Technical Innovations & Patient Support in Radiation Oncology 31 (2024) 100265

Contents lists available at ScienceDirect

Technical Innovations & Patient Support in Radiation Oncology

journal homepage: www.sciencedirect.com/journal/technical-innovations-and-patient-support-in-radiation-oncology

Research Article

# Dosimetric benefits of customised mouth-bite for head neck cancer patients undergoing modern proton therapy – An audit

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ARTICLE INFO

*Keywords:*
Mouth-bite
Proton therapy
Mucositis
Oral cancers

ABSTRACT

*Background and aims:* Proton therapy (PRT) for Head Neck Cancer (HNC), in view of the Bragg peak, spares critical structures like oral mucosa better than IMRT. In PRT, mouth-bites, besides immobilising and separating mucosal surfaces, may also negate the end-of-range effect. We retrospectively analysed the details and dosimetric impact of mouth-bites in PRT for HNC.

*Materials and methods:* The data of consecutive HNC patients treated with IMPT from May 2020 to August 2022 were studied retrospectively. Details of the mouth-bite used, compliance and resultant mucosal separation were noted. Further analysis, restricted to previously unirradiated patients, comprised volumetric dosimetric data pertaining to the mouth-bite and distal mucosal surfaces. High LET zones, corresponding to 6–12 keV/micron, for mouth-bite doses above 30 Gy, were recalculated from existing plans.

*Results:* A mouth-bite was used in 69 of 80 consecutively treated patients, ranging from 8 to 42 mm in thickness, and 12 to 52 mm in the resultant mucosal sparing. In 42 patients in whom the mouth-bite V 32 Gy was $>$ 0, median Dmean, absolute V32, V39, V50 and V60 GyE (Gray Equivalent) of the mouth bite was 35.65 GyE (Range: 2.65 – 60 GyE), 10 cc (Range: 0.1 – 32 cc), 7.6 cc (Range: 0.1 – 30.8 cc), 5.7 cc (Range: 0.2 – 29.2 cc) and 1.45 cc (Range: 0.2 – 18.1 cc) respectively, all significantly more than the spared adjacent mucosal surface. In absence of a mouth-bite, the spared mucosa would have at least partially received the high dose received by the mouth-bite. High LET zones were noted in 12 of 48 mouth-bites.

*Conclusion:* In PRT for HNC, mouth-bites play a vital role in improving the sparing of mucosa outside the target.

## Introduction

Radiotherapy is an essential component of the treatment of head-neck cancers (HNCs) [1]. Treatment planning for HNCs is a multistep process based on clinical indication and the patient's general condition; the fabrication of an immobilisation device appropriate to the disease subsite is a crucial first step [2]. This may include the fabrication of a mouth-bite, which serves various functions in head-neck radiotherapy. The primary function of a mouth-bite is to create distance between the target and adjacent uninvolved oral mucosa. This allows most of the dose fall-off in the high-dose region to occur in the mouth-bite rather than the mucosa, thus reducing the incidence and severity of radiation-induced oral mucositis (RIOM) [3]. This is relevant, given the association of radiation dose with oral mucositis and of the latter with pain, aspiration, infection, risk of tube insertion, hospitalisation and possibly even mortality [4–7].

Besides reducing oral mucositis, using mouth-bites to depress the tongue in oral/base tongue cancer reduces the dose to the palate which reduces the subjective sensation of sticky saliva [3,8]. In addition, depression or deviation of the tongue when treating alveolar lesions reduces the dose received by taste buds, thereby reducing the possibility of dysgeusia.

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https://doi.org/10.1016/j.tipsro.2024.100265
Received 10 March 2024; Received in revised form 6 July 2024; Accepted 29 July 2024
Available online 31 July 2024

