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# Fabrication of customized tongue-displacing stents

## Considerations for use in patients receiving head and neck radiotherapy

**Bart Johnson, DDS, MS; Lindsay Sales, MD; Amy Winston, DDS; Jay Liao, MD; George Laramore, PhD, MD; Upendra Parvathaneni, MD, BS, FRANZCR**

In the United States, more than 52,000 new cases of head and neck cancers (HNCs) are diagnosed each year, and it is estimated that these led to more than 11,000 deaths in 2012.<sup>1</sup> Radiotherapy, with or without chemotherapy, is the only curative nonsurgical treatment for HNC. This modality achieves high local tumor control rates of more than 80 percent for stages I and II disease and 60 to 70 percent for stages III and IV disease.<sup>2</sup> A large proportion of patients with HNC receive either curative or palliative radiation therapy at some point during the course of their disease.<sup>3</sup>

Technical advances in head and neck radiation therapy, such as intensity-modulated radiation therapy (IMRT); have allowed for highly conformal treatment planning while sparing healthy structures.<sup>2,4-7</sup> Despite these advances, oral mucositis is the predominant, acute, dose-limiting toxicity in head and neck radiotherapy. Oral mucositis can be

### ABSTRACT



**Background.** Conformal or intensity-modulated radiation therapy can be improved by using a customized tongue-displacing (CTD) stent. These stents are designed to either move healthy oral tissues out of the path of the radiation beam or stabilize mobile tissues to allow more precise field control.

**Methods.** The authors describe CTD stent construction for both tongue-deviating and tongue-depressing applications.

**Results.** CTD stents enable clinicians to achieve more predictable and consistent radiation dosimetry planning while sparing greater volumes of healthy tissue from damage. They have been well tolerated by patients.

**Conclusions.** Use of CTD stents results in increased oral mucosal sparing, ensures reproducible immobilization and is incorporated readily into the clinical practice of radiation oncology.

**Practical Implications.** Clinicians can reduce or avoid significant morbidity to healthy oral tissues by using CTD stents. This can lead to better outcomes and improved quality of life for patients receiving head and neck radiation therapy.

**Key Words.** Radiotherapy; dental stents; mucositis; tissue sparing.

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associated with pain, difficulty with swallowing and speech, impaired nutrition and dehydration. This can have a profound negative effect on a patient's quality of life. In addition, it may interfere with the patient's ability to comply with treatment, which, in turn, may jeopardize tumor control.<sup>8,9</sup>

Historically, clinicians have used simple, non-customized bite blocks or corks to immobilize oral structures. However, their outcomes are poorly reproducible, as these devices provide limited and inconsistent displacement of uninvolved oral tissues. For optimal results, conformal treatment planning with IMRT requires reproducible immobilization of targeted mucosal structures.

Customized tongue-displacing (CTD) dental stents are devices that reproducibly displace the tongue during radiotherapy. Sales and colleagues<sup>10</sup> used CTD stents to spare the oral tissues of an initial cohort of 23 patients with HNC who underwent radiotherapy at the University of Washington, Seattle. The treating radiation oncologist evaluated mucositis on the basis of the Radiation Therapy Oncology Group (RTOG)<sup>11</sup> acute radiation morbidity scoring criteria. These authors reported that a mean of 51 cubic centimeters (range, 23-95 cm<sup>3</sup>) of oral tissue was spared.<sup>10</sup> Specifically, with the CTD stent in place, an estimated mean of 10 percent of displaced oral mucosal volume avoided exposure to 70 gray of radiation, 22 percent avoided 66 Gy, 56 percent avoided 50 Gy and 79 percent avoided 35 Gy. No patients in the study by Sales and colleagues<sup>10</sup> developed mucositis of greater than RTOG grade 3. Sparing of mucosa in the oral cavity by physically repositioning the tissue away from the primary radiation beam can decrease the volume of acute oral mucositis, the severity of acute oral mucositis or both. By logical association, repositioning the tissue also can decrease the damage to taste buds and salivary glands, reduce muscle fibrosis and lessen any other soft-tissue effects of the high-dose radiation therapy. The results of a study by Shogan and colleagues<sup>12</sup> demonstrated a correlation of the radiation dose and volume of oral cavity irradiated with the grade of acute mucositis in patients who had HNC and were treated with IMRT and chemotherapy.

