

ABSTRACT

Objectives: Xerostomia is the subjective sensation of dry mouth. Our aim was to learn if a hyaluronic acid formulation identified in laboratory tests (without organoleptic additives), and by preliminary clinical impressions, as showing superior lubricity and resistance to desiccation would be accepted by xerostomic individuals.

Methods: Institutional IRB approval was given to enroll 20 individuals with xerostomia in this study. Subjects were given two water-clear oral rinses and instructed to alternate the use of each daily for fourteen days. Control Solution A consisted of only 5% aqueous xylitol, and Active Solution B consisted of 5% aqueous xylitol containing 0.5% hyaluronic acid (HA). Participants were given a questionnaire and re-interviewed after fourteen days of product use.

Results: Thirteen individuals completed this on-going study. Seven (54%) reported an improvement in oral lubrication from Solution A compared to other previously used xerostomic relief products, and noted similar oral comfort compared to previously used products. Nine (69%) reported that Solution B provided oral lubrication that was much better than other xerostomic relief products, with six (46%) noting Solution B provided oral comfort for a longer amount of time. Twelve (92%) recommend Solution A to xerostomic individuals, while only eight (62%) recommend Solution B, attributing the difference to the “thicker” consistency of the HA-containing formulation.

Conclusion: Although active Solution B provided superior tissue lubrication in the laboratory, and also provided oral lubrication and comfort, more individuals recommend the less-viscous Solution A to other individuals with xerostomia. Organoleptic additives will be included in future formulations.

INTRODUCTION

Xerostomia is the subjective sensation of dry mouth that is predominantly seen in the aging population (Orellana et al 2006, Fox et al 2008). It is caused by a multitude of factors, the most common being prescription medication. Systemic diseases such as Sjogren’s Syndrome, and head and neck cancer therapies also play a large role (Fox et al 2008). Patients who suffer from xerostomia may have a decreased salivary flow. Other symptoms include oral “burning”, altered taste, difficulty with speech, and difficulty swallowing (Orellana et al 2006). Xerostomia can also increase susceptibility to dental caries, periodontal disease, denture discomfort, and oral fungal infection (Orellana et al 2006, Bhide et al 2009).

Subjective perception of dry mouth varies widely among individuals who have a similar cause for their complaint. Water is often used for oral comfort in this patient group. Salivary substitutes are often recommended but have modest clinical improvement of patients’ symptoms (Levine 1993). Salivary substitutes often need to be used many times throughout the day (Levine 1993). In two recent faculty-supervised Master’s Degree Thesis projects within the Biomaterials Graduate Program, School of Dental Medicine, over 20 commercially available mouth rinses were tested for their ability to lubricate bovine pericardium (Ganesh R, MS Thesis, 2010). The author also compared the lubricity of saliva from normal and xerostomic volunteers (Ganesh R, MS Thesis, 2010). Rodgers discovered (UB STOR New Technology Disclosure # R-6334) that a formulation of cavity-preventing sugar (xylitol), gave significantly better results when “thickened” with hyaluronate (Rodgers L, MS Thesis, 2010).

Objective:

The aims of this study were to

1. Compare a hyaluronate-enriched xylitol solution (0.5%) to aqueous xylitol for the relief of xerostomic symptoms.
2. Determine if there was sustained oral soft tissue lubricity and comfort without the addition of exogenous fluids.

MATERIALS and METHODS

Institutional IRB approval was given to enroll 20 subjects experiencing xerostomia in this preference study. Individuals who were at least 18 years of age and experiencing any degree of xerostomia were deemed eligible to participate. Informed consent was obtained for each subject. Each subject received a one-week supply of two different mouth rinses. Solution A consisted of 5% xylitol, and Solution B was thickened with 0.5% sodium hyaluronate. Each subject was instructed to alternate the use of the solutions over a two-week period (Solution A on day 1, Solution B on day 2 etc.). Subjects were instructed to rinse with either solution three times per day. Emphasis was placed on the use of either solution before going to sleep. Subjects recorded their use of each solution in a daily log sheet, and were examined after the two-week trial period. At the second visit, subjects were given a visual analog scale regarding their preference for Solution A and/or the Solution B formulation. The subjects were asked whether either solution provided symptomatic relief and which one was considered superior. All subjects were thoroughly examined by a board certified Oral and Maxillofacial Surgeon at each visit.

RESULTS

- Informed consent was obtained for 16 subjects
- 3 subjects were lost to follow-up after failing to return for their follow-up examination.

