- Official Title: Use of Two Dissolvable Therapeutics Under Removable Partial Dentures: Reported Effects on Denture Comfort, Retention, and Dry Mouth Conditions

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Objective: The primary aim of the present study is to quantify the change in a patient's saliva buffering capacity when MI Paste and Biotene Dry Mouth Gel is used under a removable prosthesis.

Design: This is a randomized, case-crossover study (*ClinicalTrials.gov identifier-NCT05441527*). The study population consists of adult subjects (ages 18-99) had a removable prosthesis (e.g., partial denture, complete denture that was made at the University of Iowa College of Dentistry and Dental Clinics (primarily the Family Dentistry Clinic and the Prosthodontics Clinics) within the past 10 years. Subjects cannot have any of the following criteria: casein (i.e., protein found in milk or other dairy products) allergy, lactose intolerance, multiple food or cosmetic ingredient allergies in their health history, ill-fitting dentures that need to be remade or relined.

Methods: Consented subjects will be randomly assigned to Group A or Group B. Randomization will be done as 1:1, in which subjects will have a 50% chance of being assigned to Group A (i.e., use MI Paste during the first week, use Biotene Dry Mouth Gel during the second week) or a 50% chance of being assigned to Group B (i.e., use Biotene Dry Mouth Gel during the first week, use MI Paste during the second week). Once a subject completes using the first product, they will voluntarily complete the questionnaire and be instructed to switch to the next product. Once the subject completes the second product, they will voluntarily complete the questionnaire.

Statistical Analysis Plan: The primary outcomes are: (i) change from baseline in patient comfort for MI Paste as assessed by numerical scale, (ii) change from baseline in patient comfort for Biotene Dry mouth gel as assessed by numerical scale, (iii) change from baseline in retention for MI Paste as assessed by numerical scale, (iv) change from baseline in retention for Biotene Dry Mouth Gel as Assessed by Numerical Scale. Descriptive statistics will be conducted to depict all the variables in the study. A paired-sample t-test or a Wilcoxon signed-rank test as appropriate will be used to detect the difference in saliva buffering capacity between pre- and post-MI paste application. Moreover, McNemar's test or 4 Bowker's test of symmetry will be used to compare the denture fit and function and dry mouth relief between pre- and post-MI paste application. All tests utilize a significance level of 0.05, and statistical analyses will be performed using the statistical package SAS® System version 9.4 (SAS Institute Inc., Cary, NC, USA).