In addition to reducing acute oral mucositis, sparing of oral structures results in other clinical benefits. For example, the numerous minor salivary glands and taste buds that are located in the spared oral cavity tissues can be expected to escape radiation injury. This may improve the patient's quality of life, reduce xerostomia

and expedite taste recovery. Researchers in two randomized studies<sup>13,14</sup> investigated the efficacy of oral positioning stents in patients treated with radiation for HNC. Although the sample sizes were small, they reported a decrease in oral mucositis, xerostomia and taste dysfunction compared with the results in patients in the control group. In addition, updated clinical practice guidelines for the prevention and treatment of mucositis recommend the "use of midline radiation blocks and three-dimensional radiation treatment to reduce mucosal injury."<sup>15</sup>

No published studies or reports, to our knowledge, describe the steps involved in creating a clinically useful CTD stent. Therefore, the purpose of this article is to describe in detail the process of fabricating a CTD stent and to outline the principal types of CTD stents that we have used to minimize oral mucositis during head and neck radiotherapy. We also briefly outline the dental considerations for a patient who is about to undergo radiotherapy for HNC.

## METHODS

As soon as a diagnosis confirms the presence of HNC that will be treated with radiation therapy, the radiation oncologist refers the patient to a dental group or dentist familiar with the benefits and adverse effects of this treatment modality. The written referral contains information about the primary tumor location (including laterality), tumor extent, histologic findings, type of planned radiation therapy, anticipated treatment fields and dose distribution. In particular, the referral specifies the teeth that are expected to receive a high dose (> 50 Gy) and indicates the expected degree of parotid and submandibular/sublingual salivary gland sparing. The referring oncologist also requests the type of stent that is expected to maximize sparing of mucosal tissue: a tongue-depressing stent (Figures 1 through 3) for nasopharyngeal and base-of-tongue cancers or a tongue-deviating stent (Figure 4) for lateralized tonsil cancers.

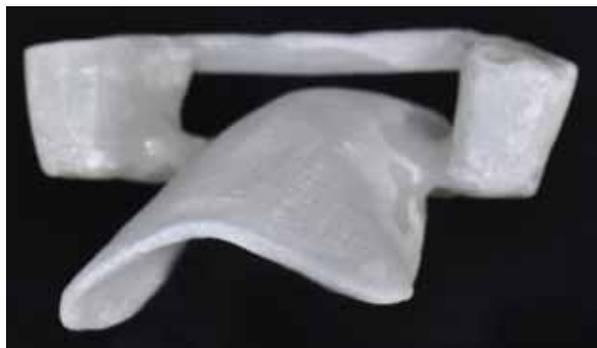
The dentist performs an oral examination and obtains radiographs to determine whether the patient has any pressing dental problems that require attention before he or she undergoes irradiation. The most common finding, in our experience, is the need to extract teeth in the proposed high-dose radiation fields that are

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**ABBREVIATION KEY.** **CT:** Computed tomographic. **CTD:** Customized tongue-displacing. **HNC:** Head and neck cancer. **IMRT:** Intensity-modulated radiation therapy. **PTV:** Planned target volume. **RTOG:** Radiation Therapy Oncology Group.



**Figure 1.** Anterior view of tongue-depressing stent.



**Figure 2.** Posterior view of tongue-depressing stent.



**Figure 3.** Superior view of tongue-depressing stent.



**Figure 4.** Superior view of tongue-deviating stent.

unsustainable. Any such care is completed before the CTD stent is fabricated.

The clinician takes upper and lower alginate impressions of the existing dentition or edentulous ridges. He or she takes a bite registration with the intent to place the interincisal distance between 10 and 15 millimeters for a tongue-deviating stent and between 10 and 20 mm for a tongue-depressing stent. The models are poured,

trimmed and articulated on a standard hinge articulator. The patient returns the next day for completion of the stent fabrication.

**Stent construction.** During the intervening time, the clinician begins stent construction by using a light-cure, acrylic, custom impression tray material (such as Triad TruTray Visible Light Cure Custom Tray Material, Dentsply Trubyte, York, Pa.). The clinician places horseshoe-shaped segments of the material over each model arch to engage the cusp tips and light cures them. He or she then places two vertical struts between the posterior segments of the horseshoe-shaped segments and light cures them. For tongue-deviating stents, the clinician places a third vertical strut in the anterior segment and light cures it.

For the tongue-deviating stents, the clinician constructs a teardrop-shaped “paddle” that will be used to displace the tongue. He or she adds a temporary handle to help manipulate the stent into position. For the tongue-depressing stents, the clinician constructs a triangular-shaped paddle with rounded corners for the patient’s comfort. It also is made with a temporary handle. To make the paddle concave on the tongue side, the clinician can fabricate it against the outer surface of a tablespoon.

