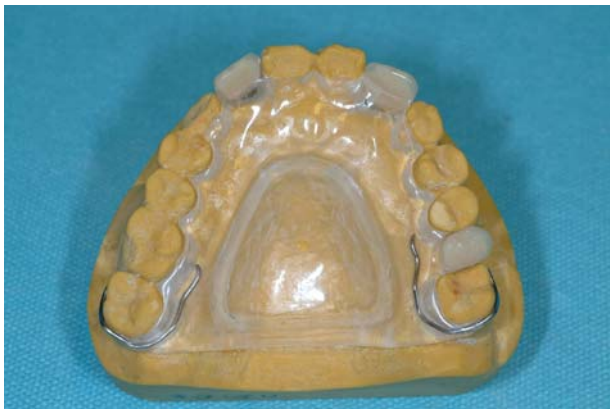

Fig. 2 Base plate

Cover

1. The reservoir located on the base plate was blocked out with dental stone (Kaffir D; British Gypsum, Leicestershire, United Kingdom).
2. A cover was waxed-up on top of the reservoir then processed into clear heat-cured acrylic resin.
3. A ball-valve opening (4–5 mm diameter) was made on the central part of the cover.
4. A spring coil was made using 0.7-mm thick stainless steel wire (K.C. Smoth and Co., Gwent, UK) and attached to the inner surface of the cover using cold-

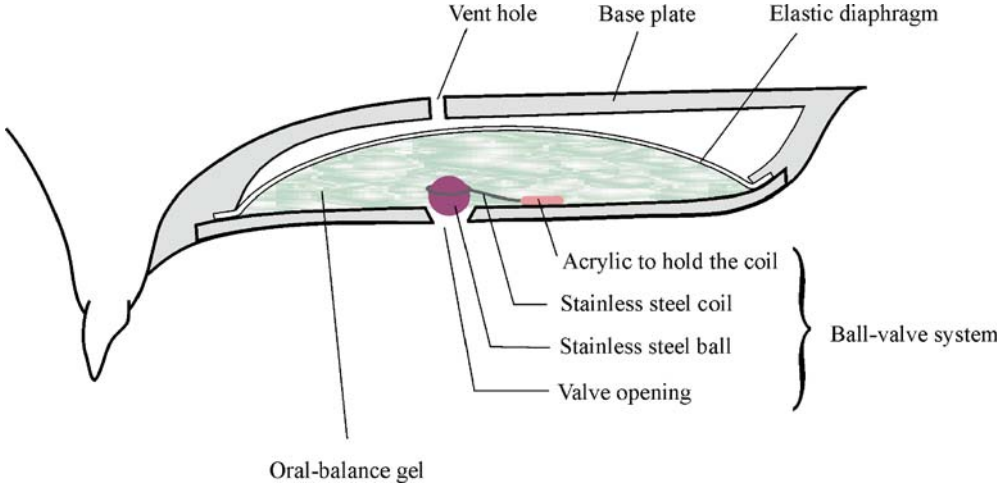

Fig. 1 Schematic diagram of the lubricating device

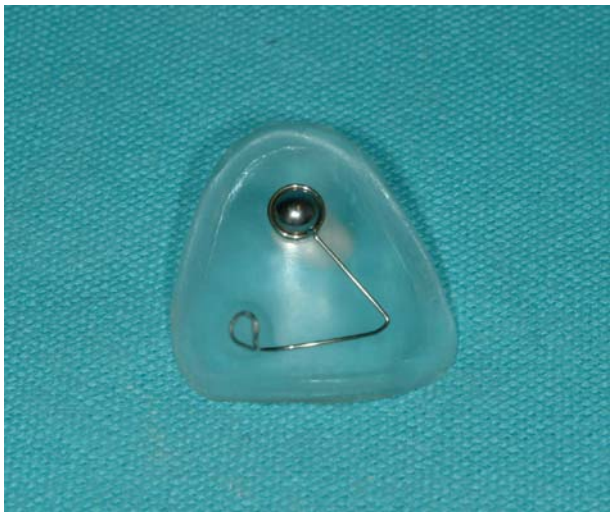

Fig. 3 Cover and the ball-valve system

cured acrylic resin (Probase Cold; Ivoclar Vivadent AG). A stainless steel ball (6 mm diameter) was placed between the coil and the cover opening (Fig. 3).

Elastic diaphragm

1. A piece of rubber dam (Hygenic Dental Dam; Coltène Whaledent Dentalvertriebs GmbH, Konstanz, Deutschland) was tailored according to the size and shape of the reservoir (Fig. 4) and attached to the base plate using medical grade cyanoacrylate adhesive.
2. The cover was then cemented onto the base plate with cold-cured acrylic resin.
3. The device was finished and polished (Fig. 5).

