Rehabilitation of Maxillectomy Defects with Obturator Prostheses Fabricated Using Computer-Aided Design and Rapid Prototyping: A Pilot Study

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Purpose: To establish an alternative method to design and fabricate an obturator prosthesis within the maxillectomy defect using a computer-aided design (CAD) and rapid prototyping (RP) technique and to evaluate the functional results of this technique. ***Materials and Methods:*** Eleven patients with acquired maxillary defects resulting from head and neck cancers were treated using a protocol based on three-dimensional (3D) reconstruction, CAD, and RP technologies to fabricate obturator prostheses. To evaluate the quality of the obturator prostheses and the patients' satisfaction, the Obturator Functioning Scale (OFS) of the Memorial Sloan-Kettering Cancer Center was applied. ***Results:*** Each patient received an individualized obturator that exactly matched the static shape and fit of the defect. Clinical modifications were required to improve border contours. The patients showed good results in all fields of functional outcomes and social acceptance. The OFS scores were comparable with those reported in other studies using traditional maxillectomy impression methods. ***Conclusions:*** This study combined CAD with RP technology to explore an alternative and feasible method for manufacturing individualized obturators for patients after maxillary resection. It has shown significant clinical value, especially for use in developing countries. *Int J Prosthodont 2014;27:480–486. doi: 10.11607/ijp.3733*

After maxillary surgery, patients can suffer to various degrees from hypernasal speech, fluid leakage into their nasal and maxillary cavities, impaired masticatory function, and cosmetic deformities. An obturator prosthesis assists in restoring functions of mastication, speech, and swallowing; it also improves the patient's psychological and social well-being.[1–6] Therefore, it is essential that patients are provided an appropriate obturator prosthesis with satisfying retention, a peripheral seal, and harmonious occlusal relationships. However, it is sometimes difficult to fabricate such a prosthesis because of access limitations due to soft tissue fibrosis and trismus that can persist after maxillectomy and radiation.

With the development of three-dimensional (3D) reconstruction and rapid prototyping (RP), some researchers have reported on the design, development, and fabrication of dental prostheses, such as copings, crowns, and molds for complete dentures, using the computer-aided design/computer-assisted manufacture (CAD/CAM) technique.[7–11] Researchers also have applied this technique in the maxillofacial field to get a 3D photographic image and fabricate the facial prostheses, plan the implant location for placement concurrent with resection, and fabricate obturators.[12–20] Using CAD/CAM can reduce much of the labor-intensive and time-consuming hands-on work for dentists and technicians.[12] In this article, *(1)* a new method is established to facilitate the procedure of fabricating one-piece obturator prostheses with a CAD and RP technique, and *(2)* clinical measurements of functional outcomes are reported.

Materials and Methods

Patients

Eleven patients (two edentulous and nine partially dentate) with cancer related to acquired maxillary defects, treated from 2011 to 2012 at the Division

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Table 1 Clinical Data of the 11 Patients

Patient	Sex	Age (y)	Diagnosis	Aramany classification	Skin graft	Approach	Soft palate	Radiation treatment
1	Male	60	R Squamous cell carcinoma (fully edentulous)	I	Yes	Weber-Fergusson	Not involved	N/A
2	Female	28	R Adenoid cystic carcinoma	I	No	Intraoral	Involved	Yes
3	Male	38	L Mucoepidermoid cancer	I	Yes	Intraoral	Not involved	Yes
4	Male	25	Nasal squamous cell carcinoma	VI	Yes	Intraoral	Involved	Yes
5	Female	33	R Myofibroblast sarcoma	I	Yes	Weber-Fergusson	Involved	Yes
6	Female	68	R Squamous cell carcinoma (fully edentulous)	I	Yes	Weber-Fergusson	Involved	N/A
7	Female	62	L Squamous cell carcinoma	I	Yes	Weber-Fergusson	Not involved	Yes
8	Male	56	R Adenoid cystic carcinoma	I	No	Intraoral	Involved	Yes
9	Male	27	R Fibromyxoid sarcoma	I	Yes	Intraoral	Not involved	Yes
10	Male	32	R Squamous cell carcinoma	I	No	Intraoral	Not involved	No
11	Male	58	R Squamous cell carcinoma	I	Yes	Mandibular extraoral	Not involved	Yes