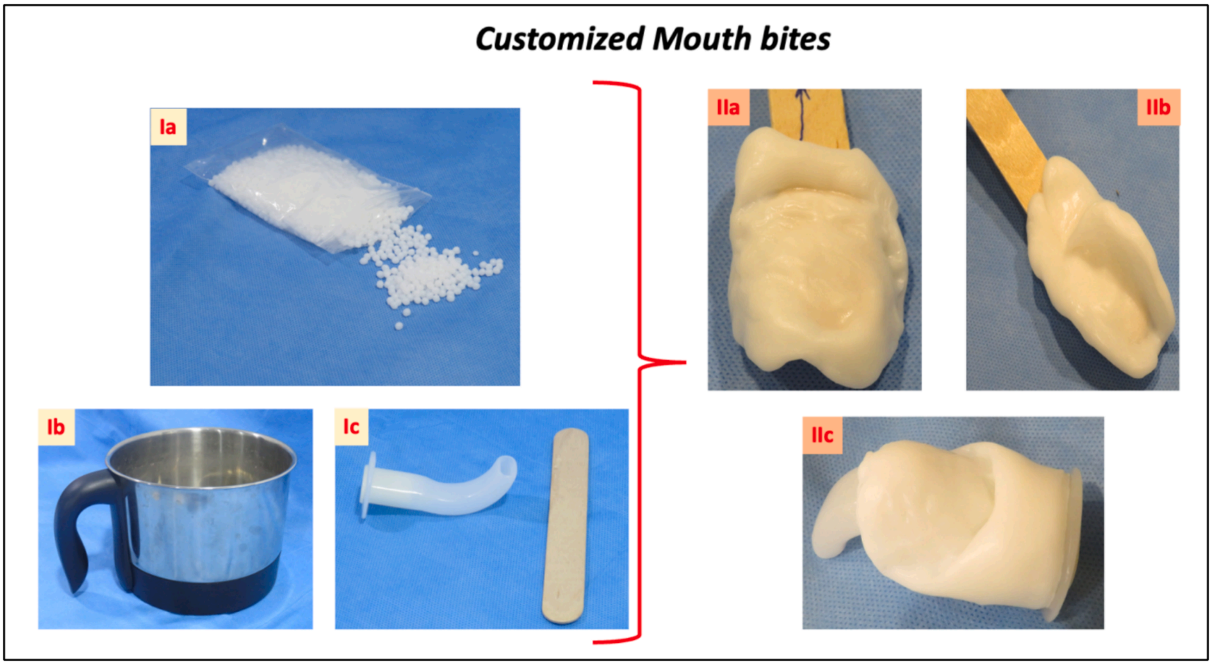


**Fig. 1.** Mouth-Bite customisation (Image reproduced with permission from Gaikwad U, Mookaiah M, Karthekeyan S, Wakde M, Noufal MP, Chilukuri S, Sharma D, Jalali R, Nangia S. Standard Operating Procedure (SOP) for mould room practices and simulation of head neck cancer patients undergoing proton therapy. Technical Innovations & Patient Support in Radiation Oncology. 2022 Dec 1; 24:48–53). Ia – Acrylic granules. Ib Hot water kettle. Ic – Guddle airway and wooden stick/ spatula. IIa – Mouth-bite using acrylic granules and wooden stick to push tongue down. IIb – Mouth-bite using acrylic granules and wooden stick to push tongue laterally. IIc – Mouth-bite using acrylic granules and Guddle airway to push jaw down. IId- Mouth-bite using acrylic granules with retaining flange for edentulous patients.

Mouth-bites are also known to reduce radiation doses to salivary glands, the temporomandibular joint (TMJ), the maxilla and the mandible, reducing the incidence and severity of late toxicities of xerostomia, trismus and osteoradionecrosis, respectively [9,10].

In treating tongue malignancies, mouth-bites immobilise the tongue [11]. The same purpose is served in laryngeal malignancies, i.e., reduction of laryngeal motion by preventing the action of swallowing. The reduction of setup errors secondary to better immobilisation has been confirmed [12].

Proton therapy (PRT), increasingly being used to treat HNCs, is characterised by a sharp dose fall-off distal to the Bragg peak. This allows superior sparing of distal structures and is the basis of its use in HNCs [12]. The efficacy of proton therapy in reducing the dose received by organs at risk in HNCs has been correlated with a reduced risk of tube insertion, hospital admission and narcotic requirement, and improved quality of life and work performance in various studies [13–15].

While the generic relative biological effectiveness (RBE) of protons is estimated as 1.1, the RBE at the end-of-range of the Bragg peak may be significantly higher. The impact of the higher RBE may be partially negated by attention to beam placement, leading to the distribution of the end-of-range effect. In addition, the end-of-range impact may be further reduced by using mouth-bites, which allow the beam to end range in the mouth-bite rather than on the mucosa outside the target. This is particularly relevant when treating unilateral lesions such as bucco-alveolar and tonsil cancers, wherein all beams may end on the tongue.

