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RESEARCH PAPER

Assessment of mouth opening before and after head and neck radiotherapy in patients with intraoral stents

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ABSTRACT

Background: We evaluated the evolution of mouth opening before and after radiotherapy of the head and neck in patients using intraoral stents.

Materials and methods: Twenty-one patients with head and neck cancer who were indicated for radiotherapy participated in this study. Maximum interincisal opening measurements were performed before and after radiotherapy. Paired analyses of the pre- and post-radiotherapy groups were performed using paired samples t-tests and correlation analyses using Spearman's correlation test, with $p < 0.05$ considered statistically significant.

Results: Paired analyses of the pre- and post-radiotherapy groups revealed a statistically significant reduction in post-radiotherapy maximum interincisal opening ($p < 0.001$). However, only four individuals were diagnosed with trismus after radiotherapy. Regarding the correlation tests, no statistically significant differences were observed between the differences in pre- and post-radiotherapy maximum interincisal opening values and the study variables.

Conclusion: The use of prosthetic devices during head and neck radiotherapy can reduce radiation doses in areas of no interest, thereby preventing the acute and late toxicities associated with cancer therapy.

Key words: adverse effects; head and neck neoplasms; trismus; radiotherapy, intensity-modulated; intraoral stents

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Introduction

Despite advances in oncology, head and neck radiotherapy (RT) is still associated with significant toxicity, leading to oral mucositis, salivary changes, bone necrosis, dysgeusia, dysphagia, and trismus [1, 2]. Trismus is a well-known adverse effect of head and neck RT, and although its definition has varied in the oncological context, a maximum cutoff of 35 mm for the maximum interincisal opening (MIO) is commonly recognized [3]. The prevalence of trismus has been estimated at 79% [4].

Trismus in irradiated patients has been attributed to various factors that differ among individuals, possibly owing to a single cause or a combination of variables such as direct tumor interference with the jaw opening, radiation-induced fibrosis in the masticatory and temporomandibular muscles, and surgical scarring [1, 5]. A problem of this magnitude has a significant impact on quality of life,

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including difficulty with phonation, oral hygiene, and food intake [6]. Furthermore, cancer follow-up and dental treatments can be difficult in patients with severe trismus [1].

The use of prosthetic devices during RT, such as intraoral stents (IOSs), can help reduce the occurrence and severity of side effects from therapy by stabilizing the irradiated area and allowing the lowest dose of radiation to reach structures close to the tumor. However, the true impact of these devices on trismus prevention has not been determined [7–9].

Thus, we aimed to evaluate the evolution of mouth opening before and after RT in patients who used IOSs, correlating with sex, cancer treatment, tumor staging [tumor (T) and node (N)], total radiation dose, and dose prescription for the jaw.

Materials and methods

This prospective observational study was approved by the Human Research Ethics Committee (CAAE: 94436518.7.0000.5417) of our institution and conducted according to the principles of the Helsinki Declaration of 1975, as revised in 1983.

Study population

Patients with head and neck cancer who underwent intensity-modulated RT from a center specializing in oncology care of systemically compromised individuals were included in this study. A dental team followed all patients before, during, and after RT.

Sample calculation

Initially, we conducted a pilot test in order to determine the sample size that would provide sufficient power for this investigation, based on the difference between two means with dependent groups (paired t-test). We determined an initial sample of 13 patients, with $\alpha = 20\%$ and $\beta = 5\%$, using 10 mm as the minimum difference to be detected between pre- and post-RT mouth openings and a standard deviation of 12.1 mm. As these are cancer patients, we projected a 40% element loss and calculated that the appropriate sample size would be at least 21 volunteers.

Intraoral stents

IOSs were constructed with acrylic resin after all patients had undergone initial dental treatment and were provided complete information regarding the cancer treatment and its potential risks and side effects. The devices were composed of two individualized plaques, one corresponding to the maxilla and the other to the mandible, which were later joined by two anterior pillars while aiming for a strong union between the two plaques and guaranteeing the reproducibility of the position. In addition, a plateau was created for tongue stabilization. After fabrication, the IOS was sent to the laboratory for finishing and polishing. The patients were instructed to use the device during all RT sessions (Fig. 1).

