

Shielding Effect of a Customized Intraoral Mold Including Lead Material in High-dose-rate 192-Ir Brachytherapy for Oral Cavity Cancer

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Border-molding/Customized intraoral mold/High-dose-rate brachytherapy/Lead shield/Oral cavity cancer.

A high-dose-rate (HDR) 192-Ir brachytherapy using a customized intraoral mold is effective for superficial oral cavity cancer, and the surrounding normal tissue is kept away from the radioactive source with gauze pads and/or mouth piece for reducing the dose on the normal tissues. In the Tokushima university hospital, the mold has a lead shield which utilizes the space prepared with sufficient border-molding by a specific dental technique using modeling compound. In HDR 192-Ir brachytherapy using a lead shielded customized intraoral mold, there are no reports measuring the absorbed dose. The purpose of the present study is to measure the absorbed dose and discuss the optimum thickness of lead in HDR 192-Ir brachytherapy using a customized intraoral mold with lead shield using a 1 cm thickness mimic mold. The thickness of lead in the mold could be changed by varying the arrangement of 0.1 cm thickness sheet of the acrylic resin plate and lead. The measured doses at the lateral surface of the mold with thermoluminescence dosimeter were reduced to 1.12, 0.79, 0.57, 0.41, 0.31, 0.24 and 0.19 Gy and the ratios to the prescription dose were reduced to 56, 40, 29, 21, 16, 12 and 10 percent as lead thickness increased from 0 to 0.6 cm in 0.1 cm increments, respectively. A 0.3 cm thickness lead was considered to be required for a 1 cm thickness mold, and it was necessary to thicken the lead as much as possible with the constraint of limited space in the oral cavity, especially at the fornix vestibule.

INTRODUCTION

Radiation therapy for oral cavity cancer has been performed widely, and provides great potential of tumor control with preserving the shape and function of the oral cavity. Brachytherapy can prescribe relatively high-dose per day to primary tumor compared with external beam radiotherapy (EBRT). Recently, intensity-modulated radiation therapy (IMRT) has been applied to oral cavity cancer, and showed better dosimetric profiles compared with conventional EBRT, as well as excellent clinical results.^{1,2)} The neck metastasis is the important prognostic factor in oral cavity

cancer; therefore, management of the lymph nodes is important in the treatment of oral cavity cancer. In oral cavity cancer patients without cervical lymph node metastasis, the treatment option is either the “wait and see” policy or the prophylactic neck treatment. The prophylactic neck treatment is easily possible in IMRT compared with brachytherapy. Although it is widely accepted to treat the neck electively when the risk of the metastases is estimated to be greater than 20 percent,³⁾ the risk of cervical lymph node metastases is not known in superficial oral cavity cancer. Therefore the need for prophylactic neck irradiation in superficial oral cavity cancer is not as obvious, and brachytherapy for patient without cervical lymph node metastasis is an indication.

In oral cavity cancer, it is difficult to keep the position of the radioactive source other than those of the oral tongue, oral floor and buccal mucosa because of the thin thickness of the surrounding normal tissue. Therefore, brachytherapy in superficial oral cavity cancer except for the regions has been reported using a customized intraoral mold.⁴⁾ Recently, a high-dose-rate (HDR) remote afterloading system (RALS), using 192-Ir microsources, is performed. The catheters are flexible and fitted for uneven regions such as the oral cavity. A HDR 192-Ir brachytherapy for oral cavity cancer using a

