

Efficacy of conventional and implant-supported mandibular resection prostheses: Study overview and treatment outcomes

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Statement of problem. While surgical restoration of mandibular resections has advanced dramatically with free-flap techniques, oral function and patient perceptions of function, as well as treatment outcomes, often indicate significant impairment.

Purpose. This longitudinal prospective study was designed to determine whether conventional prostheses (CP) or implant-supported prostheses (IP) and current surgical reconstructive procedures restore patients' oral functions and quality of life to their status prior to segmental mandibulectomy with immediate fibula free-flap reconstruction. Study design and implementation, characteristics of the study sample, treatment completion rates, and selected presurgical and postsurgical functional and perceptual outcomes are presented.

Material and methods. Forty-six subjects were enrolled. Longitudinal evaluations of medical and dental histories, oromaxillofacial examinations, questionnaires, and sensory and functional tests were planned before and after surgery and after CP and IP treatment. Sample characteristics are described with descriptive statistics and comparisons of subject responses to questionnaire items at entry and postsurgical intervals were made with Fisher exact tests ($\alpha=.05$).

Results. Conventional prostheses were completed in 33 of 46 subjects, and 16 of 33 CP subjects were treated with IP. Reasons for noncompletion of IP were recurrent/metastatic disease (16), refusal of implant therapy (7), lost to follow-up (4), treatment with a reconstruction plate (1), excessive radiation at implant sites (1), and death (1). All 16 recurrences/metastases occurred within 13 months of surgery. Only 3 of the 58 implants placed in 17 participants were considered failures. One failed due to lack of integration 31 weeks following placement, and 2 were buried due to unacceptable positioning for prosthetic restoration during denture fabrication. The remaining 55 implants were successful at final evaluation, ranging from 58 to 123 weeks following implant placement (mean duration=78.9 \pm 16.0 weeks).

Conclusions. While 72% (33/46) of the subjects enrolled were able and willing to complete treatment with CP, only 35% (16/46) completed IP treatment. Careful consideration must be given to selection of the type of prosthetic rehabilitation and the timing of implant placement if an IP is planned. (*J Prosthet Dent* 2006; 96:13-24.)

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CLINICAL IMPLICATIONS

Due to the high rate of recurrence/metastasis within the first year following ablative surgery, consideration of extensive implant therapy, particularly in partially dentate patients, should be delayed for at least a year.

Oral cancer represents 2.5% of all cancers and 1.5% of cancer deaths in the United States. Approximately 30,200 people were diagnosed for oral cancer, and 7800 died of this disease in the United States in 2000. Estimated 5-year survival rates of 53% in whites and 32% in blacks have been reported in the United States.¹⁻³ High mortality rates and possible physical disfigurement and functional impairments^{4,5} associated with tumor ablative surgery are a challenge to health care providers treating patients with oral cancer. Only minimal longitudinal evidence exists to describe the functional and perceptual impairments resulting from ablative oncologic surgery and the rehabilitative effect of current surgical reconstructive techniques and dental restorative procedures.⁶⁻¹¹

In 1990, a review¹² of 32 articles described outcomes of various mandibular reconstruction techniques and indicated that functional rehabilitation was rarely addressed. Assessments of functional outcomes in terms of deglutition, mastication, and esthetics were provided for only 4% of the 782 patients evaluated. Prosthetic rehabilitation was presented for only 16 patients (2%) of all mandibular reconstructions. The same paper included a retrospective evaluation of a small number of patients who had undergone mandibular resection with and without mandibular reconstruction and concluded that restoration of mandibular continuity does not enhance functional rehabilitation of the majority of patients. Significant strides in microvascular surgical approaches during the past decade have permitted predictable restoration of bony and soft tissue orofacial defects.¹³⁻¹⁷ However, limited studies indicate only varying degrees of improvement in terms of esthetics, speech intelligibility, swallowing, and masticatory performance.^{9,10,18-22}

It appears that even new surgical reconstructive techniques may not sufficiently restore sensory-motor functions, and in most instances they fail to provide adequate support for dental prostheses. Poor tissue support after mandibular reconstruction has hindered prosthodontists in constructing stable and functional dental prostheses for these patients. Based on dentition status and soft and hard tissue configuration, dental implants are used to increase support, stability, and retention of prostheses. Treatment with implant-supported prostheses has been described for oral cancer patients with mandibular reconstruction,²³⁻²⁹ and there is limited indication that levels of masticatory function and occlusal forces

similar to normal individuals with implant dentures may be achieved.³⁰⁻³³ Although dental implants are used in selected patients at a number of healthcare centers, neither the functional efficacy nor the treatment success rates of conventional and implant prostheses have been established in oral cancer patients with reconstructed mandibles.

To provide assessment of the effects of surgical and dental rehabilitation in patients undergoing partial mandibulectomy, a longitudinal prospective clinical study was designed to compare functional and perceptual outcomes between conventional and implant-supported dental prostheses in patients requiring segmental mandibulectomy and surgical reconstruction. The primary purpose was to test 2 hypotheses: (1) that the 2 types of prostheses each restore specified oral functions and oral perceptions to presurgical levels, and (2) that both types of prostheses are equally effective in restoring specified oral functions and perceptions.

The aim of this paper is to describe the study design and implementation, sample characteristics, and treatment completion rates for the conventional and implant-supported prostheses and selected oral functional and perceptual outcomes following surgical mandibular reconstruction but prior to prosthetic rehabilitation. Extensive evaluation of treatment effects on oral functions and subject perceptions will be presented in subsequent reports.

