CLINICAL RESEARCH

Period between Completion of Radiation Therapy and Prosthetic Rehabilitation in Edentulous Patients: A Retrospective Study

Peter J. Gerngross, DDS, MS;[1] Charles D. Martin, PhD, MBA;[2] John D. Ball, DDS;[3] Robert L. Engelmeier, DMD, MS;[4] Harry D. Gilbert, DDS;[5] John M. Powers, PhD;[6] Sena Narendran, DDS, DDPH, MSc;[7] and Mark S. Chambers, DMD, MS[8]

Purpose: **The primary purposes of this study were: (1) to describe the number and types of complications patients had before and after insertion of a removable prosthesis (i.e., denture) following radiation therapy to the head and neck and (2) to investigate whether the time between radiation therapy and denture insertion might contribute to those complications.**

Materials and Methods: **This research evaluated edentulous patients and those who were rendered edentulous as a result of their cancer treatment. After obtaining institutional approval following HIPAA regulations, a total of 349 charts were identified: 152 patients from Houston Veterans Administration Medical Center (HVAMC) and 197 patients from M. D. Anderson Cancer Center (MDACC). A total of 190 patients met the inclusion criteria with data available for review.**

Results: **No significant differences were found in any of the comparisons made, except when comparing complications that occurred after the dentures were inserted and the amount of time it took for prosthetic rehabilitation. The majority of patients had no complications. The patients who received their dentures in 180 days or less had the same number of complications when compared with those patients who received their dentures in 181 to 365 days and those who had to wait longer than a year for prosthetic rehabilitation. Patients with more pre-insertion complications tended to have delayed prosthetic rehabilitation. Those patients who had complications both before and after denture insertion tended to have bilateral dosing of their radiation treatment. Patients who had received radiation therapy were 1.7 times more likely to have post-prosthesis insertion complications. The majority of patients who experienced complications before and after denture insertion had greater than 5000 cGy.**

Conclusions: **The numbers of complications reviewed in this retrospective analysis were considerably fewer than the number expected. There appears to be no difference in the number of pre- and post-insertion complications as a function of the time delay from oral surgical procedure to start of radiation treatment (10 to 21 days vs. 22 days or more).**

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[1]*Maxillafacial Prosthodontist, Veteran's Administration Hospital, Houston, Texas.*

[2]*Assistant Professor (retired), Department of General Internal Medicine, MDACC, Houston, Texas.*

[3]*Assistant Chief, Central Dental Lab, Veteran's Administration North Texas Health Care System, Dallas, Texas.*

[4]*Professor and Director, Graduate Prosthodontics, The University of Texas, Health Science Center at Houston, Dental Branch, Houston, Texas.*

[5]*Chairman, Dental Services, Veteran's Administration Hospital, Houston, Texas.*

[6]*Associate Dean for Research and Professor, Department of Restorative Dentistry and Biomaterials, and Director, Houston Biomaterials Research Center, University of Texas Health Science Center at Houston, Dental Branch, Houston, Texas.*

[7]*Professor, Department of Epidemiology, The University of Texas, Health Science Center at Houston, Dental Branch, Houston, Texas.*

[8]*Associate Professor, Department of Head and Neck Surgery, Department of Radiation Oncology, MDACC, Houston, Texas.*

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Correspondence to: Dr. Mark S. Chambers, The University of Texas, M. D. Anderson Cancer Center (MDACC), Department of Head and Neck Surgery, Section of Oncologic Dentistry, Box 441, 1515 Holcombe Boulevard, Houston, TX 77030-4009. E-mail: mchamber@mdanderson.org

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THE MOST recent data in the United States, compiled from the Surveillance, Epidemiology, and End Results (SEER) Program, show that although the demographics of oral cancer changed between 1973 and 1996, there was little change in overall 5-year survival rates during this period.[1] In the year 2004, an estimated 40,000 new cases of oral and pharyngeal cancers will be diagnosed, accounting for 3.0% of the total number of new cancer cases.[2] Approximately 50% of patients diagnosed with an oral or pharyngeal cancer will be alive 5 years after the diagnosis.[3]

A survey conducted in the late 1960s by Elzay et al found that 56% of prosthodontists and 68% of radiotherapists (combined response, 63%) recommended that dentures be worn at any time after mucositis subsides.[4] Among the respondents, 25% believed that dentures could be worn 1 year after radiation therapy if the mucous membranes appeared healthy. Most of the prosthodontists surveyed believed it was impossible to make a denture that did not produce trauma to the oral mucosa. Although the majority of those surveyed felt dentures could be worn at some time, there was no consensus as to a specific time. The authors suggested that dentists should be knowledgeable of the effects of radiation and should be particularly careful when treating irradiated patients.[4]

