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**研究題目：頭頸部がん放射線治療時の歯科金属冠への対処方法の比較研究：  
歯科金属冠除去 vs スペース作製**

**目 的：**

During head and neck radiotherapy, backscatter from metallic dental restorations (MDRs) causes oral mucositis. Thus, MDR management before radiotherapy is recommended. Currently, two MDR handling methods are used : the replacement of MDRs with provisional restorations (MDR removal) and fabrication of dental spacers before radiotherapy. We compared the effects of these two methods on the incidence of oral mucositis during head and neck radiotherapy.

**対象および方法：**

We retrospectively enrolled 76 patients with MDRs who underwent radiotherapy for head and neck cancer between April 2016 and March 2020. All patients received perioperative oral management. MDR removal was followed by replacement with a non-metallic provisional restoration. A dental spacer was a device with a thickness of 3-5 mm that covers MDRs. We set grade 2 oral mucositis as an outcome. After adjustment of all covariates using propensity score (PS) , we analyzed the data using a Cox proportional hazards model. In addition, subgroup analysis was performed by stratifying the data into quintiles based on PS.

**結果および考察：**

**Patient characteristics and outcomes**

The patients' baseline characteristics and outcomes are shown in Table 1. No values were missing from the data. Thirty-four patients were in the MDR removal group and 42 were in the dental spacer group. Radiation methods differed significantly between groups. In total, 48 (63.2%) patients developed grade 2 oral mucositis. Of them, 16 (21.1%) patients developed grade 3 mucositis. Receiver operating characteristic analysis showed that the area under the curve for the PS was 0.903 (95% confidence interval, 0.830-0.976). The area under curve for the PS was very large (0.903), indicating that the selected factors were appropriate. When oral mucositis deteriorates during head and neck radiotherapy, pain makes oral intake difficult, patients' body weight decreases by 5% , and 11% of patients discontinue radiotherapy. In the present study, the prevalence of grade 3 oral mucositis was 21.1% , lower than the 34.0-53.0% reported previously. This difference may be attributable to the performance of perioperative oral management, including oral care, for all patients in our sample. The importance of oral care is unquestionable, but the performance of a randomized controlled trial examining this

factor is ethically impossible. Thus, evidence for the ability of oral care to prevent oral mucositis has not been established. Under these circumstances, the evidence from the present study is an important contribution.

Table 1 Patient demographic and clinical characteristics at baseline

Factor and outcome		MDR removal group (n = 34)	Dental spacer group (n = 42)	P value
Gender				
	Male	26 (76.5)	37 (88.1)	0.227
	Female	8 (23.5)	5 (11.9)	
Age		67.4 (11.2) *	64.6 (10.9) *	0.277
Body mass index (kg/m <sup>2</sup> )		22.3 (3.3) *	22.0 (2.9) *	0.674
Diabetes		3 (8.8)	5 (11.9)	0.725
Primary site				
	Nasopharynx	4 (11.8)	2 (4.8)	0.253
	Oral	5 (14.7)	4 (9.5)	
	Oropharynx	5 (14.7)	16 (38.1)	
	Larynx	3 (8.8)	5 (11.9)	
	Hypopharynx	11 (32.4)	9 (21.4)	
	Others	6 (17.6)	6 (14.3)	
Radiation method				
	3D-CRT	17 (50.0)	1 (2.4)	< 0.001
	IMRT	13 (38.2)	38 (90.5)	
	3D-CRT + IMRT	4 (11.8)	3 (7.1)	
Total dose (Gy)		70.0 (70.0-70.0) †	70.0 (70.0-70.0) †	0.833
Concomitant chemotherapy		28 (82.4)	33 (78.6)	0.776
Number of teeth		22.5 (16.0-25.8) †	24.0 (17.8-27.5) †	0.293
Moderate periodontitis		26 (76.5)	35 (83.3)	0.565
Denture use		11 (32.4)	14 (33.3)	1.000
Pilocarpine hydrochloride		2 (5.9)	1 (2.4)	0.584
Hemoglobin (g/dL)		12.9 (1.9) *	12.9 (2.1) *	0.956
Leukocyte (/μL)		2.2 (1.7-3.2) †	2.4 (1.9-3.4) †	0.726
Lymphocyte (%)		6.6 (3.9-11.5) †	6.3 (3.8-8.4) †	0.598
Grade 1 oral mucositis		14 (41.2)	14 (33.3)	0.633
Grade 2 oral mucositis		15 (44.1)	17 (40.5)	0.817
Grade 3 oral mucositis		5 (14.7)	11 (26.2)	0.267

