Phase 2: Oral Material Microbial Hazard Risk Analysis

Alexia Vence[1], Micah Ruff[2], Sarah Nickel[2], Heidi VanRavenhorst-Bell[1]
[1]Department of Human Performance Studies, [2]Department of Medical Laboratories

It is important when diagnosing or treating Orofacial Myofunctional Disorders (OMD) to assess the patient's tongue strength and endurance. The anti-slip patch is an adhesive material that reduces slippage of the Iowa Performance Instrument (IOPI) bulb when assessing patients and acquiring reliable lingual measures. The purpose of this study is to determine the microbial safety of the patch without antibacterial ointment for use in the oral cavity. A total of three bulbs in each of the three IOPI bulb conditions (bulb with patch washed, bulb with patch not washed, bulb without patch washed) were submerged and soaked in saliva across three durations of time (15, 30, and 60 minutes). Each IOPI bulb was then washed (hot water, disinfectant soap) for 30 seconds before being streaked on individual plates, and incubated for 48 hours before being examined for bacteria. Then the patch was removed from the bulb (patch no wash), washed (hot water, disinfectant soap) and streaked again. A final examination for bacteria was done afterwards. A repeated-measures ANOVA test will be administered to determine whether bacterial colony count differed based on bulb condition and time. Post hoc comparisons will be administered if significant findings are found. All analyses will be administered at a $p \leq 0.05$. Based on prior literature and preliminary observations, the findings of this study will further guide next steps in the hazard risk analysis process for FDA medical device clearance.