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Two-Implant Supported Maxillary Overdentures: One-Year Assessment of Patient-Centered Outcomes.

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One-Year Assessment of Patient-Centered Outcomes.

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Abstract

Statement of Problem: Maxillary overdentures supported by four implants have been shown to be more effective and provide improved patient-centered outcomes as compared to conventional dentures, particularly when alveolar ridges are resorbed and when palate form is shallow. However, there is minimal data on patient-centered outcomes of using 2 implants to support maxillary complete dentures

Purpose: The purpose of this study is to evaluate the patient reported outcomes of the 2-implant maxillary overdentures with complete palatal coverage, over a 1-year period.

Materials and Methods: A total of 17 patients were enrolled in this pilot clinical study. Each patient received two dental implants bilaterally in the maxillary anterior region at the lateral incisor or canine region. After successful osseointegration, two solitary abutments (Locator) were inserted over the implants and the patient's existing denture was attached to the abutments through a laboratory reline of the denture and thus converted to a two-implant retained maxillary overdenture. Thereafter follow-up exams were performed and patient-reported outcomes were studied at baseline (conventional complete dentures); 1 week post-insertion of relined maxillary overdenture; 6-months; and 1 year post-insertion (all two-implant supported maxillary overdenture). The patient-centered outcomes were recorded at follow-up appointments using visual analog scale (VAS) for 8 variables and a modified oral health impact profile (OHIP-14 short form). These variables were compared to the conventional dentures (baseline) and at the 1 year follow-up by using Wilcoxon signed-rank test and Likert scores, respectively using an alpha value of 0.05.

Results: One-year follow-up data were available for 11 out of the 17 patients enrolled in the study. There was a statistically significant difference in VAS score from baseline (existing denture with no implants) to insertion of overdentures for all variables (P<.05). However, the difference was noted for the variable "ability to clean the denture". There was a statistically significant difference in VAS score from baseline (existing denture with no implants) to 1 year after insertion of overdentures for the following variables: retention, stability, support, tissue health, and overall comfort (P< .05) For the OHIP-14, the proportions were significantly different from baseline to both insertion and 12-months follow-up, respectively for the subgroups psychological disability, social disability and handicap. Additionally, 9 out of 11 patients who previously used denture adhesives reported that they no longer used any denture adhesive during the 1-year evaluation period.

Conclusion: Within the limitations of this pilot study, two-implant supported maxillary overdentures increased patient satisfaction based on various variables studied using 2 standardized instruments. The patient satisfaction variables remained stable at the 1-year evaluation. Additionally, the 2-implant maxillary overdentures eliminated the need for a denture adhesive in all 11 patients during the 1-year evaluation period.

Introduction

Review of the literature

According to the Centers for Disease Control and Prevention (CDC), edentulism in the United States has decreased from 10.8% in 1988-1994 to 7.7% in 1999-2002.[1] Despite this decrease in percentage, the prevalence of the number of patients in need of complete dentures is expected to increase with the increase in the aging population. In the year 2000 Douglass et al. estimated the needs of at least one complete denture in 2020 for more than 61,000 adults. Comparing to 2000 with 56,493 and 2010 with 59,265 he reported that there will be an increase in the number of edentulous patients. Furthermore, the prevalence of edentulism in the maxilla was higher,[2] whereas mandibular edentulism was much less frequent.[3]

Different treatment options have been described in the literature to manage the edentulous maxilla: conventional complete denture, implant-supported overdentures with and without palate, metal-resin fixed complete denture and metal-ceramic fixed implant-supported prostheses.[4,5,6] Taking into consideration the different clinical situations and the patient's needs the dentist is obliged to give all the different treatment options for adequate dental care.

Complete dentures represent a reversible and effective form of treatment for patients with missing teeth and have been the conventional standard of treatment for almost 100 years.[7,8] For the majority of edentulous patients, the conventional complete denture fulfills the necessary comfort and function to replace their dentition. Despite this success, some patients have difficulty obtaining the necessary support, retention, and stability to be considered a successful denture wearer, despite clinical expertise. One of the reasons could be due anatomical features such as a nonexistent anterior maxillary undercut, resorbed maxilla, a shallow palatal vault or an acute soft palatal form palate.[9] Angulations at the incisor and the premolar region between the

edentulous crest and the base can vary from 65-85°.[10] The contour of the bone tissue dictates the intaglio surface of the artificial removable prostheses, whereas the muscle fibers attached to the external surfaces of the bony edentulous jaws determine the denture borders.[9,11,12] The retention of the conventional complete denture has been discussed extensively in the prosthodontics literature and is based on various factors such as atmospheric pressure, adhesion, cohesion, viscosity of the saliva, shape and weight of the denture, denture material, occlusion and articulation.[45] Other authors have theorized that the viscosity of saliva may have a very important role in denture retention. Schulze discovered that two glass slabs with a layer a saliva between them will stay together better than with a layer of water.[46] Cedervärn stated that although he could not prove the importance of viscosity be believed that it did play a role in denture retention.[47] This classic literature emphasizes the importance of saliva in the retention of complete dentures. Systemic issues and side effects of various modern drugs can decrease the saliva and increase xerostomia.[48] This condition appears especially in the elderly population. Therefore, it can be assumed that in case of loss of retention due to xerostomia, the complete denture may benefit from an additional retentive element.

Multiple options have been developed to aid in the retention of complete dentures, including the use of denture adhesives.[13] But the adverse effects related to long-term use of denture adhesives on oral and systemic health is unknown. Without periodic professional recommendations, adhesives are contraindicated and moreover they can mask the presence of a pathology.[14] When denture adhesive fails to provide the necessary retention, additional alternatives can be taken into consideration, such as the anchoring of the denture to implants placed in the maxilla. The indication for implants in completely edentulous jaws is either to

stabilize the dentures by placement of implant-retained overdentures or to avoid removable complete dentures by placement of implant-supported fixed prostheses.[5]

Since the introduction of implants, patients could be provided with implant-retained overdentures, which results in a high level of satisfaction.[15] A systematic review reported that the patient-centered outcomes for mandibular implant prostheses compared to conventional complete dentures were superior.[16] Furthermore the author described in the second part of his systematic review different treatment options for the edentulous maxilla. He reported that chewing ability and satisfaction can be improved by implant retained overdentures.[17]

Increasing patient satisfaction and improvement in oral and health-related quality of life was shown by Zembic et al when they compared the patient reported outcomes between conventional complete dentures and implant supported overdentures.[18] In a second part of their study they presented one-year implant survival rate of 97.3% on their implant overdentures, retained by solitary ball anchors.[19] However, these authors also reported early bone loss for many study implants, which were placed as a single stage surgery and included patients who were smokers.

Choosing the right attachment system plays an important role for the clinical outcome and patient's fulfillment. It has been found that there is no significant difference in the overall satisfaction of the patient between solitary versus bar attachments.[20] But in the same study the bar showed to be more maintenance sensitive compared to the two individual attachments. After comparing two different solitary attachment types (ball/locator) there was no significant difference for general satisfaction, comfort, speech, esthetics, chewing ability, denture stability, as well as post-insertion maintenance of the prosthetic parts.[21] In general these attachment systems, e.g. the Locator (Zest Anchors LLC, Escondido, CA, USA) consist of a matrix and a

patrix. The component that is part of the overdenture prosthesis generally includes a metal housing that mechanically accommodates the replaceable patrix, which is composed of a nylon insert. The technique to incorporate the attachment in the implant-retained overdenture has been discussed in detail by Bidra et al.[22] With an already existing denture, there are two techniques recommended: A direct chairside method and an indirect laboratory procedure. Though the indirect method creates an additional laboratory procedure and more expense, it is reported to be longer lasting and provides a stronger bond between the attachment and acrylic resin. If needed, it also allows for reline of the denture at the same time.[22]

In summary, maxillary implant-supported overdentures represent a reliable treatment option. The clinician and the patient determine the number of implants that will be used to support the prostheses, whether they will be splinted with a bar or unsplinted with solitary attachments, and if the chosen design will include full palatal coverage. Although there are no specific guidelines for the number of implants necessary to support a maxillary overdenture, In his review, Sadowsky reported there is a consensus that a palateless overdenture should be supported by a minimum of four implants.[23] However, he concluded that there is a lack of scientific evidence regarding maxillary implant-supported overdentures and that further studies with greater sample size (and statistical power) were required to establish evidence-based treatment planning principles. The minimum number of four implants was also recommended in other publications related to the maxillary overdenture.[5,24,25] Zitzmann et al. reported that whenever only two implants are present, the prosthesis should be designed similar to a complete denture with a posterior seal and flange.[6] In general, the treatment of the edentulous maxilla should take into consideration criteria such as degree of atrophy of the jaw, prospective location and inclination of the implants, tissue volume dimensions, facial morphology, esthetics, function

and phonetics. Treatment planning for this area should also take into account the prosthetic design, the distribution, number and location of implants, the nature of the dentition or type of prosthesis in the opposing jaw, the intermaxillary relationship, the occlusal scheme and esthetic considerations.[5] A literature review by Laurito et al. recommended placement of the implants mesial to the first premolars to enhance stability.[26] Complications associated with overdenture treatment include loss of retention/adjustment, relines, attachment fracture, prosthesis fracture, opposing prosthesis fracture, and acrylic resin base fracture.[27]

As noted above, it is generally accepted that a maxillary overdenture requires the placement of four implants.[6,28,29,30,31,32] Many clinicians prefer this number of implants based on empiricism/clinical experience when selecting a horseshoe design overdenture prosthesis (that does not result in full palatal coverage), which reduces prosthesis bulk as well as improving taste perception and patient comfort.[33] However, the greater number of implants causes additional treatment expense and may preclude many patients from receiving overdenture treatment. As such, the 2-implant maxillary overdenture with full palatal coverage provides an intermediary solution between the 4-implant overdenture and the conventional complete denture. It does not resolve the issue of complete palatal coverage for the patient, but can possibly provide better service that the conventional complete denture through improved preservation of the peripheral seal, better support and stability, eliminating the need for denture adhesive and decreased movement during function. Thus, it has the potential for improved quality of life for the patient. On the other hand, it is a more expensive treatment compared to a conventional complete denture that does not require additional surgical and prosthetic procedures. There are few clinical and patient-centered outcomes related to the 2- implant maxillary overdenture reported in the literature.[34] One recent study has shown that the patient satisfaction overall is significantly

increased by a two-implant overdenture compared to the conventional complete denture. This reinforces the possibility of an effective and cost-effective implant-supported overdenture treatment option.[18]

To evaluate the patient's satisfaction with treatment, it is important to assess the oral health and related factors that are important in their everyday lives. The Oral Health Impact Profile (OHIP) was developed by Slade et al. in order to provide a comprehensive measure of self-reported dysfunction, discomfort and disability attributed to oral health conditions [35] The OHIP is divided into 7 sections (functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, handicap) with 7 questions under each section. These 7 dimensions are based on Locker's theoretical model of oral health.[36] The original authors later abbreviated the OHIP questionnaire to create a shorter form with 14 questions, addressing 2 questions for the same 7 sections. This is referred to as the OHIP-14.[37] The OHIP-14 questionnaire has been utilized and validated by several studies in prosthodontics around the world. However, the OHIP-14 presents with certain limitations such as questions that may be too general and not as treatment specific as desired. The questionnaire tends to be difficult for use as a direct treatment application/decision based on its results. (see Appendix III)

A Visual Analogue Scale (VAS) is a measurement instrument that measures characteristics or attitudes that range across a continuum of values and cannot easily be directly measured.[38,39] It includes a standard ruler of 100mm and participants (raters) are asked to draw a mark on the 100mm line for satisfaction related to each element that is in question. The evaluator measures the distance from 0mm to the mark and records the number in integers. The VAS method has been validated in numerous studies and can yield quantitative values for qualitative elements.