The treatment modalities for oral cancer can drastically affect quality of life.[5-9] The morbidity of head and neck irradiation, for instance, include xerostomia, laryngeal edema, trismus, hearing loss, facial hair loss, and loss of taste.[10-14] Patients who keep their teeth are susceptible to rampant dental caries, and all oral cancer patients can develop osteoradionecrosis (ORN) that could lead to gross disfigurement or death.[15-21] The literature on oral cancer presents an array of philosophies ranging from conservative treatment involving maintenance of dental health to more invasive approaches involving surgery or the extraction of all teeth.[22-27]

Optimal health, particularly in the oral cavity, before the initiation of radiation therapy reduces the risk of complications resulting from therapeutic administration of ionizing radiation administered to the head and neck.[24-27] These complications can be categorized as either acute (e.g., mucositis, infectious stomatitis, alteration of taste or smell acuity, dermatitis, pain, inflammation, dysphagia, or odynophagia) or chronic (e.g., ORN, xerostomia, caries, abnormal development, fibrosis, trismus, photosensitivity, or pain).[27-31] The severity of treatment-induced morbidity depends on multiple factors, including the radiation dose, energy source, volume of tissue treated, pretreatment performance status, and pretreatment periodontal condition. The volume of tissue irradiated is susceptible to dermatitis and mucositis, which are often accompanied by salivary gland hypofunction, dysgeusia, dysphagia, odynophagia, hypovascularity of soft and hard tissues, fibrosis, or trismus.[27-31]

Along with facing surgery, radiation therapy, and chemotherapy, many patients may have to consider having their remaining teeth removed. It is important for dentists to inform patients what their dental future can hold and to discuss the risks and benefits of each treatment option. After receiving dentures, patients can experience additional complications. The decision to fabricate dentures for use by a patient after radiation therapy depends on the patient's oral status as well as the treatment philosophy of the restoring dentist. The dentist may decide to never make a patient a set of dentures or to wait up to 2 years before rehabilitating a patient. Many patients, however, will receive their dentures within 2 to 6 months after completion of radiation therapy.[4,5]

Common complications experienced by patients following denture insertion include pressure areas, pain, erythema, increased gag reflex, fibrosis leading to trismus, and decreased salivary flow.[32] Many dental professionals believe that such complications are usually seen in the first 12 months after radiation therapy. Pressure areas, ulcers, and erythema are some of the acute oral complications expected to occur within 24 hours after insertion. Other complications involving hard tissue do not arise for several days or weeks. A properly made denture, well adapted to the oral mucosa, can still have post-insertion complications in patients who have had cancer therapy.[27]

The present study involves edentulous patients and those who were rendered edentulous as a result of their cancer diagnosis and treatment. The primary purposes of this study were to: (1) describe the number and types of complications patients had before and after removable prosthesis (i.e., denture) insertion following radiation therapy

to the head and neck, and (2) investigate the relationship between those complications and the time between radiation therapy and denture insertion.

Materials and Methods

As regulated by federal policies of the Department of Health and Human Services, this protocol was formatted into institutional applications for research at The University of Texas M. D. Anderson Cancer Center (MDACC), Houston Veterans' Affairs Medical Center (HVAMC), Baylor College of Medicine, and The University of Texas-Houston Health Science Center. Applications, support documentation, and assurance policies (HIPAA) were successfully completed for each required Institutional Review Board (IRB) approval process.

Patient Selection

The study population for this retrospective study consisted of patients from MDACC and HVAMC. Every effort was made to record the following information from the patient record: chart number, gender, date of birth, past medical history, social history, tumor stage, tumor location, radiation start date, radiation completion date, total dose of radiation, fractionation, bid dosing, volume of tissue irradiated, surgical procedures for tumor removal, induction or concurrent chemotherapy, oral/dental status, dental surgery, complications pre-denture insertion, initial impression, final impression and denture insertion, and complications post-denture insertion. The radiation summary was also used to obtain this information. Whenever possible, a date was recorded to correspond to events where applicable.

At MDACC, using billing records for radiation and prosthetic rehabilitation from 1991 to 1999, 211 patients were identified; 197 charts were located and reviewed. At the HVAMC, the tumor board summaries from 1991 to 1999 were used, and 394 patients were identified out of which 152 were treated in the dental clinic. Thus, the total study population was 349.

Of the total study population, 236 patients had the majority of the data required for inclusion into the study. Forty-six patients had to be excluded from the study for the following reasons: 13 patients had dentures made before radiation therapy, 8 died before insertion of dentures, 6 had radiation data missing, 6 had no staging information available, 6 were lymphoma patients, 2 had denture relines, 2 had no record of dentures, 1 the insertion date could not be found, 1 patient died with a bony exposure before dentures were made, and 1 patient was lost to follow-up. Of the 349 charts reviewed, 190 charts had all the data required to be included in this study. These data included gender, date of birth, tumor-node-metastasis (TNM) staging, dental status preradiation treatment, radiation dose, date of start of radiation, date of completion of radiation, dosing, volumes, dates of pre-denture insertion complications, description of the complication, date of denture insertion, date of any post-insertion complications, and description of the complication.