We initiated Intensity Modulated Proton Therapy (IMPT) for HNCs and skull base lesions (SBLs) in Jan 2019. Our immobilisation protocol, published earlier, incorporates mouth-bites [16]. Since limited data is available regarding the rationale and usage of mouth-bites in PRT for HNC, we retrospectively analyzed the details and dosimetric impact of the usage of mouth-bites. Amongst the various benefits of mouth-bites discussed earlier, we have focused mainly on reducing mucosal dose which will consequently impact the odds of developing RIOM and resultant side-effects.

## Materials and methods

We performed an audit of 80 consecutive HNC patients treated with IMPT from May 2020 to August 2022. All patients underwent PRT following multidisciplinary-tumour board (MDT Board) discussion and informed consent. A pre-planning audit (PPA) was conducted by the treating physician, planning physicist and radiotherapy technologists (RTTs) to discuss immobilisation and simulation for all patients as a part of our standard operating procedure (SOP) [14]. We used customised Intraoral spacers (IOSs) / mouth-bites for all HNC patients planned for proton therapy unless the target was not in proximity to the oral mucosa or if $\geq$ grade 3 trismus was present.

Mouth-bites were fabricated by the RTT who had followed an in-house training program to create these mouth-bites; this was done with hygiene precautions, using thermoplastic acrylic granules (Adapt-IT, Affix, Avondale, USA), as shown in Fig. 1. Mouth-bites were moulded per the patient's oral anatomy and the role of mouth-bite prescribed by the treating physician, i.e., whether to depress or deviate the tongue. Once the mouth-bite was moulded and reviewed by planning physicists and treating physicians, further immobilisation, i.e. a customised headrest (Moldcare Cushion, Affix, Avondale, USA) and thermoplastic mask (Fibroblast, QFix, Avondale, USA) was prepared. Planning computed tomography (CT) images were acquired using the Canon Aquilian Large Bore CT scanner (Canon Medical Systems, Singapore) from vertex to carina with a slice thickness of 2 mm (mm). Additional CT images with oral contrast (thin layer of contrast around mouth-bite) were acquired to delineate the mouth-bite better. Mouth-bites and the palate/tongue distal to the mouth-bite were contoured by the physician. The various dimensions of the mouth-bite and mucosal separation were measured in the planning CT using the measuring tool provided in the Treatment planning system (RayStation/ RaySearch Laboratories AB, Stockholm, Sweden).

**Table 1**
Demographic and mouth-bite details.

| | N (%) |
|---|---|
| n | 80 |
| Sex ratio (Male: Female) | 62:18 (77.5: 22.5) |
| Age Median (Range) | 53 (20–69) |
| Age groups | |
| • </= 50 | 37 (46.25) |
| • 51–64 | 22 (27.50) |
| • >/=65 | 21 (26.25) |
| Radiation | |
| • Proton only | 74 (92.5) |
| • Proton-photon | 6 (7.5) |
| Immobilisation used | |
| • 3 clamp head only mould | 4 (5) |
| • 4 clamp head and neck mould | 75 (93.75) |
| • 4 clamp head and neck mould with vacloc | 1 (1.25) |
| Mouth-bite used | |
| • Yes | 69 (86.25) |
| • No | 11 (13.75) |
| Type of Mouth-bite | |
| • Central | 55 (79.7) |
| • Lateral | 14 (20.3) |
| Materials used for Mouth-bite | |
| • Spatula and acrylic granules | 49 (71) |
| • Guedel airway and acrylic granules | 19 (27.5) |
| • NG Tube and Acrylic granules | 1 (1.5) |
| Reasons for not using mouth-bite | |
| • Poor mouth opening | 5 (45.5) |
| • Not required | 4 (36.4) |
| • Patient not comfortable | 2 (18.1) |

In this audit, we have performed the following:

1. Documentation of the type, dimensions and function of mouth-bites and their acceptance by patients and the mucosal separation achieved by using mouth-bites.
2. Analysis of plans of patients undergoing their first course of radiotherapy to determine whether a high Linear Energy Transfer (LET) zone, corresponding to 6–12 keV/micron for doses above 30 GyE, was present in the mouth-bite. To calculate LET, the treated plan had been copied and recalculated using RayStation V12.
3. Determining the volume of doses pertinent to the development of RIOM viz., Dmean, V32, V39, V50 and V60 GyE (Gray Equivalent) in patients in whom the mouth-bite received at least 32GyE, i.e. performed the function of mucosal sparing. These volumes have been previously noted to correlate with the duration and intensity of mucositis by Narayan et al and Mazzola et al [17,18].
4. The dose received by the sub-site distal to the mouth-bite, either hard palate or tongue, as appropriate, with reference to the location of the high dose target, was compared with the dose received by the mouth-bite, in the above-mentioned group of patients.