The present study utilizes the VAS method to allow patients to rate a set of outcomes that are directly related to their 2-implant maxillary overdenture treatment. (see Appendix II)

Rationale

It has been reported in the literature that a maxillary overdenture should be supported by four to six implants. The surgical placement of this many implants increases surgical risk, requires adequate bone volume at a large number of sites and with higher treatment costs. On the other hand, one recent preliminary study from Europe has shown that there is no significant change in patient satisfaction and quality of life when comparing a four-implant supported maxillary overdenture to the more cost-effective two-implant overdenture.[18,33] The 2-implant approach appears to provide adequate support, retention and stability for the prosthesis with decreased surgical risk and cost.[18,33] For this modality of treatment to be better accepted, additional studies are needed illustrating objective clinical and patient-reported outcomes.

The goal of the project was to study patient-centered outcomes for two-implant supported maxillary overdentures. This allowed for comparison of numerous variables for overdentures compared to each patient's previous complete denture and then outcomes post implant placement over time. For this purpose, the Oral Health Impact Profile-14 questionnaire and a Visual Analog Scale ratings for key elements related to denture performance were employed for all patients.

The results from this descriptive pilot study will help in defining a new standard for a minimal invasive treatment with implant overdentures and should be used to design a subsequent analytic study with a larger sample size.

Objectives and Hypothesis

Objectives of research

This descriptive pilot study will validate the following objective:

To know if there are any differences in patient satisfaction outcomes when measured at baseline with existing conventional complete denture and for two-implant supported maxillary overdentures when measured at a one-year follow-up evaluation.

Hypothesis

This study will test the following null hypothesis:

There is no difference in patient satisfaction outcomes of the two implant supported maxillary overdentures when compared at baseline and at one-year evaluation.

Materials and Methods

Overview

This study underwent a process of careful planning and has received approval from the UCHC Institutional Review Board (#14-221-3). All procedures described were standard of care and best practice procedures. Surgical placement of two implants, conversion of the conventional denture to an overdenture and follow-up's were performed under direct supervision of a major or associate advisor. Both operators (Kernen, Thomas) were calibrated and standardized forms/questionnaires were used.

Patients were recruited with IRB approved flyers in the University of Connecticut post-graduate prosthodontics clinic. Patients who qualified for the study paid a decreased fee and were reimbursement for every follow-up appointment.

Potential risks related to the treatment procedures were primarily related to common risks of implant therapy. Implant placement is largely considered to be a highly successful treatment with long-term survival ranging up from 95% to 100% in healthy individuals. Implant survival for maxillary overdentures with complete palatal coverage has been reported to come up to 95.5% after 8 years.[43] Patients were explained in detail about the risks of the surgical procedures and potential post-treatment sequelae as part of the informed consent process.

In the event that a patient was not satisfied with the outcome of the overdenture treatment during this clinical trial, the treatment was reversible by removing the locator abutments and allowing the adjacent gingival tissue to close over the implants. This would have allowed the patient to revert back to the existing complete denture.

Experimental Design and Research Location

This descriptive pilot study was conducted in the post graduate Prosthodontic clinic of the University of Connecticut School of Dental Medicine. It was part 2 of a 2-part study on two-implant supported maxillary overdentures. Part 1 of this study focused on clinical outcomes using clinical findings and part 2 focused on patient satisfaction using patient-reported data.

Sample selection

A total of 17 patients were enrolled in this pilot clinical study. The patient population included maxillary edentulous patients who were wearing a maxillary conventional denture opposing natural teeth, a removable partial denture, or an implant supported or retained mandibular prosthesis. Interested patients went through the informed consent and HIPAA process on IRB approved forms. All patients had a clinical exam and a brief history of their current condition recorded to determine eligibility into the study. If the patient did not meet inclusion criteria, the patient was allowed to seek care according to the standard procedures established in the postgraduate prosthodontic clinic (Dental Clinic 1) or pre-doctoral dental clinic (Dental Clinic 4).

The patient's eligibility for the study was defined by the following inclusion and exclusion criteria:

Inclusion criteria of the patients:

- Adults older than 18
- Edentulous for at least 1 year
- Currently wearing an upper complete denture in reasonably good condition, satisfied with esthetics and without history of denture fractures within the past year

- In good general health
- Able to be present for multiple appointments on time for the length of the study
- Healthy oral tissues
- Able to travel to the Health Center for the length of the study
- Able to understand and respond to self-reporting measurement scales (visual analog scale) and questionnaires as well as participate for the length of the study
- Able to understand written and verbal English instructions or the ability to bring their own translator.
- Opposing dentition, fixed restorations, or overdenture

Exclusion criteria of the patients:

- Unable to fulfill inclusion criteria
- Significant cognitive impairment
- Compromised health status
- American Society of Anesthesiologists (ASA) type 4 patients
- Pregnant
- Smoke >10 cigarettes a day
- Immunocompromized (including HIV)
- Poorly controlled diabetes (A1C above 7)
- Metastatic cancer
- Any chronic medical disorder
- Mandibular complete denture or edentulous
- Patients wearing immediate maxillary dentures
- Patients wearing ill-fitting dentures (unless relined before inclusion in the study)

- Patients with clinical signs of bruxism, severe denture wear, or other functional disorders
- Maxillofacial patients with resected/reconstructed jaws
- Maxillary anterior undercut creating substantial challenges for implant placement
- Inability to acquire all necessary diagnostic information for proper evaluation
- Psychiatric or psychological conditions that could influence the patient's reaction to treatment.
- History of IV bisphosphonate use.

A cover letter/informational sheet was given to each patient who was eligible for the study. This form gave a brief description of the study purpose and a statement that participation is voluntary.

Consent process

Patient consent was obtained at beginning of the patient interview in a private operatory at the University of Connecticut School of Dental Medicine post-graduate Prosthodontic Clinic.

The step-by-step process for obtaining consent was as follows: The investigator obtaining consent reviewed the information presented in the basic information sheet and informed consent with the potential subjects. After reviewing the material, the patients was asked if they have any questions, if not they were asked to summarize their understanding of what enrollment in the study involves. If they could not do this adequately, the material was reviewed again. If after three tries the potential patient still could not adequately summarize the information, s/he was not be enrolled. It was emphasized at every time that this study was voluntary. Patients were informed that even if they did not participate in the study, they were still eligible to seek care according to the standard procedures established in the post-graduate prosthodontic clinic. All

descriptive data including patient's age, gender, race, years of edentulism, years of wearing an existing maxillary denture, House classification, history and years of previous smoking, type of dentition/prosthesis in the mandible was also collected.

Procedures

The following were the projected treatment procedures:

- Screening: When a patient was enrolled in the study, and finances related to the study were explained (Figure 1).
- Initial exam and pre-operative visit. Consent forms were obtained and baseline VAS and OHIP-14 data was taken related to their existing maxillary denture. The rationale of the CBCT scan was explained (Figure 2).
- Surgical placement of implants.
- Post surgical follow-up as needed.
- Three-month post-implant placement follow-up with implant evaluation and surgical exposure where necessary. Locators abutments inserted and attachments picked up by indirect method.
- Insertion of converted two-implant supported maxillary overdenture
- One-week recall and OHIP-14 and VAS rating for two-implant supported maxillary overdenture.
- 12-month recall and OHIP-14 and VAS rating for two-implant supported maxillary overdentures

The surgeries were performed by two residents (Kernen and Thomas) of the post-graduate Prosthodontic clinic at the University of Connecticut School of Dental Medicine, supervised by the principal investigators (Bidra and Freilich). Two implants were placed in the anterior maxilla in the lateral incisor or canine region using conventional surgical procedures. After administering local anesthesia, midcrestal incisions were performed that extended through the mucoperiosteum and attached gingiva down to the alveolar bone (Figure 3). Extension of the flap and incisions slightly varied due to the anatomical locations of the implant placement.[40] However, the incision was long enough to permit adequate reflection of the flap and provide an adequate view and access to the surgical site. Alveolar bone anatomy such as sharp areas or bone irregularities required use of a bur or hand instruments in order to create a smooth boney crest surface (Figure 4).[40]

The implant bed was prepared by using a surgical drill-unit with adequate external irrigation (sterile saline) to minimize the potential for overheating the bone. Sequential drilling sequence followed as per implant manufacturer recommendations (Camlog Biotechnologies AG, Basel, Switzerland) using a straight up-and-down motion to avoid creation an oval-shaped osteotomy site. With the help of a surgical guide confirmation was made after every drill sequence to check verify correct location and angulation of the osteotomy. After preparing the site, the implants (Conelog Screw Line implants, Camlog) were inserted following the manufacturer recommendations (Figures 5-7).

In case of minor bone defects, such as dehiscence or fenestrations, guided bone regeneration (GBR) procedures (not compromising primary implant stability) were used. Bio-Oss (Geistlich Pharma AG, Wohlhusen, Switzerland) was applied to the dehiscence and covered by a resorbable bilayered collagen membrane Bio-Gide (Geistlich Pharma AG, Wohlhusen,

Switzerland). Bio-Oss composed of particulate bovine bone is a bone substitute material for natural bone regeneration. Additionally, Platelet-rich fibrin (PRF) was used with the intent of improving soft tissue healing. This outcome has been reported in the literature and is said to be beneficial to the patient.[44] PRF is an autologous substance that can be isolated from the blood and is rich in fibrin and Vascular Endothelial Growth Factor.

A dedicated research nurse assigned to this study collected venous blood using a blood tube holder with an attached sterile blood collection needle (21-guage x 1 ½ thin wall) into three 10 mL Vacutainer blood collection tubes, immediately before commencement of the surgery. The blood was then centrifuged in a Clinaseal centrifuge for 20 minutes at 3000 rpm. During centrifugation, each sample forms three layers that include a red blood cell layer on the bottom, a plasma layer on the top, and a middle layer containing the fibrin clot. The middle PRF layer was separated from the other two layers using sterile tweezers and placed on sterile 2x2 gauze. The fibrin clot was used in two ways. First, using Salvin PRF-Box (Salvin Dental Specialties, North Carolina), any remaining serum was squeezed from the fibrin clot and the fibrin clot was then compressed to a 1 mm thick membrane (Figure 8). This membrane was used as an additional membrane and was placed under the raised surgical flap (Figure 9). Second, the fibrin clot was mixed with the aforementioned bovine bone graft material before it is placed in the patient. PRF will help to concentrate the growth factors, fibrin, and platelet to this wound-healing site.