The recordings of the complications for this study were summarized from physician notes. No attempt was made to interpret a qualitative description as a definition. Specifically, no attempt was made to classify bony exposures by size or duration in order to define them as an ORN. The tumors were staged using The American Joint Committee on Cancer TNM classification system. The data collected had various end points. The first was duration of time, determined by counting the number of days between the completion of radiation therapy and the day the dentures were delivered to the patients (insertion). The groupings of these days were 90, 180, 365, and more than 365 days. The next set of data recorded were the complications that occurred between the completion of radiation therapy and prosthesis insertion: these were termed pre-prosthesis insertion complications. Post-prosthesis insertion complications were recorded after the dentures were inserted. A complication was defined as a patient visit that was not part of routine denture fabrication.

Radiation therapy was grouped into categories on the basis of dose: 0 to 5000 cGy, 5001 to 6000 cGy, 6001 to 7000 cGy, and 7001 cGy or more. A Gray was defined as 1 joule per kilogram and was the amount of energy absorbed per unit mass. The volume of tissue irradiated was defined as a unilateral (ipsilateral) dose, which involved 1 to 3 salivary glands or a bilateral dose, which involved 4 or more salivary glands (Fig 1). Tables were created using time, number of complications pre- and post-prosthesis insertion, total dose of radiation, volume of tissue irradiated, and days between completion of oral surgery and the start of radiation therapy.

Statistical Methods

Continuous variables such as days between treatment and dental insertion were described using means and standard deviations. Categorical variables such as number of complications were reported as frequencies. Continuous variables were also divided into categories, such as months being divided into days, where categorization would aid in analysis and interpretation.

Two-way contingency tables were created to assess the relationship between time to prosthesis insertion

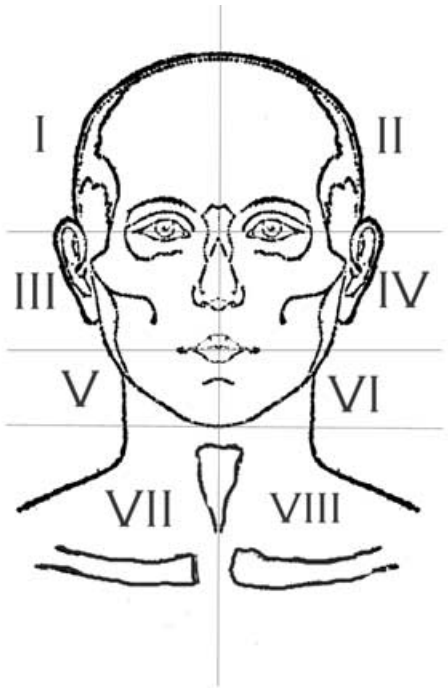

Figure 1. Radiation Zones: Zones I to VIII separate the major salivary glands into individual areas.

and complications both pre- and post-prosthesis insertion, pre- and post-prosthesis insertion complications, total dose of radiation and time to prosthesis insertion, total dose of radiation and pre-prosthesis insertion complications, total dose of radiation and post-prosthesis insertion complications, volume of tissue irradiated and time to prosthesis insertion, volume of tissue irradiated and pre-prosthesis insertion complications, volume of tissue irradiated and post-prosthesis insertion complications, pre-prosthesis insertion complications as a function of days between oral surgery and radiation, and post-prosthesis insertion complications as a function of days between oral surgery and radiation.

These tables were analyzed using the Pearson Chi-square statistic with Yates corrections and the Fisher exact test. The Fisher test was used in analyses where the small sample sizes made the Chi-square test inappropriate. The significance level was set at 0.05. The Statistica® computer program (Stat Soft Inc., Tulsa, OK) was used for the analysis. The tables were recorded as 2 × 2 tables, and an odds ratio (OR) analysis was performed using EpiInfo® (CDC, Atlanta, GA). The OR provides an estimate with confidence interval for the relationship between 2 binary variables and allows the examination of the effects of other variables on that relationship using logistic regression. The OR was computed at a 95% confidence level. Log-linear models were also used to assess relationships between 2 variables when influenced by a 3rd variable. Because of the small sample sizes, the log-linear analysis and the logistic regressions had little power and the results were not informative. As this was an exploratory study, actual *p*-values were reported. A *p*-value as low as 0.20 indicated a potential relationship that would require further study. As in many retrospective chart review studies, much of the data were incomplete. No attempt was made to use statistical methods to account for missing data.