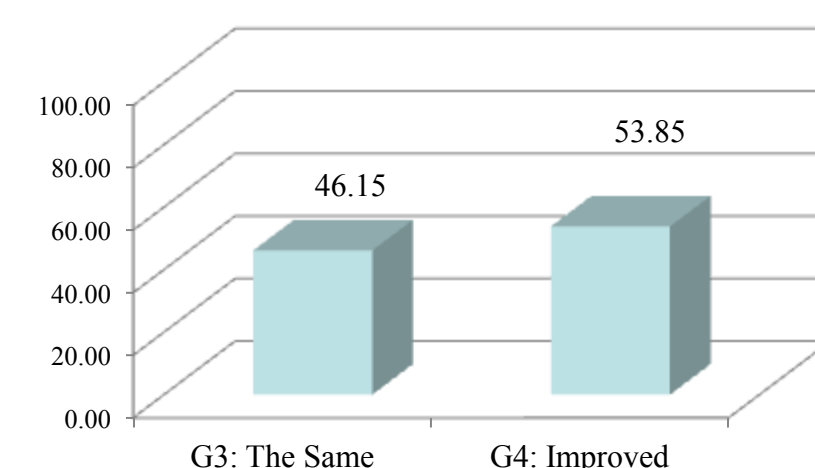


Figure 1: Subject response to How well does the **THIN** solution lubricate your mouth, compared to other oral dryness relief products that you have used?

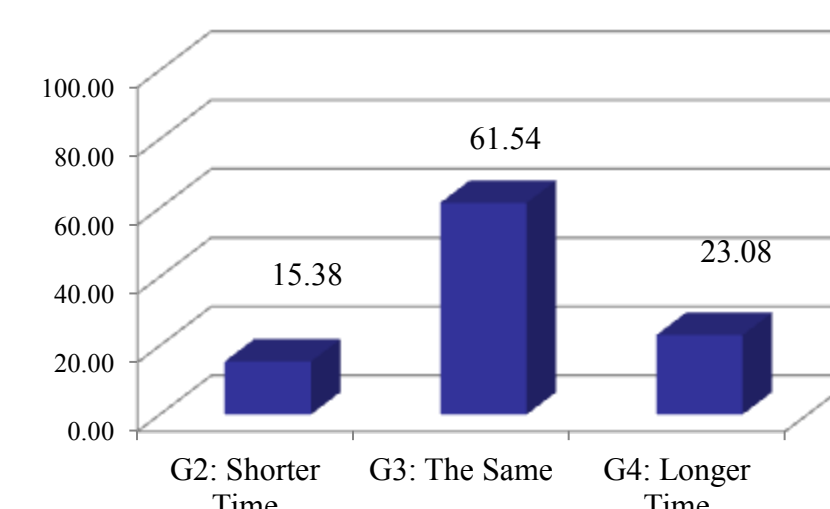


Figure 2: Subject response to How long does the oral comfort last for the **THIN** solution compared to other products you have used?

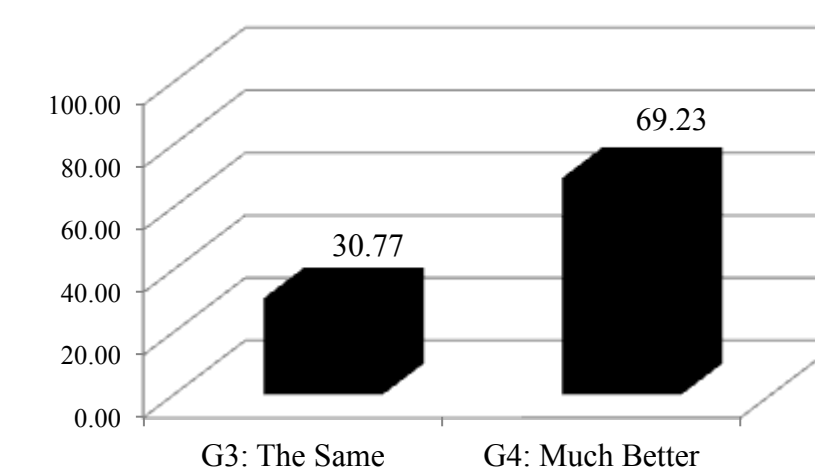


Figure 4: Subject response to How well does the **THICK** solution lubricate your mouth, compared to other oral dryness relief products you have used?