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customized intraoral mold, is reported.⁵⁻⁸⁾ The treatment time of HDR brachytherapy by RALS is shorter than that of a low-dose-rate (LDR) brachytherapy. In addition, isolation in a radioisotope room is not required, and the medical staffs are not exposed to radiation during the treatment. On the other hand, the adjacent normal tissue to the primary tumor is delivered relatively high doses of radiation on primary tumor since a tongue, (upper and lower) gingiva, buccal mucosa, oral floor and palate are adjacent mutually. It is possible to keep the surrounding normal tissue away from the radioactive source by inserting gauze pads and/or mouth piece in the oral cavity at set the customized intraoral mold. However an opening mouth is usually required at installing the mold. A gauze pad is soft compared with the tensioned buccal mucosa by opening the mouth, and the surface of the mold is faced the buccal mucosa. In addition, brachytherapy in oral cavity cancer is generally scheduled as a fractionated radiation therapy.⁹⁾ Therefore, the distance between the radioactive source and the buccal mucosa is narrow and the reproducibility of the shape of the structures which constitute an oral cavity is not stable at installing the mold. In our institution, HDR RALS using a customized intraoral mold with border-molding sufficient has been performed. The details of the mold have been published previously.¹⁰⁾ In summary, the mold was shielded by lead which utilized the space with border-molding sufficient for the purpose of reducing the absorbed dose of the surrounding normal tissue. The schedule administrated by HDR brachytherapy was 30 Gy in 10 fractions, twice daily after completion of conventional EBRT of 60 Gy in 30 fractions. The absorbed dose at the lateral surface of the mold was necessary to be low as much as possible in aspect of the adverse events of the normal tissue adjacent to the primary tumor. The mold was able to have a 0.4 cm lead shield which utilized the space with border-molding sufficient by a specific dental technique using modeling compound.

In interstitial brachytherapy, there are reports measuring the absorbed dose of brachytherapy using lead shield.¹¹⁻¹³⁾ However, in HDR 192-Ir brachytherapy using a lead shielded customized intraoral mold, there are no reports measuring the absorbed dose. The purpose of the present study is to measure the absorbed dose and discuss the optimum thickness of lead in HDR 192-Ir brachytherapy using a customized intraoral mold with lead shield.

MATERIALS AND METHODS

A mimic mold was consisted of clear acrylic resin plates (AcrylSunday, Tokyo, Japan) of 0.1 cm thickness and/or leads of 0.1 cm thickness, and a flexible applicator tube (6F, 0.2 cm diameter, Nucletron, Veenendaal, Netherlands) was fixed at the center position of the two clear acrylic resin plates using quick cure resin (UNIFAST II CLEAR, GC, Tokyo, Japan) (Fig. 1a). The size of the clear acrylic resin

plates and lead sheets was 5×5 cm. The total thickness of the mimic mold was set at 1 cm, and the total thickness of lead could be changed by inserting lead of 0.1 cm thickness (Fig. 1b), instead of the sheet of 0.1 cm thickness clear acrylic resin plate. Therefore, the distance between the flexible applicator tube and the lateral surface of mold was 0.7 cm, and the lateral surface of the mold was required by covering the acrylic resin plate in order to keep a lead from being exposed to an oral cavity, the thickness of lead was 0.6 cm at most.

The radiation dosimeter was one thermo-luminescence dosimetry (TLD) rod. The type of TLD rod used in this experiment was UD-170L (BeO, Panasonic, Osaka, Japan). The coefficient of variation was 2.9 percent after ten measurements at HDR 192-Ir radioactive source. The TLD reader was a UD-5120PGL (Panasonic). The outer diameter of the TLD case was almost 0.4 cm.

An agar impression material (Dupligel, Shofu, Kyoto, Japan) was used in order to fix the mimic mold. In order to fix the mimic mold in the center of the agar impression material, two cases made of 0.1 cm thickness clear acrylic resin plate were used in house. The size of the large case was 15.2 cm cubic and the size of the small case was 15 cm cubic. The agar impression material was poured into the large case so that the size was $15.2 \times 15.2 \times 7.2$ cm. Then one acrylic resin plate and two acrylic resin plates attaching the flexible applicator tube were placed onto the center position of the agar impression material with a hole so that the flexible applicator tube passed besides the large case after the agar impression material was stiffened (Fig. 2a). And the agar impression material was poured to be $15.2 \times 15.2 \times 0.3$ cm so that those materials were embedded by the agar impression material. The rest of the mimic mold plus TLD rod were placed onto the two acrylic resin plates attaching a flexible applicator tube, and the agar impression material was poured to be $15.2 \times 15.2 \times 1.1$ cm (Fig. 2b). The agar impression material was cut off the size of $5 \times 5 \times 0.4$ cm by knife so that TLD rod positioned the center of the agar impression material after the agar impression material was stiffened. As the result, the rest of the mimic mold and TLD rod were removable from the large case (Fig. 2c).