R = right; L = left.

of Maxillofacial Prosthetics, Shanghai 9th People's Hospital, were included in the study. The defect types were classified according to Aramany's classification.[21] A protocol based on 3D reconstruction, CAD, and RP technologies was followed to fabricate definitive obturator prostheses for the patients. To evaluate the quality of the obturator prostheses and to determine patients' satisfaction, the Obturator Functioning Scale (OFS)[5] of the Memorial Sloan-Kettering Cancer Center was applied. The OFS consists of 15 questions divided into 3 subcategories. The first category addresses problems with eating, the second category concentrates on speech difficulties, and the last category concerns other problems, such as dry mouth, paresthesia of the upper lip, difficulties in inserting the obturator, and avoidance of routine social interactions. The patients can rate each problem as 1 (not at all or a little), 2 (somewhat), or 3 (very much or extremely). This study was conducted in accordance with the Helsinki Declaration of 1975, as revised in 2000, and all of the patients understood the study and signed informed consent forms. The protocol (#2011-8) was approved by the hospital's Ethics Committee. The clinical data for the 11 patients are presented in Table 1.

Clinical Procedures

The patients were scanned with a spiral computed tomography (CT) scanner (GE Light Speed 16, GE Medical Systems), which extended from the supraorbital margin to the cricoid cartilage and had a slice thickness of 1.25 mm. While being scanned, cotton rolls were placed in the maxillary vestibule of the residual dentition, and gauze was used to separate the palate and the tongue. Doing so yielded a clear, separate shape of the residual dentition, the residual palatal shelf, and a relative anatomical shape of the cheek inferior to the cicatricial band. In addition, patients were told to open their mouth during scanning, simulating at least one clinical movement of border molding in traditional maxillary defect impression making, to obtain a marginal seal in prosthesis functioning. The total slices were captured and stored as digital imaging and communications in medicine (DICOM) images on a CD-ROM. Next, the original 3D model of the patient's head was reconstructed by stacking the DICOM images using Mimics software (Materialize NV).

The 3D model of the patient's head was exported in .stl format. The .stl file was imported into Geomagic Studio 12.0.0 software (Geomagic Software Co) to design the defect portion of the prosthesis.

3D reconstruction of hard and soft tissues. The CT threshold was confined from –718 to 3,071 HU, which included the complete range of soft and hard tissues. In Geomagic software, the threshold of skin tissue is confined from –718 to –177 HU, while the threshold of muscle is confined from –25 to 139 HU. The threshold of mucosa falls between that of skin tissue and muscle. Hard tissue was confined from 226 (bone) to 3,071 (enamel).

On the premise of deleting redundant data and separating the cavities between maxillary defects, the "Custom Region Tool" was used to create the superior and the palatal boundaries of the defect. Full use was made of buccal anatomic undercuts to obtain the retention of the prostheses. The height extended

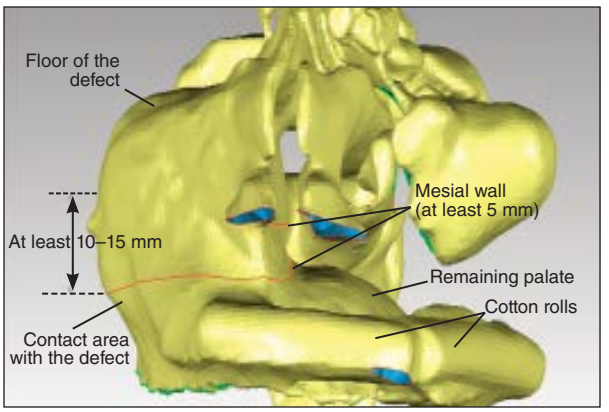

Fig 1a Front view of the 3D reconstruction of the soft tissue. The cotton rolls represent the floor of the vestibule, so the cicatricial band (or contact area) can be estimated around the cotton level. The lateral wall should be at least 10 to 15 mm above the red line, and the mesial wall of the nasal septum should be at least 5 mm above it.