Filling the reservoir system

The refilling system comprised a locating device and a disposable syringe (Fig. 6):

1. A tripod of small spherical indentations was made around the ball-valve opening on the cover.

Fig. 4 Base plate, diaphragm and cover

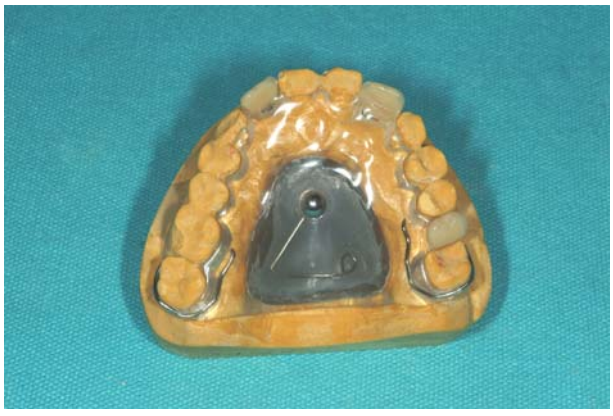

Fig. 5 Finished intra-oral lubricating device

2. The ball-valve opening was blocked by wax then a layer of separating medium was applied to the cover.
3. Cold-cured acrylic resin was prepared and placed over the area to develop the locating device.
4. The tip of a disposable syringe (5 ml) was inserted towards the ball-valve opening through the acrylic resin before it set.
5. When the acrylic resin had set, the syringe tip was retrieved and the channel in the locating device refined.
6. A reference point (arrow) was marked on the locating device to facilitate placement.

Filling the reservoir with gel (Fig. 7):

1. Oral Balance gel (2 ml) was inserted into the syringe.
2. The locating device was fitted onto the cover of the intra-oral device.
3. The filled syringe was then inserted into the locating device.
4. The gel was injected into the reservoir using the syringe.
5. Injection was stopped when resistance was felt and no further injection is possible.
6. The location device and the syringe was removed and the reservoir was filled.

Fig. 6 Locating device and syringe

Fig. 7 Filling the reservoir using the locating device and syringe

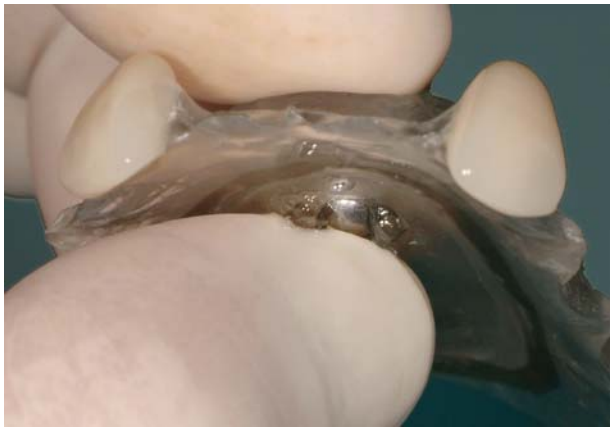

Fig. 8 Release of gel when slight pressure was applied to the valve

7. The flow of the gel was tested by slight finger pressure on the ball valve (Fig. 8).

Questionnaire

A measure comprising seven questions was used to explore patient acceptance of the lubricating device. The questions were developed in English then translated into Chinese then back-translated by two bilingual dentists. The questions focused on aspects of comfort, utility and function (Table 1).

Clinical procedure

During the first clinical appointment, subjects were examined and maxillary and mandibular impressions made. The device was then fabricated in the laboratory (q.v.). At the second appointment the device was delivered and the subject shown how to clean and fill the reservoir system with gel. Patients were asked to wear the device for at least 4 h each day for a period of one week. A questionnaire was given to the patient for self-completion at home. Participants were assured that the reply would be reviewed anonymously by another researcher. After one week, the subject was invited for clinical review and the questionnaire returned in a sealed envelope. Questionnaire data were then compiled.

Results

The participants were partially dentate and had reasonable dental and periodontal health as a consequence of regular professional review and maintenance. Two people wore maxillary and mandibular removable partial dentures, one wore a maxillary removable partial denture and two had no

Table 1 Questionnaire on the intra-oral lubricating device (English version; patients were required to mark the appropriate box)

	Very easy	Easy	Average	Difficult	Very difficult
1. How has the lubricating device been to use?					
When wearing the lubricating device, do you think that:					
	Very much better	Somewhat better	No difference	Somewhat worse	Very much worse
2. Your speech is					
3. Your ability to chew hard food is					
4. Your ability to chew soft food is					
5. Your ability to swallow food is					
6. The comfort of your mouth is					
	Yes	No			
7. Do you feel any benefit from wearing the lubricating device?					

removable denture-wearing experience. Each of them had clinical signs of xerostomia and all complained of a very dry mouth that interfered with daily living activities such as eating, swallowing and speaking. All of them had been able to wear the device for at least 4 h per day during the evaluation period.