**Table 2**
Dosimetric details of mouth-bite and distal spared structure. Dmean – Mean dose. GyE – Gray equivalent V32GyE – Volume receiving 32 Gray equivalent V39GyE – Volume receiving 39 Gray equivalent V50GyE – Volume receiving 50 Gray equivalent V60GyE – Volume receiving 60 Gray equivalent.

| Group N=42 | Dmean GyE (Median) | V32GyE (Median) | V39GyE (Median) | V50GyE (Median) | V60GyE (Median) |
|---|---|---|---|---|---|
| Distal Spared structure /subsite | 22.3 | 4.2 cc | 3.5 cc | 2.4 cc | 0.7 cc |
| Mouth-bite | 34.8 | 14.6 cc | 13.1 cc | 9.4 cc | 4.5 cc |
| p value | 0.01 | 0.0003 | 0.0008 | 0.003 | 0.01 |

## Results

Demographic details of our cohort of 80 consecutive HNC patients, with further information of immobilisation devices used, mouth-bite type, etc., are summarised in Table 1. A mouth-bite was used in 69 of 80 patients; its fabrication was aimed at creating distance between the clinical target and uninvolved oral mucosa. Out of these 69 patients, 48 received their first course of radiation and the remaining underwent reirradiation. The mouth-bite was omitted in 11 patients. In 5 patients, this was due to poor mouth opening, and in 2, due to discomfort; it was not considered necessary in 4 patients.

The mouth-bite was moulded around a spatula, Guedel's airway, or a nasogastric tube in 49, 19 and 1 patient, respectively. The average thickness was 20 mm and ranged from 8 to 42 mm in mouth-bites used to depress the jaw and 10 and 32 mm in mouth-bites used for lateral deviation of the tongue. The resultant mucosal separation ranged from 16 to 52 mm, median of 30 mm, for central mouth-bites and 12 mm to 34 mm, median 25 mm, for mouth-bites used for lateral deviation of the tongue.

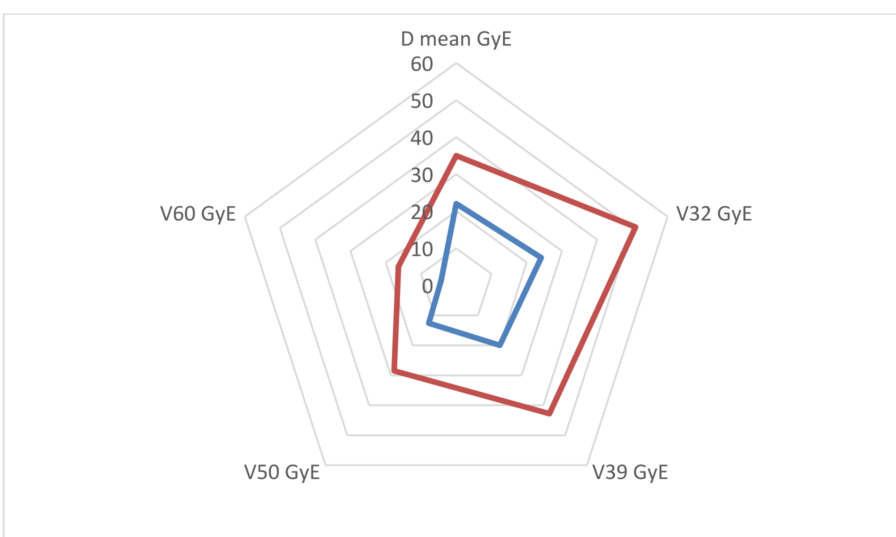


**Fig. 2.** Spider plot showing dosimetric comparison between mouth-bite and spared structure. Dmean – Mean dose. GyE – Gray equivalent. V32 GyE – Volume receiving 32 Gray equivalent. V39 GyE – Volume receiving 39 Gray equivalent. V50 GyE – Volume receiving 50 Gray equivalent. V60 GyE – Volume receiving 60 Gray equivalent. Orange – Mouth-bite doses. Dark blue – Spared structure.

