Characterization of Oral Stent Stability in a Radiotherapy Environment


Purpose: Oral mucositis can be a major dose limiting toxicity for head-and-neck radiation therapy. Customizable oral stents provide reproducible patient setup while achieving improved mucosal sparing. This study evaluated physical stability over repeated use and irradiation of the GrayDuck Stent, a new oral stent by POLL Medical.

Methods: Using anthropomorphic jaws for realistic force distribution and an Instron mechanical testing device, a 250lb force was applied to the stent once before photon treatment and repeated after each 2Gy fraction of a 70Gy total dose to the stent (i.e. 35 fraction radiation treatment). The 250lb force was chosen as 10% above typical reported maximum human bite force. Displacement-per-unit-force was recorded on the Instron for each fraction and analyzed over time to detect changes to stent structural integrity over the course of treatment. Correlation between measurements and fraction number was characterized via Pearson Correlation Coefficients, and variability compared to baseline measurements of setup variability. After the 70Gy treatment was completed, an additional 50Gy was delivered in one fraction to the stent and final Instron data was compared to previous 35 fractions.

Results: Initial baseline setup variability (.009in or 0.23mm) was greater than variability over all 36 fractions (.008in or 0.20mm). Additionally, the variability in response to the applied load shows little correlation with fraction as measured by the Pearson Correlation Coefficient of -0.3. The difference between largest maximum extension (fraction 7), and smallest maximum extension (fraction 13) was 0.033in or 0.84mm.

Conclusion: Inter-fraction variability in response to stress was within that expected for experimental setup uncertainty. Change in stress-response for the stent under increased radiation and physical stress was not significant. Phantom analysis demonstrates stent structural integrity is maintained over clinical radiation dose ranges, and the oral stent is safe to use for radiation exposure up to at least 120Gy.

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