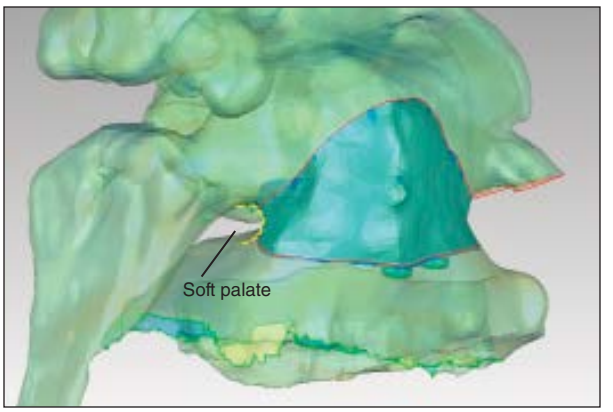

Fig 1b Lateral view of the 3D reconstruction of the soft tissue. The yellow dotted line is the anterior of the residual soft palate.

10 to 15 mm along the buccal mucosa, and the superior height of the medial palatal margin extended approximately 5 mm. The whole visual image was in the defect cavity or almost at the same level of the residual palatal level (Fig 1). Using the "Fill Hole" tool, according to tangent changes, the palatal side formed a natural transition with the patient's residual palate. To reduce the weight of the obturator and make it easier to remove the resin mold from the master cast with the acrylic bur, the resin mold is designed to be hollow, with a 3-mm wall. Using the "Deviating" tool allowed the shape to be made similar to but smaller than the defect cavity. Therefore, the virtual inside wall of the obturator can be obtained by deviating 3 mm from the copy data according to the normal direction. Combining the aforementioned wall of the defect and this inside wall allows for the hollow mold. In addition, three small positive orientation indices were designed on the palatal side of the virtual maxillary defect model to index the acrylic resin mold to the subsequent routine dental impressions.

The virtual mold of the defect was saved as an .stl file. Stereolithography (SLA) technology (ProJet HD 3500, 3D Systems) was used to manufacture a resin positive mold that represented the shape of the defect cavity.

The SLA-derived resin obturator mold was placed in the patient's defect to determine the fit. The mold was seated superior to the buccal undercut first and then rotated against the medial wall. When necessary, adjustments to the mold were made to reduce undercuts at the anterior, posterior, or medial wall that conflicted with the rotational path of insertion against the anatomical walls of the maxillary defect. The contours of the defects are relatively static during function, except for movement of the soft tissue displaced by the movement of coronoid process and the anterior border of the ramus of the mandible, the slight movement of the lip and cheek, and, in some patients, the elevation of the residual soft palate.[22] Therefore, for defects that affected the soft palate junction, border molding (ISO functional compound, G.C. Dental Industrial Co) was done at the posterior and posterolateral walls of the resin mold to obtain soft palate functional movements and border sealing. Patients also were instructed to perform eccentric mandibular movements to account for the movement of the anterior border of the ramus and the coronoid process of the mandible (Fig 2). The ISO functional compound is low fusing and recommended as soft palatal impression material.[22] The contour of the soft palate and ramus is shown in Fig 2c. The compound height is about 3 to 5 mm. For the trismus patient, it may be necessary to reduce the height of the mold if it is too high to be rotated into the mouth.