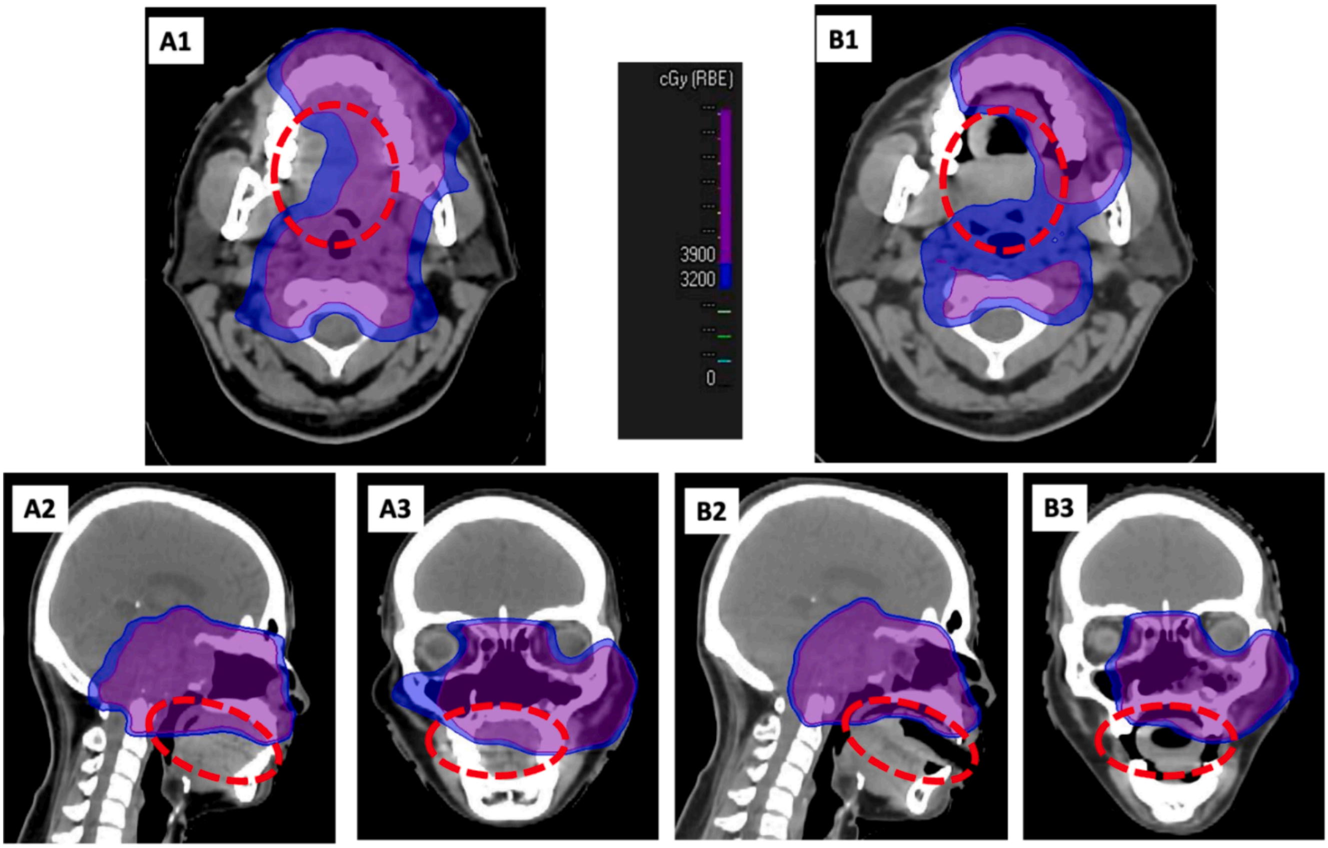


**Fig. 3.** Plan comparison with and without Mouth-bite. A1 – Axial view of IMPT plan without mouth-bite. A2 – Sagittal view of IMPT plan without mouth-bite. A3 – Coronal view of IMPT plan without mouth-bite. B1 – Axial view of IMPT plan with mouth-bite. B2 – Sagittal view of IMPT plan with mouth-bite. B3 – Coronal view of IMPT plan with mouth-bite. Pink – 39 GyE dose colourwash. Dark blue – 32 GyE dose colourwash. Red dotted circle showing dosimetric benefit of uninvolved mucosa.