In the small case, the agar impression material was poured to be $15 \times 15 \times 6.6$ cm (Fig. 3a), and it was able to be inserted onto the large case (Fig. 3b). Finally, the total size of the agar impression material was almost 15 cm cubic (Fig. 3c). The position of the TLD was matched to dummy source visually because of the clear acrylic resin plate (Fig. 3d).

A schema of mimic mold without lead was shown in Fig. 4. The large case was poured the agar impression material and embedded one acrylic resin plate and two acrylic resin plates attaching the flexible applicator tube at the center position of the agar impression material with a hole so that the flexible applicator tube passed besides the large case. The small case poured the agar impression material, then

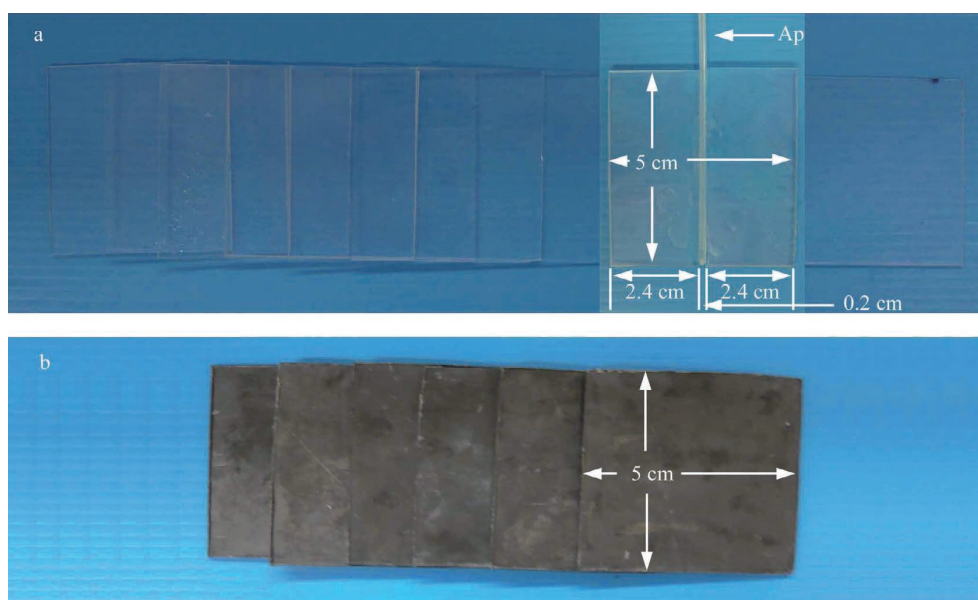


Fig. 1. Constitution of a mimic mold. A mimic mold consisted of one sheet of clear acrylic resin plate of 0.1 cm thickness, two sheets of 0.1 cm thickness used for attaching a flexible applicator tube, seven sheets of 0.1 cm thickness clear acrylic resin plate and/or lead from medial to lateral. The size of the clear acrylic resin plates and lead sheets was 5×5 cm. (a) Clear acrylic resin plates and a flexible applicator tube fixed at the center position of the two acrylic resin plates using quick cure resin, (b) lead. Ap, flexible applicator tube.