Impression to relate the resin mold to the dentition. The resin mold was well seated in the mouth. For the edentulous patients, a custom tray was border molded by compound (Shanghai Dental Material Co) along the residual labial tissues, palatal defect margin, and soft palate border seal. A silicone wash (Heraeus Kulzer) was used for the final impression of the residual palate and the indexed palatal portion of the mold. For the partially dentate patients, after preparations of the residual teeth, an alginate impression (Heraeus Kulzer) was made of the remaining palate, the dentition, and the indexed palatal portion of the resin mold (Fig 2d).

Master cast. Since there was an opening in the hollow stereolithographic resin model, as is often the case in the CAD/CAM method, tissue paper was used

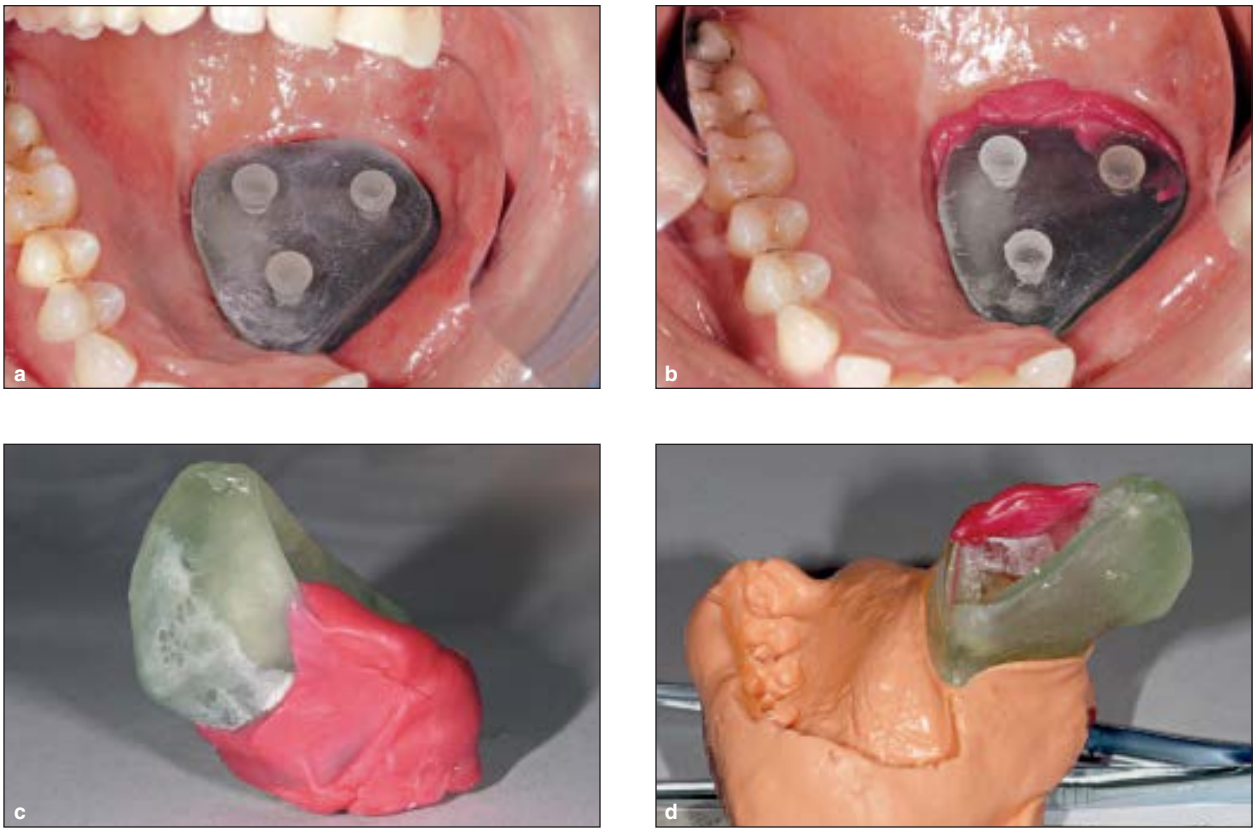

Fig 2 Border molding and impression of the patient. **(a)** The resin mold is seated in the patient's defect. **(b and c)** Border molding of the soft palate of the defect. **(d)** Impression of the defect and the residual dentition.