MATERIAL AND METHODS

Study sample

Masticatory performance (MP) was selected as the primary variable for sample size determination because of its possible effects on ingestion, dietary intake, and social behavior. Furthermore, masticatory performance is the outcome of several other proposed key measures, including the ability to clear particles from the mouth (oral clearance), oral stereognosis, occlusal force, and masticatory muscle effort. Unfortunately, no pre- or post-surgical estimates were available in the literature for the proposed study population to provide the basis for power analysis to determine sample size. Estimates of anticipated impairments in masticatory function were based on extensive data on populations ranging from completely edentulous to completely dentate³⁴⁻³⁷ and selected limited studies of function in partial

mandibulectomy patients.^{7,9,31} Masticatory performance was estimated from pilot data of pre- and postsurgical dentition status for this patient population. To test the hypotheses that the 2 treatments are equally effective in restoring function, a change of 10 in MP from the estimated presurgical performance score of 44.5 (on a 0-100 scale) was considered clinically significant. Based on these estimates, a sample of 33 was required to provide a power of 0.8 (alpha 0.05, effect size 0.71). Assuming a 20% patient loss during the first year of participation, 40 patients were planned to be enrolled. An additional 6 patients were later added to offset the greater than anticipated loss of study subjects.

Recruitment

The study protocol and use of human subjects was approved by University of California at Los Angeles (UCLA) Human Subjects Protection Committee. Subjects requiring segmental mandibulectomy were recruited from the UCLA Maxillofacial Prosthetics Clinic and the UCLA Head and Neck Surgery Clinic, including referrals from affiliated medical centers in Los Angeles (VA Greater Los Angeles Healthcare System, West Los Angeles; Olive View-UCLA Medical Center; Harbor-UCLA Medical Center, and Kaiser Permanente Medical Centers in Greater Los Angeles). The purpose of the study was explained to patients and all subjects signed an approved informed consent form. Only patients planning to receive segmental mandibulectomy involving the ramus (R), body (B), or symphysis (S), as classified by the Urken classification,³⁸ were accepted for the study. Patients with defects expected to involve the mandibular condyle were excluded. Exclusion criteria are listed in Table I.

Present treatment practices at UCLA and its affiliated institutions

The treatment of a patient with oral cancer is a collaborative team effort among head and neck surgeons, reconstructive surgeons, radiation oncologists, and maxillofacial prosthodontists. Free tissue transfers are routinely used to reconstruct both the soft tissue and bone defect immediately following the ablative surgery. A large percent of patients receive radiation 4 to 6 weeks postoperatively. The total radiation dose to the tumor bed depends on the presence or absence of microscopic disease at the surgical margin. The tumor dose is generally limited to 55 Gy for patients with clear margins, and up to 65 to 70 Gy in patients with close margins. Radiation positioners are used extensively, and radiation fields are configured to minimize exposure of the major salivary glands to high doses of irradiation; however, intensity-modulated radiation therapy (IMRT) was not employed. With careful planning, radiation dose to bone can often be minimized in areas of proposed implant sites. Although hyperbaric oxygen (HBO)

Table I. Exclusion and treatment failure criteria

Exclusion criteria

- Unable to perform tests due to lesion size or restrictive opening
- More than 55 Gy radiation at potential implant sites
- Defects involving mandibular condyle
- Total glossectomy
- Bilateral resection of motor and sensory nerves
- Need for implants to be placed at time of mandibular reconstruction
- Insufficient bone to accommodate implants ≥ 10 mm in length after reconstructive surgery

Treatment failure criteria

- Patient does not use prosthesis frequently during eating
- Implant-supported prostheses becomes tissue-supported due to loss of implant

therapy has been proposed³⁹⁻⁴² to improve vascularity and quality of the tissues,^{39,43} issues related to cost and potential complications precluded use of HBO in this study.

Treatment and research protocol

The complete sequence and projected timing of clinical and research procedures performed for subjects with and without postsurgical radiation are shown in Figure 1. Immediately after enrollment in the study, participants completed a series of objective and subjective functional tests, questionnaires, and examinations (Table II). Within 1 to 7 days after testing, participants underwent composite resection and immediate fibula free-flap reconstruction. Approximately 6 weeks after the ablative surgery, it was anticipated that 60% of subjects would receive radiation therapy for 5 to 7 weeks. New conventional prostheses were fabricated as soon as the healing from reconstructive surgery and radiotherapy would permit. Cast frameworks were used for conventional removable partial dentures (RPDs) (Fig. 2). It was planned that implants would be placed 4 to 6 months after reconstruction, depending on the need for postoperative radiation therapy. Although primary implant placement has been advocated in some reports,^{44,45} all implants were placed secondarily⁴⁶ following healing of the osteotomy sites and resolution of acute radiation therapy effects. Two to 4 dental implants (3i Implant Innovations, Inc, Palm Beach Gardens, Fla), 10 mm or longer and 3.75 mm in diameter, were placed. Implants were located in the available native bone and/or in the free vascularized bone of the reconstructed mandible. Surgical guides were fabricated for each subject to assist the surgeon in positioning implants for ideal prosthetic restoration.^{24,46} Segments of impeding reconstruction plates were removed at this surgery prior to the placement of implants.

The planned healing time prior to implant exposure (Stage II surgery) was 6 months (Fig. 1). A peri-implant