Results

Of the 190 patients, 115 (60.5%) were alive at the completion of the review of the records. All but 12 patients (6.3%) had some history of tobacco and or alcohol use; 156 patients (82.1%) were men. Only 53 patients (27.9%) had received some form of chemotherapy, whereas 34 (17.9%) had twice daily dosing of their radiation as compared to traditional daily dosing.

The prevalence of ORN among the study population was 2.1% among the 190 patients. This information was taken directly from the notes in the charts and no attempt was made to interpret other bony exposures as an ORN. Of the 4 cases, 2 developed ORN before denture insertion and 2 developed after denture insertion. One post-insertion ORN patient received hyperbaric oxygen (HBO) therapy. All cases of ORN were resolved with either surgical intervention, or by augmenting wound healing capacity with hyperbaric oxygen therapy. A total of 6 (3.2%) patients (including the patients with ORN) received HBO. Four of them had the treatments completed before they had their dentures fabricated. The HBO treatments were completed at outside hospitals and established guidelines were observed with 30 to 50 treatments delivered at 2.2 to 2.4 ATA (90-minute treatments) and patients breathing 100% oxygen throughout the course of HBO therapy.

The majority of patients experienced no oral complications; however, 35 (18%) experienced pre-prosthesis insertion complications, and 53 (28%) experienced post-prosthesis insertion complications. The majority of patients (92%) received their dentures after 90 days.

Table 1. Pre- and Post-Prosthesis Insertion Complications

Pre-Prosthesis	
Exposed bone	24
Sequestrum removal	14
Sensitive/erythematous areas	5
Delayed treatment	5
Ulcer	4
Hematoma	1
Post-Prosthesis	
Ulcer	15
Exposed bone	13
Sequestrum removal	12
Denture sore/pressure areas	10
Sensitive/erythematous areas	5
Stopped wearing denture	4
Failed implant	3
Leukoplakia	2
Reline (under 6 months)	1
Reset new bite	1

Reviewing population characteristics, the majority of the patients (85.3%) were over 50 years of age when they started radiation treatment. Only 1 patient was younger than 40 years of age. The distribution of tumor size as reflected by the T classification in the TNM staging system revealed the majority of patients (78.9%) had a tumor that was more than 2 cm in size. Few tumors (13.1%) were detected when less than 2 cm in size.

Complications were grouped by similar descriptions. Table 1 describes the number and types of complications before and after denture insertion. The descriptions in these tables reflect the descriptions of the complication as noted by the clinicians in their reports. If a patient had multiple complications of the same type, it was only recorded once. The majority of pre-prosthesis insertion complications involved hard tissue, whereas the most frequently described complication after the dentures were inserted involved the soft tissues.

Table 2 shows the relationship between time elapsed prior to insertion of the prosthesis and number of complications experienced by patients before their prostheses were inserted. The majority of patients (81.6%) had no complications, whereas 18.4% experienced complications. The data reveal that there is a tendency towards more complications for patients who waited a year or more for their prosthesis ($\chi^2 = 20.3$, $df = 12$, $p = 0.06$). This statistical analysis indicates that there may be a relationship between time to prosthesis insertion and number of pre-prosthesis insertion complications ($\chi^2 = 3.65$, $df = 1$, $p = 0.06$).

Table 3 relates the number of complications experienced before prosthesis insertion to the complications experienced after prosthesis insertion. This table was created to determine whether the same patients had complications before and after prosthesis insertion. This statistical analysis

Table 2. Pre-Prosthesis Insertion Complications Versus Time to Prosthesis Insertion

Number of Oral Complications	*Number (Percents of Row Totals)*				
	0–90 Days	*91–180 Days*	*181–365 Days*	*366 + Days*	*Total*
0	12 (7.7)	55 (35.5)	45 (29.0)	43 (27.7)	155 (100.0)
1	1 (6.7)	2 (13.3)	7 (46.7)	5 (33.3)	15 (100.0)
2	2 (18.2)	2 (18.2)	4 (36.4)	3 (27.3)	11 (100.0)
3	0 (0.0)	2 (50.0)	0 (0.0)	2 (50.0)	4 (100.0)
4+	0 (0.0)	0 (0.0)	0 (0.0)	5 (100.0)	5 (100.0)
Total	15 (7.9)	61 (32.2)	56 (29.5)	58 (30.5)	190 (100.0)

$\chi^2 = 20.3, df = 12, p = 0.06.$

Collapsed Table

Number of Days	*Number (Percents of Row Totals)*		
	1 + Complication	*0 Complications*	*Total*
181+	26 (22.8)	88 (77.2)	114 (100.0)
0–180	9 (11.8)	67 (88.2)	76 (100.0)
Total	35 (18.4)	155 (81.6)	190 (100.0)

$\chi^2 = 3.65, df = 1, p = 0.06.$
OR = 2.20 (95% CI = 0.91,5.45).

