

Original Article

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Radiotherapy of tongue cancer using an intraoral stent: a pilot study

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Abstract

Aim: The aim was to evaluate the feasibility of an intraoral stent (10 and 20 mm thickness) in radiotherapy of tongue cancer, and to measure the reduction in acute mucositis in the palate.

Materials and method: There were six patients in the intervention group, and seven patients in the control group. Target coverage was measured by the minimum dose covering 98% of the clinical target volume (CTV). Data were collected from the planning CT and daily cone-beam computer tomography (CBCT).

Results: The 10 and 20 mm stent yielded a mean distance of 26 and 36 mm, respectively, between the tongue and the hard palate. We found comparable dose coverage of the CTV in the treatment plan, and on the CBCT. The stent reduced mean dose to the hard palate by 61.0% ($p = 0.002$). Dose to the soft palate was not reduced ($p = 0.18$). Average Common Terminology Criteria for Adverse Events (CTCAE) mucositis scores of the hard palate were 0 and 0.8 in the intervention and control group, respectively. The mucositis scores of the soft palate were 1.2 and 1.8.

Findings: Use of an intraoral stent substantially reduced the dose to the hard palate. CTV coverage was maintained. We did not find any significant reduction in visually scored radiation-induced mucositis.

Introduction

Radiotherapy, either as post-operative or primary treatment, is often necessary to cure tongue cancer.¹ Despite progress in radiotherapy techniques with possibly improved disease control, this treatment is associated with a range of acute and late morbidities in the oral cavity. Mucositis, xerostomia, hyposalivation, painful ulcerations, trismus, progressive caries, loss of taste and osteoradionecrosis, are well-known side effects, often detrimental to the patient's health and quality of life.^{2–5} Especially, mucositis is likely to occur after cumulative doses as low as 30 Gy, and the frequency may be as high as 80%,^{4,6,7} compromising the patient's nutritional status and quality of life. Without an intraoral stent, the clinical target volume (CTV) comprising the tongue is often adjacent to the palate leading to almost therapeutic doses to the palate and maxilla. An intraoral stent will counteract this problem by increasing the tongue–palate distance with consequential dose reductions in normal tissues.^{8–14} Previous studies have focused on the performance of quite advanced, customised intraoral stents.^{8,12–18} The manufacturing process has been described as quite demanding.^{12–14,17} Wilke pointed out that fabrication of an individually customised stent required at least two extra appointments, was time-consuming and depended on dedicated personnel.¹⁷ It has been described as helpful to have a close collaboration between the dentistry department and the radiotherapy department.¹⁹ Some radiotherapy departments, like ours, do not have a dentistry department at the same geographical location. Therefore, we have so far treated the patients without an intraoral stent.

The aim of this study was to include a fabric-made, affordable intraoral stent in the radiotherapy of tongue cancer. We wished to measure the impact of the intraoral stent on (1) stability of the tongue between treatment fractions, (2) coverage of the CTV between treatment fractions, (3) dose reduction in normal tissues and (4) reduction in acute mucositis.

Materials and Methods

Patients

The study was planned to include five patients in the intervention group and a comparable number in the control group. Inclusion criteria were: 1. Patients with tongue cancer planned for curatively intended radiotherapy requiring a total dose of 50–70 Gy. 2. Age >18 years. 3. Performance status, Eastern Cooperative Oncology Group (ECOG) 0–2. Thirteen patients, 12 men and 1 woman with tongue cancer, stages I–IVC according to the American Joint

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Table 1. Patient and treatment details

Patient No.	TNM	Intraoral stent	Tolerated stent	Radiation dose (Gy)	Chemotherapy
1	T2N0M0		No	50	
2	T3N1M0	Yes		60	Yes
3	T3N0M0		No	60	Yes
4	T3N0M0	Yes		66	
5	T1N0M0	Yes		50	
6	T3N3bM0	Yes		60	Yes
7	T1N0M0	Yes		50	
8	T2N0M0			50	
9	T3N2bM0			68	
10	T2N0M0	Yes		60	
11	T2N0M0			68	
12	T3N2bM1			68	Yes
13	T3N2cM0			66	

Patient Nos. 9, 11 and 12 (68 Gy) received radical radiotherapy. The other patients received post-operative radiotherapy (50–66 Gy). Patient No. 4 chose after CT simulation not to receive radiotherapy. We have no toxicity data for patient No. 1. TNM was assessed according to the AJCC/UICC 8th edition.²⁰ Chemotherapy = weekly cisplatin, 40 mg/m², maximum 70 mg i.v.

