Clinical study of a spacer to help prevent osteoradionecrosis resulting from brachytherapy for tongue cancer

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Objective. We sought to describe a simple method to construct a spacer and to evaluate with the use of computed tomography the spacer's effectiveness in preventing osteoradionecrosis of the mandible.
Study design. Fifty-three patients with oral tongue cancers who were treated by means of interstitial brachytherapy were included in this study. Patients underwent a computed tomography examination immediately after the implantation of radioactive sources, with the spacers in place. Distances between the radioactive sources and the lingual surfaces of the mandible were measured on transverse computed tomographs and were evaluated in terms of the development of osteoradionecrosis in the mandible.
Results. Statistically significant differences in the frequency of osteoradionecrosis were observed between patients who had received spacers equal to or thicker than 5 mm and those who had received spacers less than 5 mm thick.
Conclusion. A spacer should have a minimum thickness of 5 mm on its lingual flange to prevent the development of osteoradionecrosis of the mandible.
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Radiotherapy, especially interstitial brachytherapy, has a high local control rate in the treatment of early tongue cancer comparable to that of surgery.[1] This method of treatment also makes it possible to preserve the shape and function of the tongue. Consequently, it is one of the best treatment modalities in patients with early tongue cancer. In contrast, radiation-related late complications may be of sufficient severity and scope to affect the patients' physical and emotional well-being and overall quality of life.[2]

Osteoradionecrosis (ORN) of the mandible is one of the severe complications of curative external-beam radiation therapy. This condition also occurs when brachytherapy is used in the treatment of tongue cancer. Several factors, some more significant than others, are related to the development of ORN, with radiation dose contributing more than any other single factor. High total dose and dose rate, along with large fraction size of the irradiation, can increase a patient's risk for ORN.[3-5] The use of multiple modalities—that is, radiation therapy combined with surgery and/or chemotherapy or even a combination of external and interstitial radiation therapies—may contribute to increased risk of ORN.[6] Habits that irritate the oral mucosa, such as alcohol and tobacco use, may also increase the risk of mucosal breakdown leading to ORN.[6] (It is well known that maintaining good oral hygiene can prevent the spread of dental and periodontal infection to bone.[4-6]) Traumatic stimuli such as a dental extraction or denture irritation resulting in bone exposure may also increase the risk for ORN.[6,7] Edentulous patients are still at risk for developing ORN; however, their risk is significantly lower than that of dentulous patients.[7]

The use of a spacer, a prosthesis that reduces the intensity of radiation at the surface of the mandible, has been shown to be an effective means of preventing ORN. A variety of spacers may be used in interstitial brachytherapy although, despite the use of these devices, some patients invariably develop ORN of the mandible. We describe a simple method for spacer construction and evaluate its effectiveness in the prevention of ORN of the mandible with the use of computed tomography (CT).

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Table I. Patient characteristics

Total no. of patients	53
Mean age in y (range)	59 (28–87)
Sex	
Male	36
Female	17
Median follow-up period in months (range)	78 (11–120)
T-stage (no. of patients)	
T1	15
T2	37
Unknown	1
N-stage (no. of patients)	
N0	50
N1	3
Radiation modality (no. of patients)	
Ext (35 Gy) + Int (40 Gy)	35
Int (70 Gy) alone	18

Ext, External-beam radiation therapy; *Int*, interstitial brachytherapy.

PATIENTS AND MATERIAL

Patients

A retrospective analysis of 53 patients with T1 or T2 oral tongue cancer who were treated with radiation therapy at the Department of Radiology, Hokkaido University Medical Hospital, Sapporo, Japan, between 1990 and 1994 was conducted. Thirty-six men and 17 women with an average age of 59 years (range, 28-87 years) were included in this study. The median follow-up period was 78 months (range, 11-120 months).

According to TNM classification, 15 patients were classified as T1 and 37 were classified as T2. One patient who underwent surgical excision was unclassified. Three subjects were classified as N1, and the remaining patients were classified N0.

Of the 53 patients in the study, 35 patients underwent combined external-beam radiation therapy and interstitial brachytherapy. The remaining 18 subjects were treated by means of interstitial brachytherapy only. External radiation therapy was performed with cobalt-60 or 4MV photons. Interstitial brachytherapy was conducted by using cesium-137 needles with a single-plane implantation. External radiation therapy consisted of 35 Gy/14 *f*, with a daily fraction size of 2.5 Gy, 4 fractions per week, whereas interstitial brachytherapy consisted of 40 Gy in cases of combined radiation therapy and 70 Gy in cases of brachytherapy alone. The dose rate of interstitial bracytherapy was approximately 0.5 Gy/h (Table I).