to cover the hole on the top of the resin. A cast of the resin mold, residual palate, and natural dentition was poured in dental stone. The resin mold was removed from the master cast by sectioning the thin resin with an acrylic bur. Then a conventional obturator prosthesis was fabricated on the master cast. The insertion path of the framework was designed to parallel the occlusal plane. Subsequent appointments consisted of trying in the framework/trial base, establishing vertical dimension of occlusion (VDO), and trying in the prosthetic dentition.

Prosthesis insertion. When the obturators were delivered to the patients, it was important to rotate the prosthesis into the defect as the framework was seated. Adjustment of the resin mold within the defect was sometimes necessary to reduce the mesial height or undercut area of the mesial wall so that the framework could be seated nearly parallel to the occlusal plane path of insertion. The retention, marginal fit, and occlusion of the prosthesis was assessed and adjusted. Pressure-indicating paste was used to delineate areas of excessive tissue displacement within the resection site. The patients were asked to complete a questionnaire 1 week later.

Figure 3 is a flowchart of the CAD/CAM method.

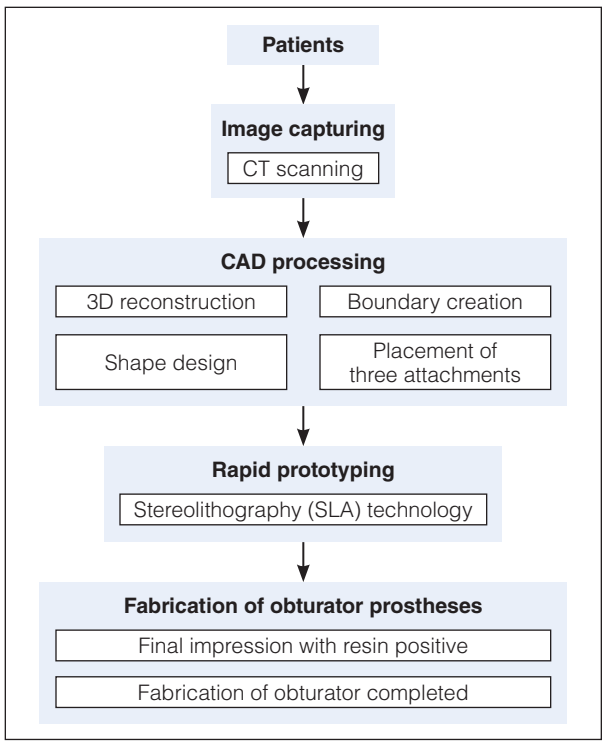

Fig 3 Flowchart of the CAD/CAM method for the design and fabrication of obturator prostheses.

Table 2 Patients' Ratings of Function with the Obturator Prosthesis (N = 11)

	Not at all/ a little difficult	Somewhat difficult	Very much/ extremely difficult
Eating problems subscale			
Difficulty chewing foods	9	2	–
Leakage when swallowing liquids	10	1	–
Leakage when swallowing foods	11	–	–
Speech problems subscale			
Voice different from before surgery	9	2	–
Difficult talking in public	11	–	–
Speech is nasal	9	2	–
Difficulty pronouncing words	9	2	–
Speech is difficult to understand	11	–	–
Other items in subscale			
Mouth feels dry	5	3	3
Dissatisfaction with looks	8	3	–
Clasps on front teeth are noticeable	8	3	–
Upper lip feels numb	4	4	3
Avoidance of family/ social events	11	–	–
Difficulty inserting obturator	8	3	–
Upper lip looks funny	9	2	–

Results

All patients were able to undergo the planned procedures and have a definitive obturator fabricated. The obturator prostheses achieved maximum support, stability, and retention. The patients underwent the entire treatment in five appointments and reported quick adaptation to the prostheses. Six of the 11 patients had soft palate involvement (6 with defects and 1 fully edentulous patient). Three of the 11 patients had some problems of fluid leakage or nasal sound. The leakage was solved by adjusting and relining of the soft palate area in two appointments, and two voice problems were solved by adding a little height on the posterior wall of the prostheses in one appointment.