Committee on Cancer/Union for International Cancer Control (AJCC/UICC) 8th edition,²⁰ were enrolled in the period of March–December 2018. Median age was 65 years (range 37–89). Eight patients tried fixation with the intraoral stent. Two patients did not manage to keep the stent in the mouth because of gag reflex. One patient, tolerating the stent at mask preparation, later refused to start radiotherapy. This decision was not related to the stent. Seven patients were included in the control group. Information about the inclusion process is shown in Figure 1. Four patients received concomitant weekly cisplatin, 40 mg/m², maximum 70 mg i.v., two in each group (Table 1). Mucositis was scored towards the end of radiotherapy using ‘Common Terminology Criteria for Adverse Events’ (CTCAE) v3.0 by 2 oncologists (not blinded). Oncologist E.D. scored 9 out of 11 patients.

Immobilisation device and imaging

The intraoral stent applied in this study is developed at the Nederlands Kanker Instituut (Antoni van Leeuwenhoek Ziekenhuis, Amsterdam, the Netherlands), and is produced by Materialise (Materialise Medical, Leuven, Belgium). The spacer is made of polyamide and available in two sizes (Figure 2), 10 and 20 mm, which is the thickness between the upper part which touches the hard palate, and the lower part which rests against the tongue. The stent has an airway opening that protrudes through the fixation mask and makes it easy for the patient to breathe. The CT scan for radiation treatment planning was acquired using a Philips Brilliance CT Big Bore with a slice thickness of 2 mm (Philips, Amsterdam, the Netherlands). For immobilization, we used MacroCast, a thermoplastic fixation mask from MacroMedics (Waddinxveen, the Netherlands). During each treatment, the patient was positioned by lasers indicating the isocentre. A cone-beam computer tomography (CBCT) scan was performed and the best match was applied to adjust the couch before treatment.

Treatment planning

The CTV comprised the whole tongue. For the patients in the control group (without intraoral stent), our institution’s standard

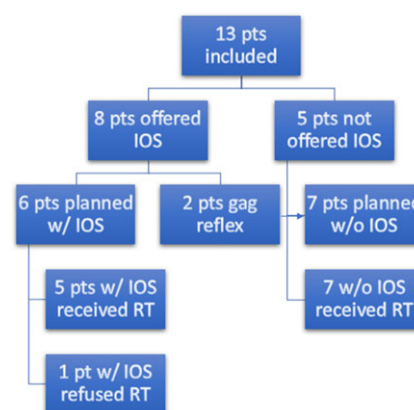


Figure 1. Patient inclusion process. The aim was to include five patients in the IOS group. Thereafter, a comparable number of patients (seven) were included in the control group, without IOS. Abbreviations: pts, Patients; w/, With; w/o, Without; IOS, Intraoral stent; RT, Radiotherapy.

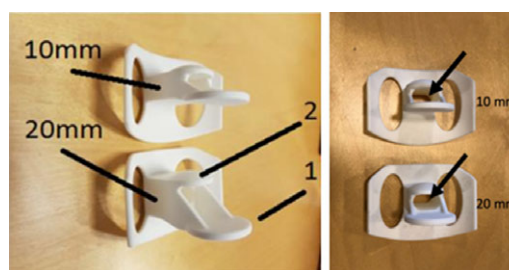


Figure 2. Left: The two available sizes, 10 and 20 mm, of the intraoral spacer used in this study, with tongue depressor part (1) and rounded part against the palate (2). Right: Photo showing airway opening (arrow) in the intraoral spacer.

procedure is to expand the CTV cranially to include the air pocket cranial to the tongue to account for intra- and interfraction movement of the tongue (Figure 3). For the patients in the intervention