After placement of the implant, bone graft (if needed) and PRF, the mucoperiosteal flap was closed with sutures (Figure 10). The implant was submerged or non-submerged depending on operator judgment (Figure 12). Implant position was documented with a standardized peri-apical radiograph (Figure 11) and the patient was given post surgical instructions.

After a healing period of 3 months (Figure 13), the implants were uncovered (where needed) with minimal surgical excision of overlying gingiva and the appropriate abutments (Locator, Zest Anchors LLC, Escondido, CA, USA) were placed according to the implant manufacturer's instructions. To incorporate the attachments using an "indirect" technique it is necessary to place the corresponding attachment on the abutment and pick up the attachments in an impression made inside the patient's maxillary denture. While the impressions were made, the patients were asked to close into centric occlusion. The dentures containing the polymerized impressions and attachments were sent to the lab to incorporate them into the inner surface of the denture. These denture relines were done according to conventional laboratory procedures (Figures 14 and 15) using heat-polymerized acrylic resin.[22] In certain situations, a direct attachment technique was used after the relining procedure and the attachments were incorporated by drilling 2 holes in the complete denture and using composite resin material (Quickup; Voco)

After insertion of the overdenture conversion prostheses, patients returned to the clinic for a 1-week follow-up and any additional follow-up for adjustments, where needed. They also returned for data collection follow-up exams at 6- and 12-month time periods. During all follow-up appointments, any needed standard of care adjustment procedures were performed at the postgraduate Prosthodontics clinic.

Patients described here were followed for a minimum period of 12 months. In accordance with the IRB protocol and standard of care protocol followed in the post-graduate Prosthodontic clinic at the University of Connecticut School of Dental Medicine, photographs were made documenting the treatment of each patient.

Survey instrument and implementation

The current standard measurement was used for this purpose: The OHIP-14 questionnaire and a VAS scale ratings.

The following patient-centered outcomes were evaluated at various follow-up intervals, using the Visual Analog Scale (VAS) (see Appendix I):

- Tightness
- Absence of movement while functioning
- Bite/Chewing ability
- Absence of sore spots in the mouth
- Absence of food underneath the denture (Adaptation of denture bases)
- Speech
- Ability to clean the denture
- Overall comfort with the denture.

Study patients were also provided with the OHIP-14 questionnaire (see Appendix II). The goal of this instrument was to provide a comprehensive measure of self-reported dysfunction, discomfort and disability arising from oral conditions. Responses are made on a five-point scale, where 0 stands for "never" and 4 means "very often". Higher scores mean poorer patient satisfaction. All 14 different questions can be multiplied by a specific weight to get a subscale score. The 14 questions are divided into 7 main dimensions (functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, handicap) with 2 questions for each dimension. Within each dimension the coded responses can be multiplied by the weights so that at the end they equal 1. For example, in the first dimension ("functional limitation) if a patient selects the option "occasionally" for the first question (scored

as 2) and for the second question selects “very often” (scored as 4). The standard weights for these responses are 0.51 for the first question and 0.49 for the second question respectively. The patient’s responses, multiplied by the weight now equal 1.02 and 1.96. Therefore, the 14 questions obtained from a controlled selection procedure reflect patient’s judgments about the dissatisfaction of each pair of items within dimensions.[37] In comparison to the OHIP-14, the VAS measures patient satisfaction the opposite way: Higher scores implied higher satisfaction and lower scores implied lower satisfaction.

Both surveys were conducted on a printed sheet of paper and in a face-to-face manner in a private operatory in the post-graduate Prosthodontic clinic at the University of Connecticut School of Dental Medicine after clinical examination at each of the follow-up visits.

Data analysis

VAS: The VAS scores (by question and difference between time points) were summarized by median and range (results of mean and standard deviation are also provided). By Wilcoxon signed-rank test, we tested against the null hypothesis that the change from one time point to another time point is zero on average. An alpha value of 0.05 was chosen to represent a significant difference in VAS score changes within patients.

OHIP: The Likert scores of each question were summarized by mean and standard deviation as well as the proportion of reporting item occasionally, fairly, or very often. We compared the proportions between time points by McNemar’s test and performed Wilcoxon signed-rank test to compare Likert score distributions. An alpha value of 0.05 was chosen to represent statistically significant difference between baseline and studied intervals.

Results

Descriptive Data

A. Summary of Data Collected

At the time of data analyses, one-year follow-up data were available for 12 out of the 17 patients enrolled in the study. One out of 24 implants failed yielding a 1-year implant survival rate of 95.8%. There were 3 females and 9 males with a mean age of 68.24 (±9.9) as represented in table 1. Table 1 describes the demographics of the study patients, which were classified based on age, gender, years of edentulism in the maxilla, years of wearing existing denture and type of dentition/prostheses in the opposing arch. The mean number of years for edentulism was 3.95 and ranged from a minimum of 1 year up to 10 years. The number of years wearing the existing denture was in average 1.91 years. Regarding the nature of the opposing arch in these 12 patients,,5 had a mandibular overdenture, 4 an intact natural dentition, 2 had a removable partial denture and one had a full arch fixed dental prosthesis supported by four implants.

B. Number of Patients evaluated at Baseline and 12 months

Of the 12 subjects presented for analysis, 1 patient withdrew from the study (after loss of an implant 7 months after insertion, Patient #7). This patient was offered replacement of the failed implant but chose to submerge the existing contralateral implant and re-converted the maxillary prosthesis to a conventional maxillary complete denture.

Data subjected to statistical analysis

A. Data Values

Table 2 represents the VAS master sheet and table 3 the OHIP-14 master sheet for all 11 patients whose outcomes were analyzed at time points baseline, insertion of the overdenture and 12 months. Table 2 shows values measured from the VAS rounded to the nearest hundredth of a point. Table 3 shows values of the OHIP-14 questionnaire at the same 3 time points. The data VAS values presented in table 2 were then converted and statistically analyzed using the mean averages and standard deviations shown in table 4.

B. Statistical Analysis

A total of 11 patient-centered outcomes were studied and data recorded on a VAS and OHIP-14, and data were computed, tabulated and are presented below.

VAS (table 5)

Table 5 shows median VAS scores at baseline, Insertion, and 12 months for:

- Q1. Fit/"Tightness of the denture
- Q2. Absence of movement while functioning
- Q3. Bite/Chewing ability
- Q4. Absence of sore spots in the mouth
- Q5. Absence of food underneath the denture
- Q6. Speech
- Q7. Ability to clean the denture
- Q8. Overall comfort with the denture

Q1. Fit/"Tightness" of the denture: At baseline, patients rated retention to be 67.91 (table 4) and at the time of insertion of the converted prosthesis 95.55. Comparatively, at 12 months patients rated it at 94.45. Based on the median values in table 5, this variable showed statistical significance when comparing baseline (maxillary complete denture) to insertion and 12-months follow-up, respectively.

Q2. Absence of movement while functioning: This variable shows how patients evaluated stability or absence of rocking with the denture. Table 5 shows statistical significance when comparing patient's ratings from baseline to insertion and 12-months follow-up, respectively.

Q3 Bite/Chewing ability: Patients evaluated chewing ability and occlusion. Based on the results in table 5, there was statistical significance when comparing patient's ratings from baseline to insertion and 12-months follow-up, respectively.

Q4 Absence of sore spots in the mouth: Question 4 focused on how patients evaluated Tissue health and comfort. This variable was statistically significant according to data analysis when comparing patient's ratings from baseline to insertion and 12-months follow-up, respectively.

Q5 Absence of food underneath the denture: Patient evaluated Support of the maxillary dentures. This variable showed statistical significance when comparing baseline to insertion. It was not statistically significant when comparing baseline to 12-months follow-up according to data analysis.

Q6 Speech: Patients rated the ability to speak normally and speech sounds in question 6. It can be seen in table 4 that the mean continuously increased from baseline 77.91, to insertion 88.73 to 12-months follow-up 91.27. The median on the other hand showed 90, 98, and 89, respectively. These values only resulted in statistical significance from baseline to insertion, but not from baseline to 12-months follow-up.

Q7 Ability to clean the denture. This variable showed how patient rated the ability to clean the denture with and without the incorporated attachment matrices (nylons). Mean and median values were similar and the variable resulted in being not statistically significant.

Q8 Overall comfort of the denture. The patient gave their general impression of their dentures before and after conversion. This variable was statistically significant when comparing baseline to insertion and 12-months follow-up, respectively

In summary, the VAS scores significantly increased from baseline to 3 months for all questions except for question 7 and from baseline to 12 months for questions 1, 2, 3, 4, and 8. There was no significant increase in VAS scores between 3 months and 12 months for any of the questions.

OHIP-14

Mean changes in time for each question are described in table 6: The OHIP-14 scores differed between the questions in a time-dependent manner. This observation was based on

Wilcoxon signed rank test performed on the 11 patients. The mean values of the OHIP-14 with standard deviations for baseline, Insertion and 12-month follow-up are presented in Table 6. The Likert score distributions show statistical significance between baseline and Insertion (3 months after implant placement) for question 8 (Have you had to interrupt meals because of problems with your teeth, mouth or dentures?).

The OHIP-14 mean scores significantly differed when comparing baseline to 12 months for questions 2 (Have you felt that your sense of taste has worsened because of problems with your teeth, mouth or dentures?), 5 (Have you been self-conscious because of your teeth, mouth or dentures), 7 (Has your diet been unsatisfactory because of problems with your teeth, mouth or dentures?), and again 8.

Significant differences occurred more often when comparing baseline to 12 months rather than baseline to insertion indicated the gradually increasing patient satisfaction and the improvement of oral-health-related quality of life over time. Similar to the VAS scores, there was no significant difference between insertion and 12 months for any of the questions indicating stability in patient satisfaction.

For the 14 questions, the prevalence of reported impacts (at the threshold of occasionally, fairly often or very often) ranged from 64% (Q4) to 0% (Q12, Q14) at baseline and 36% to 0% at Insertion and 12 months follow-up as described in table 7. The proportions are significantly different at baseline and Insertion for questions 9, 11, and 14 and at baseline and 12 months for questions 9 and 11. The significance was also observed between 3 months and 12 months for questions 3, 6-9, and 13-14.