Construction of the spacer

Before the commencement of brachytherapy, an impression of the lower jaw was made with irreversible hydrocolloid material (Algiace; Sankin Co, Tokyo, Japan). A cast of the impression was subsequently generated by using hard plaster (Newplastone; GC Co, Tokyo, Japan). A 2-mm-thick plastic disk (Erkodur; Erkodent Co, Pfalzgrafenweiler, Germany) was pressed onto the plaster cast of the jaw by means of thermoplastic former (Erkopress; Erkodent Co). Once the curing was completed, the plastic disk was cut away from the plaster cast and the final shape of the spacer was established. The rough edges were polished. Once the spacer was formed, enough quick self-curing resin (Orthofast; GC Co) or silicone-impression material (Tosicon; Sankin Co), or both, was added to the lingual surface of the spacer facing the tumor to obtain a final thickness of approximately 5 to 10 mm (Fig 1, *A*). The thickness of the lingual flange was determined by estimating the potential space between the tongue tumor and the mandible for each individual. Before interstitial brachytherapy began, the spacer was placed into the patient's mouth and necessary adjustments were made. Adjustments consisted mainly of cutting away excess material to ensure the stability of the spacer and a comfortable fit for the patient throughout the treatment period (Fig 1, *B*).

CT image tracing

All 53 patients underwent CT examination immediately after the implantation of cesium needles, with the spacers in place. The shortest distances between each cesium needle and the lingual surface of the mandible were measured for all needles on transverse CT images. The shortest distance to the nearest needle was defined as the *minimum distance*. Furthermore, the average value of the shortest distances for all needles was calculated and defined as the *average distance* (Fig 2). These distances were evaluated in terms of the development of ORN of the mandible. Statistical analysis was conducted by using the χ^2 test. A P value $< .05$ was considered significant.

RESULTS

ORN occurred in 4 of 53 patients (7.5%; Fig 3); these 4 subjects underwent combined external and interstitial radiation therapy. Statistical analysis did not reveal a significant difference between patients who had ORN and underwent external radiation therapy and those who had ORN but did not undergo such treatment. Furthermore, all individuals who developed ORN healed with conservative treatment (ie, antibiotic administration or sequestrectomy, or both) without surgical intervention (ie, mandibulectomy).

Three of the 8 patients (37.5%) with minimum distances of less than 5 mm between cesium needles and lingual surfaces of mandible developed ORN. In contrast, only 1 of 45 patients (2.2%) with a minimum distance greater than 5 mm developed ORN. A statis-

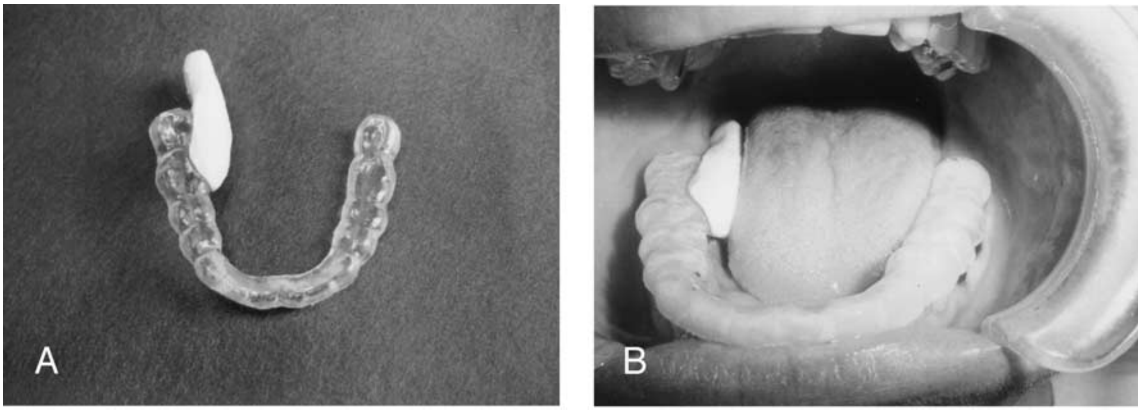

Fig 1. **A,** A spacer with silicone-impression material added to the lingual surface. **B,** A spacer placed in the patient's mouth.

Fig 2. The method for computed tomography image tracing.

tically significant difference was observed between the 2 patient groups ($P < .01$; Table II). However, statistical significance was not apparent at 6 mm.