The OFS was used to evaluate the quality of the obturator prostheses. The results indicated that the patients had minimal problems with eating, speech, and other functional items. Only one patient reported some leakage in drinking liquid (9.09%), and none complained of leakage while swallowing food. Two patients (18.2%) complained that their voices were somewhat nasal and that they had difficulty pronouncing some words and some differences from before surgery. Three patients (27.3%) complained about clasps that were noticeable on the anterior teeth. Extreme numbness of the upper lip was noted by three patients (27.3%), and three patients (27.3%) suffered from dry mouth. Three patients (27.3%) had some difficulties inserting the obturator. All of the patients were satisfied with the prostheses and reintegrated into their family and social lives. No patients had problems being understood by others. The patients' ratings of the prostheses are presented in Table 2.

Discussion

In this study, CAD-RP technology was established as an alternative method to fabricate obturator prostheses. The results demonstrated that this method can satisfy the needs of patients and improve their quality of life.

Advantages and Shortcomings

An advantage of this method is the ability to offer "remote" prosthodontic expertise to local practitioners. In China, only a small number of maxillofacial prosthodontists are well trained to rehabilitate the defects of head and neck cancer patients. Most prosthodontists have little experience treating such patients, especially in obtaining precise impressions of their defects. In patients exhibiting extreme trismus, border molding can be difficult for prosthodontists and patients. This CAD/CAM method may negate the impression technique that border molds the defect with repeated additions of compound. The CAD/CAM method offers a precise combined impression of both the defect and dentition using alginate impression material. With the Internet, prosthodontists in other cities can conveniently send CT data to the authors' SLA facility to acquire the resin mold and subsequently treat the cancer patient with a removable partial denture. It is hoped that oral cancer patients, especially those in developing countries, can benefit from this technique by reducing their medical expenses and the time and effort necessary to seek treatment in cancer centers.

A shortcoming of the technique is the inability to capture functional movements at the posterior defect border. When we design the resin mold at the posterior aspect, we draw the border at the posterior margin of the nasal cavity (Fig 1b). This is the anterior area of the residual soft palate. The soft palate is relaxed during CT scanning, and the height of the posterior wall is about 5 mm. However, during speech and swallowing, the soft palate will have some motion despite the fact that this margin is often scarred from surgery and radiation. The lateral border of the defect and soft palate (area of the pterygoid bone and muscle resection) also changes with mandibular movement. It is said

that the border molding of the soft palate extension should extend about 1 cm onto the oral surface of the residual soft palate,[22] which helps deflect the food and liquid bolus from this tissue margin. Therefore, border molding of the soft palate and the pharynx is needed at the posterior and posterolateral aspect of the resin mold. Unfortunately, with the CAD/CAM method, it is not possible to predictably evaluate the speech and leakage at try-in of the resin mold, as the mold is not retentive within the defect. Although border molding can achieve a border seal, the dynamic motion of the soft palate junction cannot be well recorded due to potential over- or underextension of the resin mold. Also, a functional impression of the pharynx in speech and swallowing is not possible with this technique when the patient has undergone extensive resection of the soft palate in conjunction with maxillectomy. Speech or leakage may be impacted. Therefore, when delivering the prosthesis, it is necessary to check the tissue adaptation at the posteromedial and posterolateral margins (at the prosthesis/soft palate junction). Tissue conditioner should be applied on the obturator portion of the prosthesis and the extension checked. If the material is thick and successfully decreases reflux, a relining procedure should be considered for this area.[23]

In the OFS scores, one patient showed some leakage in drinking liquid and two patients complained that their voices were somewhat nasal. They all underwent reline procedures at additional appointments, which took care of the problems. The OFS data of the present study are comparable to the results of the conventional method reported by Kornblith et al[4] and Irish et al.[5] Therefore, we believe this method is acceptable as an alternative approach to make a prosthesis.