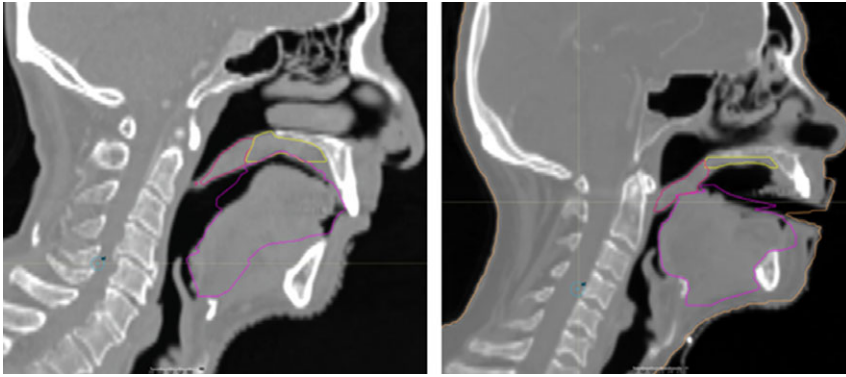


Figure 3. Left: CTV delineation (purple), hard palate (yellow) and soft palate (pink) in patient No. 8 without spacer. Right: CTV delineation (purple), hard palate (yellow) and soft palate (pink) in patient No. 2 with spacer.

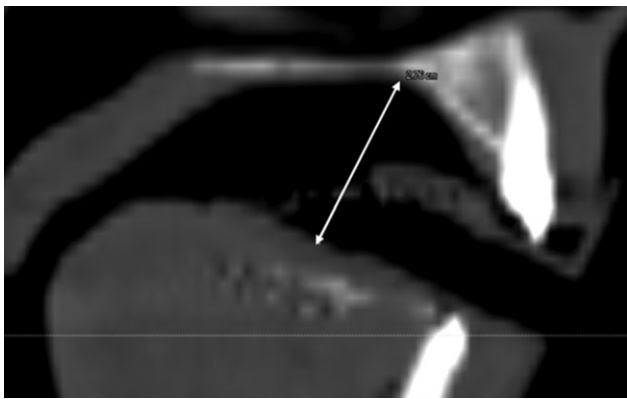


Figure 4. Sagittal profile from planning CT of patient No. 10. The arrow indicates the measured distance from the middle of tongue/caudal border of the intraoral stent to the most cranial localisation of the palate.

group, the CTV was expanded 5 mm into the spacer. The margin from the CTV to the planning target volume (PTV) was 3 mm. Organs at risk (OAR) were the spinal cord, brain stem and both parotid and submandibular glands. In addition, the soft and hard palate were delineated as OARs. The treatment was planned on RayStation version 7.0 (RaySearch Laboratories AB, Stockholm, Sweden), using volumetric arc therapy (VMAT) technique and 6 MV photons. The treatment plans were optimised according to the following criteria: the minimum dose to 98% of the PTV (D_{98PTV}) > 95%, D_{98CTV} > 95%, mean dose to the submandibular gland < 39 Gy, mean dose to the parotid gland < 26 Gy, maximum dose to the spinal cord < 48 Gy and maximum dose to the brain stem < 54 Gy. The dose per fraction was 2 Gy. Post-operative radiotherapy was given using five fractions per week. The three patients receiving radical radiotherapy were treated with an accelerated regimen of six fractions per week. The patients were treated on a Varian TrueBeam STx linear accelerator (Varian Medical Systems, Palo Alto, California, U.S.) with a six degrees of freedom couch.

In the intervention group, data were collected from both the planning CT and from each daily CBCT. We calculated the accumulated dose based on CBCT scans from each treatment session. Dose was calculated on the CBCT images and then mapped to the planning CT by deformable image registration. Target coverage was measured by D_{98CTV} at each treatment fraction. The dose to the OARs; the hard and soft palate were characterised by D_{mean} . In the control group, accumulated dose was not calculated, that is, only data from the CT planning images were analysed.

Three measurements from the sagittal images were obtained: The vertical air gap from the cranial border of the tongue to the

palate on the; (1) midline, (2) lateral left, 6 mm from the midline and (3) lateral right, 6 mm from the midline (Figure 4).

Statistics

The Mann–Whitney U-test (one-sided) was used to test whether two independent samples were selected from populations having the same distribution. Linear regression was performed using the ‘least squares’ method. A *p*-value less than 0.05 was considered statistically significant. Data were analysed using RStudio version 1.1.383²¹ and Excel version 1908, Microsoft Office 365 ProPlus.