Table 3. Pre-Prosthesis Insertion Complications versus Post-Prosthesis Insertion Complications

	Number (Percents of Row Totals)					
	0 Complications After Insertion	*1 Complication After Insertion*	*2 Complications After Insertion*	*3 Complications After Insertion*	*4+ Complications After Insertion*	*Total*
0 Complications before insertion	115 (74.2)	20 (12.9)	7 (4.5)	6 (3.9)	7 (4.5)	155 (100.0)
1 Complication before insertion	9 (60.0)	5 (33.3)	0 (0.0)	0 (0.0)	1 (6.7)	15 (100.0)
2 Complications before insertion	6 (54.5)	2 (18.2)	0 (0.0)	1 (9.1)	2 (18.2)	11 (100.0)
3 Complications before insertion	3 (75.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (25.0)	4 (100.0)
4 + Complications before insertion	4 (80.0)	0 (0.0)	0 (0.0)	1 (20.0)	0 (0.0)	5 (100.0)
Total	137 (72.1)	27 (14.2)	7 (3.7)	8 (4.2)	11 (5.8)	190 (100.0)

$\chi^2 = 18.6, df = 16, p = 0.29.$

Collapsed Table

	Number (Percents of Row Totals)		
	Complications	*No Complications*	*Total*
Post-prosthesis insertion complications	53 (27.9)	137 (72.1)	190 (100.0)
Pre-prosthesis insertion complications	35 (18.4)	155 (81.6)	190 (100.0)

$\chi^2 = 4.79, df = 1, p = 0.30.$
OR = 1.71 (95% CI = 1.03, 2.80).

indicates that it is unlikely there is any relationship between pre- and post-prosthesis insertion complications ($\chi^2 = 18.6, df = 16, p = 0.29$). A collapsed table reveals that an irradiated patient was 1.7 times more likely to have a post-prosthesis insertion complication than a pre-prosthesis insertion complication (OR = 1.71; 95% CI = 1.03, 2.80).

Table 4 shows the number of complications after prosthesis insertion as a function of length

Table 4. Post-Prosthesis Insertion Complications versus Time to Prosthesis Insertion

Number of Oral Complications	*Number (Percents of Row Totals)*				
	0–90 Days	*91–180 Days*	*181–365 Days*	*366 + Days*	*Total*
0	8 (5.8)	46 (33.6)	37 (27.0)	46 (33.6)	137 (100.0)
1	6 (22.2)	4 (14.8)	12 (44.4)	5 (18.5)	27 (100.0)
2	1 (14.3)	4 (57.1)	2 (28.6)	0 (0.0)	7 (100.0)
3	0 (0.0)	2 (25.0)	2 (25.0)	4 (50.0)	8 (100.0)
4+	0 (0.0)	5 (45.5)	3 (27.3)	3 (27.3)	11 (100.0)
Total	15 (7.9)	61 (32.1)	56 (29.5)	58 (30.5)	190 (100.0)

$\chi^2 = 21.6, df = 12, p = 0.04.$

Collapsed Table

	Number (Percents of Row Totals)		
Number of Days	*1 + Complication*	*0 Complications*	*Total*
181+	31 (27.2)	83 (72.8)	114 (100.0)
0–180	22 (29.0)	54 (71.0)	76 (100.0)
Total	53 (27.9)	137 (72.1)	190 (100.0)

$\chi^2 = 0.07, df = 1, p = 0.79.$
OR = 0.92 (95% CI = 0.46, 1.84).

of time before a prosthesis was inserted. The majority of patients (72.1%) had no complications. The group of patients who had complications comprised 27.9% of the patient pool. Those patients who received their dentures in the first 6 months tended to have fewer complications, while those who received them after 6 months tended to have a slightly increased number of complications ($\chi^2 = 21.6$, $df = 12$, $p = 0.04$). Collapsing the data reveals no association between such variables (OR = 0.92; 95% CI = 0.46, 1.84).

The next group of data compared total radiation dose to the tumor with the time it took for the patient to receive the final prosthesis. There were few patients (n = 17) who had any complications at doses below 5000 cGy, so the first group has a large range of total dose of radiation. The higher doses of radiation induced more complications; these doses were separated into 1000 cGy increments. Only 8.9% (17 of 190) of the patients received less than 5000 cGy of radiation, whereas the largest group of patients—49.5% (94 of 190) received 6001 to 7000 cGy of radiation. Of the patients who received higher doses of radiation, 40% had their dentures within 6 months of completing radiation therapy ($\chi^2 = 12.9, df = 9, p = 0.16$). This statistical analysis indicated that it was unlikely there was any relationship between total dose of radiation and time to prosthesis insertion. The collapsed analysis revealed that there was no association between such variables (OR = 0.5; 95% CI = 0.34, 3.19).

