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RCT Comparing Two Intraoral Appliances to Reduce Oral Sequelae Post-Radiotherapy

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Objectives To assess oral health outcomes associated with the use of two different intraoral appliances—thermoplastic dental splints and 3D-printed tissue retraction devices (TRDs)—following head and neck radiotherapy (RT).

Methods In this pilot randomized controlled trial, 29 patients diagnosed with head and neck cancer were randomly assigned to use either a conventional splint (n=14) or a TRD (n=15) during their radiotherapy sessions. The former serves as an active control by shielding against backscatter radiation from dental restorations, while the latter, designed to conform semi-individually to patients' anatomy, aims to further minimize radiation exposure to healthy tissues. Assessments of saliva quality and quantity (Saliva-Check, GC), taste perception (Taste strips, Burghart-Messtechnik), and oral function (JFLS-8, OHIP-14, and maximum mouth opening) were conducted at baseline and three months post-RT. Treatment specifics such as RT target volume, modality, total dose, fractionation, and imaging guidance were tailored to individual cases. Intra-group changes over time were analyzed using Wilcoxon tests, differences between groups using Mann-Whitney-U tests.

Results Three months post-RT, taste perception remained unchanged in both groups. Although oral function showed no significant alterations, saliva production under stimulation notably decreased with conventional splints (median reduction: 4 mL, p=0.016) compared to an insignificant reduction with TRDs (median reduction: 2 mL, p=0.07). Dropout rates were higher in TRD group (6/15) than in control group (1/14). While inter-group differences were not statistically significant, trends (p < .1) suggested improved outcomes in terms of functional disability and saliva quality in the TRD group.

Conclusions The limited size and variability of the patient cohort necessitate cautious interpretation of these findings. Nonetheless, the initial favorable results for TRDs, particularly in reducing negative oral health impacts, warrant further investigation. The likelihood of adverse effects from TRD use appears low, underscoring the potential of this novel technology in enhancing radiotherapy outcomes.