Results

The 10 mm stent yielded a mean distance of 26 mm (SD 2 mm) between the tongue and hard palate measured on the CBCT images at each treatment. The mean distance was 36 mm (SD 1 mm) for the 20 mm stent (1 patient). The three vertical distances (tongue to hard palate, in the sagittal plane) were found to be similar, with the largest right–left variation in patient No. 10 of 1.4 mm. Patient No. 7 had the largest standard deviation due to displacement of the stent at several fractions (Figure 5).

The CTV coverage (D_{98CTV}) derived from the treatment plan was on average 97.7% (range 97.0–98.5%) in the intervention group and 98.8% (range 97.9–100.0%) in the control group. We found comparable dose coverage of the CTV in the treatment plan and on the CBCT at each treatment (Figure 6). In the intervention group, the estimated delivered D_{98CTV} was 96.9% (range 95.0–98.0%). The estimated delivered D_{98CTV} was not derived from the control group.

In Figure 7, the effect of the intraoral stent in one patient can be observed. In the intervention group, planned D_{mean} to the hard palate was 31.1% (range 6.5–80.4%). In the control group, planned average D_{mean} to the hard palate was 92.1% (range 80.9–99.0%; Figure 8). The stent reduced D_{mean} to the hard palate by 61.0% (range 0.5–92.5%; $p=0.002$). For each 10 mm increase in tongue–palate distance, the D_{mean} to the hard palate was reduced by 24.9% (Figure 9).

In the intervention group, planned D_{mean} to the soft palate was 80.7% (range 46.5–93.4%). This did not differ from the control group; D_{mean} 89.5% (range 80.0–95.7%; $p=0.18$).

The mean CTCAE mucositis scores of the hard palate were 0 (range 0–0) and 0.8 (range 0–3) in the intervention and control group, respectively (Figure 10). For two patients in the intervention group and one patient in the control group, the hard palate toxicity could not be scored, because of candida infection. The mean CTCAE scores of the soft palate were 1.2 (range 1–1)

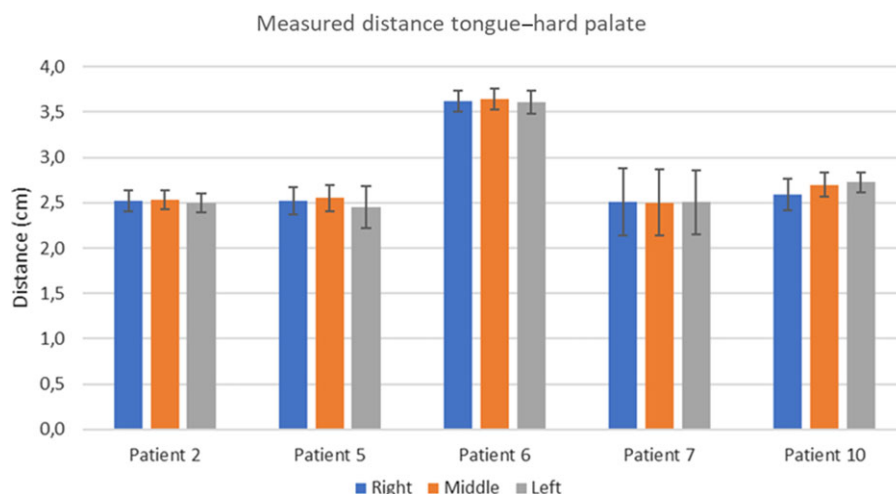


Figure 5. Mean air gap between tongue and hard palate for the intervention group. Right (blue), middle (orange) and left (grey). Patient No. 6 used the larger 20 mm stent while the standard size was 10 mm. Standard deviations are represented in error bars.

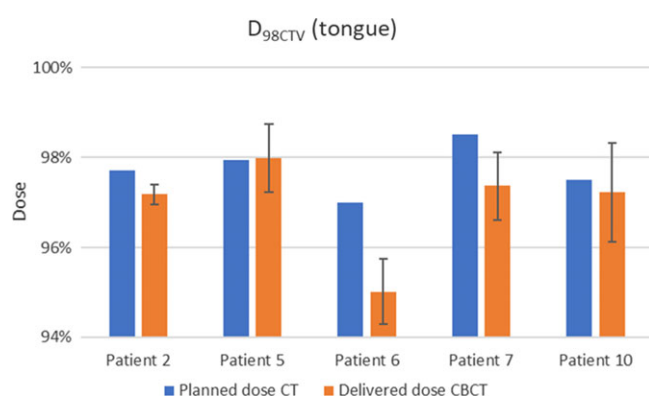


Figure 6. The minimum dose to 98% of the CTV (D_{98CTV}) in the intervention group. 'Delivered dose' was the average D_{98CTV} derived from each CBCT scan during the treatment period. Standard deviations are represented in error bars.

and 1.8 (range 1–2) in the intervention and control group, respectively (Figure 11). Due to the small sample size, we did not perform any statistical testing on the difference in CTCAE scores. All five patients using the intraoral spacer tolerated the stent well. There were no unexpected toxicity or unplanned treatment breaks.