Discussion

It is commonly accepted that the fabrication of a maxillary overdenture involves the placement of four implants.[6,28,29,30,31,32] A greater number of implants results in additional treatment expense and may preclude many patients from receiving overdentures. As such, the 2-implant maxillary overdenture with full palatal coverage provides an intermediary solution between the 4-implant overdenture and the conventional complete denture. In comparison to the complete denture the two implant maxillary overdenture gives more retention, stability, support, tissue health and overall comfort to the patient when comparing baseline to the 12-months follow-up. It can replace the use of denture adhesives and it can also concluded to increase the patient overall satisfaction.[18] None of the eleven patients reported the use of denture adhesive at the 12-months follow-up. Due to this interesting finding, all patients currently enrolled in the study were contacted to find out whether they currently use denture adhesive or not. Thirteen out of 16 patients were using denture adhesive before receiving treatment in the maxilla and none of them reported use of any denture adhesive after insertion of the overdenture. This is a significant finding for clinical practice.

This treatment modality has been minimally researched regarding the overall clinical and patient-centered outcomes.[34] One recent study has shown that the patient satisfaction overall is significantly increased by a two-implant overdenture compared to the conventional complete denture. This reinforces the aforementioned idea of being able to provide the patient with a more cost-effective treatment option for an implant-supported overdenture.[18]

OHIP parameters improved significantly in the following subgroups from baseline to insertion: Psychological disability, social disability and handicap decreased most significantly (greatest satisfaction).

In summary, from baseline to 12-months follow-up, the VAS improved significantly in 5 out of 8 questions and the OHIP in 4 out of 14 questions. But more importantly, when comparing Insertion to 12-months follow-up, no significant changes were noted in the VAS or the OHIP-14. This leads us to the assumption that patient satisfaction remained stable at the 12-months evaluation.

Unlike the findings of the present study, a previous within-subject comparison did not find a significant improvement in general satisfaction, stability, retention, esthetics, mastication or speech with maxillary implant-supported prostheses compared with conventional maxillary prostheses[49]. In this previous study, four implants were splinted with a bar in contrast to the present study with two un-splinted maxillary implants.

Zembic et al.[18] found that implant-supported dentures revealed a statistically significantly increased satisfaction when compared to new conventional dentures when evaluating functional limitation, psychological discomfort, physical disability, and social disability. The VAS score showed significantly increased, general satisfaction, chewing ability, speech, and stability significantly improved in implant-supported dentures. These results are comparable to the current study's results. Direct comparison of these two studies cannot be made because the Zembic group altered the OHIP questionnaire. Instead of using a Likert-type scale where 4=”very often, 3="fairly often", 2="occasionally", l="hardly ever" and 0="never", responses by patients were given on a VAS scale. Patients answered the questions on a 100mm horizontal line where the two anchor words were “none” and “severe”.

The OHIP was developed with the aim of providing a comprehensive measure of self-reported data about perceptions of impact on well-being.[35] Following these guidelines and using the standardized measures may help the future clinician to compile and compare results from all

different studies. Altering the OHIP-14 questionnaire makes it more difficult for a later review to numerically compare the results.

Both, the VAS and OHIP-14 are proven instruments to evaluate patient satisfaction. Whereas the VAS is a simple, well-validated method to quantify, record and evaluate qualitative outcomes, the OHIP-14 provides the opportunity for the clinician to compare the results in the literature. The challenge of the OHIP-14 is to follow the rather complex guidelines, which is not always guaranteed as described above. Additionally, the method of rating in the OHIP-14 incorporates zeroes, which can compromise the ability of the OHIP-14 to detect within-subject change.[50]

In contrast to our findings, a systematic review found almost no significant improvement in general patient satisfaction, stability, retention, esthetics, mastication and speech for implant-supported maxillary dentures when patients were satisfied with their current maxillary conventional dentures[23]. This could raise the question of denture evaluation at the time of screening. The dentures in the current study were clinically evaluated at the time of screening and the patient had to be satisfied as well, to become a part of the clinical trial. Nevertheless, maxillary implant-supported prostheses may not have to be the first treatment choice for patients with good bony support and/or anterior bony undercut. Patients with an atrophic maxilla, shallow palatal vault, or xerostomia patients with no anterior maxillary undercut can benefit most of the treatment described. On the other hand, maxillary implants in patients who are satisfied with their conventional complete dentures should be used with caution due to the surgical component of the treatment as well as the need for bone reduction.

The current study has clear limitations. The patient population is small, although comparable to the only similar published study to date[18,19]. Furthermore, two prosthodontics

residents with limited clinical experience provided all treatment.. A safeguard was the constant supervision of one of the principal investigators, both of who are experienced clinicians. Another limitation is the new treatment concept. Limited previous outcome data, experience and recommendations were available at the time of initiation. The study population had various opposing prostheses or natural dentition, smoking histories, various anatomical conditions from advantageous maxillary anterior undercuts to thin ridges and shallow palatal vaults. This heterogeneity along with small sample size limits statistical power and can mask actual differences that might be evident between baseline and follow-up exams. However, small descriptive studies like the one described here can be used effectively to generate outcomes and show effect size differences for primary dependent (outcome) variables that can determine sample size for a larger analytic studies with good statistical power.

Conclusions

Within the limitations of this small sample cohort study with a 1-year follow-up, the following conclusions were made:

1. There was a significant increase in patient satisfaction using VAS scores for retention, stability, chewing ability, tissue health, support, speech sounds, and overall comfort when evaluated at baseline and insertion

2. There was a significant increase in patient satisfaction using VAS scores for retention, stability, chewing ability, tissue health, and overall comfort when evaluated at baseline and 12-months follow-up.

3. There was a significant improvement in patient satisfaction using OHIP-14 for the question "Have you had to interrupt meals because of problems with your teeth, mouth or dentures?" when evaluated at baseline and Insertion.

4. There was significant improvement in patient satisfaction using OHIP-14 for the questions "Have you felt that your sense of taste has worsened because of problems with your teeth, mouth or dentures?", "Have you been self-conscious because of your teeth, mouth or dentures", "Has your diet been unsatisfactory because of problems with your teeth, mouth or dentures?", and "Have you had to interrupt meals because of problems with your teeth, mouth or dentures?" when evaluated at baseline and 12-months follow-up.

5. Patient satisfaction using VAS scores and OHIP-14 scores remained stable when evaluated at Insertion and 12-months follow-up.

6. The two-implant maxillary overdentures eliminated the need for a denture adhesive in all 11 patients during the 1-year evaluation period.

The placement of two implants in the maxilla to retain the denture may be a viable treatment option for enhancement of patient satisfaction and reduce dependency on denture adhesives. The results suggest that maxillary dentures retained by two implants provide significant short-term improvement over conventional dentures in oral- and health-related quality of life.

Moreover, the positive results from this pilot study can contribute to the new knowledge base and can eventually be progressed to a larger clinical studies that may have an impact in re-defining the minimal intervention necessary for rehabilitation of the edentulous maxilla.