Values mean n ( %) unless indicated otherwise; \* values are mean (standard deviation); † median (25-75 percentile).

Abbreviations : 3D-CRT = three dimensional conformal radiation therapy, IMRT = intensity modulated radiation therapy

## Incidence of oral mucositis

Figure 1 shows the relationship between the number of days elapsed since the initiation of radiation and the incidence of oral mucositis. For the incidence of grade 2 oral mucositis due to head and neck radiotherapy, the hazard ratio for the MDR removal group relative to the dental spacer group was 0.344 (95% confidence interval, 0.121-0.980), and the hazard differed significantly between groups ( $P=0.046$ ). Subgroup analysis showed that the hazard ratio for the MDR removal group relative to the dental spacer group was 0.339 (95% confidence interval, 0.122-0.943 ;  $P=0.038$ ). The subgroup analysis yielded similar results, confirming the robustness of the findings. To our knowledge, this study is the first to compare the effects of the two pre-radiotherapy MDR handling methods (MDR removal and dental spacer placement). MDR removal is advisable to reduce the incidence of oral mucositis during head and neck radiotherapy.

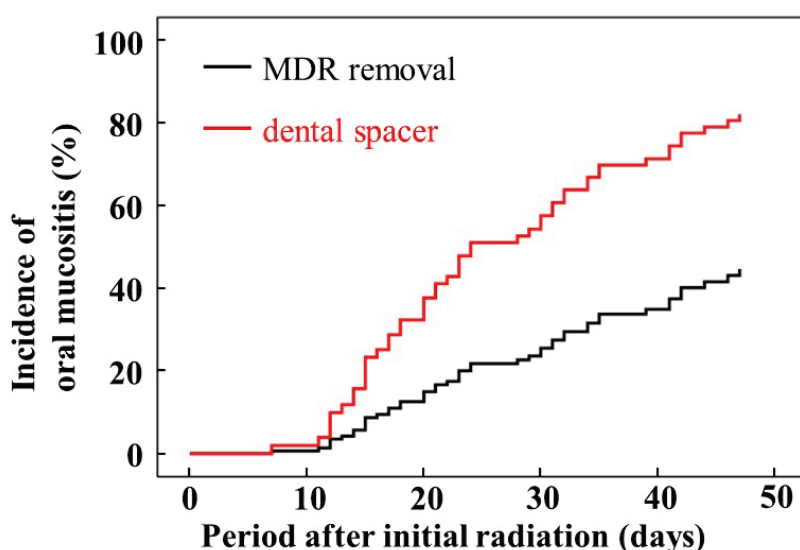


Fig. 1 Relationship between the number of days elapsed since the initiation of radiation and incidence of oral mucositis

**成果発表：**(予定を含めて口頭発表、学術雑誌など)

1. Toshihiro Motoi, Takahiko Oho. Comparative study of methods for handling dental metal crowns during radiotherapy for head and neck cancer. The 1st Annual Meeting of the International Society of Oral Care. Tokyo (Web). April, 2021.
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3. Toshihiro Motoi, Takahiko Oho. Comparison of methods for the handling of metallic dental restorations before head and neck radiotherapy : a retrospective study. (投稿中)