When the patient returns to the dental practice the next day, he or she is placed in a supine position with the chin elevated to approximate the position in which he or she will be placed during radiotherapy. The clinician performs all

subsequent stent fabrication procedures with the patient in this position. He or she inserts the double-arch strut forms into the patient's mouth and adjusts them until comfortable. The clinician then confirms stability and ease of insertion.

The challenging part of constructing a stent is optimizing the tongue position. We aim for maximum displacement of healthy oral tissues away from the high-dose regions, while preventing gagging and development of pressure points that potentially could develop into ulcerations. The clinician must instruct the patient to place the tip of the tongue between the anterior portions of the superior and inferior horseshoe-shaped rims (Figures 5 and 6). This results in better "hiding" of the posterior tissue behind or under the paddle while providing a reproducible tongue position. Most patients eventually learn to automatically wedge their tongues into this reproducible position.

In this anterior tongue position, the clinician uses the paddle and handle combination to manipulate the tongue until a satisfactory tissue displacement outcome is achieved. This often requires adding more material to the paddle or trimming off some of the existing material. If the patient gags because of the length of the paddle, the clinician can trim the posterior edge until it is acceptable.

**Securing the paddle.** Once optimal positioning is achieved, the clinician must secure the paddle to the horseshoe assembly. For tongue-deviating stents, he or she adds a horizontal strut made of the light-cure material between the ipsilateral posterior strut and the convex aspect of the paddle and then cures it into place intraorally. The clinician uses a small amount of additional material to secure the anterior portion of the assembly to the anterior strut. For tongue-depressing stents, the clinician secures the sides of the paddle to the bilateral posterior struts. For these stents, an anterior strut usually is not needed, but the clinician may elect to add one for strength and stability.

The clinician places the completed stent into the light-curing unit for a full cure. He or she then uses acrylic burs to smooth, shape and modify the entire assembly to ensure it will be comfortable and nonirritating during radiation therapy. Edges are rounded, weak spots reinforced and excess material removed. In our practice, we use a permanent marker to add a mark at the maxillary dental midline to help our radiation oncology colleagues verify correct positioning. We also add the patient's name to the stent by printing it on a clear label, creating a slot depression



**Figure 5.** Tongue-deviating stent in place. Note the anterior positioning of the tongue by the patient.



**Figure 6.** Tongue-depressing stent in place. Note the anterior positioning of the tongue by the patient.

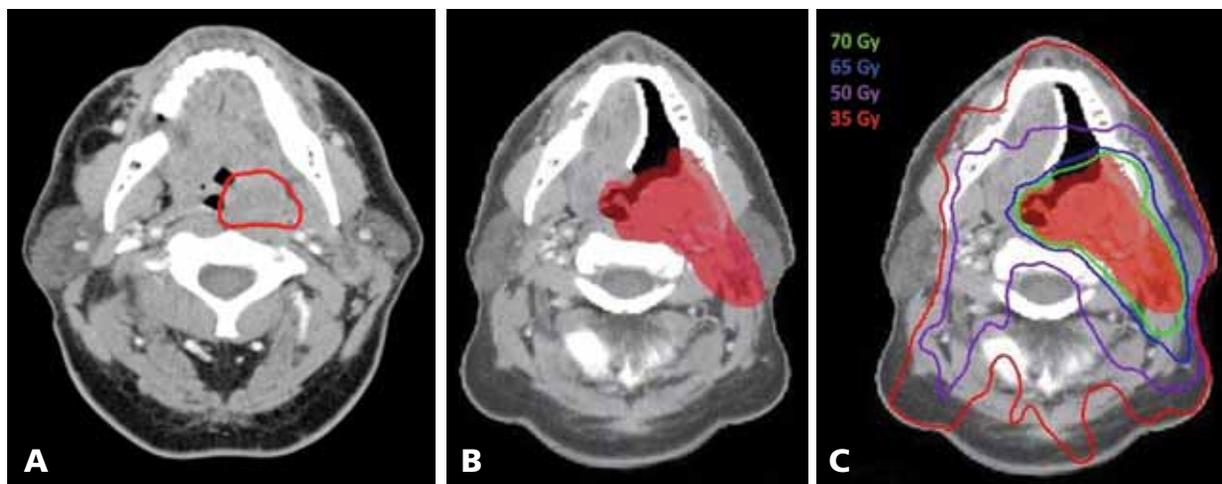
in one of the struts, placing the label inside and curing clear acrylic over it. Finally, the clinician polishes the entire stent with pumice and a rag wheel until it is as smooth as possible; the Triad light-cured material polishes only to a satin level, not to a shiny luster.