Removal of the resin mold from the master cast requires special consideration. It takes several minutes to remove the hollow resin mold from inside the master cast. If undercuts exist within the master cast, the removal of the resin can cause fracture or scarring of the cast. Creating a wax mold rather than a resin mold would simplify the laboratory procedure. However, the authors' SLA RP machine cannot fabricate in wax, and a suitable selective laser sintering or 3D print RP machine and wax to manufacture a wax obturator could not be found.

Design of Obturator

When the digital obturator is designed, suitable buccal and medial flanges should be considered. Although there is some controversy regarding extension of the buccal wall, it is recommended that the buccal cicatricial band be covered.[24–27] Kwon et al[25] mentioned that a lateral wall 5 mm above the contact area with the defect is a low-bulb obturator, and above 5 mm is a medium or high-bulb obturator. We prefer medium or high superior extension along the posterior and lateral margins of the defect. The cotton rolls represent the floor of the intact vestibule, so the cicatricial band (or the contact area) can be estimated around the cotton level. The buccal height should be fully extended at least 10 to 15 mm above the cicatricial band along with the defect. Some researchers[26,27] also have indicated that the extension superiorly along the nasal septum should be low. We recommend that it be approximately 5 mm in height and relieved from any undercut to allow seating of the prosthesis and avoid interference with breathing.

Further Study

In this study, a spiral CT with a thickness of 1.25 mm was used for 3D reconstruction of the head. Further studies need to be conducted using cone beam CT. Additional classifications of the maxillary defects and closer attention to evaluation of the soft palate junction need to be undertaken to validate the method.

Conclusions

This study combined CAD with RP technology to explore an alternative method for creating obturators for patients after maxillary resection. The practice on these 11 patients demonstrated the feasibility of this method. These patients have regained their functions of mastication, pronunciation, and swallowing. This new method has shown significant clinical value, especially for developing countries.

Acknowledgments

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Literature Abstract

Cancer risk among gingivitis and periodontitis patients: A nationwide cohort study

This retrospective population-based study was conducted to evaluate the risk of cancer among patients with gingivitis and periodontitis. Data from the National Health Insurance (NHI) program in Taiwan was used in this study to randomly select 1 million patients from 1997 to 2010. All patients in this study were older than 20 years old. The study cohort consisted of patients newly diagnosed with periodontitis, and the comparison cohort consisted of patients newly diagnosed with gingivitis during this period. Both cohorts were followed until a malignant cancer diagnosis, lost to follow-up, death, termination of insurance, or the end of 2010. The multivariable Cox proportional-hazard regression model was used to assess the risk of developing cancer associated with periodontitis and gingivitis. The Kaplan-Meier analysis was used to show the probability of remaining cancer free, and a log-rank test was used to evaluate differences between the two cohorts ($P < .05$). The incidence rate of cancer was found to be 1.14 times higher in patients with periodontitis than in patients with gingivitis (confidence interval [CI] = 1.11–1.17). Multivariate analysis showed that patients with periodontitis have a higher risk of developing oral cancer (95% CI = 1.42–2.25). The Kaplan-Meier analysis showed a significantly lower oral cancer-free rate in the periodontitis cohort than in the gingivitis cohort (log-rank $P < .0001$). In conclusion, the results of this study indicated an increased risk of developing oral cancer in patients with periodontitis. However, large-scale prospective studies will be required to confirm these findings.

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