

## reports

# Oral Rehydration: A Pilot Study of a Liquid Delivery System for Management of Nocturnal Dry Mouth

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## ABSTRACT

**Objectives:** This pilot study aimed to evaluate the clinical effect of a simple apparatus to drip-feed water to the mouths of participants with sleep-related xerostomia.

**Method:** Ten participants from a hospital out-patient clinic who complained of sleep disturbance from dry mouth, and who met the criteria for primary Sjögren's Syndrome (Porter et al, 2004), trialled the device over two months. Baseline unstimulated whole salivary flow measurements (USFR), Xerostomia Inventory (XI; Thomson and Williams, 2000), and Epworth Sleepiness Scale (ESS; Johns, 1991) scores were recorded. After two weeks, XI and ESS were repeated, then USFR, XI, and ESS were again repeated at eight weeks, and verbal reporting of patient satisfaction with the apparatus was also recorded.

**Results:** No statistically significant changes over baseline were noted for USFR; XI values showed a pattern towards improvement, and ESS values a statistically significant improvement with  $p=0.04$ . Overall, 50% of participants felt the device improved sleep and oral dryness. A number of practical concerns were exposed, most concerning the obtrusive nature of the headpiece.

**Conclusion:** This pilot study indicates benefit in drip-feeding water to the mouths of Sjögren's Syndrome participants during sleep. Further development of the apparatus is recommended before mounting larger studies to confirm the effectiveness of the approach.

## INTRODUCTION

Saliva plays a major role in the oral environment. The functions of saliva include lubrication, digestion, protection, remineralisation and buffering, cleaning and soft tissue maintenance. Saliva also provides a level of comfort to the oral environment which may become apparent only when a person has reduced saliva flow. People with low salivary flow experience discomfort which may disturb sleep. Dry mouth can present a significant problem for sufferers, compromising the quality of life (Thomson et al, 2006), and possibly contributing to depression. A dry mouth can significantly increase dental caries, infections and ulceration of oral mucosa, and reduce the quality of taste (Porter et al, 2004). Clinicians can often provide only supportive help, which may include a combination of measures.

Various therapeutic measures to ease nocturnal oral dryness have been proposed, including room humidification (Hay et al, 2006), systemic pilocarpine (Ferguson, 2002), night guards (Yamamoto et al, 2008), and intra-oral lubricating devices (Frost et al, 2002). Hay *et al* (2006) investigated the

efficacy of delivering heated humidified air overnight and concluded that their system was successful in alleviating the major oral and pharyngeal symptoms of xerostomia.

The aim of this pilot study was to test the clinical effectiveness and acceptability of the application of drip-fed water to individuals with nocturnal xerostomia.

## MATERIALS AND METHODS

Ten individuals with Sjögren's syndrome who were currently under management at the Oral Medicine service at Christchurch Hospital—and who complained of disturbed sleep due to dry mouth—gave written informed consent for the trial. The study was approved by the Upper South A Regional Ethics Committee of the Ministry of Health. All participants were female, and the mean age was 71 years (range 55 to 84). The participants were confirmed by one clinician as meeting standardised diagnostic criteria for Sjögren's syndrome (Porter et al, 2004). All had routine assessment and blood tests with full blood count and measurement of C-reactive protein, Sjögren's antibodies, haematinics, and antinuclear antibodies.

Subjective reporting of sleepiness was measured using the Epworth Sleepiness Scale (ESS; Johns, 1991). The ESS is a summated rating scale of 8 situations where the participant's sleepiness is rated from 0 (would never snooze) to 3 (high chance of snoozing). The scale measures daytime sleepiness, which may be a reflection of the participant's sleep disturbance (Johns, 1991). Scale scores greater than 10 suggest significant sleepiness (Table 1).

Participants also completed the Xerostomia Inventory (Thomson and Williams, 2000), an 11-item summated rating scale which results in a single continuous scale score representing the severity of chronic xerostomia. The average score seen in older populations is about 20, and a change in score of six or more scale points over time is considered to be clinically meaningful (Thomson, 2007). The unstimulated saliva flow rate was measured by the passive drain method, in which saliva was gravity drained over 5 minutes into a graduated tube, after which the flow rate was determined volumetrically.

The apparatus (Figure 1) consisted of three major components: the water reservoir and stand (A), the flow controller (B), and the mouthpiece and supporting frame (C). These components were connected by 0.35 mm internal diameter silicon tubing. The reservoir was a one-litre commercially-available bottle of water held in a fabric carrier, and suspended in a simple stand one metre above mattress level. There was an air bleed tube and outlet port in the screw-top of the bottle, and the port was connected by tubing to the water flow controller. The flow controller (*Acuset*<sup>TM</sup>, Medicine Mondiale, Auckland) was a patented device proposed as a replacement for the roller control clamp used in intravenous lines (Figure 2). The tubing from