At the end of the visit, the dentist gives the stent to the patient and has him or her practice placing it until he or she is able to do so successfully. This often requires considerable practice, adjustments to the stent or both. It is critical that the patient knows how to place the stent properly and position it with the tongue forward so that the positioning is reproducible and identical to the anterior position used during stent construction.

The entire process described above requires between two and three hours of chair time, and clinicians need to inform patients that they must anticipate considerable waiting time between each step of the construction.

## RESULTS

Figures 5 and 6 show the final positioning of patients' tongues while using customized tongue-deviating and tongue-depressing stents,



**Figure 7.** Radiographic images of a 53-year-old man with a T3N2bM0 squamous cell carcinoma of the left tonsil who used a customized tongue-deviating (CTD) stent during radiation therapy. **A.** Diagnostic computed tomographic (CT) image with left tonsillar mass outlined in red. **B.** Treatment planning CT image with the CTD stent in place. The planned target volume (PTV) to be treated, a 70-gray field, is shown in red. Note that the tongue is displaced to the right and separated from the tonsil in comparison with placement in the diagnostic image in **A.** This spares the tongue from being included in or in close contact with the high-dose PTV. **C.** Treatment planning CT image with the salient radiation isodose lines.

respectively. Figures 7 and 8 present radiographic images from two patients. Figure 7 demonstrates a tongue-deviating stent used in a patient with a lateralized tonsil primary cancer. Figure 8 demonstrates a tongue-depressing stent used in a patient with a nasopharyngeal primary tumor.

## DISCUSSION

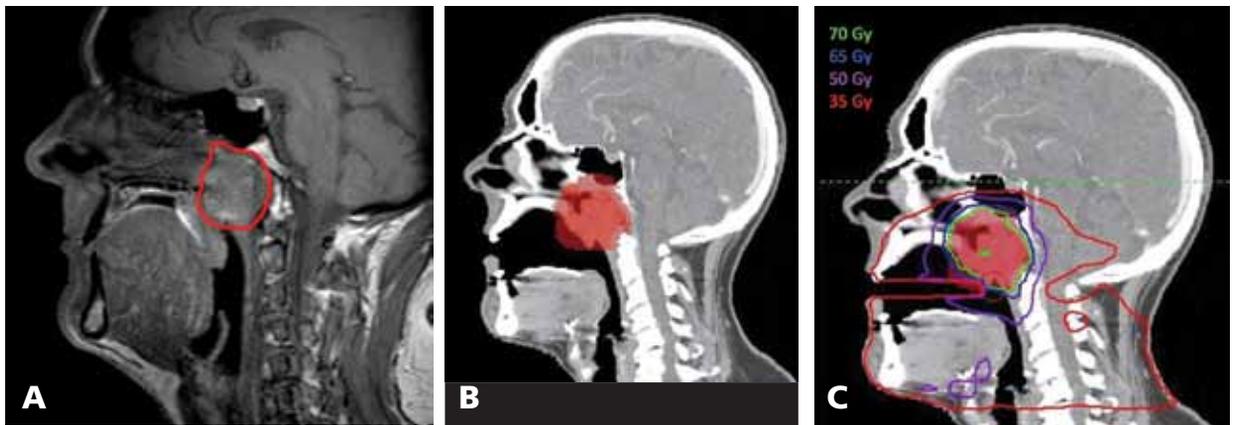
To our knowledge, this is the first report in the literature that describes in detail the two principal types of CTD stents that help minimize oral mucositis during head and neck radiotherapy, as well as the process of fabricating them. We have found these devices to be beneficial to the patients' outcomes and their construction feasible to incorporate into our routine clinical practice.

The results of multiple studies have proven the beneficial effects of these devices.<sup>10,13,14,16</sup> Qin and colleagues<sup>13</sup> randomized 43 patients with nasopharyngeal cancer to an individualized dental stent (n = 19) versus no stent (n = 24). Patients in the stent group demonstrated a decrease in grade 3-4 oral mucositis and taste dysfunction compared with those in the control group. Goel and colleagues<sup>14</sup> evaluated the short-term efficacy of positional dental stents in patients with lingual carcinoma. They randomly assigned 48 patients to a dental stent (n = 24) versus no stent (n = 24). The authors reported that patients in the control group experienced more severe palatal mucositis, xerostomia and salivary changes compared with the outcomes in the study group.