Four of 22 patients (18.2%) with an average distance of less than 10 mm developed ORN. In contrast, none of 31 subjects (0%) with an average distance greater than 10 mm developed ORN. However, differences between the 2 groups were not statistically significant ($.05 < P < .1$; Table III).

Four of 35 patients undergoing combined radiation therapy developed ORN; there was a statistically significant difference between patients with minimum distances of 5 mm and those with distances greater than 5 mm ($P < .05$; Table IV).

DISCUSSION

Interstitial brachytherapy is an important treatment modality available to clinicians for the management of patients with tongue cancers. The advantage of this strategy is that surgery is avoided, thereby preserving the normal structure and function of the oromasticatory complex. However, brachytherapy occasionally causes radiation-induced complications such as ORN in some patients. Unfortunately, some of these patients may have to undergo severe hardships for several years and eventually undergo surgery. Therefore, an effective spacer to increase the separation between brachytherapy needles and the mandible is an indispensable appliance for patients treated with brachytherapy for tongue cancers.

Historically, pieces of gauze or cotton rolls have been placed between the tongue and the mandible to provide necessary separation between brachytherapy needles and the mandible. The effectiveness and stability of these devices have been questioned. Custom-made spacers constructed with acrylic resin or impression material have subsequently been used.[5,8-10] Yuasa et al[8] introduced a simple method to make spacers for patients undergoing interstitial brachytherapy for tongue cancer. This device was constructed of plastic resin with self-curing resin added to the lingual flange, facing the tumor, to obtain a final thickness of approximately 8 to 10 mm. After this, tissue-conditioning material was added to smooth the entire surface of the appliance so that the patient could wear it comfortably. With the use of this device, ORN of the mandible was reduced to a minimum, (ie, 1 of 53 [1.9%] patients who underwent brachytherapy for tongue cancers).

Tamamoto et al[9] developed an acrylic resin spacer that was easy to use and comfortable for patients. The technique they used to construct this type of spacer was almost the same as that used to construct a denture. Furthermore, ball clasps were used to retain the spacer. This type of spacer was rigid and easy to use, and fit well in the mouth of the patient. However, the complete construction process for this type of spacer took at least 5 days.

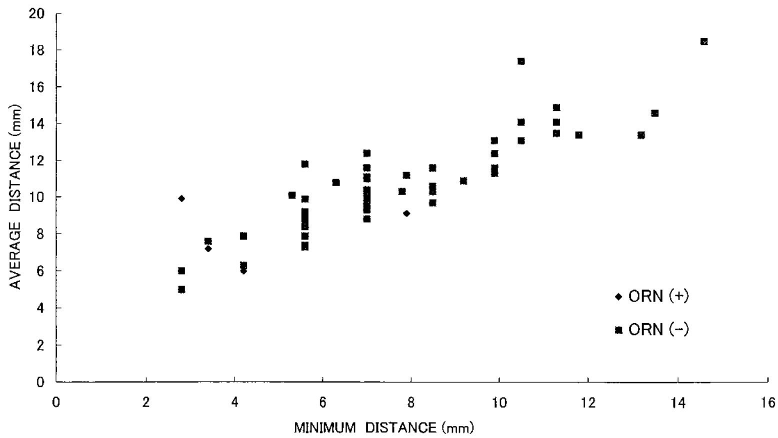

Fig 3. The relationship between the distance from the needle to the mandible and the development of osteoradionecrosis.

Table II. Relationship between minimum distance and the development of ORN

	ORN(+)	*ORN(–)*	*Total*	
5 mm >	3 (37.5%)	5	8	*P*<.01
5 mm ≤	1 (2.3%)	44	45	
Total	4 (7.5%)	49	53	

ORN, Osteoradionecrosis.

Table III. Relationship between average distance and the development of ORN

	ORN(+)	*ORN(–)*	*Total*	
10 mm >	4 (18.2%)	18	22	NS
10 mm ≤	0	31	31	
Total	4 (7.5%)	49	53	

NS, Not significant.

Fujita et al[10] carried out several experimental and clinical studies to evaluate the dose-reduction properties of spacers when different materials and thicknesses were used.[10] The spacers made of acrylic resin or silicone-impression material with a thickness of 10 mm could reduce radiation by 60% and 70%, respectively, either with radium or iridium needles.