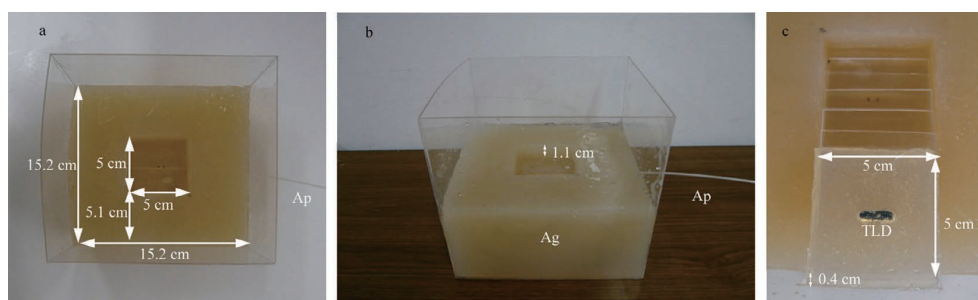


Fig. 2. Constitution of a large case. The size of a large case was 15.2 cm cubic. (a) One clear acrylic resin plate and two clear acrylic resin plates attaching the flexible applicator tube were placed at the center position of the agar impression material with a hole so that the flexible applicator tube passed besides the large case, (b) the agar impression material was poured to be $15.2 \times 15.2 \times 1.1$ cm so that the rest of the mimic mold and TLD rod embedded the agar impression material were removable from the large case, (c) the removed mimic mold the rest and TLD rod embedded by the agar impression material. Ag; agar impression material, Ap; flexible applicator tube.

TLD embedded by the agar impression material, and seven acrylic resin plates were able to remove from the large case in turn.

The RALS device was a microSelectron HDR (Nucletron, Veenendaal, Netherlands). The radiation treatment planning systems was a PLATO BPS Ver14. x (Nucletron). The localization films were shown in Fig. 5a (posterior-anterior) and 5b (lateral). The brass (the same size of the TLD rod) was set in the TLD case. The prescription dose at the reference depth was 2.0 Gy at 0.6 cm depth at the position in Fig. 5c. In Fig. 5c, the blue dot was the reference point and the yellow dot was the position of the brass, and the absorbed dose

of the position of the TLD was about 1.1 Gy.

The doses at the lateral surface of the mimic mold without lead as a control were measured five times after the irradiation according to the plan. The thickness of the lead was increased gradually from medial to lateral with respect to the radioactive source in our clinical method of making a lead shielded customized intraoral mold. The lead sheets were set so that the total thickness of the lead was from 0.1 cm to 0.6 cm, and the absorbed dose at the TLD rod was measured five times in each set after the irradiation according to the plan. A schema of mimic mold set at the total thickness of the lead was from 0.1 to 0.6 cm was shown in Fig. 6.

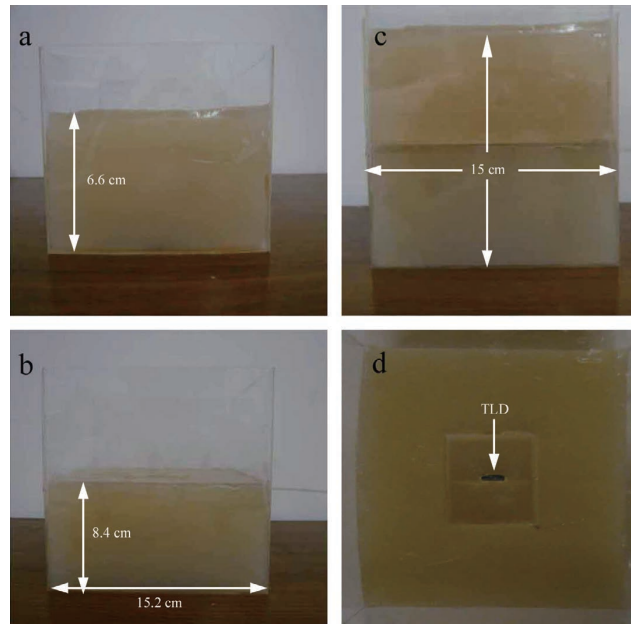


Fig. 3. Constitution of two cases. (a) Small case was fulfilled the agar impression material, and could be able to be inserted onto the large case, The size of the total agar impression material was $15 \times 15 \times 6.6$ cm, (b) The size of the large case was $15.2 \times 15.2 \times 8.4$ cm, (c) Small case was inserted onto the large case, the size of the cases was 15 cm cubic, (d) The position of the TLD was matched to dummy source visually because of the clear acrylic resin plate.