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FIGURES

Figure 1: Screening visit

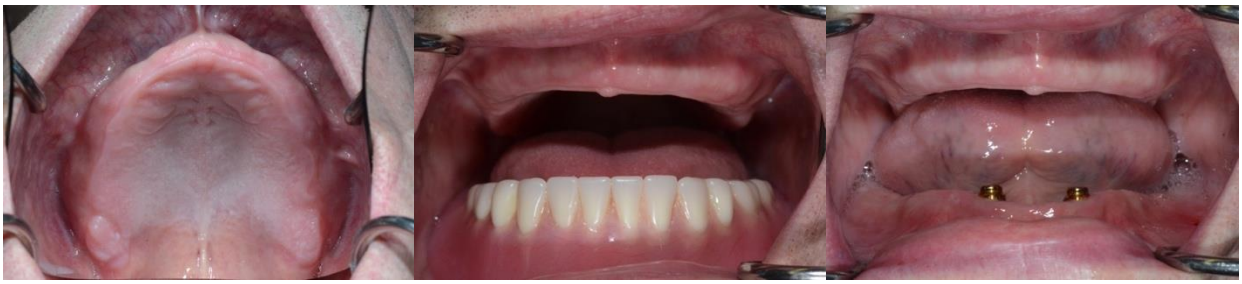


Figure 2: Three-dimentional implant planning using cone beam CT

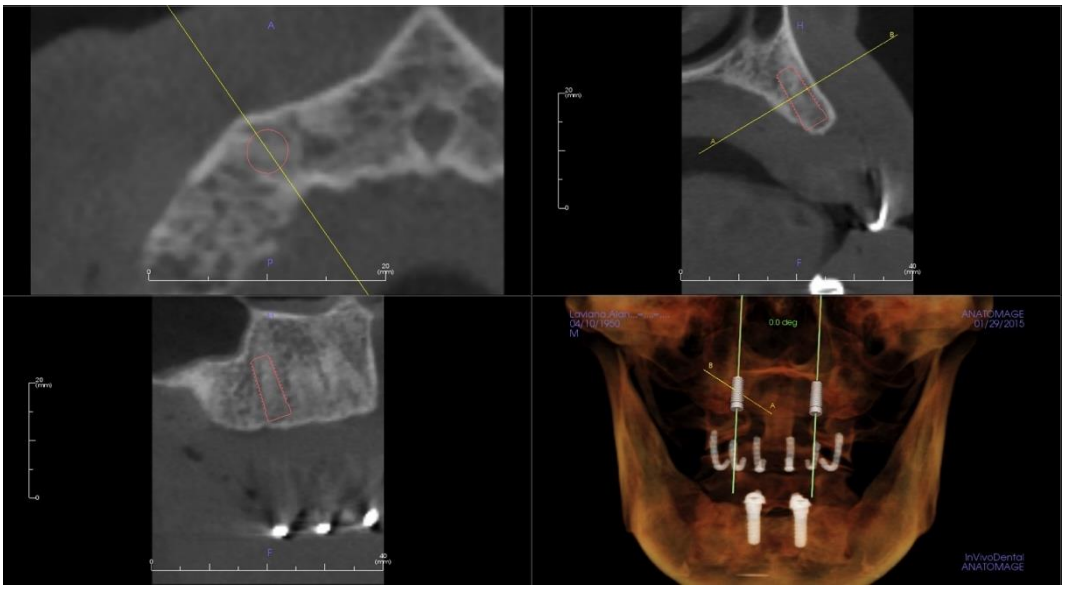


Figure 3: Midcrestal incision

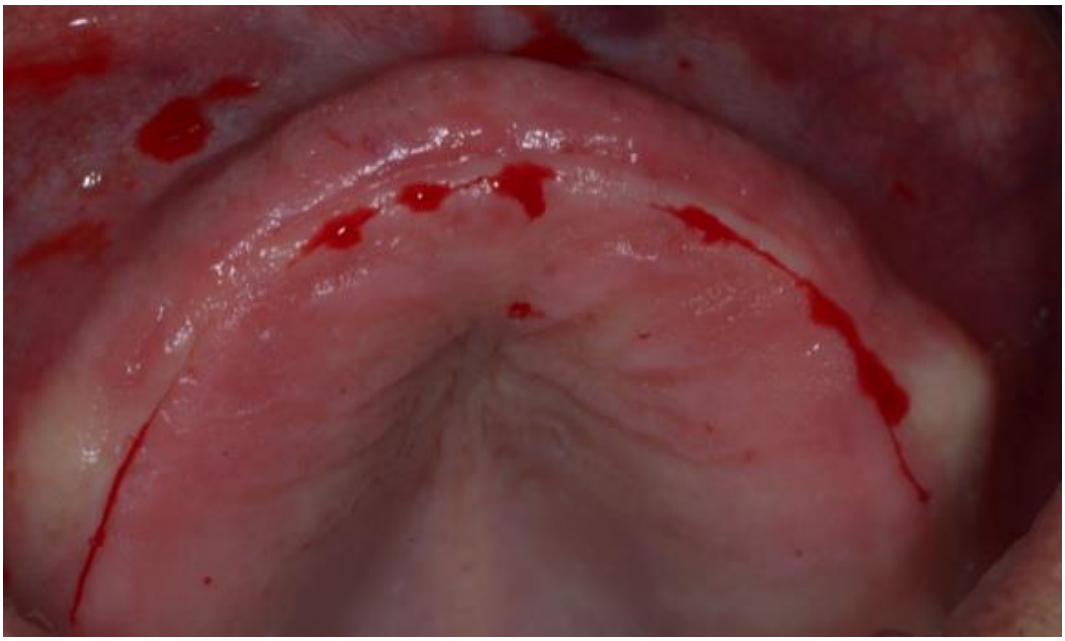


Figure 4: Creation of a flat bone plateau

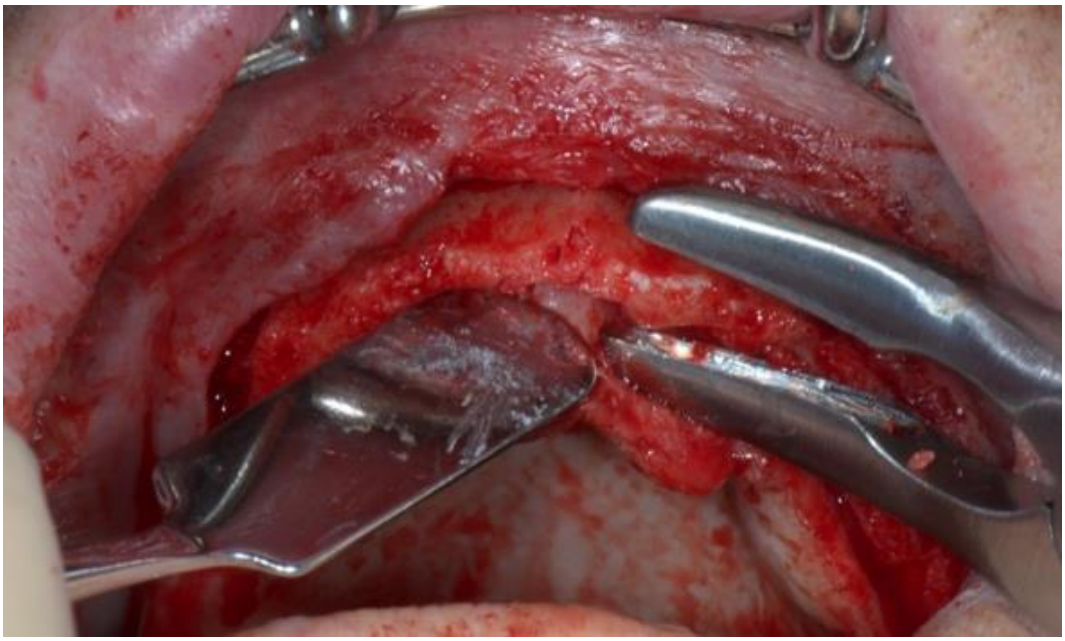


Figure 5: Intra-op confirmation of implant angulations

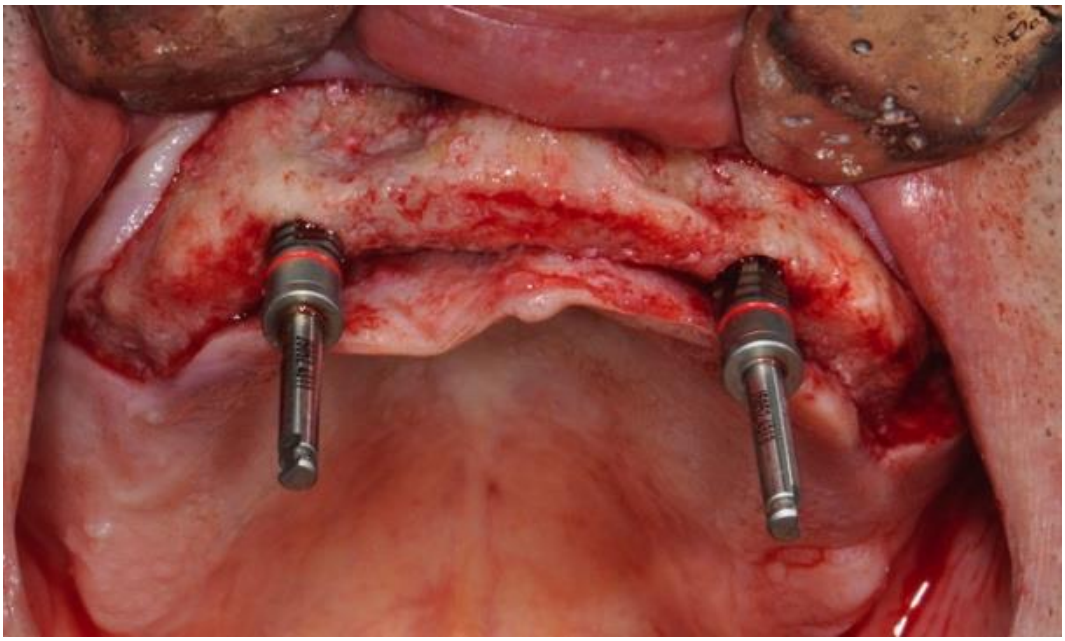


Figure 6: Inserted implants

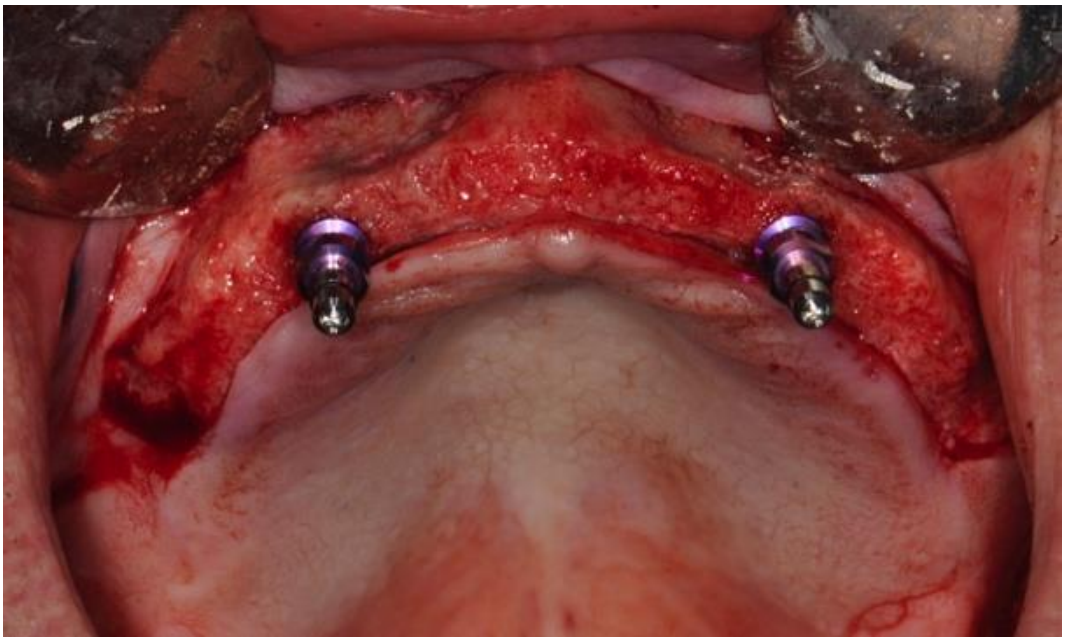


Figure 7: Verification of ideal position using prosthetic guide

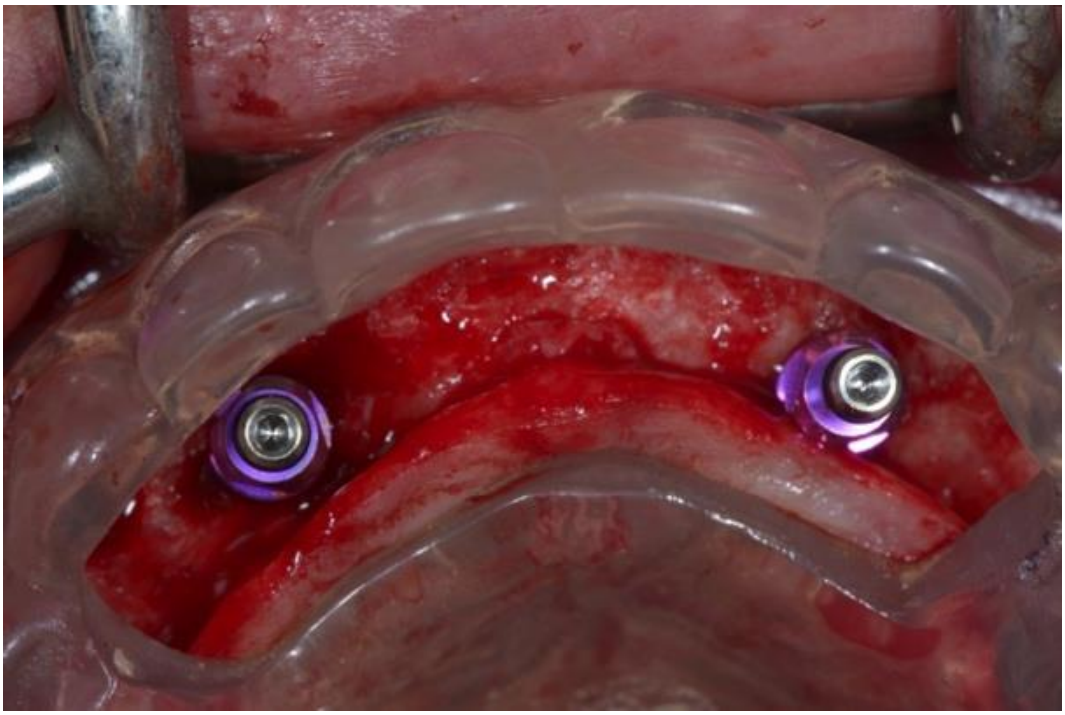


Figure 8: PRF membranes in Salvin PRF-Box

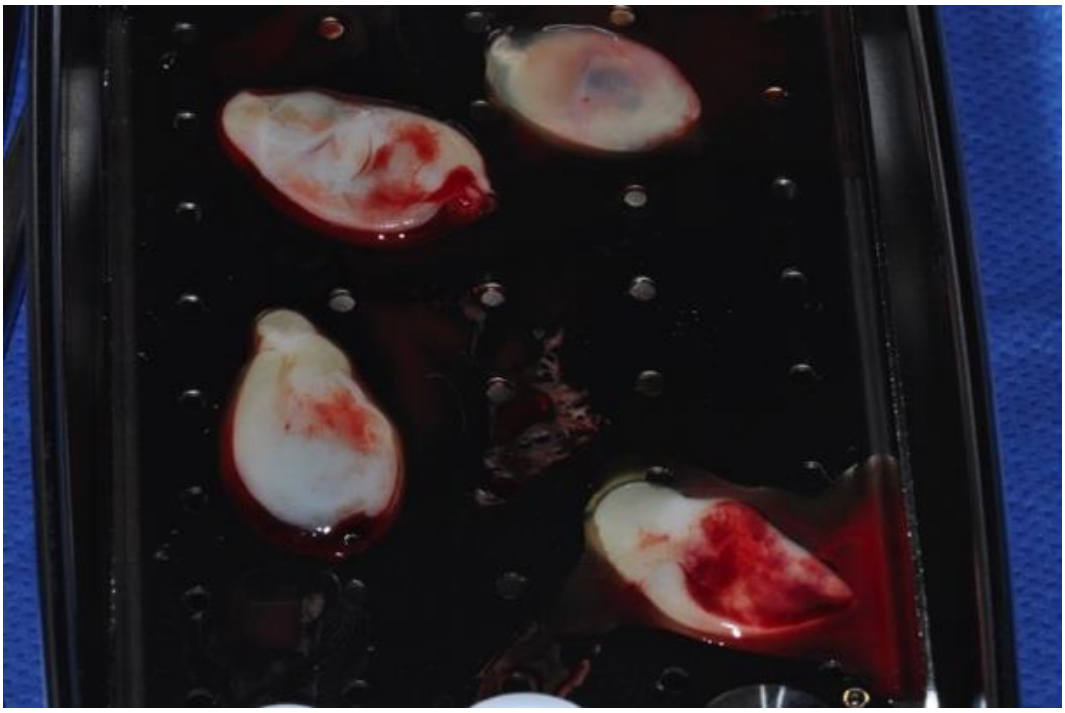


Figure 9: PRF membranes placed over inserted implants

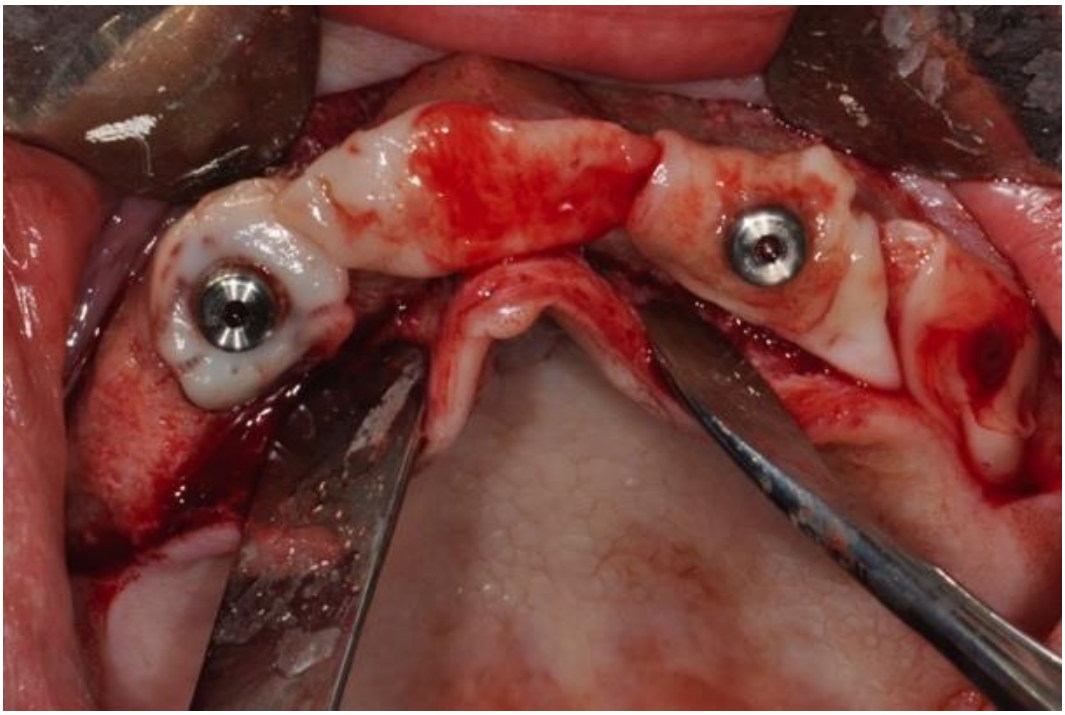


Figure 10: Primary closure with single stage approach

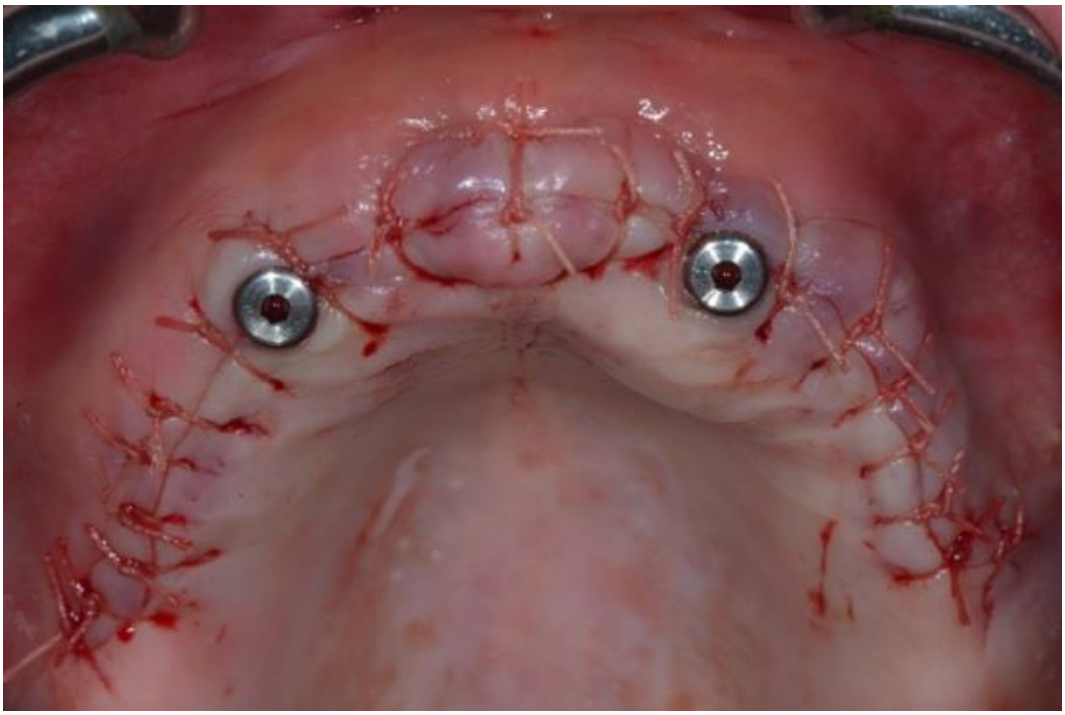


Figure 11: Radiographic confirmation of successful implant placement

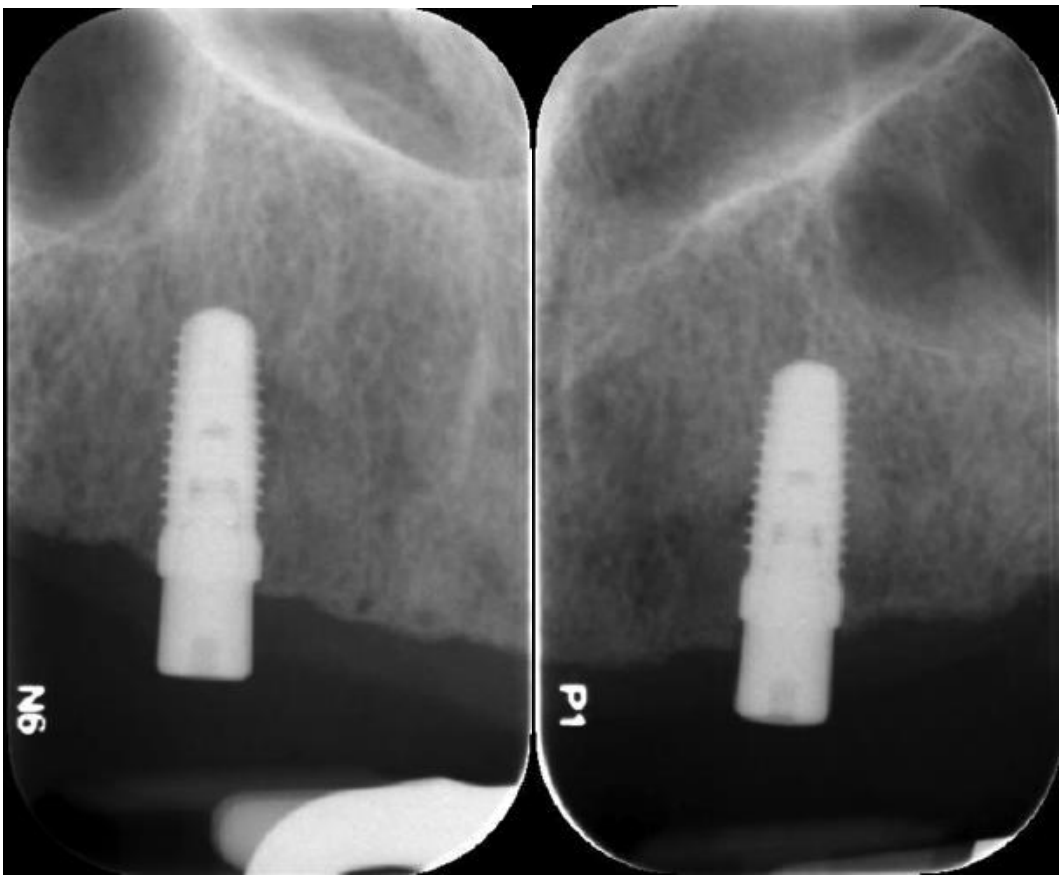


Figure 12: Primary closure with two stage approach

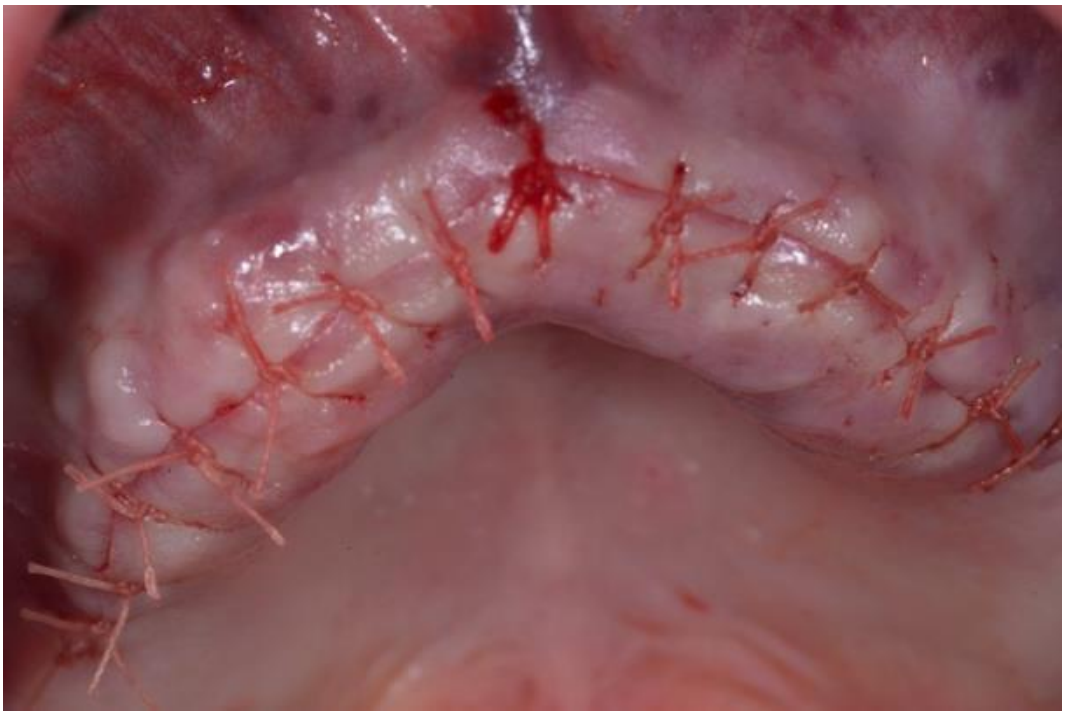


Figure 13: Three-months post-surgical follow-up and abutment insertion

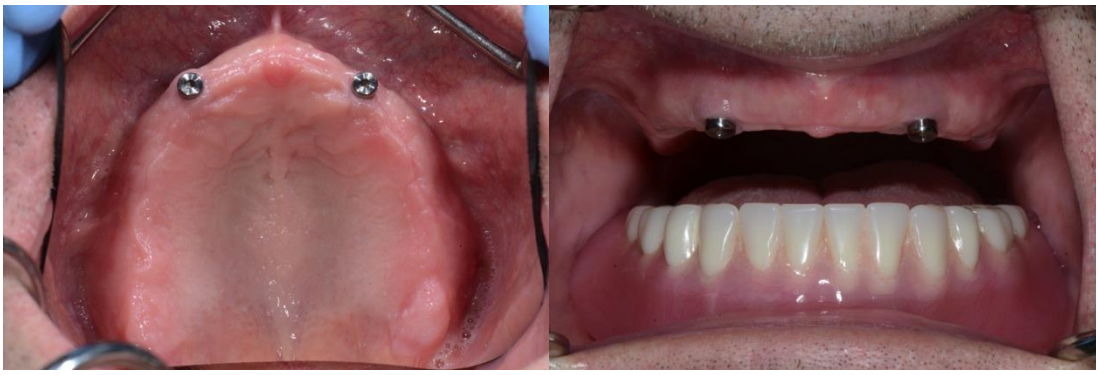


Figure 14: Reline impression and indirect lab-reline

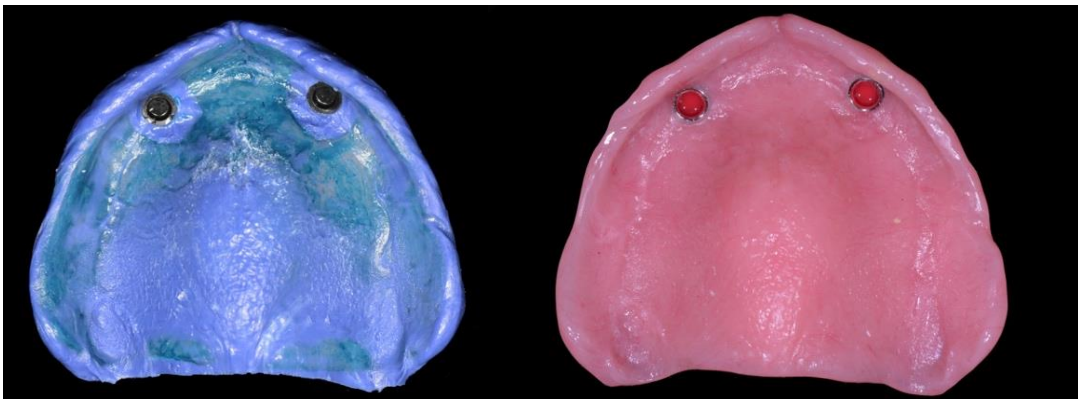
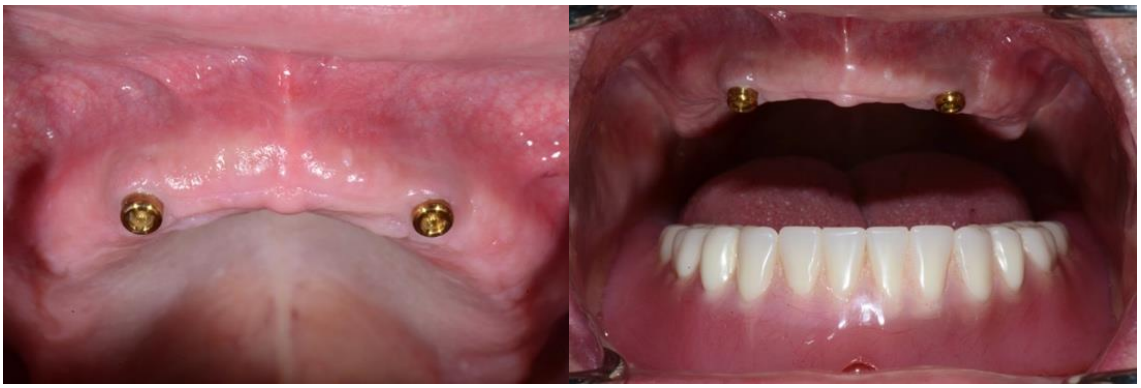


Figure 15: Insertion of converted two-implant supported overdenture and follow-up



TABLES

Table 1: Patient demographics