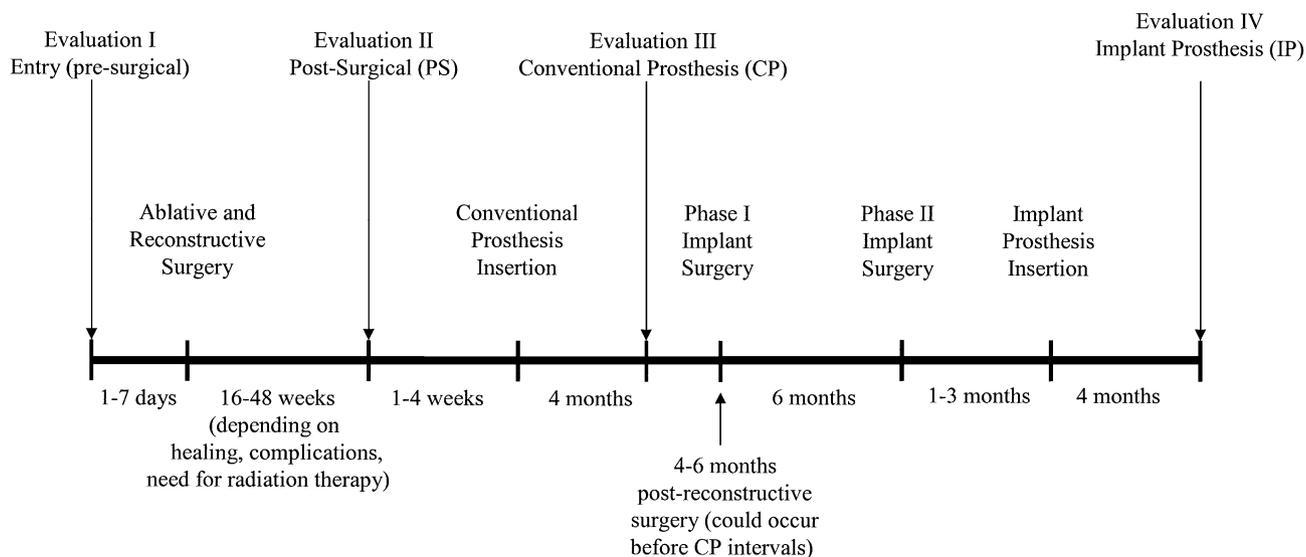


Fig. 1. Timeline for treatment and testing.

Table II. Examinations, tests and questionnaires administered at baseline and follow-up intervals

Examinations:

- Medical and social history
- Orofacial and dental exams, diagnostic casts
- Radiographs
- One week dietary intake log

Objective assessments (physiological)

- Masticatory performance, right and left sides (key variable)
- Swallowing threshold performance
- Oral clearance: with and without tongue sweep
- Oral sensation: stereognosis, two-point discrimination thresholds, tactile thresholds
- Salivary secretion rates (whole and parotid): resting and stimulated

Subjective assessment (psychological)

- Overall patient satisfaction - questionnaire
- "Chewing" preference - questionnaire
- Food preference - questionnaire
- Facial attractiveness (panel rated)
- Standardized speech recording: naturalness evaluation

Postsurgical, post-CP and post-IP intervals: All evaluations above, plus:

- Occlusal force on defect and non-defect sides
- Bilateral masseter muscle activity (right and left side mastication)
 - At rest
 - During occlusal force evaluation
 - During masticatory performance tests
- Mandibular movement patterns
 - During masticatory performance tests

Teeth and prosthesis evaluation

submucosal resection was performed at the time of implant uncovering to assure a thin layer (3-4 mm) of attached tissue around the implants. Depending on remaining mandibular dentition, participants were

provided with an implant-supported (partial overdenture) or implant-assisted (complete overdenture) prosthesis retained by a tissue bar and clips (Hader; Sterngold Implamed, Attleboro, Mass) or resilient attachments (ERA; Sterngold Implamed) (Fig. 3). The same series of tests and subjective assessments made before surgery were repeated after recovery from reconstructive surgery and radiation (postsurgical), and 16 weeks after insertion of the conventional prosthesis (CP) and implant-supported prosthesis (IP).

Objective and subjective evaluations

The series of examinations, tests, and questionnaires administered at baseline and follow-up intervals is listed in Table II. Although most of the results of these outcomes will be presented in future reports, the methods are briefly described. Medical and social histories include demographic, medical (medical problems and medications), and social information retrieved from the medical record and verified with the participant. One investigator (ER) conducted orofacial examination of the face, lips, oral cavity, and temporomandibular joints. Because of the limited access to the participants prior to surgery, the dental examination at entry was restricted to simple counts of teeth, their current status, and a general assessment of oral hygiene and gingival health. A detailed caries and periodontal health evaluation of each tooth and an assessment of the CP and IP were made at the completion of dental reconstruction. Determination of primary tumor staging was made according to published guidelines.⁴⁷

Panoramic radiographs and lateral cephalometric radiographs were made at entry as required for surgical treatment. Lateral cephalometric films were repeated on completion of dental reconstruction. Mandibular

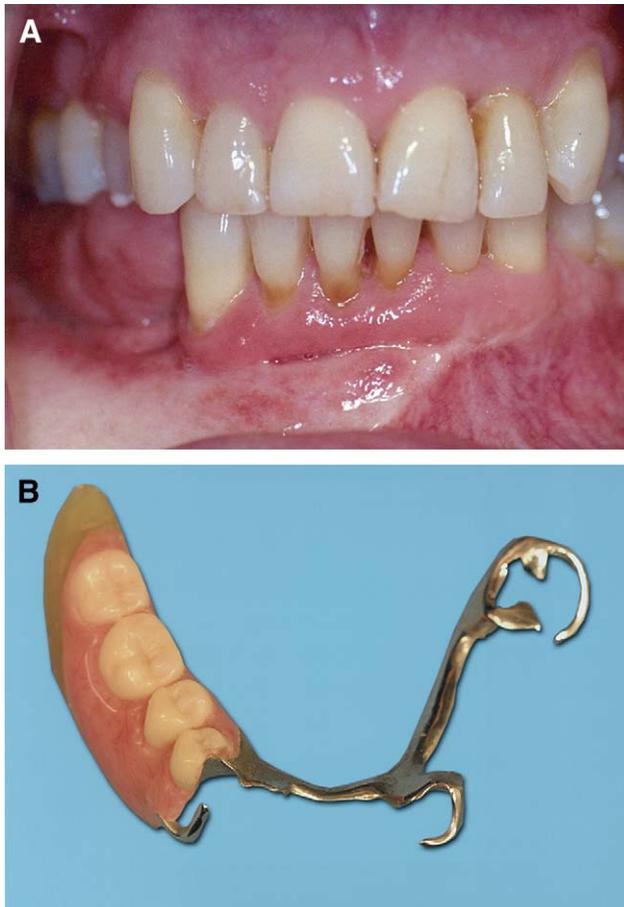


Fig. 2. Conventional removable prosthesis. **A**, Lateral edentulous space to be restored. **B**, Removable prosthesis with cast framework and retentive clasps.

and maxillary diagnostic casts in white plaster (#2; Kerrlab, Orange, Calif) were made at pre- and postsurgical reconstruction. Participants recorded a 1-week log of food intake at each evaluation interval for analysis of intake, nutritional value, and masticatory difficulty of diet.