The majority of patients (81.6%) had no complications before denture insertion regardless of the amount of radiation they received. Of the patients who received less than 5000 cGy of radiation, 1.1% (2 of 190) developed minor complications. The patients who received more than 5000 cGy experienced greater complications; 17.4% (33 of 190) had complications ($\chi^2 = 7.14, df = 12, p = 0.85$). This statistical analysis showed there was no significant relationship between total dose of radiation and pre-prosthesis insertion complications. In comparing the number of complications patients experienced after they had their dentures with the amount of radiation they received, the majority of patients (72.1%) had no complications. Of the patients who experienced complications, 1.1% received less than 5000 cGy, whereas, as expected, most patients with complications (26.8%) received more than 5000 cGy of radiation ($\chi^2 = 8.84, df = 12, p = 0.72$).

In an effort to quantify the volume of tissue irradiated, the head and neck area was divided into 8 zones drawn to separate the major salivary glands (Fig 1). Using the final radiation summary, the zones irradiated for each patient were determined to identify which of the salivary glands were irradiated. This method also revealed whether patients received a unilateral or bilateral dose of radiation. The terms "unilateral" and "bilateral" were used to describe the volume of tissue irradiated.

The majority of patients (83.7%) received radiation bilaterally, which involved the majority of their salivary glands. The majority of patients with this bilateral dose (60%) received their dentures 6 or more months after completing radiation therapy. Patients who only had a unilateral dose were almost evenly divided, with 51.6% completing oral rehabilitation within 6 months of completing radiation therapy ($\chi^2 = 7.48, df = 3, p = 0.06$). This statistical analysis indicated a relationship between the volume of tissue irradiated and time to prosthesis insertion. Even with large volumes of tissue irradiated (bilateral), 79.9% (127 of 159) of the patients had no complications before denture insertion. Of the patients who experienced complications, the majority [91.4% (32 of 35)] had a large volume of tissue irradiated (bilateral dosing) ($\chi^2 = 5.99$, $df = 4$, $p = 0.20$). This statistical analysis indicated there was unlikely any relationship between the volume of tissue irradiated and the number of pre-prosthesis insertion complications. Additionally, 72.1% of the patients had no complications after dentures were inserted, even though they had a large volume of tissue irradiated (bilateral). In all cases of complications in this table, there were more patients (81.1%; 43 of 53) with complications in the group that had bilateral radiation dosing ($\chi^2 = 7.29, df = 4, p = 0.12$).

Finally, a comparison was made between the number of complications and the number of days between oral surgery and initiation of radiation therapy (occurrence of pre-prosthetic insertion complications and those after dentures were inserted). Forty patients were edentulous and therefore were not included. The majority of patients (82.7%) had at least 10 days before radiation therapy was started. Patients who had fewer than 10 days to heal, or whose oral surgery was completed after radiation therapy, had complications [11.5% (3 of 26)]. The majority of patients (66%) who had to wait at least 10 days to heal before

starting radiation therapy had no pre-prosthetic insertion complications ($\chi^2 = 4.24, df = 12, p = 0.98$). No association was found between the number of days before starting radiation therapy and the number of pre-prosthesis insertion complications. In contrast, 15.4% (4 of 26) of the patients who had fewer than 10 days to heal, or who had their oral surgery completed after radiation therapy, had complications after receiving their dentures. The majority of patients (72.0%) had no complications after their dentures were inserted ($\chi^2 = 13.2, df = 12, p = 0.35$). No relationship was observed in this group either between number of days waited before starting radiation and the number of post-prosthesis insertion complications.

Discussion

This was a retrospective study in which numerous charts were reviewed at 2 institutions. Although these institutions had different patient populations, treatments and outcomes for head and neck cancer patients were very similar. There are several faculty members who have privileges at both hospitals, which may account for the similarities in treatment modalities. Therefore, the authors believed that the data from the 2 institutions could be combined. The purpose for reviewing data at the 2 institutions was to gain a larger patient pool for statistical analysis.

The data from this study did not follow the demographics reflected by the SEER data.[1] In the SEER database, 32% of the patients were 50 to 64 years old, and 50% were 65+ years old. In this study, 56% of the patients were 50 to 64 years old and 29% were 65+ years old. The difference in distribution by age might be attributable to the small sample size of our study (190 patients) compared with the large number of patients from the SEER database (22,499).[1] The group of patients below the age of 40 (1%) does not correspond with the SEER data (8%). This was not surprising, because the HVAMC patients were predominantly older than 40 years of age. Because HVAMC is a Veterans Administration Hospital, 82% of the patients in this study were male. Therefore, gender distribution here did not follow the SEER ratio of 1.9:1.0 males to females.