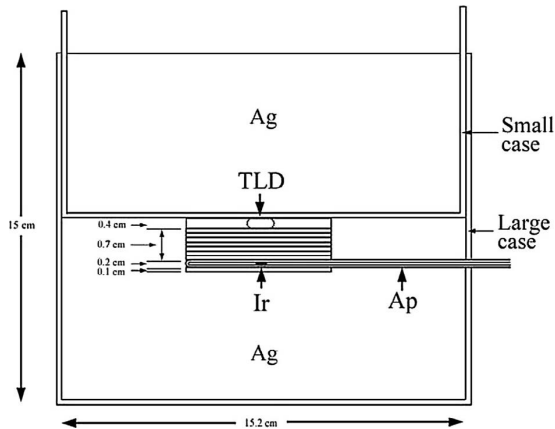


Fig. 4. A schema of mimic mold without lead. In the large case, one clear acrylic resin plate and two clear acrylic resin plates attaching the flexible applicator tube were embedded by the agar impression material at the center position of the agar impression material with a hole so that the flexible applicator tube passed besides the large case. Then TLD embedded by the agar impression material, and seven acrylic resin plates were able to remove from the large case in turn. The small case poured the agar impression material. Small case was inserted onto the large case. The total size of the agar impression material was almost 15 cm cubic. Ag, agar impression material; Ir, radioactive source; Ap, flexible applicator tube.

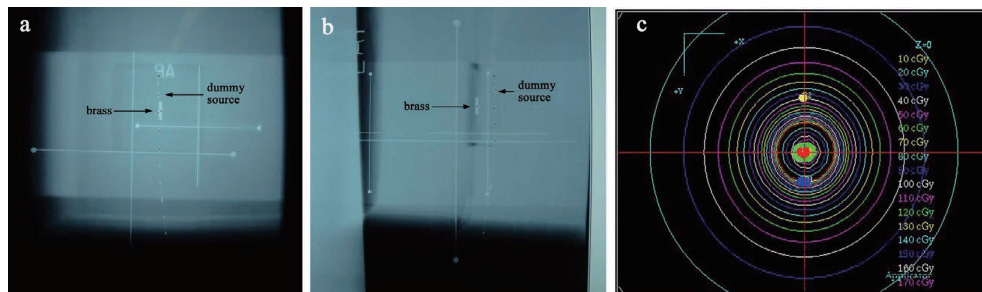


Fig. 5. Planning and the dose distribution. (a) Localization film (posterior-anterior). (b) Localization film (lateral). The brass (the same size of the TLD rod) was set in the TLD case. (c) The prescription dose at the reference depth was 2.0 Gy at 0.6 cm depth at the position of the TLD. The blue dot was the reference point and the yellow dot was the position of the brass.