Patient #	Patient	Age	Gender	Years of maxillary edentulism	Years of wearing current denture	Mandibular dentition
1	TTMS	83	Male	2	2	Natural dentition
2	FKAL	64	Male	5	5	Overdenture
3	FKBM	78	Female	1	1	Natural dentition
4	FKJJ	66	Female	10	1	Implant supported fixed dental prosthesis
5	TTMR	59	Male	4	4	Overdenture
6	TTNC	70	Male	10	1.5	RPD
7	TTRK	73	Male	3	3	Natural dentition
8	FKFG	71	Male	1.5	1	Overdenture
9	FKBL	67	Female	4	1	Overdenture
10	FKJC	77	Male	5	1.5	Overdenture
11	FKJD	77	Male	1	1	RPD
12	FKDH	66	Male	1	1	Natural dentition

Table 2: Master sheet of VAS scores at baseline (t1), Insertion (t2), and 12-month evaluation periods (t3)

Pt #	Visit	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8
1	t1	27	52	38	75	57	60	97	76
	t2	99	98	89	89	84	86	99	86
	t3	87	88	55	83	70	90	88	90
2	t1	71	64	51	93	93	92	95	83
	t2	89	91	91	95	98	98	98	98
	t3	96	95	84	96	95	95	95	95
3	t1	9	5	9	81	2	25	75	20
	t2	94	91	92	95	51	57	94	95
	t3	97	96	95	98	71	86	98	86
4	t1	95	98	95	98	98	82	100	100
	t2	95	100	97	97	97	87	99	98
	t3	97	94	97	98	97	88	98	97
5	t1	63	50	49	84	48	95	97	80
	t2	100	100	98	84	99	100	100	99
	t3	100	100	99	100	99	100	100	100
6	t1	95	93	91	92	91	91	92	91
	t2	91	93	94	92	94	91	93	93
	t3	90	92	91	82	90	87	94	93
8	t1	93	91	91	78	76	90	98	96
	t2	97	100	100	93	87	98	100	100
	t3	98	98	98	89	90	89	99	99
9	t1	97	100	68	84	97	95	96	94
	t2	98	99	48	100	81	99	88	96
	t3	95	95	78	98	80	84	78	87
10	t1	93	93	97	100	99	96	100	98
	t2	96	99	98	100	100	100	98	99
	t3	95	97	98	100	100	100	100	100
11	t1	48	48	47	74	62	73	99	51