Maximum interincisal opening

MIO measurements were obtained before and after the end of RT. The measurements were obtained

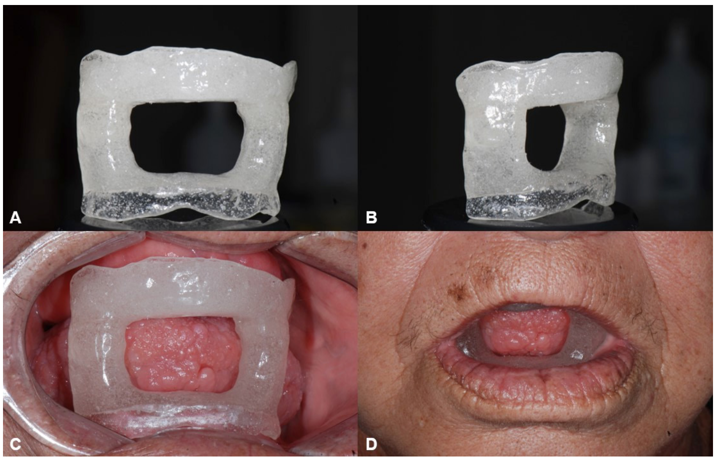

Figure 1. Intraoral stent made of acrylic resin. **A.** Front view; **B.** Side view; **CD.** Positioned in the mouth

using an analog steel caliper (FORTGPRO-FG8330, Grupo Gurgelmix, Franca, SP, Brazil) by two independent calibrated examiners (a physical therapist and a dentist) and subsequently compared. When differences were found, a consensus was reached with a third blinded external observer. Using an adaptation of the Late Effects of Normal Tissues Subjective-Objective Management Analytic (LENT SOMA) Scale (1995) [10], the MIO was classified as one of four grades. The patient's ability to eat was also considered in this categorization as follows:

- Grade 0: absence of restricted mouth opening (> 30 mm);
- Grade 1: restricted mouth opening of 21–30 mm;
- Grade 2: restricted mouth opening of 11–20 mm and difficulty eating;
- Grade 3: restricted mouth opening of 5–10 mm and difficulty eating soft foods;
- Grade 4: restricted mouth opening < 5 mm and nasogastric tube feeding.

Data analysis

The following information was collected for all patients: sex, age, histological tumor subtype, tumor staging (T and N), total prescribed radiation dose and prescribed radiation dose for the mandible, cancer treatment, deleterious habits (e.g., smoking, chewing tobacco), and MIO measurements pre- and post-RT. For the tabulation of statistical data, we organized the collected information in an Excel spreadsheet (version 2016, Microsoft Corporation, Redmond, WA, United States). The obtained data were analyzed using Jamovi software (version 1.6.15; The Jamovi Project 2021, Sydney, NSW, Australia). A percentage descriptive analysis of global data was also performed, as well as paired analyses of the two groups (pre-RT and post-RT) using paired samples t-tests. Correlation analysis was performed using Spearman's correlation test. Kappa index was used to assess interobserver agreement. Statistical significance was set at $p < 0.05$ in all tests.

Results

Patient characteristics

The male sex predominated among the 21 participants (62%, n = 13), and the mean age was 53.5 (±17.5) years. Squamous cell carcinoma was the most common histological subtype (90.5%, n = 19), and the tongue was the most affected region (52.4%, n = 11). Tobacco use was reported by 43% of participants (n = 9) and alcohol consumption by 33% (n = 7). These findings are summarized in Table 1.

Regarding cancer therapy, surgery + RT, surgery + RT + chemotherapy, RT + chemotherapy, and RT alone was used in 47.6% (n = 10), 28.6% (n = 6), 19% (n = 4), and 4.8% (n=1) of patients, respectively. The mean radiation dose administered was 63.6 (±6.6) Gy, with the mandible receiving a mean dose of 65.1 (±16.5) Gy (Tab. 1). MIO measurements were obtained pre- and post-RT, and the results are presented in Table 1.