High LET≥6keV/micron for doses ≥ 30 GyE was noted in 12 of 48 mouth-bites. The maximum dose LET ranged from 6.3 to 8.1 keV/micron and dose from 31.7 to 49.1 GyE.

The mouth-bites of 42 of these 48 patients had V32 more than 0 %. V32 was 0 % in 6 patients. In the cohort of 42 patients, there was a significant difference in dosimetric parameters (Dmean, V32, V39, V50 and V60) between mouth-bite and spared structure doses (Fig. 2). The dose received by the mouth-bite and the distal spared structures is summarised in Table 2. The median Dmean, absolute V32, V39, V50 and V60 GyE of the mouth-bite was 35.65 GyE (Range: 2.65 – 60 GyE), 10 cc (Range: 0.1 – 32 cc), 7.6 cc (Range: 0.1 – 30.8 cc), 5.7 cc (Range: 0.2 – 29.2 cc) and 1.45 cc (Range: 0.2 – 18.1 cc) respectively in this cohort.

## Discussion

In this article, we have discussed our experience of using mouth-bites to reduce the radiation dose received by the uninvolved oral mucosa when using PRT to treat HNC.

Our study documents the mouth-bites used in 69 consecutive patients, who constituted 89 % of the total number of HNC patients treated with proton therapy. We noted that mouth-bites were easy to customize and aided reproducible mechanical displacement/distancing of the uninvolved mucosa away from the target volume.

In institutes where a mouth-bite is used for HNCs, various forms of customisation are used, i.e., bite-block made of dental wax, off-the-shelf devices standard Intra oral spacer devices, as well as customised IOSs using CT scanning and or 3D printing. We used acrylic granules to fabricate mouth-bites which were easy to customise, low cost and accepted by patients. Mouth-bites made from acrylic granules have a smooth texture, no odour and are strong, unlike mouth-bites made from dental wax, which may have a waxy odour, sticky texture and can be brittle. The time required for customisation was 10–15 min, unlike 3D printed mouth-bites. The fabrication required no major setup or accessories except acrylic granules, and either a wooden spatula or Guedel's airway and a kettle. The cost of fabricating the customised acrylic mouth-bite was less than 1 USD (approximately 70 INR). The fabrication does require expertise to prevent the acrylic sticking to the patient's dentition. This can be ensured by performing the fabrication when the acrylic is lukewarm. The acceptance rate was noted to be high and only 2 of 69 patients recommended a mouth-bite could not tolerate it. Both patients who were uncomfortable with the use of mouth-bite were post-op HNC patients with poor alignment of the jaw post-surgery.

The average thickness of the mouth-bite in these patients was 20 mm, allowing sufficient thickness for dose fall-off to occur, the dose fall-off from 100 % to 10 % occurring in 12 mm (10–15 mm) in IMPT plans. The resultant supero-inferior mucosal separation, median 30 mm, was naturally more than the medio-lateral displacement, 25 mm, since the supero-inferior separation, applicable to both tongue and palate, is determined by mouth opening while lateral displacement, relevant only for the tongue, would be limited by the mandible. Cleland et al have previously reported a supero-inferior separation of 35–37 mm using a customizable 3D printed intra-oral stent [19].

The use of IOSs for HNC patients undergoing radiation therapy, is not universal, due to a combination of factors, viz., lack of an easy-to-use device, the cost and time involved in modern spacing devices such as 3D printed mouth-bites, and possibly, a lack of awareness regarding the significant benefits of mouth-bites.

Notwithstanding the advancement of radiation techniques, such as sophisticated calculation algorithms and hardware-driven modulated radiation and image guidance, mouth-bites remain relevant in the treatment of HNCs, whether using photons or protons. Various intraoral spacing devices such as customised mouth-bites, universal mouth-bites, 3D- printed customised intraoral prostheses, intraoral stents etc., have been tried in HNC patients over the years. Brandao et al, addressed IOSs and their clinical implication, in a *meta*-analysis. They identified 201 studies and analysed 7, 2 retrospective, 3 prospective and 2 randomised control trials (RCTs). In these 7 studies, of 251 HNC patients treated with external beam radiotherapy, IOSs were used in 77.3 % patients, and there was a statistically significant benefit of IOSs in preventing RIOM, salivary changes and trismus [9].