In a similar study, Miura et al[5] showed that only 2.1% of the patients who wore a spacer had ORN develop, whereas 40% of the subjects without a spacer experienced this complication.[5]

Our use of the thermoplastic former for spacer construction is very simple. Spacers are easily fabricated; in fact, the complete process of spacer construction requires less than 1 hour, excluding the setting time of the plaster. Silicone-impression material added to the lingual surface of the spacer is suitable in that it is comfortable for patients to wear and easy for physicians to adjust.

In our study, we measured the actual distances between the radioactive sources and the lingual surface of the mandible on CT images. We then assessed the relationship between these distances and the development of ORN. Our results clearly demonstrated that there was a significant reduction of ORN in patients in whom the minimum distance between the radioactive sources and the lingual surfaces of the mandible was greater than 5 mm. None of the patients had ORN develop when the average distance was greater than 10 mm. Therefore, we conclude that a radiation-protection spacer should have a minimum thickness of 5 mm on its lingual flange, with a preferred thickness of 10 mm, to prevent the development of ORN of the mandible. In our study, the sample size was fairly small, and only 4 of 53 patients developed ORN; therefore, it is difficult to draw firm conclusions about the desired thickness of spacers. We speculate that in the case of larger lesions, where multiplanar implants could be used, thicker and more efficient material (eg, lead) for radiation-dose reduction in spacers has to be used. Spacer requirements related to different modes of radiation delivery should be the subject of future investigations.

Table IV. Relationship between minimum distance and the development of ORN (cases of combined radiation therapy)

	ORN (+)	*ORN (–)*	*Total*	
5 mm >	3 (37.5%)	5	8	*P*<.05
5 mm ≤	1 (3.7%)	26	27	
Total	4 (11.4%)	31	35	

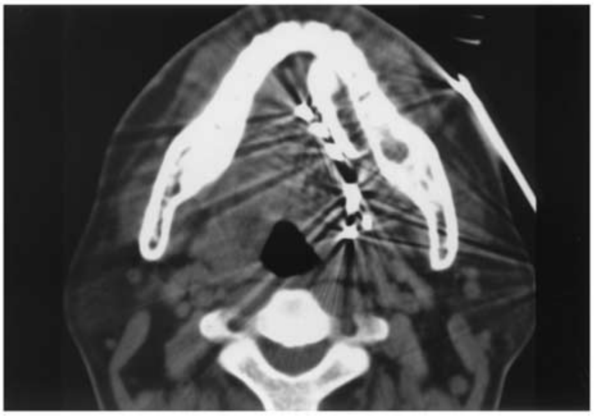

Fig 4. A properly seated spacer, which was achieved by using silicone-impression material. Cesium needles are located at sufficient distances from the mandible.

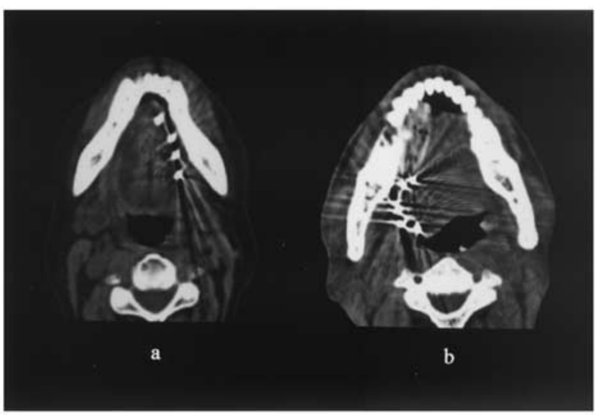

Fig 5. Improperly seated spacers. **a,** Cesium needles are positioned too close to the mandible. **b,** Cesium needles are located behind the spacer.

CT images taken after implantation of the radioactive sources also indicate whether the spacer is properly seated in the patient's mouth (Figs 4, 5). Therefore, CT affords physicians the opportunity for easy adjustment not only at the point of implantation, but also after the evaluation of the CT images.

As the survival rates in cancer patients have improved with advances in modern therapeutic modalities, it has become absolutely essential to maintain the patients' quality of life once the disease is eradicated. To this end, it is very important to use radiation prostheses to prevent complications such as ORN. Santiago[11] implored dentists to become familiar with radiation therapy techniques used in the orofacial region.[11] The following are the various types of radiation prostheses used in modern radiotherapy units: carrier prostheses for holding radioactive sources or radiation beam cones, prostheses for displacing normal tissues, prostheses for protecting radiosensitive tissues, and prostheses for measuring radiation doses. Whatever the circumstances, dentists should play a crucial role in making and evaluating the radiation prostheses used in radiotherapy units.

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