Customized tongue stents have been described in the literature, but the information provided about their fabrication is insufficient to allow the average dentist to create this helpful device.<sup>16,17</sup> In this article, we have addressed this gap in the dental profession's knowledge.

Despite the aforementioned benefits of a CTD stent, these devices have been perceived as being uncomfortable to use and expensive to fabricate. However, in our study with the research group of 23 patients treated over two years—as well as our experience with more than 300 patients treated since—patient compliance has been excellent.<sup>10</sup> The CTD stents were well tolerated by patients and used daily for radiation treatment. There were no treatment interruptions resulting from painful acute oral mucositis or other unexpected mucosal reactions due to use of the CDT stent.

We have encountered a few challenges in fabricating these devices. The amount of chair time and in-office laboratory time spent creating the CTD stent is fairly great, yet insurance reimbursement is limited. We have found that most patients are willing to pay out of pocket for the device given the potential clinical gains. Another challenge that has arisen is the occasional need to adjust or modify a stent during radiation therapy. These sore spot adjustments usually are the result of pressure sores that develop during radiation treatment, especially in edentulous patients. Relatively infrequently, we have encountered fractures or chips that require repair. Fortunately, these issues have been easy



**Figure 8.** A 50-year-old man with a T2bN1M0 squamous cell carcinoma of the nasopharynx with a customized tongue-depressing (CTD) stent used during radiotherapy. **A.** Diagnostic magnetic resonance image of the nasopharyngeal primary tumor outlined in red. **B.** Treatment planning computed tomographic (CT) image with the CTD stent in place. The planned target volume (PTV) to receive 70 gray of radiation is shown in red. Note that the tongue is displaced downward and is separated from the palate in comparison with the diagnostic image in **A.** Thus, it is not included in or in close contact with the high-dose PTV. **C.** Treatment planning CT image with the salient radiation isodose lines.

to address, because the light-cured material is easily modifiable and repairable even weeks after construction. In general, the CTD stents have proven to be extremely durable.

The greatest challenge is the rapidity with which patients need to be seen for dental evaluation and stent construction. To allow the cancer therapy to be initiated as soon as possible, we have developed a valued and important close collaboration with our radiation oncology colleagues. The oncologists identify patients who will benefit from using a CTD stent as early as possible and refer them immediately. The dental team strives to take no more than two to three days to evaluate the patient, educate him or her about the oral effects of radiation therapy, provide critical preventive and interventional care, and construct the CTD stent. As soon as the CTD stent is fabricated, the patient returns to the oncologist for radiation therapy simulation. We encourage all dentists interested in working with patients who have HNC to develop a similar collaborative effort with their radiation oncology colleagues. In our experience, this provides a best-practices approach to the patient's therapy, while engendering a valuable relationship between dentistry and medicine.

To date, we have not found any tumor types for which the CTD stent cannot be used. Squamous cell carcinoma is the most common type of head and neck tumor treated with photon radiation, but we also have used these stents for patients with adenocarcinomas, Merkel cell carcinomas, acinic cell carcinomas and a few other rare types of cancer. The stents have performed well with both photon and neutron beam radiation,

and we will soon incorporate them into proton radiation therapy. In our experience, only those patients who have extensive disease initially do not benefit from use of the stents. The high-dose fields in these cases are so large that attempting to move tissue away from the beam is futile.

## CONCLUSIONS

We have briefly outlined the dental considerations for patients who are about to undergo radiotherapy for HNC and described in detail the process of fabricating a CTD stent. The indications for use of CTD stents and the principal types of devices used during head and neck radiotherapy are outlined. These devices are helpful in minimizing the extent of oral mucositis and other tissue damage, such as damage to muscle, taste buds, salivary glands and any other tissue types that can be guided away from the high-dose radiation beams.

Using a CTD stent helps ensure reproducible immobilization during head and neck radiotherapy, leading to more accurate dosimetry planning. We have found these devices to be well tolerated by patients, valuable to their treatment and feasible to incorporate into our routine clinical practice. Future studies, such as those in which researchers investigate quality-of-life outcomes and measure salivary flow and buffering capacity, will allow further evaluation of the clinical benefits of CTD stents for widespread use. ■

**Disclosure.** Drs. Johnson and Winston are co-owners of Grayduck Stents, a company formed to market an off-the-shelf version of the tongue-displacing stent. None of the other authors reported any disclosures.

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