Bionix® TruGuard™ helps radiation therapy departments position and protect sensitive oral tissue with an easy to fit, custom device for head and neck external beam radiation therapy treatments.

Bionix® TruGuard™ is an advanced, customizable tongue and jaw positioner. It passively positions the tongue and jaw separating sensitive healthy tissue in a reproducible way. TruGuard also helps to improve patient care by protecting dental work from radiation helping to reduce backscatter. TruGuard™ is designed to be easily formed within the department during initial set up. It eliminates the time and hassle associated with “homemade” devices and eliminates the need to send the patient for an expensive prosthodontic.

**Features:**
- Helps protect oral cavity from backscatter radiation by sparing surrounding soft tissue
- Reproducible, passive positioning of the tongue to separate sensitive, healthy tissue
- Compatible with all thermoplastic masks
- Advanced, custom positioning aid
- Quickly created within department
- Easy to assemble, clean and store

**Product Offering:**
One complete TruGuard includes the following components: (1) Dental Tray, (1) Indexing Tab, (1) Tongue Depressor, (1) Spacer, (2) Thumb Fasteners

**HNRT-3500 – The Large TruGuard™ Custom Tongue and Jaw Positioner (Box of 5)**
Ideal for patients with normal to large mouths

**HNRT-3501 – The Standard TruGuard™ Custom Tongue and Jaw Positioner (Box of 5)**
Ideal for patients with normal to small mouths

© 2019 Bionix Radiation Therapy • MKT-0011-00 • R03
U.S. Patent # 9,414,896 B2
44-year-old female who was recommended to receive adjuvant radiation therapy for a resected intermediate grade mucoepidermoid carcinoma of the right submandibular gland with high risk features.

She was simulated for treatment using an Aquaplast mask and a Bionix TruGuard with tongue depressor. A plan was generated to deliver a dose of 50 Gy in 25 fractions to a planning target volume that included her postoperative surgical bed and regional lymph nodes, followed by a 10 Gy boost in 5 fractions to a PTV encompassing her postoperative surgical bed using TomoTherapy Hi-Art rotational IMRT with 6mV photons. Daily MVCT imaging was used for IGRT. She tolerated treatment extremely well except for expected treatment-related side-effects including fatigue, grade 2 mucositis and grade 2 dermatitis.

During simulation, the Bionix TruGuard was used to further immobilize the lower jaw and to displace the oral tongue superiorly in an effort to limit the volume receiving high dose, as demonstrated in Figure 1. The TruGuard was fit first, followed by molding of the Aquaplast mask with the oral stent in place. The two stent posts were placed through two holes in the Aquaplast mask and then spacers and fasteners were attached outside of the mask. Dose volume histogram analysis as well as visual plan inspection demonstrated that nearly all of the tongue received 30% (18 Gy) or less of the prescription dose of 60 Gy (Figure 2).

Evaluation of improvement in setup reproducibility using the Bionix TruGuard was performed by comparing the average daily shifts required to those of the 10 previous patients treated at our center for head and neck cancer who were immobilized using an Aquaplast mask alone. The daily shifts were recorded in 4 directions: superior/inferior, anterior/posterior, left/right and roll. The daily shift was 8.58 mm on average for the 10 previous head and neck cancer patients immobilized using an Aquaplast mask alone versus only 5.78 mm daily average for this patient immobilized with the Aquaplast mask and Bionix Oral Stent. This translated to a 32.7% reduction in overall daily shifts.

Conclusions: The use of the Bionix TruGuard with the tongue depressor is an effective method for tongue displacement and/or immobilization in the treatment of cancers of the head and neck. A significant reduction in planned dose to the oral tongue was achieved in this case report. The Bionix TruGuard also demonstrated an improvement in daily treatment setup reproducibility. Further studies are warranted to determine if these observations are statistically and clinically significant.