Oral Material Microbiology Hazard Risk Analysis

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Orofacial Myofunctional Disorders (OMDs) are often associated with abnormal functional lingual movements. It is important when diagnosing or treating OMDs to assess patients' 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 (1) evaluate the adhesive content of the anti-slip patch in an oral environment and (2) determine the microbial safety of the patch for use in the oral cavity. **Methods:** A total of three (3) IOPI bulb conditions (with patch washed, with patch not washed, without patch washed) were submerged and soaked in saliva across three (3) durations of time (15-minutes, 30-minutes, 1-hour). Each IOPI bulb was then washed (hot water, disinfectant soap) for 30 seconds, streaked on individual plates, and incubated for 48 hours before being examined for bacteria. **Results:** A repeated-measures ANOVA was administered and found a significant within-subjects main effect across bulb conditions (p= 0.001), while main effect time and interaction (Time x Condition) were not significant. Post hoc comparison further found that the bulb with patch not washed produced significantly more bacterial colonies than the bulb with patch washed and bulb with no patch washed (p= 0.001), respectively. No significance was found between the IOPI patch washed and the IOPI no patch washed. These findings support our initial approach toward FDA medical device clearance and guide the next steps in the Hazard Risk Analysis process.