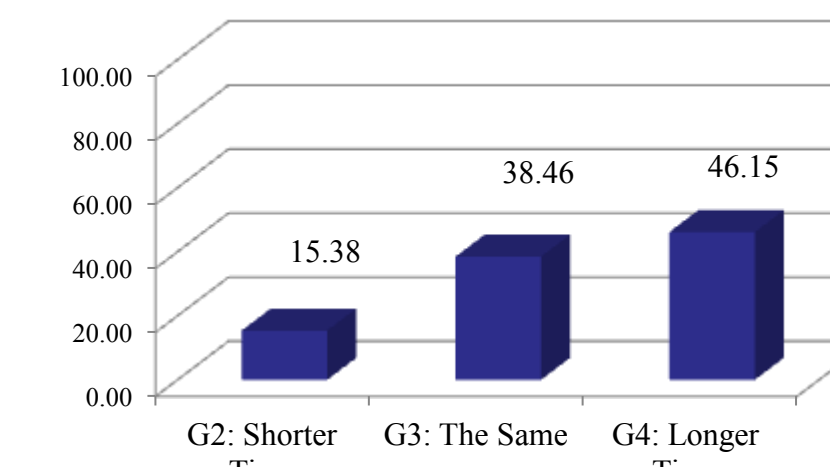


Figure 5: Subject response to How long does the oral comfort last for the **THICK** solution compared to other products you have used?

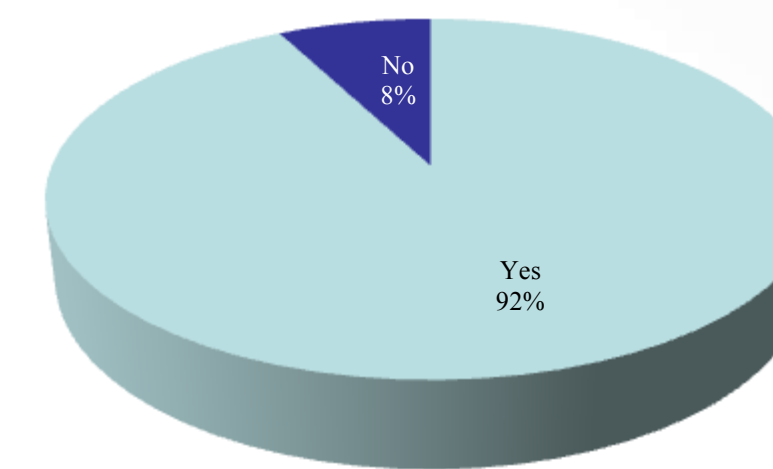


Figure 3: Subject response to Would you recommend the **THIN** oral mouth rinse to an individual with dry mouth?

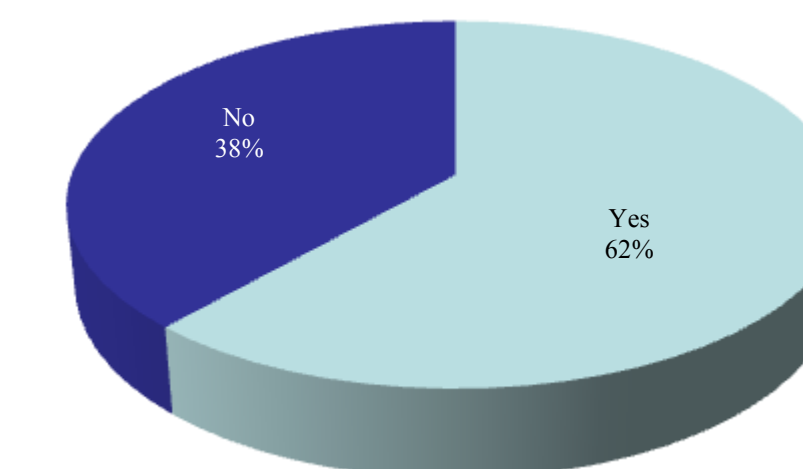


Figure 6: Subject response to Would you recommend the **THICK** oral mouth rinse to an individual with dry mouth?

CONCLUSIONS

- In this small sample of on an ongoing preference survey, there is a modest predilection for the thickened solution in terms of oral comfort and lasting oral lubricity.
- There were no reported harmful effects of either solution.
- The Oral and Maxillofacial Surgeon noted no adverse oral mucosal effects from either solution.
- A common complaint about Solution B was its high viscosity.
- Re-formulation of Solution B into a spray vehicle will be tested in order to combat this complaint.

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