Three questionnaires were presented to the participants, both verbally and in written form, with responses recorded by a trained research assistant. The first questionnaire included 20 items for participants to rate their experience related to mastication, speech, odor, denture hygiene, comfort, security, and general satisfaction (Table III). Items 1-18 were rated on a 4-point Likert scale (1, most positive; 4, most negative response), and items 19-20 were rated on a 6-point scale (1, complete satisfaction; 6, complete dissatisfaction). These questionnaire items were adapted from a similar questionnaire used in previous studies of CPs and IPs.⁴⁸ A food preference questionnaire elicited the subject's preferences in terms of taste, texture, frequency of eating, and ease of mastication for 13 common foods.⁴⁹⁻⁵³ A third set of question items was designed for this study,

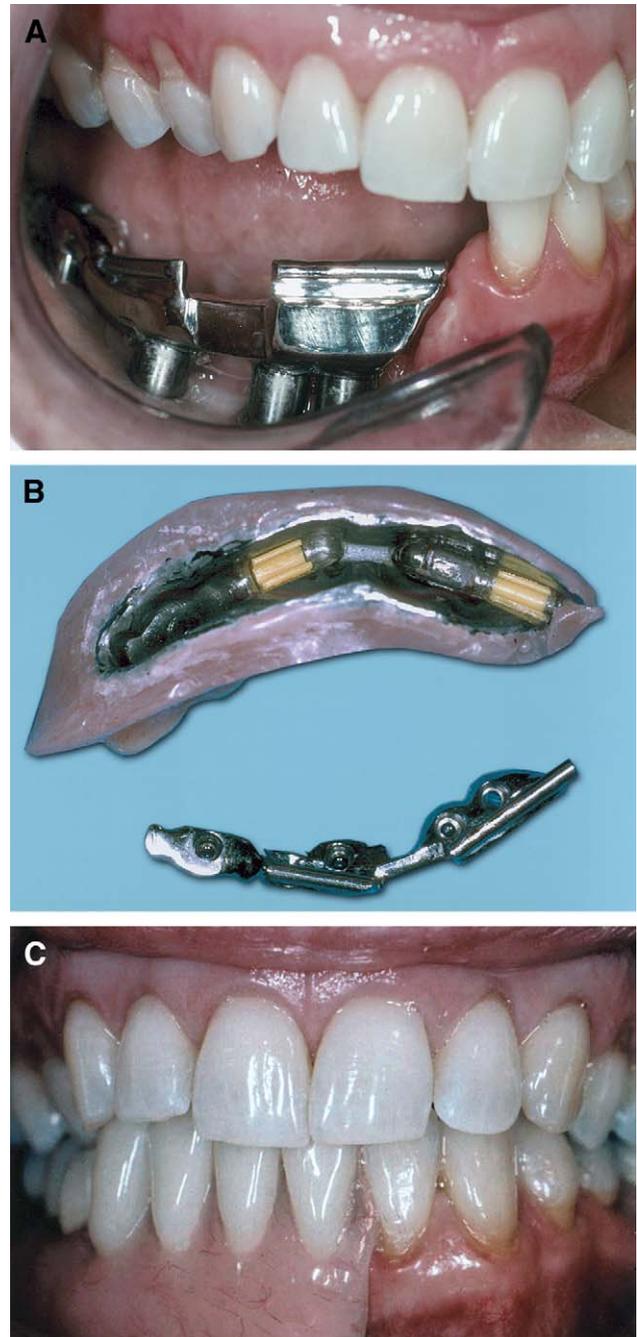


Fig. 3. Implant-supported prosthesis. **A**, Lateral edentulous space restored with implant-supported milled bar. **B**, Removable partial denture with cast suprastructure with Hader clips and milled bar. **C**, Implant-supported prosthesis in position over milled bar.

based on the authors' experience, to evaluate the effects of surgery and dental rehabilitation on the side preferred by the participant to masticate food. Frontal and profile 35-mm color slides were made with the participant's head in a standardized upright position. Panel evaluations will be made using a visual analog scale of 0 mm (least attractive) to 100 mm (most attractive).⁵⁴

Table III. Patient satisfaction questionnaire items

| |
|---|
| Do you experience any discomfort when you chew: |
| 1. I experience no discomfort when chewing |
| 2. I experience slight discomfort when chewing |
| 3. I experience moderate discomfort when chewing |
| 4. I experience great discomfort when I chew |
| How well can you chew? Do you enjoy eating? |
| Does your chewing ability affect your choice of foods?your social life? |
| Do you find food particles collecting under your tongue?sticking inside your cheeks? |
| Do you experience any problem in the taste of food? |
| How satisfied are you with your speech? |
| Do you experience any bad mouth odor? |
| Do you experience any difficulty cleaning your teeth? |
| After cleaning, are you satisfied with the cleanliness of your teeth? |
| How satisfied are you with your facial appearance? |
| Do you feel that your facial appearance affects your social life? |
| Do you experience any mouth dryness? |
| Do you experience problems with oral continence (drooling)? |
| Do you use your dentures for eating? |
| How secure do you feel with your dentures? |
| How satisfied are you with your teeth? |
| How satisfied are you with your dentures? |

Whole saliva secretion rates were collected at rest and while masticating a standardized bolus (rubber bands).⁵⁵ In separate tests, parotid saliva was collected using a modified Carlson-Crittenden vacuum cup (custom-made; Maxillofacial Prosthetics Laboratory, UCLA School of Dentistry) on the opening of Stenson's duct on the nonsurgical side.⁵⁶ Specimens were obtained at rest and while a gustatory stimulus (sucrose solution) was placed on the dorsum and lateral surfaces of the tongue. Taste discrimination and perception thresholds for the sweet modality were established using a forced choice method.⁵⁵ Tactile thresholds on the cheeks, tongue, and palate were determined using a method of limits procedure.⁵⁷ Two-point discrimination thresholds were established for the tip of the tongue, lateral tongue, and buccal mucosa.

