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The Effect of Using Conventional VS Digital Oral Positional Radiation Stent on Healthy Oral Tissues

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Aim: The study aimed to compare the effect of using conventional versus digital oral positional radiation stents on healthy oral tissues.

Materials and Methods: Patients with head and neck cancer (HNC) were divided into two groups. Group A: oral positing radiation stent (OPRS) was constructed according to the conventional technique. Group B: OPRS was constructed digitally using CAD/CAM technology. Each patient was evaluated for Dosimetric analysis and assessment of mucositis.

Results: There was no statistically significant difference between the two groups as regard the amount of radiation dose to organs at risk. In the mucositis assessment, there was a statistically significant difference with respect to the amount of radiation dose to organ at risk (OAR) by comparing the same patients using OPRS and without it, as the use of the stent led to a reduction in the amount of radiation dose to OARs. Severity of mucositis increased weekly, but it remains within the tolerable degree.

Conclusion: It was concluded that OPRS can be considered an important therapeutic modality for HNC patients' immobilization, which decreases the intensity of radiation toxicity. The method used in the construction of OPRS has no effect on how efficiently it controls radiation exposure.

Keywords: Radiotherapy, HNC, Digital, Mucositis, Removable.

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Introduction

Head and neck cancer are a group of malignancies involving oral cavity, pharynx, ear, larynx, nasal cavity and para nasal sinuses, represent 6% of all cancers that are diagnosed in the world. [1, 2]

The most important reasons are the greater exposure to risk factors, and genetic susceptibility which are likely to play a role. Other risk factors such as environmental, occupational, and dietary may also play a role in carcinogenesis and potentially may contribute to the oral and oropharyngeal carcinogenesis.[2]

Tobacco and alcohol abuse are the most common etiologies for oral cavity, hypopharynx, larynx, and human papillomavirus (HPV)-unrelated oropharynx cancers. These tumors affect the patient's basic physiologic functions, the senses, uniquely human characteristics. [3]

Cancer in the oral cavity is most seen in the tongue, the floor of the mouth, the retromolar region, the alveolar ridge, the hard palate, and the buccal mucosa following suit.[4]

Treatment for HNC varies depending on the stage of the illness, the anatomical location, and surgical accessibility, thus evaluation by a multispecialty team is critical[4]. Multidisciplinary treatment, as well as the cooperation of several medical professionals, is required for structural and functional preservation, reduction of morbidity, and long-term maintenance of quality of life. [5]

Radiotherapy (RT) is one of the most effective treatments for cancer that plays an important role in the treatment of both resectable and unresectable.[6,7] By excluding some healthy tissues from the planning target volume (PTV), the OPRS aims to decrease the radiation dose absorbed by healthy structures and minimize the side effects caused by RT. [9-11]

Toxicity following radiotherapy is described as harmful events or problems that arise because of radiation include any temporary or permanent damage in normal tissues, Mucositis, dermatitis, dysphagia and odynophagia, hoarseness of voice and loss of taste due to laryngeal edema are common acute toxicities. On the other hand, osteoradionecrosis, xerostomia, subcutaneous fibrosis, thyroid dysfunction, trismus, sensorineural hearing loss, myelitis, and pharyngeal or oropharyngeal stenosis are common late toxicities.[12]

One of the most common ionizing radiation toxicities and normal tissue damage caused by radiotherapy is radiation-induced oral mucositis (RIOM). It develops as an acute inflammation of the oral mucosa, tongue, and throat that lasts between 7 and 98 days after radiotherapy.[13, 14]

Salivary glands are usually affected by head and neck radiation, which results in a decrease in salivary flow rate and a change in salivary composition. The amount of radiation-induced salivary dysfunction is determined by the radiation dosage, the volume of irradiated gland tissue, and the type of the irradiated salivary glands. [16,17]

Oral radiation stents are individualized devices that aim to reduce the negative effects of radiotherapy in the head and neck area by limiting radiation exposure to healthy tissues adjacent to the treatment target volume.[17-19]

These placement stents can also be utilized to raise the jaws vertically, position the mandible out of the radiation field, or restrict the affected mandible inside the radiation field[20,21]. Extra-oral fixation is done by using thermoplastic masks which immobilize patients and reduce fluctuations in patient setup, these masks may support the head and neck, but the tongue and mandible remain able to move without use positioning radiation stent.[22-24]