Four out of five people found the device generally easy to use and one found it difficult. Two people found their speech to be somewhat better and three found it to be somewhat worse. Two people found their ability to chew hard and soft foods to be somewhat better and three felt that it was somewhat worse. Three people reported no difference when swallowing food, one felt it was somewhat better and one felt it was somewhat worse. Comfort of the mouth was rated as somewhat better by two people, somewhat worse by two, and very much worse by one. Three people indicated some benefit from wearing the device whereas two did not. In general, participants reported that the device improved oral comfort by moistening the mouth. The effect was most noticeable during speaking, where longer conversations were easier and articulation was improved. The functional difficulties associated with wearing the device appeared to be related to the bulkiness of the reservoir. Some participants indicated that a smaller reservoir requiring more frequent refills would be more acceptable. Cleaning and refilling the device did not appear to be particular problems.

Discussion

To achieve sustained oral lubrication, saliva substitute delivery should be by slow release via an intra-oral device. Ideally, the intra-oral device should not impede normal oral functions such as eating and speaking, and it should be simple to use and easy to clean.

The design and testing of a prototype intra-oral device for the management of radiotherapy-related xerostomia has been described. The present device permits patient-controlled delivery of saliva substitute as required. The fabrication of the device was relatively simple and employed routine prosthodontic laboratory techniques. All components were inexpensive and readily available in a dental technical laboratory. The design addressed key physical problems related to saliva substitute flow that were associated with previous lubricating designs [5, 8]. In addition, the design avoided coverage of the occlusal surfaces of the teeth, so normal occlusion and articulation were preserved unlike previous devices used in dentate people [5].

The nature, size and location of the device, particularly its reservoir, are pivotal features of the lubricating system design, especially when aiming to maintain normal oral functioning. The location of the reservoir should be as unobtrusive as possible whilst containing a useful amount of saliva substitute. In edentulous people, the interior of a mandibular complete denture has been used as a reservoir although cleanability and saliva substitute flow were concerns [9]. In dentate people, the palate is generally the location of choice although anatomical features, especially the width and depth of the palatal vault, are important considerations when determining the size and shape of the reservoir.

Whilst care was taken to achieve an optimum prototype design, the ultimate test was patient acceptance. Patient reports on the comfort, utility and function of the device provided valuable feedback. At this stage, only a small number of participants were recruited to provide information on general utility in the short term. All participants were able to wear the device for at least the minimum time per day for the duration of the study. The device was generally easy to use and clean. No problems with filling the reservoir were reported. The device did appear to impair oral functions, with speech and chewing affected in three people. The lubrication system appeared to be effective, as general oral comfort and ability to speak for long periods was improved. The "on-demand" system was easy to operate with only infrequent refilling of the reservoir required. A number of participants indicated that a smaller reservoir with more frequent refilling would be more acceptable. As a consequence of the patient reports, it was considered desirable to reduce the bulk of the prototype reservoir with a subsequent reduction in reservoir volume in order to improve oral functioning.

The prototype device described was tested in partially dentate people. It could equally be employed in edentulous people with the reservoir incorporated in the palate of the maxillary complete denture. The device was designed primarily for use in the management of post-radiotherapy xerostomia. It does, however, have potential benefit in the management of xerostomia obtained due to other medical conditions such as Sjögren's syndrome. The device may also have utility in the slow release of oral disinfectants such as chlorhexidine, anti-fungal agents and neural fluoride in patients at high risk from dental caries and other oral infections. A prospective clinical trial to evaluate the efficacy of the device in the management of radiotherapy-related xerostomia is planned.

Conclusion

A novel, intra-oral lubricating device for use in the management of post-radiotherapy xerostomia was designed and tested clinically. The design of the device overcame the majority of problems associated with previous intra-oral lubricating systems. Patient feedback provided key information on the device's utility and permitted patient-centred modification of the prototype design to improve oral function and patient compliance.

Acknowledgements The authors are grateful for the assistance of Dr W.K. Leung in obtaining access to patients in the dry mouth clinic at the Prince Philip Dental Hospital. The study was supported by a CRCG grant #10204277 from the University of Hong Kong.

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