	t2	100	98	100	98	99	100	100	100
	t3	100	100	100	100	100	100	100	100
12	t1	56	58	39	42	31	58	60	70
	t2	92	85	100	75	89	60	98	96
	t3	84	76	91	96	69	85	100	93

Table 3: Master sheet of OHIP 14 scores at baseline (t1), Insertion (t2), and 12-month evaluation periods (t3)

Pt #	Visit	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14
1	t1	2	3	1	3	1	2	3	2	1	2	0	1	2	0
	t2	0	2	1	2	2	1	2	1	1	1	0	0	1	0
	t3	1	2	0	2	1	1	2	2	1	2	1	0	2	0
2	t1	1	2	1	1	1	1	1	0	0	0	0	0	1	0
	t2	1	1	1	1	1	1	0	1	0	0	0	0	0	0
	t3	1	1	0	1	0	0	0	0	0	0	0	0	0	0
3	t1	3	2	1	3	4	3	3	1	3	2	0	0	3	1
	t2	2	3	0	1	4	2	1	0	1	2	0	0	4	0
	t3	2	1	2	2	3	0	1	0	1	2	0	0	4	0
4	t1	2	0	0	2	0	0	1	1	0	0	0	0	0	0
	t2	2	0	1	1	0	0	1	0	0	0	0	0	0	0
	t3	1	0	0	1	0	0	0	0	0	0	0	0	0	0
5	t1	0	1	2	2	1	1	1	2	1	1	0	0	0	0
	t2	0	0	2	1	1	1	1	1	1	1	0	0	0	0
	t3	0	0	1	1	0	0	0	1	0	0	0	0	0	0
6	t1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	t2	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	t3	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8	t1	0	0	1	0	0	0	0	1	0	1	0	0	1	1
	t2	1	1	0	1	1	1	0	1	0	1	0	0	1	0
	t3	1	0	1	1	0	1	0	0	1	1	0	0	0	0
9	t1	0	3	1	2	1	1	0	2	1	1	1	0	0	0
	t2	0	3	1	2	3	1	2	1	1	2	1	0	1	4
	t3	1	1	1	2	1	2	0	1	2	3	1	0	0	0
10	t1	1	0	0	0	0	0	0	1	0	0	0	0	0	0
	t2	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	t3	0	0	0	1	0	0	0	0	0	0	0	0	0	0
11	t1	1	2	2	2	2	1	2	3	2	2	2	1	3	0
	t2	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	t3	0	0	0	0	0	0	0	0	0	0	0	0	0	0
12	t1	2	3	2	3	3	2	2	2	1	2	2	1	1	0
	t2	2	2	1	0	0	0	0	0	0	1	0	0	0	0
	t3	2	1	0	2	2	1	1	1	0	1	0	0	0	0