The conventional workflow is often challenging due to the need for multiple appointments together with the laboratory work. Although conventional techniques have worked valuably for decades, using CAD/CAM system has countless options for preserving oral health and minimized treatment time, decreased error potential and better-quality assurance.[25]

Digital technology is widely used in all the branches of prosthodontics.[26] Using these technologies, several types of restorations and dental prostheses can not only be designed but also machined with accuracy and precision. [27-29]

The following techniques are employed for 3D printing of various applications in dentistry: Stereo-lithography (SLA), Fused Deposition Modeling (FDM), Photopolymer Jetting, Electron Beam Melting (EBM), Power binder printers, Direct light processing Stereo-lithography and Selective Laser Sintering.[30]

The conventional technique for radiation positioning stent fabrication is often challenging due to the need for multiple appointments for impression making, mounting, wax pattern adjustment and extra time for processing the final prosthesis and necessary clinical experience.[8]

This study was conducted to compare different construction techniques of positional prosthesis and to reveal their effect during radiation therapy on oral healthy tissues, salivary PH.

The null hypothesis was that no difference will be found between the conventional and digital construction techniques of the positional radiation stent regarding to their effect on the health of oral tissues and salivary PH together with patient satisfaction.

Materials and methods

Sixteen patients with HNC were enrolled for this study and were selected from those who attended the outpatient clinic of the Department of Clinical Oncology -Tanta University. The patients were divided randomly using block randomization[31] into two equal groups, a block size of 4 was chosen and all possible balanced combinations of assignment within the block were calculated. Blocks were then randomly chosen to determine the participants' assignment into the groups. Group A: OPRS was constructed according to the conventional technique. Group B: OPRS was constructed digitally using CAD /CAM technology.

The study was approved by the Research Ethics Committee, Faculty of Dentistry, Tanta University (R-2-21-8). ClinicalTrials.gov Identifier: NCT06353724

Inclusion and exclusion criteria

The inclusion criteria for in the study were: age between 20-40 years old, Inter-arch distance ≥ 1.5 cm and acceptable oral hygiene.

The exclusion criteria for this study were: patients with conditions that limited the construction of the stent (e.g., gross tumor block most of the oral cavity, sever limited mouth opening), patients with recurrent cancerous lesions, edentulous patients, previously radiotherapy for head and neck and smoking.

The following steps were done for all patients:

Personal and medical history were recorded, and panorama X-Ray was done. Mouth preparation was performed before the beginning of treatment which include elimination of all septic focus in the oral cavity, periodontal treatments (scaling / pocket eradication), conservative treatment to restore any carious tooth and extract any hopeless teeth. Mouth opening measurements were obtained to delineate the occlusal plate distance of the OPRS.

Sample size of the study:

The sample was collected based on a previous study. [24] The significance level was

0.05 and the power sample size was more than 80% for this study and the confidence interval 95% and the actual power is 95.99%. The sample size was calculated using a computer program G power version 3.

$$\text{Sample size} = \frac{Z^2\widehat{P}(1-\widehat{P})}{C^2}$$

Where:Z = Z value (1.96 for 95% confidence level), p = percentage picking a choice, expressed as decimal and c = confidence interval, expressed as decimal.

Stent design

All oral positioning radiation stents were designed after consultation with the attending radiotherapist regarding the set-up of radiation fields and the tissues to be spared.

For group A (conventional workflow)[23]

1. Maxillary and mandibular silicone impression were made and poured in dental stone.
2. The appropriate mouth opening for each patient ranged between 10 -20 mm was planned according to the radiotherapist's advice.
3. Suitable inter-occlusal distance was obtained, and the casts were mounted on the articulator then wax pattern of the OPRS was developed by making horseshoe wax block which was then attached to a double layer of baseplate wax to create a tongue-stabilizing plate.
4. The occlusal portions of the wax blocks were softened with heat and brought to the mouth, and indentations of the occlusal surface of mandibular and maxillary teeth were recorded.
5. After that, the wax pattern was tried and adjusted on the casts and processed in heat-polymerized acrylic resin.
6. Guiding tongue index (opening) was opened in the anterior part of the tongue barrier just lingual to the lower anterior teeth to function as a guide for tongue position.
7. Finishing & polishing were done as the conventional steps for acrylic prosthesis (Figure 1).
8.

Figure (1): Conventional OPRS.

For Group B (digital workflow)

Intraoral scanning:

Intraoral scan was done using Medit i500 intraoral scanner which was used to generate 3D images: the first of the upper arch, the second of the lower arch, and the third of the maximum inter-cuspation.