There is limited published experience of using mouth-bites during PRT for HNCs. Hong et al have studied the dosimetric benefits of a semi-customised tongue displacement device (scTDD), fabricated using a 3D printer for 7 patients receiving IMPT to unilateral or bilateral head neck region over a standard mouthpiece (sMP). This retrospective study noted a statistically significant reduction in the radiation dose received by the tongue and uninvolved/contralateral oral mucosa using scTDD, compared to sMP [20].

Although many studies have demonstrated the benefit of mouth-bites, in our dosimetric analysis, we have quantified this benefit. In our study, we have documented the mean dose and volume of the V32GyE, V39 GyE and V50 GyE received by the mouth-bite. We hypothesised that in the absence of a mouth- bite, the critical organ at risk, the oral mucosa, would have been in the place of the mouth-bite. Therefore, the dose received by the mouth-bite, would have been, at least partially, received by the oral mucosa in case the device was not used. These volumes have been previously noted to correlate with the duration and intensity of mucositis by Narayan et al and Mazzola et al [15,16]. Narayan et al have noted that the severity and duration of RIOM, correlate with volume receiving 32 Gy and 39 Gy, respectively [17]. Mazzola et al have noted that $\geq$ Grade 2 mucositis correlates with D50Gy $>$ 30 % of the spared oral mucosa, i.e., the mucosa outside the planning target volume (PTV) [18]. In order to study a uniform population, we have performed this analysis only in patients undergoing their first course of radiation, since the target delineation and dose prescription of patients undergoing reirradiation follows a different philosophy.

Step further to quantification, we compared the difference in these dosimetric parameters between mouth-bite and structures it was required to spare. We intentionally analysed patients in whom the V32 of mouth-bite was more than 0 %.

We analysed the volume of mouth-bites receiving various dose levels, as a surrogate for the displaced mucosa that would have received this dose. We then calculated the dose received by the displaced mucosa and compared it with the dose received by the mouth-bite and have noted 37 %, 52.6 %, 53.3 %, 55.8 % and 73.8 % reduction in the mean dose, V32Gy, V39Gy, V50Gy, and V60Gy, respectively, all being statistically significant. Given the correlation of high LET with an RBE more than the universally accepted 1.1, in 12 of 48 i.e. 25 % patients, the mouth-bite served to displace mucosa which would have otherwise been the site of high LET [21]. We believe that analysis of the dose within the mouth bite, spared mucosa and LET is novel, and previous studies have not addressed these issues [22].These data stress that mouth-bites remain relevant in patients undergoing PRT for HNCs, in spite of the sharp dose fall-off when using this technique. Fig. 3 is a representation of dose distribution with and without the usage of a mouth bite.

While mouth-bites may retain their relevance for the purpose of immobilisation and reproducibility, they did not serve any dosimetric function in 6 patients. These patients comprised 3 (50 %) hypopharyngeal cancer patients, 2 (33 %) PNS and nasopharyngeal cancer patients, and one (16.7 %) submandibular cancer patient. All 4 patients in whom mouth-bites were not considered necessary had skull-base leions. All patients of oral and oropharyngeal cancers derived dosimetric benefit from mouth-bites. The limitations of our study are its retrospective nature, lack of correlation of toxicity and QOL data, and subsite-based analysis documenting the benefit of mouth-bites in each group. Further, there is no comparison of plans made with and without mouth-bites and the analysis was based on the assumption that the normal mucosa would have been in the position of the mouth-bite and therefore the dose received by the mouth-bites represents the dose to the normal mucosa had the latter not been displaced. Notwithstanding these limitations, our analysis helps provide requisite information regarding mouth-bite fabrication and utility in PRT for HNC.

## Conclusion

Notwithstanding the sharp dose fall-off in proton therapy, the use of mouth-bites reduces the dose received by the mucosa outside the target volume and thereby the odds of developing oral mucositis, in patients being treated with PRT for HNCs. Our study provides a novel, low-cost method of fabricating mouth-bites and analyses their dosimetric advantage in HNC patients; this will help both existing and established modern proton therapy centres.

## Funding

The authors declare that this research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

## Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

## Acknowledgement

The authors thank their patients and their families for their support.

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