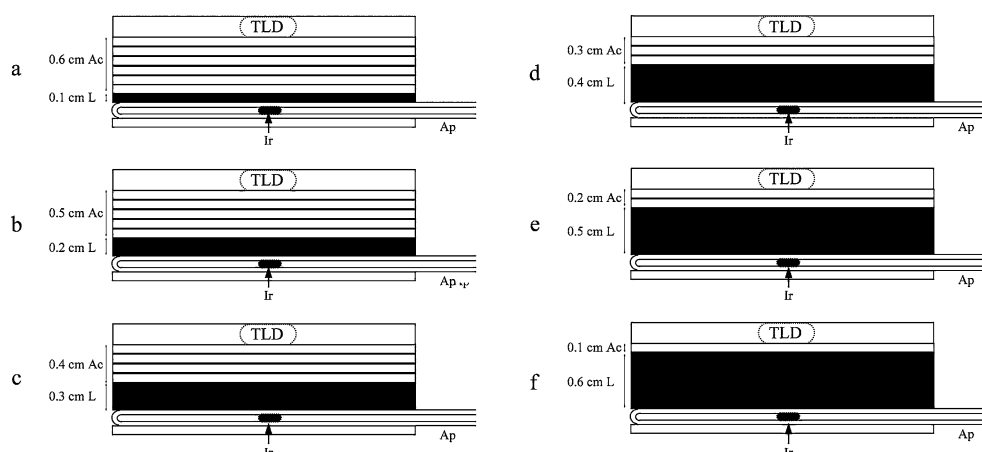


Fig. 6. Schema of mimic mold from 0.1 cm to 0.6 cm thickness of lead. The lead layers set to be the thickness of the lead at (a) 0.1 cm, (b) 0.2 cm, (c) 0.3 cm, (d) 0.4 cm, (e) 0.5 cm and (f) 0.6 cm. Ac, acrylic resin plate; L, lead sheet; Ir, radioactive source; Ap, flexible applicator tube.

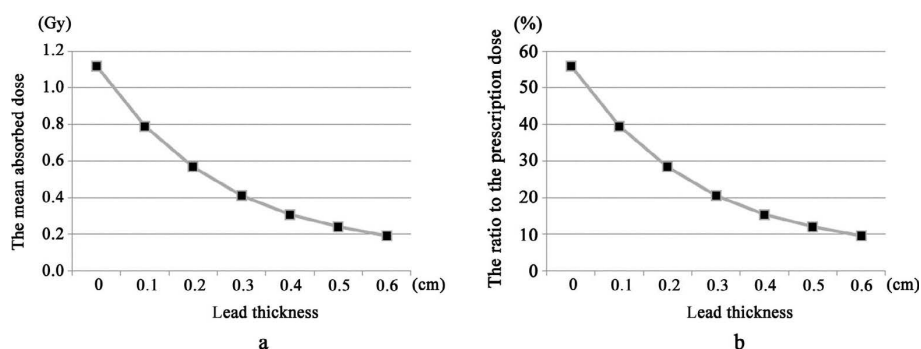


Fig. 7. The mean absorbed doses and the ratios to the prescription dose. (a) The mean absorbed doses with the change in the thickness of lead from 0 (without lead) to 0.6 cm in 0.1 cm increments, (b) the ratios to the prescription dose with the change in the thickness of lead from 0 (without lead) to 0.6 cm in 0.1 cm increments.

Table 1. The five times measured absorbed doses.

Total thickness of lead (cm)	First measurement (Gy)	Second measurement (Gy)	Third measurement (Gy)	Forth measurement (Gy)	Fifth measurement (Gy)	Mean (Gy)	Standard Deviation
0 (no lead)	1.11	1.09	1.14	1.12	1.14	1.12	0.02
0.1	0.761	0.817	0.795	0.780	0.773	0.79	0.02
0.2	0.569	0.565	0.568	0.568	0.569	0.57	0.00
0.3	0.417	0.419	0.407	0.409	0.405	0.41	0.01
0.4	0.310	0.305	0.304	0.312	0.314	0.31	0.00
0.5	0.239	0.245	0.243	0.240	0.242	0.24	0.00
0.6	0.193	0.193	0.193	0.191	0.186	0.19	0.00

RESULTS

The five times measured absorbed doses at the TLD and the ratio of the mean absorbed dose to the prescription dose, with the change in the thickness of lead from 0 cm to 0.6 cm

in 0.1 cm increments, are shown in Table 1.

The mean doses at the lateral surface of the mold were reduced to 1.12, 0.79, 0.57, 0.41, 0.31, 0.24 and 0.19 Gy as lead thickness increased from 0 to 0.6 cm in 0.1 cm increments. And the ratio to the prescription doses were reduced to 56, 40, 29, 21, 16, 12 and 10 percent as lead thickness

Table 2. The dose fractionation schedules in HDR 192-Ir mold brachytherapy with or without external beam radiotherapy.