Stereognostic ability was assessed using a series of 10 distinct shapes of approximately 5 mm in diameter made from raw carrots. Participants identified each figure from an enlarged drawing following oral manipulation of the item.⁵⁸ Two measures of oral clearance ability were made separately for the right and left sides of the mouth. Controlled specimens of ground peanuts were placed in the participant's right or left lower buccal cavity. In one test, the subjects were asked to expectorate as much of the ground food as possible in a 20-second period without using the tongue to sweep the buccal cavity. In the second test, they were instructed to use the tongue to sweep the buccal cavity in each lower quadrant only 2 times and expectorate the food in a cup. The remaining food was retrieved separately. The cleared and

Table IV. General sample characteristics at entry (prior to surgery), CP evaluation, and IP evaluation

| | Entry | CP | IP |
|---------------------------------|-------------|-------------|-------------|
| Male (N) | 22 | 11 | 7 |
| Female (N) | 24 | 14 | 8 |
| Total (N) | 46 | 25 | 15 |
| | Mean (SD) | Mean (SD) | Mean (SD) |
| Age (y) | 60.0 (15.6) | 60.2 (13.0) | 58.1 (10.4) |
| No. principal medical diagnoses | 2.8 (1.8) | 1.7 (1.0) | 1.9 (1.0) |
| No. medication categories | 1.7 (1.6) | 1.3 (1.3) | 1.3 (1.4) |
| Years smoked cigarettes | 31.0 (16.1) | 33.9 (10.6) | 31.7 (9.1) |
| Packs per day | 1.1 (0.6) | 1.0 (0.2) | 1.0 (0.2) |
| | % | % | % |
| Smokers | 50.0 | 56.0 | 66.6 |
| Currently smokes cigarettes | 13.0 | 12.0 | 6.7 |
| Currently drinks alcohol | 28.3 | 28.0 | 20.0 |
| Education > high school | 91.3 | 84.0 | 87.7 |
| Disease status | N (%) | N (%) | N (%) |
| Primary tumor | 25 (54) | 13 (52) | 9 (60) |
| Recurrent tumor | 10 (22) | 3 (12) | 1 (7) |
| Benign neoplasm | 5 (11) | 3 (12) | 2 (13) |
| Osteoradionecrosis | 4 (9) | 4 (16) | 2 (13) |
| Plate fracture | 1 (2) | 1 (4) | 1 (7) |
| Metastatic disease | 1 (2) | 1 (4) | 0 (0) |

retrieved particles were separately dried and weighed. The ratios of weights of cleared particles to total particles recovered were calculated and expressed as percents.³⁴

Standardized masticatory tests were performed by participants on the right and left sides separately, with peanuts as the test food.³⁴ Three test portions, 3 grams each, were masticated on the directed side by the subject for 20 strokes. The masticated food was expectorated into a cup, the mouth rinsed to clear the remaining particles, and the rinsing (liquid) added to the cup. The masticated food for all 3 portions for a given test food was pooled for a single measurement. For analysis, the masticated food was sieved into coarse and fine particles using a US standard sieve #12 mesh (Fisher Scientific Intl, Hampton, NH). The particles were centrifuged (Dynac Centrifuge; Clay Adams, Div of Becton, Dickinson & Co, Parsippany, NJ) for 3 minutes at 1500 rpm, and the volume of the test materials was recorded. Masticatory performance scores were calculated by dividing the volume of the fine particles by the total volume of test food recovered and expressed as a percent.

A swallowing threshold test with raw carrots provided additional assessment of the participants' routine mastication.³⁴ A 3-g carrot portion was divided into 4 equal parts. Subjects were instructed to "chew normally, without regard to side or number of strokes, until ready for swallowing." The masticated food was expectorated,

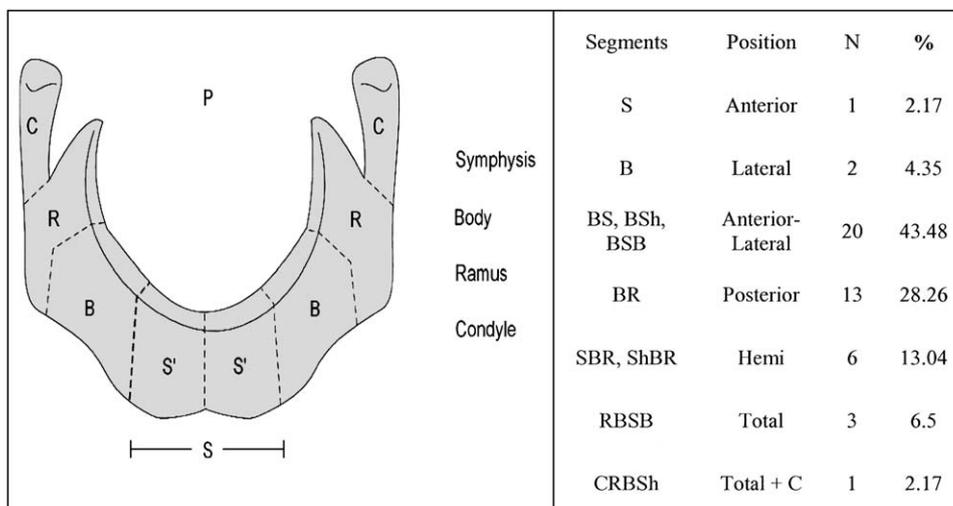


Fig. 4. Distribution of mandibular bony defects. *Sh*, Unilateral half of the symphysis.

and the remaining particles were retrieved for particle size analyses as described for masticatory performance tests. Participants not able to attempt the masticatory or swallowing threshold tests at an evaluation interval received a score of zero performance for that interval.

Electromyographic (EMG) recordings were made from the left and right superior masseter muscles with the mandible in resting position, during occlusal force measurements, and during the standardized right and left side masticatory tests.⁵⁹ Mandibular jaw movements were concurrently recorded (Biopak 1.7R; BioResearch Associates, Inc, Milwaukee, Wis) during the masticatory tests. Variables quantified included total EMG activity, peak EMG activity, cycle duration, and for jaw movement, the maximum velocity and the maximum range of excursion on each of the axes (vertical, lateral, and anteroposterior).