Pre-RT and Post-RT MIO

A paired analysis of the two groups was performed to determine whether there was a statistically significant decrease in MIO after completion of RT. The paired samples t-test was adopted after establishing that the quantitative data were normally distributed using the Shapiro-Wilk normality test ($p = 0.978$).

We observed a statistically significant reduction in the post-RT MIO measurements among the total sample ($p < 0.001$). The pre- and post-RT means were 47.8 (±11.6) and 41 (±9.4) mm, respectively. Kappa value for interobserver agreement ranged from 0.89 to 1.00. Separate analyses by sex revealed a statistically significant reduction in men ($p < 0.001$), although not in women ($p = 0.252$). Figures 2A and 2B illustrate the differences in means, medians, and confidence intervals in the pre- and post-RT periods between men and women, respectively.

Patients with cancer of the lip or buccal mucosa (Tab. 1; P2, P14, and P18) after surgery had reduced ability to open the mouth (microstomia) due to surgery. The post-RT MIO value remained constant in P2 (29 mm) and increased in P14 (27 to 30 mm) and P18 (20 to 24 mm) after RT. In addition, two participants experienced increased post-RT MIO (P3, 53 to 60 mm; P4, 45 to 46 mm). However, four participants developed post-RT trismus (P9, 45 to 35 mm; P11, 53 to 30 mm; P12, 49 to 34 mm; P19: 38 to 31 mm).

Figure 3 illustrates the classification of the degree of openness. Notably, two participants were

Table 1. General characteristics of patients with head and neck cancer who underwent intensity-modulated radiation therapy

Participant	Sex, age [y]	Tumor site	Histological subtype	T stage	N stage	Prescribed radiation dose [Gy]	Dose in mandible [Gy]	Treatment	Tobacco smoking	Alcohol consumption	Maximum interincisal opening [mm]		
											Pre-RT (a)	Post-RT (b)	Difference (a-b)
P1	M, 66	Tongue	SCC	T4	N2	64	69.5	Sx + CTx + RT	Yes	Yes	60	49	–11
P2	F, 45	Lip	MAC	T3	N0	66	0	Sx + RT	No	No	29	29	0
P3	F, 88	Oropharynx	SCC	T3	N2	40	43.9	RT	No	No	53	60	7
P4	M, 34	Tongue	SCC	T3	N0	66	70.8	Sx + CTx + RT	Yes	No	45	46	1
P5	F, 20	Tongue	SCC	T2	N0	60	64.0	Sx + RT	No	No	52	39	–13
P6	M, 74	FOM	SCC	T4	N0	70	73.8	CTx + RT	Yes	Yes	40	37	–3
P7	M, 52	Tongue	SCC	T2	N0	60	63.8	Sx + RT	No	Yes	52	48	–4
P8	F, 57	Tongue	SCC	T4	N2	70	72.5	CTx + RT	No	No	55	45	–10
P9	M, 55	Tongue	SCC	T3	N2	66	71.7	Sx + RT	Yes	Yes	45	35	–10
P10	M, 52	Tongue	SCC	T2	N0	66	70.2	Sx + RT	Yes	No	57	49	–8
P11	F, 26	Tongue	SCC	T1	N0	70	71.7	Sx + CTx + RT	No	No	53	30	–23
P12	M, 56	Lip	SCC	T1	N1	60	65.2	Sx + RT	Yes	Yes	49	34	–15
P13	F, 66	Gingiva	SCC	T2	N2	64	68.5	Sx + RT	No	No	40	36	–4
P14	F, 56	Buccal mucosa	SCC	T4	N2	60	62.7	Sx + CTx + RT	No	No	27	30	3
P15	M, 76	Nasopharynx	SCC	T2	N1	64	80.2	CTx + RT	Yes	Yes	52	45	–7
P16	M, 32	Tongue	SCC	T2	Nx	60	65.1	Sx + RT	No	No	60	42	–18
P17	M, 62	Nasopharynx	SCC	T2	N2	70	76.0	CTx + RT	No	No	56	52	–4
P18	F, 48	Buccal mucosa	SCC	T3	N0	60	67.2	Sx + RT	No	No	20	24	4
P19	M, 30	Soft palate	AdenoCa	T3	N0	66	70.0	Sx + CTx + RT	No	No	38	31	–7
P20	M, 63	Tongue	SCC	T2	N1	70	70.9	Sx + RT	Yes	No	60	50	–10
P21	M, 66	Tongue	SCC	T4	N2	64	69.5	Sx + CTx + RT	Yes	Yes	60	49	–11