Discussion

In this study, we found that a fabric-made, affordable intraoral stent was feasible in the radiotherapy of tongue cancer. Two out of the eight patients (25%) did not tolerate the stent because of gag reflex when the stent was inserted. This is a well-known challenge as pointed out by Kil et al.²² In the study by Mall et al., 30 tongue cancer patients were randomised to radiotherapy with or without an intraoral stent. They found that 3 out of the 15 patients (20%) in the intervention group were not able to receive the assigned treatment due to 'changes in treatment planning'. The exact reason was not stated, but probably, the stent was not tolerated in these three patients.¹⁶

Apart from creating a physical space between the tongue and the palate which reduces the dose to normal tissues, another advantage is the stabilisation of the patient's tongue during fractionated radiotherapy. Indeed, Doi et al. found that setup errors measured

with CBCT were significantly reduced by employing intraoral stents.²³ In the present study, we found that in general, the inter-fraction variation in the tongue–palate distance was small, which indicated good reproducibility. The radiotherapy technologists (RTT) at the treatment units also reported that the presence of the intraoral stent made it easier to match the CBCT with the treatment planning CT. One exception was patient No. 7 who had the largest variation in the tongue–palate distance. By inspecting the daily CBCT images more closely, it appeared that the spacer was misplaced (upside down) at several fractions. The tongue depressor part was not depressing the tongue, but was located upwards, against the palate. The upper shorter part was resting against the tongue. However, there was still satisfying dose coverage of the CTV and sparing of normal tissue. Based on this case, we think it is crucial to mark the stent with an arrow indicating which way the stent should be inserted into the mouth.

To the best of our knowledge, the present study is the first to track the dose in patients using an intraoral stent, at each treatment fraction by employing CBCT at the linear accelerator. In general, there was close agreement between planned and delivered D_{98CTV} . One exception was the only patient (No. 6) tolerating the largest 20 mm intraoral stent. Even though the interfraction variation in tongue–palate distance was small (Figure 5), the CTV coverage throughout the treatment period (measured by D_{98CTV}) was not optimal (Figure 6). An explanation might be that it was difficult for this patient to maintain a large mouth opening, introducing variations in the shape of the tongue, leading to suboptimal CTV coverage. This could be improved by using a larger target margin for the patients tolerating the 20 mm stent. However, we consider the 10 mm stent as optimal in terms of patient comfort, simplicity in use, good reproducibility and CTV coverage during the treatment period.

The intraoral stent gave a mean dose reduction of 61% in the hard palate. There will be a corresponding, beneficial dose reduction in the teeth in the upper jaw close to the hard palate. Verrone et al. did a study on patients with tongue or floor of the mouth cancer. Nineteen patients were treated using an intraoral stent and 14 patients were in the control group without a stent. The dose to the maxilla was reduced by approximately 40%, somewhat lower compared to the present study.¹¹ Nayar et al. included 55 head and neck cancer patients having tumours located close to the mandible and tumours close to the maxilla. They found that a customised intraoral stent yielded a relative dose reduction of around 60%

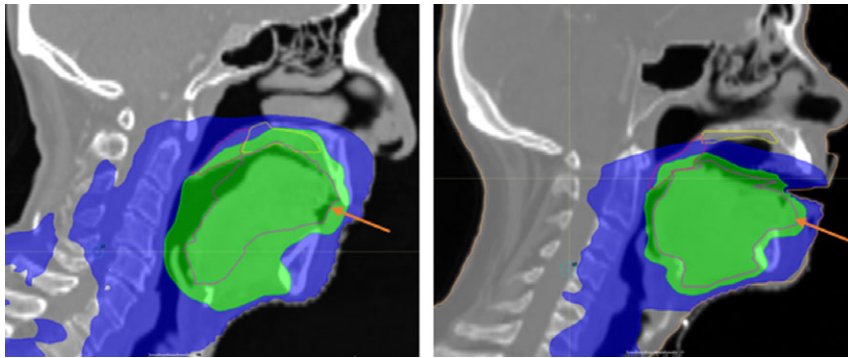


Figure 7. Dose distribution, 50% and 95% isodose, and delineation of CTV (red arrow), hard and soft palate, in patient No. 8 without stent (left), and patient No. 2 with intraoral stent (right).