Authors	Primary site	<i>n</i>	Dose fractionation schedule of mold	External beam radiotherapy
Cengiz <i>et al.</i> ⁵⁾	Upper gingiva	2	40 Gy in 10 fractions, twice daily	none
Obinata <i>et al.</i> ⁶⁾	Upper gingiva	1	30 Gy in 5 fractions	50 Gy
	Lower gingiva	1	12 Gy in 2 fractions	60 Gy
Garran <i>et al.</i> ⁷⁾	Upper gingiva	1	32 Gy in 8 fractions twice daily	46 Gy
Ariji <i>et al.</i> ⁸⁾	Oral floor	2	30 Gy in 10 fractions, twice daily	22 Gy
			30 Gy in 10 fractions, twice daily	30 Gy
	Buccal mucosa	1	35 Gy in 10 fractions, twice daily	26 Gy
	Lower gingiva	1	25 Gy in 10 fractions, twice daily	40 Gy
Kudoh <i>et al.</i> ¹⁰⁾	Upper gingiva	1	30 Gy in 10 fractions, twice daily	60 Gy

increased from 0 to 0.6 cm in 0.1 cm increments (Fig. 7).

DISCUSSION

Brachytherapy using a customized intraoral mold is an effective treatment method for superficial oral cavity cancer. Regarding the dose fractionation schedule, the traditional approach for the combination of EBRT and brachytherapy is 50 Gy followed by an LDR interstitial implant that delivers from 20 to 35 Gy, depending on the stage of the oral cavity cancer.^{14,15)} Recently HDR 192-Ir brachytherapy has become common treatment instead of LDR brachytherapy in Japan. Table 2 shows the primary sites, case number and the dose fractionation schedule in HDR 192-Ir brachytherapy using a customized intraoral mold.^{5-8,10)} With these dose fractionation schedules, the HDR 192-Ir brachytherapy using the mold is completed in the overall treatment time even or shorter than that of EBRT alone and it gives an advantage to be able to avoid accelerated repopulation.¹⁶⁾ And some American Brachytherapy Society panel members indicate that potential morbidity was associated with fraction sizes of more than 6 Gy for HDR brachytherapy in the oral cavity,⁹⁾ all the reported fraction sizes are less than or equal to 6 Gy. Brachytherapy in an oral cavity cancer consists of about 20–40 Gy, in conjunction with EBRT of about 40–60 Gy in many cases in Japan.

The treatment plan with customized intraoral mold with lead shield is not possible in this treatment planning system since localization film cannot be taken by lead. Therefore, the fundamental study of the lead shielding effect of customized intraoral mold is needed. The mean absorbed dose of no lead was 1.12 Gy. The absorbed dose of the position of the TLD was almost 1.1 Gy in Fig. 5c. An agar impression material of 15 cm cubic size was used for the purpose of establishing a state of whole scattering since the dose calculation is performed based on an ICRU sphere of 15 cm radius. The radioactive source used in this study is 192-Ir. The

dose calculation algorithm in the treatment planning system is based on AAPM-TG43, it is Monte Carlo simulation and the calculation kernel is modeled on the basis of the ICRU sphere.¹⁷⁾ However, a lack of a scattered ray exists in an oral cavity and it is considered that there has been the dose calculation region where could not follow with the present treatment planning system.

The gap between the inner diameter of the applicator tube and radioactive source was 0.06 cm. And the inner diameter of the TLD case is 0.14 cm and the size of the TLD is 0.12 cm, gap between the TLD and the case is 0.02 cm. Although the flexible applicator tube was fixed by two sheets of 0.1 cm thickness clear acrylic resin using quick cure resin and it is necessary to suppress float as much as possible in clinical setting for steep dose distribution, the floating of the mimic mold was not exist in this study. Therefore, the maximum total setup error was considered to be 0.08 cm. And this study was always performed in the same position in order to make an error as small as possible. It was difficult to fix a mould in the water phantom, and the agar impression material was used for the fixation. Since an agar impression material was an impression agent, the replacement of the mimic mold was exact and there was no collapse by repeated insertion of the acrylic resin plate and/or lead sheet. And the specific weight of the agar impression material was 1.1. It was relatively close to water, it was also used as a scatterer object in this study. The coefficient of variation of the TLD rod was 2.9 percent at HDR 192-Ir radioactive source, the beam quality conversion factor of the TLD is considered to be almost 1 at 192-Ir radioactive source and the energy characteristic is usually needlessness. As a result, the measured value and the calculated value were almost a same.