M — male; F — female; SCC — squamous cell carcinoma; MAC — mucinous adenocarcinoma; AdenoCa — adenocarcinoma; T, tumor; N — node; Gy — gray; Sx — surgery; CTx — chemotherapy; RT — radiotherapy

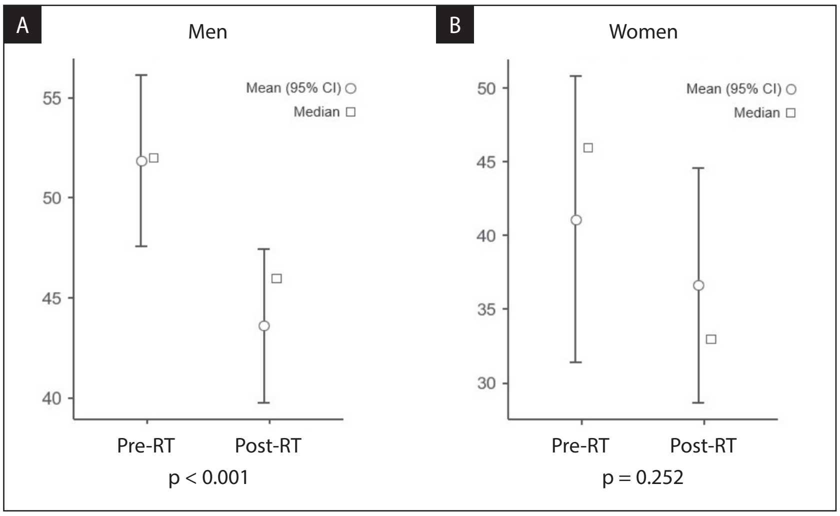

Figure 2. Maximum interincisal opening pre- (pre-RT) and post-radiotherapy (post-RT) by sex with means, medians, and confidence intervals (CIs). Circles represent means; squares represent medians

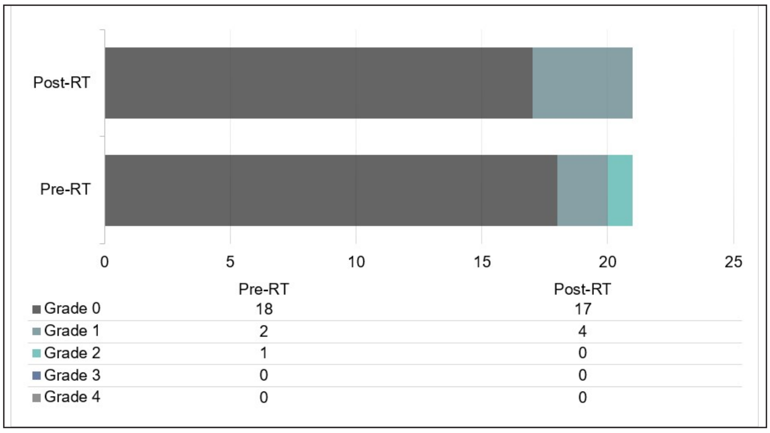

Figure 3. Pre-radiotherapy (pre-RT) and post-radiotherapy (post-RT) mouth opening classification according to Late Effects of Normal Tissues Subjective-Objective Management (LENT SOMA) Scale

classified as Grade 1 and one as Grade 2 before RT; however, after RT, the participant at Grade 2 was reduced to Grade 1.