Occlusal force measurements were made with an interleaving beam strain gauge transducer. The transducer vertical dimension was approximately 4 mm and was placed in the area of the second premolar/first molar on each side. Participants were asked to "bite as hard as possible without discomfort." The peak amplitudes from 3 trials on each side were averaged to provide measures of occlusal force. Speech was recorded while subjects read the Rainbow Passage (a phonetically balanced reading passage) and 10 sentences generated by "The Computerized Assessment of Intelligibility of Dysarthric Speech" (computer software; C.C. Publications, Tigard, Ore). A trained rater evaluated the speech quality on a 4-point scale. The rater was blinded with regard to speaker identity and time of testing.

For this overview of the study design and treatment, subject and treatment characteristics are presented with descriptive statistics (mean values and SDs, percentages, and frequency distributions) based on the level of measurement. For comparisons of subject responses to

questionnaire items at entry and postsurgical intervals, Fisher exact tests were used ($\alpha=.05$).

RESULTS

Subject recruitment began July 30, 1997 and continued to November 5, 2001. Forty-six participants with oral lesions, requiring segmental mandibulectomy with and without partial glossectomy, were enrolled.

Sample characteristics at entry

Participants ranged in age from 19 to 83 years, with a mean age of 60 years (Table IV). A positive tobacco smoking history (≥ 5 years) was found in 50% (23/46) of the sample, averaging 31 years of smoking, and only 13% (6/46) of participants were currently smoking. Alcohol was consumed by 28% (13/46) of the sample, and 1 additional subject reported a positive drinking history but had been abstinent for 4 years. Education levels were relatively high, with over 90% (42/46) having completed high school.

At entry into the study, 54.3% (25/46) of the participants presented with primary malignant tumors, 21.7% (10/46) with recurrent tumors, 10.8% (6/46) with benign neoplasms, 8.7% (4/46) with osteoradionecroses, 2.2% (1/46) with plate fracture, and 2.2% (1/46) with metastatic tumors (Table IV). The predominant defects (Fig. 4) involved the body (B) in combination with either the symphysis ([S] 43.5%, 20/46) or the ramus ([R] 28.3%, 13/46). Very large defects combining multiple segments (S-B-R, S^h-B-R, RBSB, CRBS^h; S^h denotes a unilateral half of the symphysis) occurred in 10 subjects (21.7%).

Prior to surgery, 7 subjects were edentulous and 39 were dentate, with the dentate subjects having a mean of 12.5 teeth in the maxilla and 11.8 in the mandible. After ablative and reconstructive surgery, the total

Table V. Subjects unable to complete treatment and evaluation

| | Evaluation period | | | | |
|--|------------------------|------------------------|------------------------|------------------------|------------------------|
| | Prior to PS evaluation | Prior to CP completion | Prior to CP evaluation | Prior to IP completion | Prior to IP evaluation |
| | N | N | N | N | N |
| Recurrence/metastasis | 6 | 4 | 5 | 1 | – |
| Death | 1 | – | – | – | – |
| Lost to follow-up | – | 2 | 1 | 1 | – |
| Refused implants | – | – | 2 | 5 | – |
| Requested implants buried | – | – | – | – | 1 |
| Excluded due to radiation | – | – | – | 1 | – |
| Not a candidate (reconstruction plate) | – | – | – | 1 | – |
| Total | 7 | 6 | 8 | 9 | 1 |

number of teeth for those that were dentate decreased by a mean of 4.6 teeth, from 24.2 to 19.6, due in whole to the loss of teeth in the resected mandible. The 25 subjects who completed CP treatment and evaluation and the 15 who completed IP treatment and evaluation (Table IV) showed little difference in general characteristics or disease status from the total 46 who were enrolled.

Participants treated with CP

Only 33 subjects completed CP treatment. The loss of 28% (13/46) of the subjects prior to CP completion was greater than original estimates of a 25% loss through completion of the IP phase (Table V). This loss was due to a higher than anticipated rate of recurrent and metastatic disease. Following ablative surgery and prior to treatment with the CP, 1 subject died due to medical complications, and 10 subjects had a recurrence or metastasis. Two subjects were lost to follow-up prior to CP insertion.

Of the 33 subjects completing CP treatment, 5 received complete mandibular dentures, and the remaining received RPDs. In the 28 subjects treated with an RPD, 3 to 11 mandibular teeth were present (mean 7.4 ± 2.5). Following treatment with the CP and before the evaluation period, 5 additional subjects had recurrences. Two subjects refused additional treatment and evaluation, and 1 was lost to follow-up. Evaluations of the CP were completed for 25 subjects, with a mean duration after CP insertion of 34 ± 19.4 weeks and 76 ± 29.0 weeks after reconstructive surgery. Failure of the CP treatment due to lack of use of the prosthesis occurred in 2 (6%) subjects. Although not considered failures, 3 prostheses had to be remade—one due to further surgical intervention, another due to a change in alignment of the abutment teeth, and a third due to loss of the prosthesis.

Participants treated with IP

Following evaluation of the CP and prior to treatment with the IP, 1 subject had a recurrence, 1 received

excessive radiation treatment (>55 Gy) precluding implants, 1 was lost to follow-up, and 5 refused implant placement (previously, 2 refused implant therapy prior to CP evaluation) (Table V).

While it was planned that implants would be placed soon after healing of the osteotomy sites (4–6 months) (Fig. 1), the mean duration for Stage I implant placement was 51 weeks after reconstructive surgery. The extended duration was primarily due to delays in patient acceptance of further surgical procedures. One subject did not have implants placed until 27 months after initial surgery due to personal time constraints.

A total of 58 implants were placed in 17 subjects. Nine subjects (52.9%) had 4 implants each, 6 subjects (35.3%) had 3 implants each, and 2 subjects (11.8%) had 2 implants each. One subject had implants placed, completed CP treatment, and did not return for further testing or treatment. The implant prostheses inserted were primarily unilateral removable implant-supported prostheses with milled bar attachments (81.3%, 13/16), with only 3 subjects (18.7%, 3/16) receiving complete mandibular implant-assisted overdentures.