The ratios to the prescription dose were reduced to 56, 40, 29, 21, 16, 12 and 10 percent as lead thickness increased from 0 to 0.6 cm in 0.1 cm increments. The reduction rate of the absorbed dose had become slow as the thickness of

lead increase, since the impact of the scattered ray from a lead was considered.

The prescription dose at a 0.6 cm depth from the medial surface of the mold in this study was 2.0 Gy. In consideration of the thickness of the medial plastic disc on mold therapy, the reference point was a 0.6 cm depth from a radioactive source, and the dosimeter range of BeO TLD was up to 2.0 Gy. According to the manufacturing method of the customized intraoral mold in our institution, the thickness of the lead was increased gradually from medial to lateral with respect to the radioactive source.

It is required to discuss a standard prescription dose of HDR 192-Ir brachytherapy using a customized intraoral mold for superficial oral cavity cancer for discuss the optimum thickness of lead. However, the dose of the mold therapy is variable, and varied with combination of the EBRT in Table 2. And the tolerance dose of the oral mucosa is known to be lower than the tongue, but not known the value. Therefore, the index of the dose reduction is not obvious. Pohar *et al.* could be reduced the prescription dose to 25 percent with 0.4 cm lead plus 0.7 cm wax in LDR brachytherapy.¹⁸⁾ From the point of view of radiation biology, the biological effect of HDR brachytherapy is higher than that of LDR brachytherapy at the same total dose. The incidence and grade of the late adverse events have been disputed, and there is no consensus on this issue.^{19–22)} Leung TW *et al.* reported that the dose to the corresponding sites on the gingival surface can be reduced by 75 percent at 0.3 cm thickness of lead in HDR interstitial tongue brachytherapy.¹¹⁾ If this reducing percentage was used for the index, a 21 percent reduction was obtained at 0.3 cm thickness lead in this study. Therefore, 0.3 cm thickness of lead shield was considered to be appropriate if it is possible to be ensured the space more than 1.0 cm.

From the results of experimental and clinical dose measurements, Fujita *et al.* found that the absorbed dose at the mandible was reduced to less than 50 percent with interstitial brachytherapy using a spacer of 1 cm thickness.²³⁾ And Obinata *et al.* concluded that a radiation protection spacer should have a minimum thickness of 0.5 cm on its lingual flange, with a preferred thickness of 1.0 cm.²⁴⁾ On the basis of these reports, a setting of 1 cm thickness of the mold was adopted as a standard in the present study. However, the thickness of the mold might less than 1 cm for constraint of limited space of oral cavity, especially fornix vestibule. If the dwell point is close to the surrounding normal tissue (i.e. fornix vestibule) on the plaster cast, the lead sheets should be inserted to the space between the applicator tube and the lateral surface of the mold as much as possible since the absorbed dose reduced as the thickness of lead increased.

This customized intraoral mold for oral cavity cancer with border-molding and lead shield in a HDR 192-Ir brachytherapy was confirmed to reduce the dose on the normal tissue adjacent to the primary tumor. However, an indication to oral

cavity cancer adjacent to the mandible should be prudent because 25 or more times higher frequency of osteoradionecrosis of the mandible is known compared with maxilla,²⁵⁾ and the high dose is hard to prescribe with EBRT since the tolerance dose of the mandible is known to be up to 70 Gy although it is a datum in conventional EBRT.²⁶⁾

In conclusion, a 0.3 cm thickness lead is considered to be required for a 1 cm thickness mold, and it is necessary to thicken the lead as much as possible for constraint of limited space of oral cavity, especially fornix vestibule since the absorbed dose reduced as the thickness of lead increased.

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