Correlations among study variables

Correlation analyses were performed to determine whether the differences in pre- and post-RT MIO measurements correlated with the study variables. The Spearman correlation test was used for analysis after determining that T stage, N stage, total dose prescription, and dose prescription for the mandible were not normally distributed using the Shapiro-Wilk normality test ($p < 0.05$).

There was no statistically significant correlation between the difference in pre- and post-RT MIO values and the study variables: difference in openings *vs.* total prescription of radiation dose ($p = 0.569$, $r = -0.132$), difference in openings *vs.* radiation dose in the mandible ($p = 0.375$, $r = -0.204$), difference in openings *vs.* T stage ($p = 0.082$, $r = -0.388$), and difference in openings *vs.* N stage ($p = 0.796$, $r = -0.062$).

Discussion

Trismus is a frequent and disabling condition following treatment of head and neck neoplasms that require surgery or RT in the oral cavity, oropharynx, masticatory muscles, or temporomandibular joints. This condition can be self-limiting

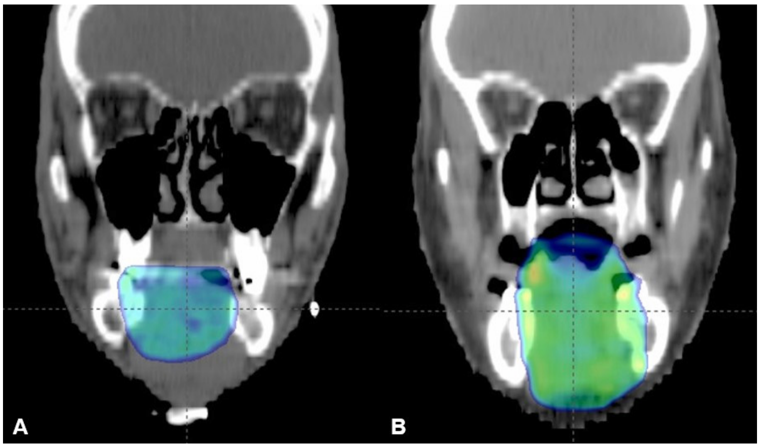

Figure 4. Computed tomography coronal reconstruction of radiotherapy planning by intensity-modulated radiation therapy. Panels A and B represent patients with tumors in the posterior third of the tongue. **A.** This patient received a maximum dose of 60 Gy (blue color); **B.** This patient received a maximum dose of 64 Gy (green color) using an intraoral stent; complete maxillary detachment from the focus of radiation can be seen

and may resolve over time; however, some degree of trismus persists in many people and may even be progressive. Both mild and severe trismus can have a significant impact on overall health and quality of life, making it difficult to chew, eat, and access the oral cavity, thereby compromising oral hygiene and dental care [6, 11]. The severity of the impact on quality of life and functional capacity increase with the severity of trismus [11, 12].

This study found that MIO reduced after RT, although the mean post-RT measurement value (41 mm) was greater than the cutoff value for trismus (35 mm). Among the total sample, four participants developed post-RT trismus and four exhibited increased post-RT MIO. We consider these results to be positive when compared to those of previous studies [11, 12]. In addition, when comparing MIO values before and after RT, the adapted LENT SOMA Scale classification [10] revealed remarkable results, with 80.95% (n = 17) of participants remaining at Grade 0, indicating the absence of restricted mouth opening, and one participant who was previously categorized as Grade 2 reduced to Grade 1 after RT.

The likelihood of developing trismus after RT is influenced by patient characteristics and treatment factors. Among the clinical features, tumor location, sex, age, tumor stage, highest total radiation dose, and baseline MIO have been previously documented as predictive variables for trismus [13–16]. Caetano et al. (2016) [17] did not observe variations in MIO values between sexes when evaluating 32 patients. In our study, however, men had a statistically significant reduction in MIO ($p < 0.001$), whereas women did not ($p = 0.252$). In addition, age, location, and tumor stage did not correlate with reduced MIO.