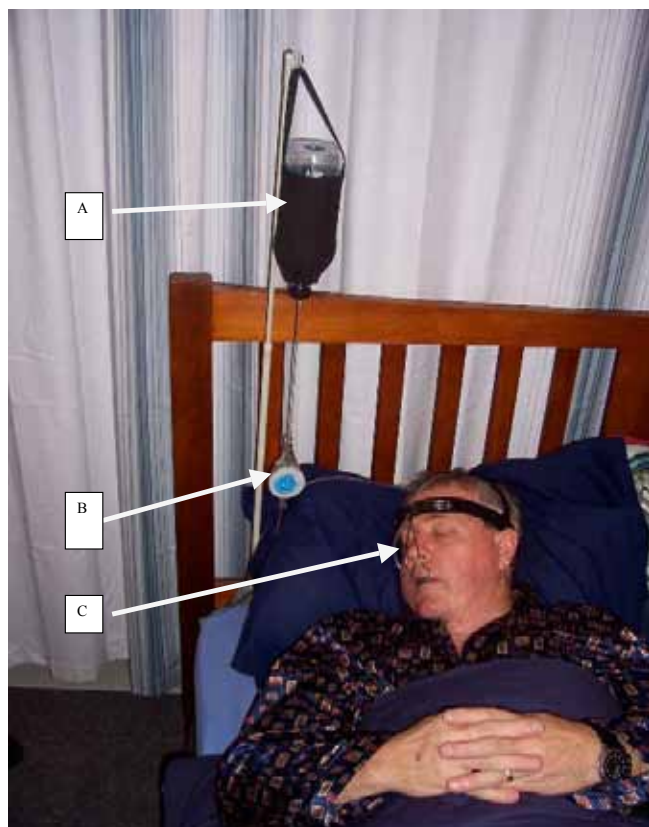


Figure 1. The apparatus (worn by a model who was not a participant in the current study) A: water reservoir; B: flow controller; C: holding frame and mouthpiece



Figure 2. Flow controller

the reservoir passed through a slot in the controller and was variably compressed by an adjustable 5cm-long cam-activated 'foot', allowing easy alteration of flow-rates by each participant. A simple on-off tap was also incorporated in the line. The holding frame of stainless steel wire was retained by Velcro™ strapping and carried the connecting tube to an acrylic mouthpiece which rested passively between the lips. Participants were instructed to adjust the water flow so that the mouth felt comfortably moist, without drooling or conscious swallowing.

The recording of subjective data was made by a different clinician at two and eight weeks for each participant,

using the USFR, ESS and XI, as well as a verbal report of participant satisfaction with the device. Statistical analysis was carried out with paired t-tests using Stata for Windows VII (Stata Corp, College Station, Texas).

## RESULTS

Three participants could not tolerate the headband and supporting frame, and also found the flow controller difficult to manage; these individuals withdrew from the study before completion.

The mean USFR (Table 1) did not show any statistically significant change before and after the intervention. The baseline and 2-week mean XI scores differed significantly, showing an overall improvement, but the baseline and 8-week scores did not (although the latter was lower). The ESS changes were statistically significant, indicating less day-time sleepiness.

This pattern was also consistent with the subjective verbal reporting, where 50% of participants (five out of ten) indicated that, in their opinion, using the device was worthwhile and gave some improvement of symptoms. The preferred water flow rates varied between 0.15 and 0.35 ml per minute.

## DISCUSSION

Short-acting relief from dry mouth may be available from chewing sugar-free gum, frequent watersips, saliva substitutes, dietary changes, and also oral lubricant preparations. Each of these requires active patient participation, and provides little comfort for sleep time symptoms. Medications such as the non-selective muscarinic receptor agonist pilocarpine can stimulate saliva production; pilocarpine has a relatively short half-life and can have significant unwanted effects, including excess sweating, and bronchial secretion and constriction interfering with breathing. A variety of innovative treatments—including acupuncture (Johnstone et al, 2002) and electro-stimulation (Fedele et al, 2008)—have also been tried, but there is no universal management strategy that suits all cases of dry mouth.

Xerostomia is frequently associated with disturbed sleep, and promotion of restorative sleep might ease the burden of fatigue in individuals so affected. Management strategies proposed for use during sleep include: various intra-oral reservoir devices to release fluid into the mouth (Kam et al, 2005; Frost et al, 2002); the use of matrices such as sponges to release fluid; mouth guards (Yamamoto et al, 2008); and room humidification (Hay and Morton, 2006). The latter requires sophisticated equipment. Application has also been made to the US patent office (Roberts et al, 2008) for an oral rehydration device with an external fluid reservoir and an electrically-driven infusion pump for delivering water to the mouth during sleep.