Steps of digital oral positioning radiation stent design (Figure 2 a-b-c-d):

- Virtual articulator was started, and the models were mounted parallel to the occlusal plane, the midline centralized according to the incisal pin, adjust the articulator angles according to the average range (the condylar angle 35 & bennet angle 15), A virtual wax up option was chosen to block out all the teeth undercuts according to the chosen bath of insertion (no tilting was selected) and the selected base thickness of the stent was 2 mm.
- The selection (Attached parts) was used to attach upper and lower stents to form the inter-incisal distance, (+Add) selected and 3D shapes were used, one for the anterior part and two for the posterior, one for each side, then oval shape was selected to form the tongue barrier.

- To form guiding tongue index, (X Subtract) selected and oval shape was used to open a slot in the tongue barrier just lingual to the lower anterior teeth.
- The finished 3D design was saved as STL file which was sent to (chitubox) program to start the process of 3D printing, after 3D printing was finished the digital stent retrieved and the supports were removed (Figure 3).

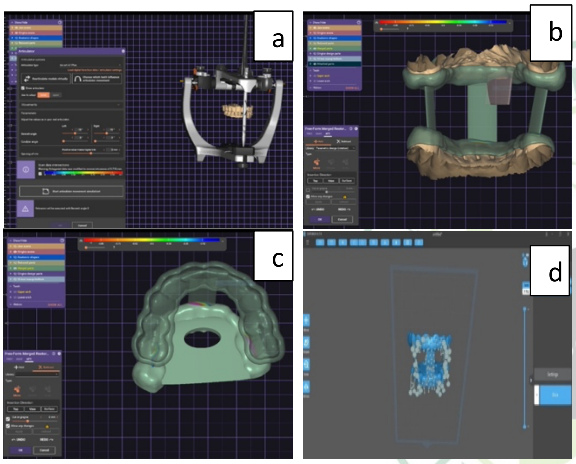

Figure 2: Steps of digital oral positioning radiation stent design, a. The models mounted using the virtual articulator, b.(+Add) option, c.(X Subtract), d.The supports selection on (chitubox) program

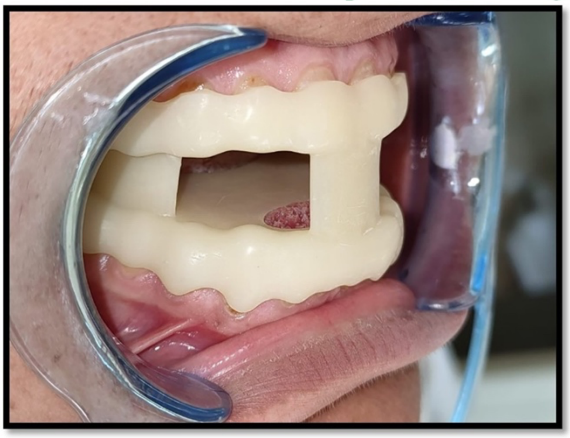

Figure (3): Digital OPRS.

Insertion

For both groups oral positioning radiation stent was inserted and checked for any necessary adjustment.

Radiotherapy techniques and dose distributions:

All patients were referred to the RT department for Intensity-modulated radiotherapy (IMRT) planning. The intraoral stent was inserted. Then, patient was immobilized by thermoplastic mask which was customized by placing the mask in hot water (45º degree) for 15 minutes then applied it on the face of the patient while lying down and let it to cool down for 5 minutes (Figure 4).

Figure (4): Thermoplastic Mask.

A computed tomography scan was conducted, all patients were scanned with the OPRS and without it, then all patients completed the radiotherapy sessions for 30 days using OPRS together with the extra oral immobilization masks.

Methods of evaluation

1. Dosimetric analysis: [11]

To quantify the radiation dose in the maxilla, it was defined and contoured in CT pre irradiation planning using ECLIPSE software to each patient with the stent and without it (Figure 5 a-b).

The mean corresponding dose of each structure was acquired using a dose volume histogram DVH. All patients completed the radiotherapy sessions using OPRS together with the extra oral immobilization masks.

2. Mucositis assessment:[12,32]

The severity of mucositis in maxillary oral mucosa (OAR) was assessed weekly by clinical examination from the beginning of

RT to the end of the treatment at RT department (table 1). The grading was scored from 0 to 4 in accordance with the National Cancer Institute for Common Terminology Criteria for Adverse Events (NCI-CTCAE).