Three implants were considered failures due to loss of osseointegration (N=1) or unacceptable position for prosthetic restoration (N=2). No prosthesis failures were due to implant loss. Failure of the IP treatment was seen in only 1 subject (6%, 1/16), who elected to have the milled bar removed and return to a conventional prosthesis. Of the 46 participants enrolled, completion of both CP and IP treatments and follow-up evaluations were achieved for 15 (32.6%) subjects.

Distribution of subjects able to attempt masticatory tests

The standardized masticatory performance tests with peanuts as a test food were difficult for many participants to complete prior to surgery (Table VI), with only 28.3% able to masticate the test food on the side dominated by the defect (defect side). After recovery from reconstructive surgery but prior to definitive CP treatment, only 5.1% of the remaining 39 subjects were able to

Table VI. Distribution of subjects able to masticate test food

| | Evaluation period | | | |
|----------------|-------------------|---------------|---------------|---------------|
| | Entry | PS | CP | IP |
| Defect side | 28.3% (13/46) | 5.1% (2/39) | 44.0% (11/25) | 92.9% (14/15) |
| Nondefect side | 69.6% (32/46) | 61.5% (24/39) | 88.0% (22/25) | 92.9% (14/15) |

masticate the test food on the defect side, and more than one third could not masticate the food on the nondefect side. After treatment with the CP, 88% of the 25 subjects completing evaluation were able to masticate the test food on the nondefect side, while half of these continued to not be able to masticate on the defect side. After treatment with the IP, 14 of the 15 subjects completing evaluation could masticate the test food on both sides.

Comparisons of subject perceptions

From the questionnaire given to assess subject perceptions of their function with teeth and dentures, the percent of favorable responses to selected questions at entry and postsurgery prior to prosthetic treatment are compared in Table VII. Prior to ablative surgery, 43.5% of the subjects reported having “difficulty with chewing,” and over 60% indicated that their food choices were moderately to greatly limited. Social life and satisfaction with facial appearance were not strongly impacted prior to ablative surgery for 67% of the sample, and only 15% indicated their social life was moderately to strongly limited. At the postsurgical interval, the percentages of subjects having a favorable response to questions related to “chewing ability,” effects of “chewing ability” and appearance on social life, and satisfaction with facial appearance were not significantly different from entry. However, the percentage of subjects experiencing moderate to severe limitations in food choices increased from 60.9% to 78.9% ($P < .05$).

DISCUSSION

Recent advancements in facial reconstructive surgery and osseointegrated dental implants provide a treatment modality that may adequately rehabilitate oral cancer patients so that they can return to a healthy, productive life. However, functional and perceptual evaluations of these efforts are necessary before such costly procedures can be accepted for application to large numbers of patients at various health care institutions. The need for such evaluations has been stressed by health care providers and is equally important for policy makers to properly prioritize health care resources.

This prospective longitudinal study was designed to assess the functional and perceptual losses following surgery and the benefits of prosthodontic treatments. Tests made prior to the ablative surgery provide initial functional estimates and assessments (presurgical), although it is recognized that impairments exist in most subjects

Table VII. Percents of favorable responses (score of 1 or 2) for selected patient perception

| Question | Entry | Postsurgery |
|--|-------|-------------|
| 1. Chewing ability | 56.5 | 54.1 |
| 2. Chewing doesn't effect food choices | 39.1 | 21.1 |
| 3. Chewing doesn't affect social life | 67.4 | 65.8 |
| 4. Facial appearance satisfaction | 67.4 | 63.2 |
| 5. Appearance affects social life | 84.8 | 76.3 |

at this time due to their medical condition.²² The second interval (postsurgical), prior to the insertion of conventional prosthesis, was selected to provide time for adaptation to the outcomes of ablative surgery and any adjunctive postoperative radiation therapy. The third test interval, 16 weeks after the insertion of the CP, was chosen to provide sufficient adaptation time to the new prosthesis. The same adaptation time, 16 weeks after insertion of the IP, was maintained for the fourth interval. The adaptation period of 4 months was selected because previous longitudinal studies on complete dentures and RPDs, including implant-supported prostheses, have shown minimal functional changes after 4 months of the insertion of a prosthesis.^{34,36,59}

There were significant difficulties with this population in meeting the targeted treatment and evaluation intervals. Enrollment was expected to be 10 to 12 patients per year for the first 42 months of the study, permitting treatment completion and data collection for both types of prostheses in all patients within 5 years. However, accrual of the predetermined study sample required 52 months. In terms of treatment, extended durations for implant placements were required due to adjunctive therapies and healing intervals for the grafted bone. Additionally, the extensive ablative and reconstructive surgeries delayed the patient's desire to proceed with additional surgical procedures for implant placement. This led to a much longer than expected average interval after reconstructive surgery for implant placement (mean of 51 ± 25.0 weeks) and for completion of the IP (106.2 ± 33.5 weeks).

In this study and in most of the clinical applications in similar patients at UCLA, overdentures are used instead of fixed prostheses for several reasons: (1) the sacrifice of the marginal mandibular and inferior alveolar nerves during lateral composite surgery results in retraction of the lower lip, which compromises speech articulation and a patient's ability to control the confinement of

saliva to the oral cavity. These problems can be resolved or minimized when the denture flange of an overlay denture repositions the lower lip labially to interact properly with the upper lip; (2) the denture flange helps to improve the facial appearance by replacing both the missing teeth as well as the alveolar segment; (3) the overdenture provides critical daily access for hygiene maintenance of implant abutments to minimize peri-implant soft tissue problems; (4) the removable denture permits the placement of teeth more posteriorly than the fixed denture, thereby enabling a compromised tongue to better manage the food bolus; and (5) the initial and maintenance costs for removable prostheses are less than for fixed denture prostheses.

