Tissue-on-Tissue Lubrication by Natural and Xerostomic Saliva and Saliva Substitutes

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Statement of Purpose: "Dry mouth" [xerostomia] is a symptom often seen in patients who take multiple medications. (Levine 1987) Primary and secondary inflammatory changes in salivary glands can also result in xerostomia (Kroneld 1997). This investigation (Ganesh 2010) applied a tissue-on-tissue lubricity test procedure to (1) unstimulated saliva from control and xerostomic test subjects, (2) commercial saliva substitutes, as-formulated, and (3) saliva substitutes admixed with unstimulated saliva. The null hypothesis was that no difference between normal and xerostomic salivary lubrication, alone or admixed with saliva substitutes, would be detected.

Methods: Using a protocol approved by the university's Institutional Review Board, lubrication by unstimulated saliva, alone, from 10 normal (control) and from 10 clinically diagnosed xerostomia patients was studied. Model tissue-on-tissue lubricity tests were used to establish possible similarities and differences in lubricity associated with normal vs xerostomic saliva sources, pH, and macromolecular components as characterized by multiple attenuated internal reflection infrared (MAIR-IR) spectroscopy. A preserved human vascular tissue-on-tissue model (Meyer et al. 2006) was adapted to employ preserved bovine pericardium (Meyer et al. 2008). The model has shown good correlations with clinical studies of formulations for relieving "dry eye" symptoms.

Nineteen of 31 identified over-the-counter [OTC] commercial "saliva substitute" products were obtained for laboratory testing of their intrinsic capabilities to (a) reduce coefficients of friction [COF] of saline-moistened articulating tissue couples, (b) sustain those COF reductions over time, and (c) demonstrate substantivity of the COF effects after further dilution by physiologic buffer. COF data were evaluated within the context of formulation pH's, surface tensions, and functional ingredients characterized by MAIR-IR spectroscopy. Clinical use of saliva substitutes will include some admixture with intraoral saliva. Therefore, lubricity of normal vs xerostomic saliva was also examined when supplemented with equal small volumes of 4 of the OTC saliva substitutes.

Results: The null hypothesis was sustained (Table 1). Tissue-on-tissue evaluations of the saliva substitutes, alone (Figure 1), demonstrated that the most effective constituents were rinse-resistant natural polysaccharides such as linseed extracts and xanthan gum, at neutral pH, while formulations with either low or high pH, or based on synthetic carboxymethylcellulose, hydroxyethyl-cellulose, hydroxypropylcellulose, natural esters or glycerin, were not as lubricious or were less substantive (except for previously undisclosed silicone components in some products). Intrinsic lubricities of saliva from both groups of test subjects (normal; xerostomic) were excellent, reducing COF values from above 0.4 to approximately 0.1 in all cases. The carbohydrate-to-protein ratios for both groups of patients were similar (MAIR-IR data). On average, xerostomic saliva pH was approximately 6; approximately 7 for normal saliva. When 4 different saliva substitutes were added to the normal and xerostomic salivas, COF reductions were sustained. It also was demonstrated that small amounts of natural saliva can convey good lubricity to saliva substitutes that, alone, are not very lubricious (Figure 2).

Conclusions: Based on these results, the xerostomic saliva samples were shown to function as excellent tissue lubricants, in spite of their lower pH values. Saliva lubricity was not significantly improved by admixture with any of the subset of OTC saliva substitutes.

Subject Type	COF (9 subjects, 4 experiments each)	highest COF (1 subj., 4 expts each)
Normal	0.09 ± 0.03	0.20 ± 0.02
Xerostomic	0.10 ± 0.03	0.20 ± 0.06

Table 1. Tissue-on Tissue COF for Saliva: Normal and Xerostomic Test Subjects (n=10; 4 expts/subject)

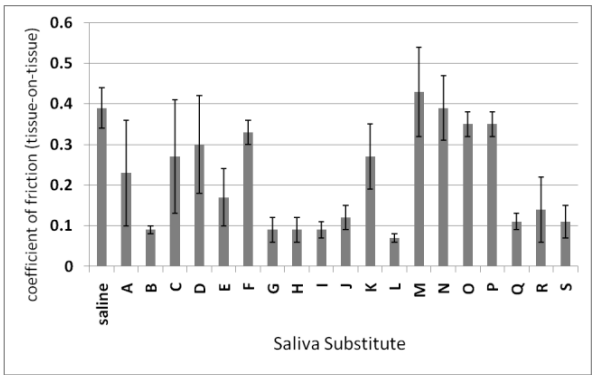

Figure 1. COF for Saline and 19 Saliva Substitutes (n=3 for each substitute; n=19x3 saline baselines)

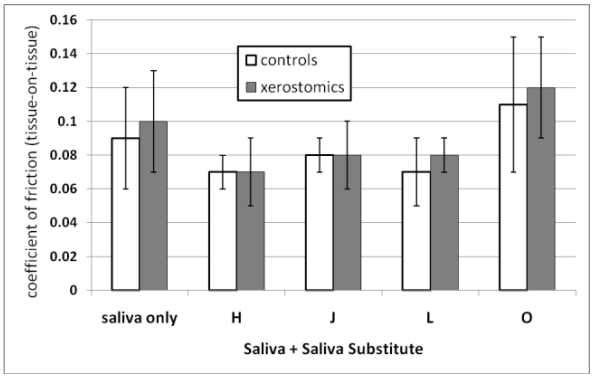

Figure 2. Comparison of Saliva-Only v. Saliva+Saliva Substitute Admixtures (n=9 each)

References: Ganesh, M.S. Thesis, SUNY/Buffalo. 2010. Kroneld et al. Scand J Immunol 45:698, 1997. Levine et al. J Dent Res 66(SI):693, 1987. Meyer et al. J Adhesion 82:607, 2006. Meyer et al. IADR abst#2912, 2008.