

## Aquoral Clinical Evidence

### Proven Clinical Performance

The safety and efficacy of OGT technology have been proven in clinical trials. Study results demonstrate a significant improvement in the symptoms of xerostomia including: chewing, swallowing, taste and speech.<sup>7,8</sup> Patients enrolled in clinical trials tested OGT spray, and researchers compared their responses to patients who used an aqueous-based saliva substitute. The clinical trials focused on geriatric patients, patients with medication-induced xerostomia and patients who had received head and neck radiation therapy.<sup>7,8,9</sup>

In all three clinical trials, OGT spray was shown to provide significant benefits to most patients.

- A majority of patients in the medication-induced xerostomia clinical trial said OGT spray enhanced both their ability to chew (73 percent) and swallow (65 percent).
- Eighty four percent of the patients said it also improved their quality of life.
- OGT spray also lasted longer, with 78 percent saying they used it three to four times per day and only 19 percent saying they used it four or more times per day.
- The taste of the spray was considered good for both products but far better for OGT spray (mean score 7.2 for the OGT spray vs. 5.5 for the aqueous-based spray).
- Eighty seven percent of the patients reported that they felt better from using OGT spray and that it was easy to use.
- There were no unpleasant or adverse effects for 94 percent of patients who used OGT spray, and 78 percent said they wished to continue using the product.

The researchers concluded that the lubricating and protective qualities of OGT, in comparison with an aqueous solution, improved the feelings of dry mouth and improved many important factors related to patients' quality of life, which can be severely affected by xerostomia.<sup>8</sup>

Published in the Cochrane Database of Systematic Reviews, a 2011 review comparing xerostomia interventions concluded that lipid-based OGT technology shows greater effectiveness when compared to water-based electrolyte sprays.<sup>10</sup>

Laboratory testing designed to mimic the effects of xerostomia products on soft tissue confirms the efficacy of OGT technology. Using novel in vitro test methods to measure lubricity and moisture retention, researchers at 3M and the University of Minnesota School of Dentistry conducted comparative experiments of OGT spray and some common, commercially available xerostomia products.<sup>11,12</sup>

### Lubricity

The University of Minnesota has developed a reciprocating mechanical system, which models the relative movement of the mandibular and maxillary structures in the mouth and was used to study the friction between simulated hard and soft oral tissues in the presence of various xerostomia relief products.<sup>11</sup> Using either dry tissue or tissue lubricated only with water as controls, researchers were able to measure the coefficient of friction, otherwise known as lubricity, for each product and found that OGT spray was the most efficient at lubricating the hard tissues tested. In the experiment, the mean coefficients of friction were significantly different between all groups tested. The mean coefficient of friction of OGT spray was four times lower than the hard tissue controls that were left dry.<sup>11</sup>

## Moisture Retention

Researchers at 3M have found a unique way to test for moisture retention. They found that OGT spray performed statistically better at preventing water loss when tested against many commercially available xerostomia relief products. Using a technique named thermogravimetric analysis, which measures moisture loss over time at specific temperatures, researchers used samples of sirloin steak to represent human soft tissue and coated them with xerostomia relief products. As the temperature of the test instrument is increased to body temperature, the sirloin steak begins to lose water. After four hours at body temperature, the percentage of weight lost by each sample can be measured and converted into the percentage of total water lost after four hours. The sirloin steak samples coated with OGT spray showed significantly less water loss compared to many competitive xerostomia products. This low level of water loss suggests a moisture-protective effect that the OGT spray exhibits on intraoral tissues. OGT spray was able to prevent water loss and provide more lubricity than any of the other products tested.<sup>12</sup>

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## **Efficacy of a new oral lubricant solution in the management of psychotropic drug-induced xerostomia: a randomized controlled trial**

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### **Abstract**

**Objective:** Xerostomia is a subjective sensation of mouth dryness often occurring as an unwanted effect of psychotropic drugs.

**Methods:** The clinical efficacy and acceptability of a new oxygenated glycerol triester (OGT) oral spray (1 or 2 sprays up to 4 times daily) in the treatment of xerostomia was compared with those of a commercially available artificial saliva substitute (ASS [Saliveze]) in a 2-week, open-labeled, randomized, parallel-group study. Clinical assessment of xerostomia included evaluation of mouth dryness by means of a 10-cm-long visual analog scale, objective blinded assessment of the oral tissue condition by a dental hygienist by means of a 4-point ordinal scale, and subjective patient-based assessment of dry mouth symptoms by means of dichotomous responses to a questionnaire. [Day 14 - baseline] patient-based mouth dryness score was the primary end point.

**Results:** Seventy-four patients (41 women and 33 men, 44 +/- 15 years) undergoing long-term psychotropic drug treatment were consecutively enrolled. At day 14, OGT resulted in better efficacy than ASS in mouth dryness score (mean difference, 1.2 +/- 0.4; P = 0.006), speech difficulties (mean difference, 1.2 +/- 0.4; P = 0.005), taste (mean difference, 1.1 +/- 0.4; P = 0.02), and overall mouth condition (mean difference, 1.4 +/- 0.9; P = 0.005). Taste of OGT was better than that of ASS (mean difference, 1.4 +/- 0.6; P = 0.04), as was OGT acceptability (mean difference, 1.4 +/- 0.9; P = 0.005).

**Conclusion:** Oxygenated glycerol triester lubricant oral spray was superior to a commercially available ASS in improving xerostomia and overall condition of the oral tissue.

## Management of Xerostomia in Older Patients.

Mouly, S., & Salom, M. (2007).