The American Dental Association (ADA) printed a special supplement in November 2001[33] to improve dentists' knowledge of oral cancer. Along with this, the ADA began an 11 city national advertising campaign in September 2001 to make the general public more aware of the importance of early detection of oral cancer. Unfortunately, the data for this study show why a national campaign was necessary. The majority of patients in this study had a lesion that was 2 cm or greater in size before it was diagnosed. This is representative of the general population, as most patients with advanced head and neck disease have a delayed presentation to their primary care physician.

The authors believed the data collected in this study would aid clinicians in determining the ideal time to fabricate dentures in patients irradiated for head/neck cancer. The authors examined numerous variables thought to influence when dentures should be fabricated. Anecdotal evidence and various clinical opinions as to when complete dentures could optimally be fabricated exist.[4,5,7] Statistical analysis revealed the relationship between number of complications post-prosthesis insertion and time to denture insertion was statistically significant. This could be a type I error due to chance or due to the fact that many of the cells in the table had fewer than 5 occurrences in them. Time to prosthesis insertion compared with pre-prosthesis insertion complications, total dose of radiation, volume of tissue irradiated, and volume of tissue irradiated compared to post-prosthesis insertion complications were all close to being statistically significant. A strong relationship was observed between the volume of tissue radiated and time to prosthesis insertion; specifically, as expected, those with unilateral radiation treatment had fewer complications. Because this is an original retrospective chart review, there may be tendencies that clearly exceed the alpha of 0.05. If a Chi-square has a p-value of 0.10, there may be significant values found in a controlled prospective study with a larger sample. The differences in p-values between the uncollapsed and collapsed tables could be a result of the number of complications increasing in the 2×2 tables.

The results of this study reflect the complications that occur in the dental clinics at HVAMC and MDACC. Before initiating this research, based on discussions with the clinicians at the 2 institutions and the supporting literature,[4,5,7] it was believed that a greater frequency of complications would be found. A survey conducted by Elzay, King, and Dettman[4] revealed that prosthodontists believed that all dentures cause trauma to the oral mucosa. Fortunately, for the patients seeking

treatment at these hospitals, the complication rates are low. This is likely because the dentists at both clinics have a great deal of experience in treating head and neck cancer patients. A great deal of time goes into patient education; a great deal of care is taken when fabricating prostheses for these patients, and prosthodontic principles are followed. When complications do arise, a course of observation is followed in which the patient is seen at regular intervals as their complications resolve.

The results of this study show that the more complications a patient experienced before the denture fabrication process began, the longer the patient could expect to wait for the prosthesis. One might predict that the patients who experienced complications before denture fabrication might be more likely to experience complications after they received their prosthesis. This was not the case in this data set. Patients who had complications before dentures were fabricated had their treatment delayed until the complications resolved and did not necessarily have a greater risk of complications after dentures were inserted.

The next set of data took the same groupings and showed the relationships depending on the doses of radiation. As expected, at higher doses, denture fabrication was more likely to occur later (over 180 days); however, the majority of patients had few complications regardless of their radiation doses. This may be attributed to the advances made in oncologic treatment; specifically, radiation delivery and sparing techniques with increased locoregional control.

The data set consisted of patients treated in the 1990s, whereas the majority of other studies were conducted before 1990.[4,5,7,9] One recent advance in radiation therapy was the introduction of computed tomography (CT). CT images can be transferred to target planning computers to define tumor volumes and normal tissues for the development of radiation-beam arrangements.[34] The process, known as 3D conformal radiation therapy (3D-CRT), enables a higher dose to be directed at the tumor while minimizing the effects on normal tissue; hence, a significant number of patients in the present study underwent such treatment with markedly fewer treatment-induced complications. Another advance is intensity-modulated radiation therapy (IMRT), which allows for tight dose gradients around tumor targets adjacent to critical structures; thus sparing normal tissues.[35]

Most studies suggest that the standard protocol includes waiting at least 10 days after an oral surgery procedure before starting radiation therapy.[36,37] The data in this study show a low incidence of complications with a 10-day waiting period. There were not enough cases in which radiation therapy was started in less than 10 days after oral surgery to make any conclusions about this timeframe. Interestingly, the patients who had their radiation treatment completed before any oral surgery had few complications. This is probably a direct result of the experience of the surgeons who would attempt to perform their surgery procedures as atraumatically as possible. In this data set, it appears that a conservative approach was practiced, in that both institutions tended to wait at least 10 days after an oral surgical procedure before starting radiation therapy. There appears to be no difference in waiting 10 or more days.