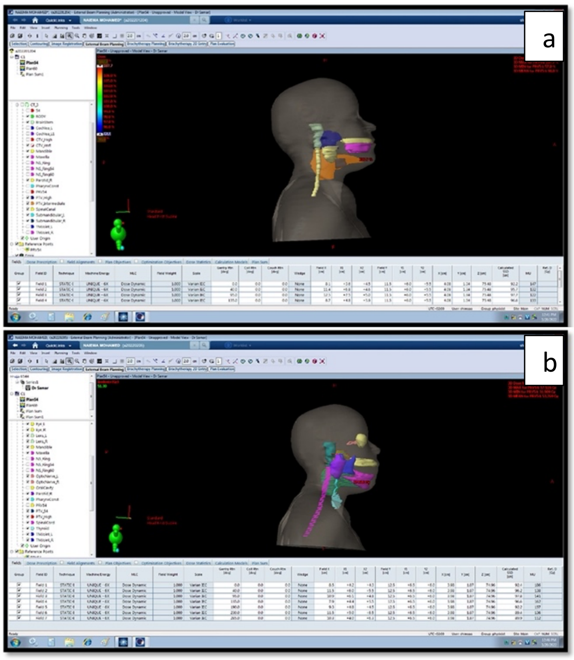

Figure 5: Contouring OARs using ECLIPSE software without the stent (a) and with it (b).

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp) Qualitative data were described using number and percent. The Shapiro-Wilk test was used to verify the normality of distribution Quantitative data were described using range (minimum and maximum), mean, standard deviation, median and interquartile range. Significance of the obtained results was judged at the 5% level.

Table 1: Mucositis grading in accordance with the (NCI-CTCAE)

Grade	Description
0	None
1	Erythema of the mucosa
2	Patchy pseudomembranous reaction (patches generally ≤1.5 cm in diameter and noncontiguous)
3	Confluent pseudomembranous reaction (contiguous patches generally >1.5 cm in diameter)
4	Necrosis or deep ulceration; may include bleeding not induced by minor trauma or abrasion

The used tests were:

- Fisher's Exact or Monte Carlo correction: Correction for chi-square when more than 20% of the cells have expected count less than 5.
- Student t-test: For normally distributed quantitative variables, to compare between two studied groups.
- Paired t-test: For normally distributed quantitative variables, to compare between two periods.
- Chi-square test: For categorical variables, to compare between different groups.

Results

Table (1) shows the mean ± SD values of radiation dose received by the maxilla. Each patient was evaluated once with an oral positioning stent and once without it.

Maxilla	Group A (n = 8)	Group B (n = 8)	P
With stent			
Mean ± SD.	30.65 ± 14.17	20.13 ± 5.06	0.105
Median (Min. – Max.)	32.50 (10.08 – 47.55)	19.29 (13.69 – 27.50)	
Without stent			
Mean ± SD.	46.61 ± 22.25	38.77 ± 13.85	0.328
Median (Min. – Max.)	54.33 (11.26 – 66.90)	35.55 (23.04 – 54.50)	
(p_0)	(0.012*)	(0.036*)	

SD: Standard deviation, p: p value for comparing between the two studied groups, p_0: p value for comparing between with and without stent, *: Statistically significant at $p \leq 0.05$

Table (2): Comparison between the two studied groups in accordance with the mucositis.

Mucositis	Group A (n = 8)		Group B (n = 8)		χ^2	p
	No.	%	No.	%		
1st week						
Grade 0	6	75.0	3	37.5	2.286	$^{FE}p=$ 0.315
Grade1	2	25.0	5	62.5		
Grade2	0	0.0	0	0.0		
Grade3	0	0.0	0	0.0		
2nd week						
Grade 0	1	12.5	2	25.0	4.523	$^{MC}p=$ 0.160
Grade 1	7	87.5	3	37.5		
Grade 2	0	0.0	3	37.5		
Grade 3	0	0.0	0	0.0		
3rd week						
Grade 0	0	0.0	0	0.0	2.286	$^{FE}p=$ 0.315
Grade 1	6	75.0	3	37.5		
Grade 2	2	25.0	5	62.5		
Grade 3	0	0.0	0	0.0		
4th week						
Grade 0	0	0.0	0	0.0	3.692	$^{FE}p=$ 0.200
Grade 1	0	0.0	0	0.0		
Grade 2	8	100.0	5	62.5		
Grade 3	0	0.0	3	37.5		

χ^2: Chi square value, FE: Fisher Exact, no: Patients numbers, p: p value for comparing between the two studied groups.