### Background

Xerostomia is a subjective sensation of mouth dryness that may frequently occur in older patients.

### Objective

To compare the clinical efficacy and acceptability of a new oxygenated glycerol triester (OGT) oral spray taken five times daily with that of a commercially available saliva substitute (Saliveze®) in the treatment of xerostomia.

### Methods

Forty-one institutionalized patients (28 women, 13 men; mean age  $84 \pm 7$  years) were randomly assigned to receive either OGT or saliva substitute in a 2-week, randomized, parallel-group study. Clinical assessment of xerostomia included evaluation of mouth dryness using a self-rated, 10cm long visual analogue scale (VAS), objective assessment of oral tissue condition using a four-point ordinal scale and subjective assessment of symptoms of xerostomia using dichotomous responses to a questionnaire. The primary endpoint was the day (D) 14 patient-based mouth dryness score measured on a self-rated VAS.

### Results

At D14, OGT resulted in significantly greater efficacy with respect to mouth dryness (mean between-treatment difference  $2.1 \pm 0.1$ , 95% CI 1.9, 2.3;  $p = 0.001$ ), swallowing difficulty ( $1.8 \pm 0.3$ , 95% CI 1.5, 2.1;  $p = 0.001$ ), speech difficulty ( $1.1 \pm 0.2$ , 95% CI 1.0, 2.4;  $p = 0.04$ ) and overall sensation of symptom relief ( $2.7 \pm 1.2$ , 95% CI 1.9, 3.8;  $p = 0.001$ ). Objective assessment of oral tissues also showed significantly better improvement with OGT spray with respect to dryness ( $p = 0.01$ ), stickiness ( $p = 0.005$ ) and dullness ( $p = 0.001$ ) of oral mucosa; severity of mucositis ( $p = 0.01$ ); and thickening of the tongue ( $p = 0.03$ ). A significant difference in taste acceptability was also noted in favor of OGT ( $1.4 \pm 0.6$ , 95% CI 1.2, 1.9;  $p = 0.04$ ).

### Conclusion

OGT lubricant oral spray was superior to saliva substitute in improving xerostomia and oral tissue condition in older institutionalized patients.

## Interventions for the management of dry mouth: topical therapies

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### Abstract

**Background:** Xerostomia (the feeling of dry mouth) is a common symptom especially in older adults. Causes of dry mouth include medications, autoimmune disease (Sjögren's Syndrome), radiotherapy or chemotherapy for cancer, hormone disorders and infections.

**Objectives:** To determine which topical treatments for dry mouth are effective in reducing this symptom.

**Search methods:** We searched the following electronic databases: the Cochrane Oral Health Group Trials Register (28 October 2011), The Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library, Issue 4 2011), MEDLINE via OVID (1950 to 28 October 2011), EMBASE via OVID (1980 to 28 October 2011), CINAHL via EBSCO (1980 to 28 October 2011), AMED via OVID (1985 to 28 October 2011), CANCELIT via PubMed (1950 to 28 October 2011).

**Selection criteria:** We included randomised controlled trials of topical interventions such as lozenges, sprays, mouthrinses, gels, oils, chewing gum or toothpastes for the treatment of dry mouth symptom. We classified interventions into two broad categories, saliva stimulants and saliva substitutes, and these were compared with either placebo or another intervention. We included both parallel group and crossover trials.

**Data collection and analysis:** Two or more review authors independently carried out data extraction and assessed risk of bias. Trial authors were contacted for additional information as required.

**Main results:** Thirty-six randomised controlled trials involving 1597 participants met the inclusion criteria. Two trials compared saliva stimulants to placebo, nine trials compared saliva substitutes to placebo, five trials compared saliva stimulants directly with saliva substitutes, 18 trials directly compared two or more saliva substitutes, and two trials directly compared two or more saliva stimulants. Only one trial was at low risk of bias and 17 were at high risk of bias. Due to the range of interventions, comparisons and outcome measures in the trials, meta-analysis was possible for only a few comparisons. Oxygenated glycerol triester (OGT) saliva substitute spray shows evidence of effectiveness compared to an electrolyte spray (standardised mean difference (SMD) 0.77, 95% confidence interval (CI) 0.38 to 1.15) which corresponds to approximately a mean difference of 2 points on a 10-point visual analogue scale (VAS) for mouth dryness. Both integrated mouthcare systems (toothpaste + gel + mouthwash) and oral reservoir devices show promising results but there is insufficient evidence at present to recommend their use. Although chewing gum is associated with increased saliva production in the majority of those with residual capacity, there is no evidence that gum is more or less effective than saliva substitutes.

**Authors' conclusions:** There is no strong evidence from this review that any topical therapy is effective for relieving the symptom of dry mouth. OGT spray is more effective than an aqueous electrolyte spray (SMD 0.77, 95% CI 0.38 to 1.15) which is approximately equivalent to a mean difference of 2 points on a 10-point VAS scale for mouth dryness. Chewing gums appear to increase saliva production in those with residual secretory capacity and may be preferred by patients, but there is no evidence that gum is better or worse than saliva substitutes. Integrated mouthcare systems and oral reservoir devices may be helpful but further research is required to confirm this. Well designed, adequately powered randomised controlled trials of topical interventions for dry mouth, which are designed and reported according to CONSORT guidelines, are required to provide evidence to guide clinical care. For many people the symptom of dry mouth is a chronic problem and trials should evaluate whether treatments are palatable, effective in reducing xerostomia, as well as the long-term effects of treatments on quality of life of those with chronic dry mouth symptoms.