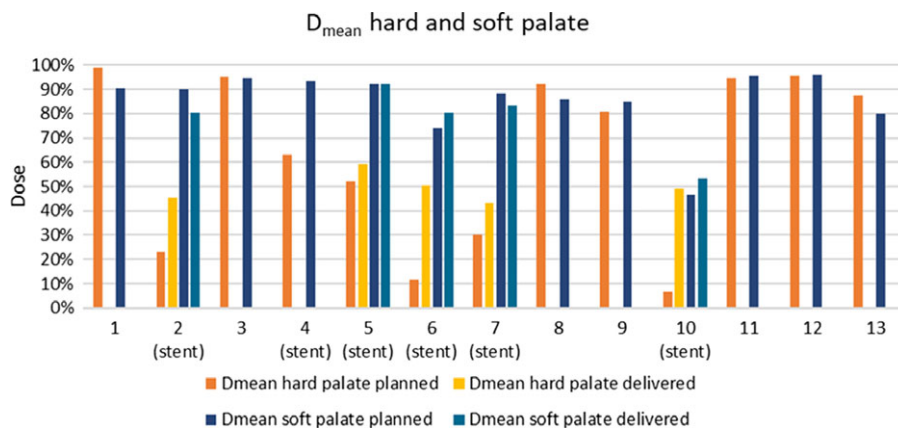


Figure 8. The hard and soft palate D_{mean} for all patients. Delivered dose was acquired only for the intervention group (from CBCT at each fraction).

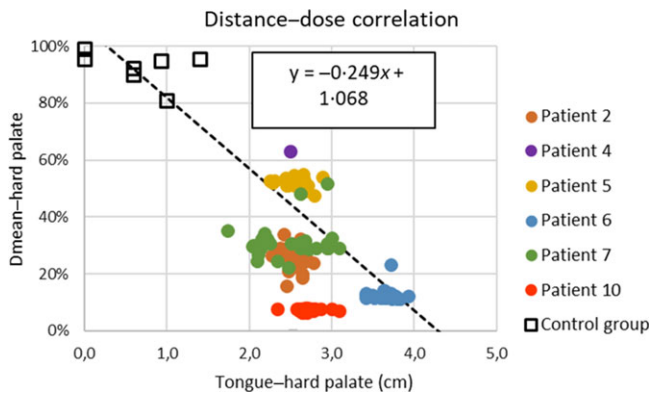


Figure 9. Dose as a function of distance between the tongue and the hard palate.

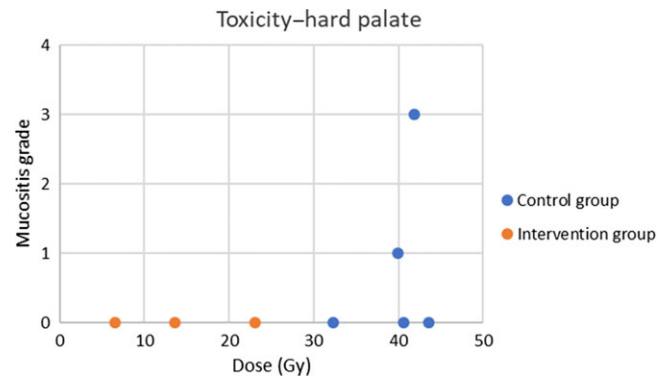


Figure 10. Common Terminology Criteria for Adverse Events (CTCAE) scores of mucositis in the hard palate as a function of mean dose.

to the opposing jaw, in agreement with our findings. In that study, the effect was more pronounced for tumours close to the mandible (and not so evident for tumours close to the maxilla).²⁴ Feng et al. studied 60 head and neck cancer patients with tumours close to the maxilla. They found that the mean dose to the tongue was reduced by 90% on average. This is a quite large dose reduction. An explanation might be that the patients tolerated quite large intraoral stents.¹⁵ We could not find the same decrease in dose to the soft palate. By inspecting Figure 7, it is seen that the intraoral stent does not push this OAR out of the high-dose region. The reason is the stent has an effect only on the anterior part of the tongue and not the base of the tongue which is closest to the soft palate. Because of the gag reflex, the stent cannot be made sufficiently long so that the

base of the tongue is pushed away from the soft palate, and therefore the soft palate dose could not be reduced.