Regarding RT, the higher the radiation dose delivered to the masticatory structures, the higher the prevalence of trismus and the worse the outcomes [16]. Previous studies suggest that the risk of developing trismus is greater with radiation doses to oral tissues higher than 60 Gy [18, 19]. Furthermore, Teguh et al. (2008) [20] stated that for every 10 Gy irradiated in the pterygoid muscle, the chance of developing trismus increased by 24%. Interestingly, the highest dose administered in our study was 70 Gy, although there was no correlation between the doses applied and decreased MIO, possibly owing to the use of an IOS during RT.

Regarding previous oncological surgeries, Cohen et al. (2005) [21] found that 80.2% of patients with head and neck cancer developed reduced ability to open the mouth after previous oncological surgeries. In our study, three patients (P2, P14, and P18) who underwent oncological surgery before RT had microstomia before RT, although the MIO increased by 3 mm in P14 and 4 mm in P18 after RT, possibly because of the action of the IOSs during RT as the device provides mouth opening training that widens the opening.

The indications for the use of IOSs have yet to be fully clarified, although some authors suggest that they may be effective in reducing the acute and late adverse effects of RT [7, 9, 22–25]. IOSs reportedly help prevent or delay the onset of severe mucositis [7, 22, 26] salivary changes [8, 22, 27, 28], trismus [8, 28], dysgeusia [8, 28], dysphagia [8, 28], and pain [8], and are associated with better quality-of-life assessment scores [27].

In addition, the use of an IOS can limit the doses of radiation that reach normal tissues, thereby reducing the toxicity produced by RT [7, 9, 27–29] as exemplified in Figure 4, which presents coronal reconstructions of the intensity-modulated RT planning using computed tomography without (Fig. 4A) and with IOSs (Fig. 4B). Figure 4B shows the complete removal of the maxilla from the focus of radiation, indicating a limited dose of radiation.

IOSs are custom-built and can be made quickly and easily [9]. Typically, only two consultations are required: one to determine the size of the mandible and maxilla and the other to build the anterior abutments [7, 9]. Acrylic resin is considered the ideal material for manufacturing this device because it is a non-toxic, durable, and low-cost substance that does not interact with radiation [7, 30]. Hence, acrylic resin was the dental material selected in this study.

Although the benefits of IOS positioning have not been sufficiently proven, we recommend the use of this device as an alternative method for preventing RT complications. However, this study has some limitations. Firstly, responses to RT or chemotherapy may vary among histopathological tumor types. Accordingly, future research should consider standardized randomization and blinding of participants. A prolonged post-RT follow-up time should also be explored to determine whether an IOS has any effect on the prevention of late adverse side effects.

Conclusions

The use of an IOS during head and neck RT can reduce radiation doses in areas of no interest, thereby preventing the acute and late toxicities associated with cancer therapy. However, longitudinal studies are required to further validate the impacts of these devices.

Conflict of interests

None declared.

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Author contributions

Conceptualization: M.C.C., G.M.C., P.S.S.S. Methodology: M.C.C., G.M.C., V.M.F., G.H.L.T., P.S.S.S. Formal Analysis and Investigation: M.C.C., G.M.C., V.M.F., G.H.L.T., P.S.S.S. Writing-Original Draft Preparation: M.C.C., P.S.S.S. Writing-Review and Editing: M.C.C., G.M.C., V.M.F., G.H.L.T., P.S.S.S. Supervision: P.S.S.S.

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Data availability statement

All data and material are available upon reasonable request.

Ethics approval statement

This study was approved by the Human Research Ethics Committee of the Bauru School of Dentistry, University of São Paulo (CAAE: 94436518.7.0000.5417) and all procedures adhered to the tenets of the Declaration of Helsinki.

Patient consent statement

Patients provided written informed consent to publish their data, with the assurance that identifying details would be removed.

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