A CP or IP was considered a failure if the patient did not use it frequently during meals, if they rejected the prosthesis, or if the IP became tissue-supported due to the loss of all implants. The decision to consider an IP a failure on the loss of all implants was made because the prosthesis support becomes similar to that of a CP. Such an outcome is clear cut. Other choices based on the number or percent of implant losses or failures would be difficult because of the wide variability in prosthesis design among patients. Only 3 prostheses that were inserted were considered failures—2 conventional prostheses and 1 implant prosthesis. Clearly, the more significant treatment issue was not the failure of implants (5.2%, 3/58) or implant prostheses (6%, 1/16 prosthesis failure), but the rejection of implant therapy by 7 of the 24 eligible subjects (29%, 7/24). While intent on being treated with the implant prosthesis at study enrollment, these subjects rejected implant treatment primarily due to difficulties coping with additional surgery, time constraints, and acceptance of the CP as being adequate.

The significant loss of subjects prior to completion of the IP leads to questions regarding primary placement of implants at the time of reconstructive surgery versus secondary placement after the patient has stabilized and determined if they have a need for additional stabilization/retention of the CP for function, esthetics, or comfort. With 35% (16 of 46) of the sample suffering recurrence, metastasis, or death within 13 months following the ablative and reconstructive surgery, there would be significant additional cost, effort, and potential complications to patients that would result in a prosthesis that would never be used. This loss would be even greater if the study sample was limited to only cancer resection patients. It should be noted that of the patients who suffered recurrences, 9 were initially treated for T₄⁴⁷ primary tumors, 1 for a T₃, and the remaining 6 for recurrent disease. In contrast, the 15 patients that completed all treatment and evaluation phases of the study included 2 treated for osteoradionecrosis, 2 for benign tumors, 1 for plate fracture, one T₁, five T₂, one T₃, two T₄, and 1 recurrent tumor. Considering that only 36 of the 46 subjects were treated for malignant

tumors, the actual recurrence rate in this sample was 44% (16/36). In addition, 7 subjects were satisfied with their CPs and remaining natural dentition and indicated the potential to improve the fit of the prosthesis did not offset the additional time, surgery, and inconvenience required for implant therapy. The fact that 88% of the subjects treated with the CP could complete a masticatory test with a difficult-to-masticate food (peanuts) on the nondefect side indicates that the CP may meet at least minimal functional needs.

The choices regarding further treatment with the IP were made without the consideration of cost, which was covered by the study. It is quite likely that the average cost of IP therapy of approximately \$15,000 (US) for the implants and prostheses, not including hospital costs, would have deterred others from completing this treatment. IP therapy could be given at an earlier stage with primary implant placement at the time of reconstructive surgery, and the issue of additional surgery would not be a major factor in rejecting IP therapy, since only minor stage II surgery would be required. Primary implant placement also has been advocated by some groups as an alternative option to overcome the problems of implant placement in irradiated bone,^{44,45} including higher implant failures and possible osteoradionecrosis. Hyperbaric oxygen therapy is generally prescribed when the implant sites are exposed to greater than 50 Gy radiation in the hopes of improving the vascularity and quality of the bone and irradiated soft tissues.³⁹⁻⁴² In this study protocol, HBO was not used due to issues related to the relatively high costs in time, dollars, and potential complications.^{39,43} Additionally, it has not been unequivocally demonstrated that primary implant placement or HBO obviates all or any of the problems or issues discussed previously.^{23,29,46}

Limitations in the number of subjects enrolled from a single institution indicate that future studies would benefit from multi-institutional participation. Greater sample size would permit an increase in the number of participants completing both conventional and implant-based prosthetic treatments, resulting in greater ability to evaluate subgroups of patients. Even with the restrictive inclusion/exclusion requirements, large differences in defects and dentition status occurred in the present study. It is difficult to assess the effects of treatment type on small subgroups of 2 to 3 subjects with similar characteristics. In addition, the relatively small participant pool necessitated a within-subject design without randomization of treatment order. The effect of a longer adaptation period to the surgical interventions at the time of evaluation of the IP compared to the CP is unknown.

CONCLUSIONS

Conventional prosthesis treatment was completed in 72% (33/46) of the subjects enrolled in this study.

However, due to high rates of recurrence/metastasis (44%) during the first year following ablative surgery for subjects treated for malignant tumors, and rejection of implant therapy by 7 of the 33 subjects treated with a CP, only 16 subjects were treated with the IP. Treatment failures of either the CP (6%, 2/33) or IP (6%, 1/16) were limited and were related to lack of use or subject preference for alternative treatment. In the reconstructed mandibulectomy patient, initial treatment with a CP and secondary implant placement permit the assessment of the functional level of the patient prior to recommending further treatment options, including use of IPs. Secondary placement also allows for a disease-free period before the initiation of extensive dental procedures.

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Noteworthy Abstracts of the Current Literature

Temporomandibular disorders among smokers and nonsmokers: A longitudinal cohort study Wanman A. *J Orofac Pain* 2005;19:209-17.

Aims: To evaluate whether smoking influences the presence and/or development of signs and symptoms of temporomandibular disorders (TMD) among adults.

Methods: A random sample of subjects 35, 50, and 65 years of age was drawn from the general population and examined with the aid of a questionnaire and a clinical examination. Within the sample, smokers were identified based on reported current smoking and nonsmokers were matched to the smokers based on age, gender, educational level, area of residence, and number of teeth. In total, 268 subjects were matched (134 pairs). Six years after the baseline examination, 122 matched pairs were re-examined.

Results: Mild symptoms of TMD were reported by approximately 30% of the sample both at baseline and at the follow-up examination 6 years later. Pain in the jaws and/or more severe symptoms of TMD were reported by approximately 15% on both occasions. No significant differences between smokers and nonsmokers were found regarding symptoms of TMD. In both examinations, mild signs (dysfunction index I) were found in approximately 40% of the sample and moderate to severe signs (dysfunction index II to III) in approximately 20%; no statistically significant differences were found between smokers and nonsmokers. No significant differences were found between smokers and nonsmokers regarding the course of symptoms or signs of TMD during the study period.

Conclusion: Smoking is not a factor related to the presence or development of signs and symptoms of TMD.—*Reprinted with permission of Quintessence Publishing.*