The device reported in this paper relies on gravity to deliver the fluid, with flow rate control by means of a simple adjustment. Participants with Sjögren's Syndrome were selected for the trial because of their familiarity with a variety of strategies for symptom control, and their readiness to try new approaches. All reported disturbed sleep patterns, although initial ESS scores did not show this in every case; the ESS score changes at the end of the trial were statistically significant, indicating better sleep quality at night. No statistically significant changes in USFR and XI were noted. The preferred water flow rates of 0.15-0.35 ml/min are in keeping with the recommendation of Dawes (2004) that unstimulated salivary flow rates greater than 0.1-0.3 ml/min

Table 1. Unstimulated saliva flow rate (ml/min), Xerostomia Inventory and ESS scores by study stage

Participant	Unstimulated saliva flow rate (USFR) ml/min		Xerostomia Inventory score (XI)			Epworth Sleepiness Scale score (ESS)		
	Baseline	8 weeks	Baseline	2 weeks	8 weeks	Baseline	2 weeks	8 weeks
1	0.12	0.14	39	39	31	14	10	5
2	0.10	0.14	51	46	46	5	2	3
3	0.02	0.04	50	46	47	18	14	3
4	0.02	0.01	43	43	46	22	16	20
5	0.01	0.00	52	42	46	10	4	5
6	0.10	0.20	44	37	47	9	6	6
7	0.15	0.24	48	37	46	0	0	0
Mean (sd)	0.07 (0.06)	0.11 (0.09)	46.7 (4.8)	41.4 (3.9) <sup>a</sup>	44.1 (5.8)	11.1 (7.5)	7.4 (6.1) <sup>b</sup>	6.0 (6.5) <sup>c</sup>

<sup>a</sup>P=0.02; paired t-test: the mean 2-week XI is significantly lower than the baseline mean

<sup>b</sup>P=0.003; paired t-test: the mean 2-week ESS is significantly lower than the baseline mean

<sup>c</sup>P=0.04; paired t-test: the mean 8-week ESS is significantly lower than the baseline mean

may be necessary for a sense of dry mouth to be avoided. Three participants did not complete the study as they found the head band and supporting frame obtrusive, further disturbing their already unsatisfactory sleep patterns. Each of those individuals also reported difficulty in managing the flow controller, as did some other participants who completed the study; this was in spite of written instruction and repeated demonstration. Nonetheless, those who completed the trial reported greater oral comfort; all continue to use the device as part of their xerostomia management strategy.

Most people with Sjögren's syndrome are elderly females who may cope less well with any new apparatus. Moreover, fatigue is a part of the Sjögren's symptom complex and it may be that more definitive findings would be obtained by using a different patient group. We believe that, with further development, the device tested could offer a simple, inexpensive, and non-invasive adjunct to the management of xerostomia which affects sleep quality. A larger study would be required to further test this.

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## REFERENCES

- Dawes C (2004). How much saliva is enough for avoidance of xerostomia? *Caries Research* 3: 236-240.
- Fedele S, Wolff A, Strietzel FP, López RM, Porter SR and Kontinen YT (2008). Neuroelectrostimulation in treatment of hyposalivation and xerostomia: a salivary pacemaker. *Journal of Rheumatology* 35:1489-1494.
- Ferguson MM (2002). The persistent dry mouth. *New Zealand Family Physician* 4:259-265.
- Frost PM, Shirlaw PJ, Walter JD and Challacombe SJ (2002). Patient preferences in a preliminary study comparing an intra-oral lubricating device with the usual dry mouth lubricating methods. *British Dental Journal* 193: 403-408.
- Hay KD and Morton RP (2006). Optimal nocturnal humidification for xerostomia. *Head and Neck* 28: 792-796.
- Johns WM (1991). A new method for measuring day-time sleepiness – the Epworth Sleepiness Scale. *Sleep* 14: 540-545.
- Johnstone PA, Niemtow RC and Riffenburgh RH (2002). Acupuncture for xerostomia; clinical update. *Cancer* 94: 1151-1156.

Kam AYL, McMillan AS, Pow AHN, Leung KCM and Luk HWK (2005). Preliminary report on patient acceptance of a novel intra-oral lubricating device for the management of radiation induced xerostomia. *Clinical Oral Investigation* 9:148-153.

Porter SR, Scully C and Hegarty AM (2004). An update of the etiology and management of xerostomia. *Oral Surgery Oral Medicine Oral Pathology Oral Radiology and Endodontics* 97: 28-46

Roberts H, Meyer M, Berger M, Herskovits C, Stratton S and Thompson C (2008). Oral rehydration device. *US Patent Application Publication* US2008/0171303 A1.

Thomson WM, Lawrence HP, Broadbent JM and Poulton R (2006). The impact of xerostomia on oral-health-related quality of life among younger adults. *Health and Quality of Life Outcomes* 4: 86 (7pp).

Thomson WM (2007). Measuring dry mouth changes over time using the Xerostomia Inventory. *Gerodontology* 24: 30-35.

Thomson WM and Williams SM (2000). Further testing of the xerostomia inventory. *Oral Surgery Oral Medicine Oral Pathology Oral Radiology and Endodontics* 89: 46-50.

Yamamoto K, Nagashima H, Yamachika S, Hoshiba D, Yamauchi K, Yamada H, Saito I and Nagagawa Y (2008). The application of a night guard for sleep-related xerostomia. *Oral Surgery Oral Medicine Oral Pathology Oral Radiology and Endodontics* 106: e11-4.

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