Previous studies have found a reduction in radiation-induced side effects by using an intraoral stent.^{8-12,14,16,24} In the previous mentioned study by Mall et al., they found better salivary flow rates at 3- and 6-month intervals in the intervention group.¹⁶ A study by Goel et al. investigating 48 patients (24 patients with stent and 24 patients without stent), found decreased incidence and severity of mucositis, xerostomia and salivary changes in the intraoral stent group.⁹ Verrone et al. studied 33 patients and detected a delayed onset of mucositis in patients using an intraoral stent.¹¹ In the present study, we did not find any statistically significant difference in acute mucositis score between the intervention group and the control group. We believe that the main reason is that the sample

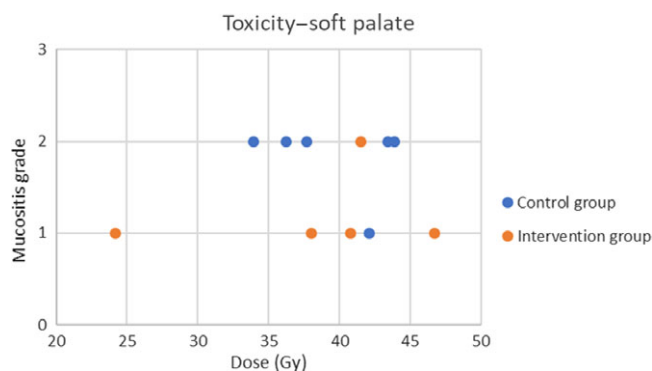


Figure 11. CTCAE scores of mucositis in the soft palate as a function of mean dose.

size was too small. In addition, there was less visible mucositis in the hard palate in the control group than expected, despite close to a full dose in this location. This might be related to the anatomy in the hard palate with a thin layer of mucosa covering the bony part of the palate making the appearance of mucositis different from mucositis in a location with thicker soft tissue, for example, the soft palate. Another reason was candida infection in the hard palate in three of the patients (two patients in the intervention group and one patient in the control group). These patients could not be evaluated for mucositis in the hard palate. Additionally, it was easier to see mucositis in the soft palate, but here the radiation dose was similar in the control and the intervention group, and thus the incidence of mucositis was similar.

This study has some limitations apart from the already mentioned small sample size. The study was not randomised, possibly introducing bias in the comparison between the intervention and control group. The measured distance between the tongue and the palate could have been affected by inter-operator variability. However, three RTTs did all these measurements in collaboration. Moreover, there was a large set of measurements providing reliable estimates of the uncertainty. We applied deformable registration to estimate the accumulated dose. This method is not reliable in the case of significant changes in anatomy. However, anatomy changes are normally not so pronounced during a fractionated radiotherapy schedule as compared with changes after larger time intervals, for example, in a reirradiation setting.²⁵

Conclusion

The use of a fabric-made intraoral stent in the radiation treatment of tongue cancer substantially reduced the dose to the hard palate. Target coverage was maintained throughout the treatment period. There was no significant reduction in visually scored radiation-induced mucositis in the palate in this pilot study. We believe that the intraoral stent is useful, and we have now started another study to assure the quality of the treatment in a larger cohort (NCT04330781).

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Conflict of interests. The authors declare none.

Ethical approval and consent to participate. The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national guidelines on human experimentation (the Norwegian Ministry of Health and Care Services) and with the Helsinki Declaration of 1975, as revised in 2008, and has been approved by the institutional committees (the institutional review board at the Oslo University Hospital). Informed consent was obtained from all patients.

Trial registration. Clinicaltrials.gov; NCT04337853. Registered 8 April 2020—Retrospectively registered, <https://clinicaltrials.gov/ct2/show/NCT04337853?cond=Tongue+Cancer&draw=2&rank=1>

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