The results of this study for both the HVAMC and M. D. Anderson hospitals support the current treatment standards regarding time period between completion of radiation therapy and initiation of complete denture fabrication. The majority of cases completed the rehabilitation more than 91 days after radiation treatment, allowing oral edentulous tissues to mature without acute radiation therapy-related sequelae. Other factors that must be included when analyzing the data regarding the amount of time required and complications encountered prior to such rehabilitation include: third-party reimbursement and fee for services [i.e., payment plans (MDACC)], volume of patient load, recurrent disease volume and delay in rehabilitation, known treatment related sequelae (acute and chronic) and average period of healing, prioritization of dental laboratory cases (active treatment patient cases take priority, e.g., radiation stents, fluoride carriers, mucosal guards, obturator prostheses), geographic constraints in returning to clinic for rehabilitation, and up-to-date education of clinicians and residents at both institutions about the complications involved in treatment of the radiated patient.

Controversy continues regarding when complete denture prostheses should be fabricated for irradiated patients.[4,5,7] Therapeutic doses of radiation for oral malignancies will induce mucositis in most patients and require edentulous patients to limit the use of complete denture prostheses during the course of therapy.[27] Some

prosthodontists advise that construction of dentures be deferred for at least 12 months postradiation treatment.[4,5,7] If greater amounts of denture-bearing surfaces are within the volume of tissue radiated, a longer period of recovery might be recommended.[4,5,7,27] The majority of the prostheses in this study were delivered to the patients after 181 days. The patients who received their dentures in 180 days or less had the same relative number of complications when compared with those patients who received their dentures in 181 to 365 days and those who had to wait longer than 1 year for prosthetic rehabilitation.

There were few complications among our study sample. This is a result of the practice guidelines that have been established at MDACC over the past 30 years and are being followed at the dental clinics of both hospitals. Oral radiation patients were treated with extreme care. Treatment is often delayed to allow for more healing. As a result, most patients wait a number of months before their oral rehabilitations are completed.

Limitations of the Study

There are many factors that could have influenced the data in this study. First, is the lack of a control group. Second, no parameters were set up in the clinics to determine the treatment protocols a patient would receive. The data were recorded directly from the patients' medical records there was no standardization in the way notes were taken. Follow-up appointments were not standardized. There was a lower complication rate than expected, suggesting that complications might have been under reported. The under reporting of complications could be attributed to patients' failures to come to scheduled follow-up appointments or the decision to seek dental care elsewhere. Because both dental clinics have a heavy patient load and are part of large institutions, the medical records might not have reflected everything that occurred at the appointments. Patients may have received the appropriate care, but it may not have been adequately documented in the patient record.

After reviewing the literature, it was determined that time, total dose of radiation, volume of tissue irradiated, and complications that occurred both before and after denture insertion were important factors to consider when deciding when dentures can be fabricated for the head and neck cancer patient who has undergone radiation therapy to treat cancer. Statistical analysis revealed that in the current data set these factors were not statistically significant. Because this was a retrospective study, it was difficult to rely on the completeness of the notes of the treating doctors. The major problem with a retrospective study is that the researcher can only record what the treating doctor notes in the medical record. The researcher is only looking for specific data points, and what is considered "pertinent study data" may be determined randomly. It is believed that the data set derived for this study reflects why little of the data were statistically significant.

Future Research

For future studies on this subject, it would be better to develop a prospective trial, including standard clinical definitions for consistent data collection. Training should be accomplished among the examiners for consistent reporting. Future research on this topic should involve a prospective study. A recording instrument would have to be formulated for standardizing diagnoses and complications. In order to accomplish this, a study with a larger sample size would be necessary. This could be achieved through a multi-center approach. A quality of life assessment should also be addressed. The patients would also have to have clinical appointments at a set timeframe (i.e., every 14 days) so that close follow-up is maintained and any adverse complications documented.

Conclusions

The number of complications described in this retrospective analysis was considerably less than the number expected (which was greater than 50%). The majority of patients had no complications. Patients with more pre-insertion complications tended to have delayed prosthetic rehabilitation. There was no association between the complications patients had before their dentures were inserted and those that occurred after their dentures were inserted. Patients who had received radiation therapy were 1.7 times more likely to have post-prosthesis insertion complications. The majority of patients who experienced complications before and after denture insertion had a higher dose of radiation (greater than 5000 cGy). Those

patients who had complications both before and after denture insertion tended to have bilateral dosing of their radiation treatment. There appears to be no difference in the number of pre- and post-insertion complications as a function of the time delay from oral surgical procedure to start of radiation treatment (10 to 21 days vs. 22 days or more). Patients who received their dentures in 180 days or fewer had the same relative number of complications when compared with those who received their dentures in 181 to 365 days, and those who had to wait longer than a year for prosthetic rehabilitation. Lastly, 92% of the patients received their prosthesis after 91 days, whereas 60% of the patients received their prosthesis after 181 days.

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