Discussion

Radiotherapy remains a critical component of passive therapy in HNC. However, it is a great challenge to deliver dose accurately with minimal toxicity to the oral tissues. Spare normal adjacent tissue from the radiation dose together with delivering the optimal dose to the target prevent radiation toxicities such as dental caries, loss of taste, xerostomia, mucositis, trismus, and osteoradionecrosis lead to achieve better quality of life to the patients.[33]

In current study intraoral scan was used for Group B (digital group) to develop the exact impression of the dentition. So, each stent is customized to ensure position maintenance during RT sessions.

As regarded to previous study, The intraoral digital impression technique has a distinct superiority in work efficiency and saving of materials.[34]

The conventional and analogic workflow is often challenging due to the need for multiple appointments, intensive labor time, and necessary clinical experience.[28]

The advantages of 3D-printed OPRS in terms of dose distribution with reduction of the integral dose to the surrounding normal tissue was suggested by a study done by Kitamori et al.[35]

The conventional technique for radiation positing stent fabrication is often challenging due to the need for multiple appointments, stent construction using conventional technique took more than 2 days at least, while fabrication of the stent using the digital workflow took about 8 to 9 hours.[8] The time required for creation of the stent is very important. Delays in the initiation of radiotherapy have been shown to adversely impact survival for patients with head and neck malignancies, any acceleration in stent fabrication process can be useful for HNC patients. [36]

In this present study the Dosimetric analysis and DVH were used to compare the radiation dose in IMRT planning to each patient with and without using positing stent, two construction technique of the oral stents were used, OAR was the maxilla, a dose volume histogram was used to compare dose received by the maxilla; The results showed dose reduction with significant difference in the maxilla using stent to (30.65 ± 14.17) in Group A and (20.13 ± 5.06) in group B which is considered a significant reduction which is reflected in the health of the normal tissues and OARs, while no significant difference was found between the two studied groups comparing Group A and B in case of using the positioning stent and without using it.

The results of this study agreed with other study which had found that the combination of oral stent with highly conformal RT techniques could be help in reducing adverse effects of RT and spare oral hard and soft tissues that could be more safely manageable also in terms of subsequent prosthetic rehabilitation. This results in enhanced masticatory function and better quality of life and observed that the combination of intra oral stent and advanced radiation techniques was able to further diminish radiation doses to OARs. This permitted a better tolerance to treatment with no need for suspension.[37]

A customized intraoral stent yielded a relative dose reduction of around 60% to the opposing jaw in agreement with our findings.[38] The reduction of radiation dose reflects in oral tissue affection and decreases the toxicity and severity of radiation and give rise to the possibility of future recovery of such tissues. [39]

In the present study, RIOM increased weekly but still within grade I, II, 100% of group A developed grade II, 62% of group B developed grade II only 37.5% of Group B developed Grade III at the end of the radiotherapy sessions without significant difference between the two Groups. This means that the RIOM was within the tolerable range due to radiation dose reduction by using oral positioning stent together with IMRT technique and accurate planning to the radiotherapy treatment plane. This technique did not lead to interruption to the radiotherapy treatment or impair normal life activities, while no significant difference was found between the two studied groups comparing Group A and B in case of using the positioning stent and without using it.

In agreement with Christopher Herpel et al[40] for our results, acute RIOM of grade I or II occurred using oral positioning stent and none of the patients developed a severe form of acute RIOM (grade IV) indicate that tissue retraction by using intra oral device had a beneficial effect on reducing acute toxicity.

The evaluation of oral adverse effects, using intra oral positioning stent has a positive effect on decreasing the severity of RIOM, as only grade II oral mucositis occurred at 13 days of RT on both lateral borders of the tongue, bilateral buccal mucosa, and lower labial mucosa and no oral ulcers were seen in the palate or upper labial mucosa. Moreover, the decrease in xerostomia severity probably resulted from the lower radiation dose in both parotid and left submandibular glands by depressing the mandible.[21]

The tied relation between prosthodontist and radiotherapist supports the treatment plan of HNC patient and participates in reducing harmful tissue affection, especially on using quick and successful positional stent.

Conclusions

Within the limitations of this study, it could be concluded that:

1. Oral positioning radiation stent can be considered as an important therapeutic modality for HNC patients' immobilization, which decreases the intensity of radiation toxicity.
2. The method used in the construction of OPRS has no effect on how efficiently it controls radiation exposure.

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