0=Never; 1=Hardly ever; 2=Ocasionally; 3=Fairly often; 4=Very often

Table 4: Mean values of each VAS score evaluated with standard deviations at baseline, Insertion, and 12-month evaluation periods

	Baseline	Insertion	12-months follow-up
Q1	67.91 ± 30.48	95.55 ± 3.72	94.45 ± 5.24
Q2	68.36 ± 29.61	95.82 ± 5.04	93.73 ± 6.83
Q3	61.36 ± 29.08	91.55 ± 14.96	89.64 ± 13.37
Q4	81.91 ± 15.93	92.55 ± 7.53	94.55 ± 6.71
Q5	68.55 ± 31.94	89 ± 14.24	87.36 ± 12.57
Q6	77.91 ± 22.33	88.73 ± 15.83	91.27 ± 6.31
Q7	91.73 ± 12.65	97 ± 3.79	95.45 ± 6.86
Q8	78.09 ± 24.13	96.36 ± 4.08	94.55 ± 5.2

Table 5: Median values (with range) of each VAS score evaluated at baseline (t1), Insertion (t2), and 12-month evaluation periods (t3)

	Baseline (t1)	Insertion (t2)	1 year follow-up (t3)	t2 - t1	t3 - t1	t3-t2	p12	p13	p23
Q1	71 (9-97)	96 (89-100)	96 (84-100)	18 (-4, 85)	25 (-5, 88)	0 (-12, 7)	0.017	0.020	0.677
Q2	64 (5-100)	98 (85-100)	95 (76-100)	27 (-1, 86)	18 (-5, 91)	-2 (-10, 5)	0.008	0.026	0.240
Q3	51 (9,-97)	97 (48-100)	95 (55-100)	40 (-20, 83)	17 (0, 86)	0 (-34, 30)	0.010	0.006	0.400
Q4	84 (42-100)	95 (75-100)	98 (82-100)	14 (-1, 33)	11 (-10, 54)	1 (-10, 21)	0.021	0.024	0.799
Q5	76 (2-99)	94 (51-100)	90 (69-100)	11 (-16, 58)	13 (-17, 69)	0 (-20, 20)	0.026	0.055	0.482
Q6	90 (25-96)	98 (57-100)	89 (84-100)	5 (0, 32)	5 (-11, 61)	0 (-15, 29)	0.006	0.062	0.889
Q7	97 (60-100)	98 (88-100)	98 (78-100)	2 (-8, 38)	1 (-18, 40)	0 (-11, 4)	0.141	0.514	0.634
Q8	83 (20-100)	98 (86-100)	95 (86-100)	10 (-2, 75)	12 (-7, 66)	-1 (-9, 4)	0.009	0.033	0.231

p12 is the p-value by Wilcoxn signed-rank test to test if there is significant change from baseline to 3 months.

p13 is the p-value by Wilcoxn signed-rank test to test if there is significant change from baseline to 12 months.

p23 is the p-value by Wilcoxn signed-rank test to test if there is significant change from 3 months to 12 months.

Table 6: Statistical analysis of OHIP-14 values at baseline (t1), Insertion (t2), and 12-month evaluation periods (t3): Part 1

	Likert scores mean □ sd					
	Baseline (t1)	Insertion (t2)	12-months follow-up (t3)	p12**	p13**	p23**
Q1	1.09 ± 1.04	0.73 ± 0.9	0.82 ± 0.75	0.203	0.299	0.773
Q2	1.45 ± 1.29	1.09 ± 1.22	0.55 ± 0.69	0.240	0.019	0.095
Q3	1 ± 0.77	0.64 ± 0.67	0.45 ± 0.69	0.203	0.105	0.588
Q4	1.64 ± 1.21	0.82 ± 0.75	1.18 ± 0.75	0.058	0.152	0.174
Q5	1.18 ± 1.33	1.09 ± 1.38	0.64 ± 1.03	0.892	0.048	0.219
Q6	1 ± 1	0.64 ± 0.67	0.45 ± 0.69	0.203	0.152	0.572
Q7	1.18 ± 1.17	0.64 ± 0.81	0.36 ± 0.67	0.234	0.018	0.345
Q8	1.36 ± 0.92	0.45 ± 0.52	0.45 ± 0.69	0.025	0.008	1.000
Q9	0.82 ± 0.98	0.36 ± 0.5	0.45 ± 0.69	0.174	0.279	0.773
Q10	1 ± 0.89	0.73 ± 0.79	0.82 ± 1.08	0.345	0.710	0.773
Q11	0.45 ± 0.82	0.09 ± 0.3	0.18 ± 0.4	0.346	0.414	1.000
Q12	0.27 ± 0.47	0 ± 0	0 ± 0	0.149	0.149	NA
Q13	1 ± 1.18	0.64 ± 1.21	0.55 ± 1.29	0.374	0.203	0.773
Q14	0.18 ± 0.4	0.36 ± 1.21	0 ± 0	1.000	0.346	1.000

Likert scores: 0=Never; 1=Hardly ever; 2=Ocasionally; 3=Fairly often; 4=Very often

p12** is the p-value by Wilcoxon signed-rank test to test for the null hypothesis that the Likert score distributions at baseline and 3 months are the same.

p13** is the p-value by Wilcoxon signed-rank test to test for the null hypothesis that the Likert score distributions at baseline and 12 months are the same.

p23** is the p-value by Wilcoxon signed-rank test to test for the null hypothesis that the Likert score distributions at 3 months and 12 months are the same.

Table 7: Statistical analysis of OHIP-14 values at baseline (t1), Insertion (t2), and 12-month evaluation periods (t3): Part 2

	percent reporting item occasinally, fairly, or very often					
	Baseline (t1)	Insertion (t2)	12-months follow-up (t3)	p12*	p13*	p23*
Q1	0.36	0.27	0.18	0.386	0.267	0.149
Q2	0.55	0.36	0.09	1.000	0.453	0.181
Q3	0.27	0.09	0.09	0.096	0.096	0.016
Q4	0.64	0.18	0.36	0.803	1.000	0.182
Q5	0.27	0.27	0.18	0.228	0.149	0.149
Q6	0.27	0.09	0.09	0.096	0.096	0.016
Q7	0.36	0.18	0.09	0.267	0.181	0.043
Q8	0.45	0	0.09	0.211	0.302	0.004
Q9	0.18	0	0.09	0.027	0.043	0.004
Q10	0.36	0.18	0.27	0.267	0.386	0.114
Q11	0.18	0	0	0.027	0.027	NA
Q12	0	0	0	NA	NA	NA
Q13	0.27	0.09	0.18	0.096	0.149	0.027
Q14	0	0.09	0	0.004	NA	0.009

Likert scores: 0=Never; 1=Hardly ever; 2=Ocasionally; 3=Fairly often; 4=Very often

p12* is the p-value by McNemar's test to test if the proprortions at baseline and 3 months are equal.

p13* is the p-value by McNemar's test to test if the proprortions at baseline and 12 months are equal.

p23* is the p-value by McNemar's test to test if the proportions at 3 monts and 12 months are equal.

Appendix I

VAS Evaluation Questionnaire for Patient

Patient #:
Date of follow-up:
Please mark a vertical line on the scale from 0 to 100mm to indicate your evaluation of the denture.
NOTE: 0 is very poor, 100 is excellent.

Fit/ "Tightness" of the dentures
0 ——————————————— 100

Absence of movement while functioning
0 ——————————————— 100

Bite/ Chewing ability
0 ——————————————— 100

Absence of sore spots in the mouth
0 ——————————————— 100

Absence of food underneath the dentures
0 ——————————————— 100

Speech
0 ——————————————— 100

Ability to clean the dentures
0 ——————————————— 100

Overall comfort with the dentures
0 ——————————————— 100

Appendix II

Oral Health Impact Profile (OHIP-14) Evaluation Questionnaire for Patient

Patient #:
Date of follow-up:

1. Have you had trouble *pronouncing any words* because of problems with your teeth, mouth or dentures?
   ☐ never ☐ hardly ever ☐ occasionally ☐ fairly often ☐ very often

2. Have you felt that your *sense of taste* has worsened because of problems with your teeth, mouth or dentures?
   ☐ never ☐ hardly ever ☐ occasionally ☐ fairly often ☐ very often

3. Have you had *painful aching* in your mouth?
   ☐ never ☐ hardly ever ☐ occasionally ☐ fairly often ☐ very often

4. Have you found it *uncomfortable to eat any foods* because of problems with your teeth, mouth or dentures?
   ☐ never ☐ hardly ever ☐ occasionally ☐ fairly often ☐ very often

5. Have you been *self-conscious* because of your teeth, mouth or dentures?
   ☐ never ☐ hardly ever ☐ occasionally ☐ fairly often ☐ very often

6. Have you *felt tense* because of problems with your teeth, mouth or dentures?
   ☐ never ☐ hardly ever ☐ occasionally ☐ fairly often ☐ very often

7. Has your *diet been unsatisfactory* because of problems with your teeth, mouth or dentures?
   ☐ never ☐ hardly ever ☐ occasionally ☐ fairly often ☐ very often

8. Have you had to *interrupt meals* because of problems with your teeth, mouth or dentures?
   ☐ never ☐ hardly ever ☐ occasionally ☐ fairly often ☐ very often

9. Have you found it *difficult to relax* because of problems with your teeth, mouth or dentures?
   ☐ never ☐ hardly ever ☐ occasionally ☐ fairly often ☐ very often

10. Have you been a bit *embarrassed* because of problems with your teeth, mouth or dentures?
    ☐ never ☐ hardly ever ☐ occasionally ☐ fairly often ☐ very often

11. Have you been a bit *irritable with other people* because of problems with your teeth, mouth or dentures?
    ☐ never ☐ hardly ever ☐ occasionally ☐ fairly often ☐ very often

12. Have you had *difficulty doing your usual jobs* because of problems with your teeth, mouth or dentures?
    ☐ never ☐ hardly ever ☐ occasionally ☐ fairly often ☐ very often

13. Have you felt that life in general was *less satisfying* because of problems with your teeth, mouth or dentures?

☐ never ☐ hardly ever ☐ occasionally ☐ fairly often ☐ very often

14. Have you been totally unable to function because of problems with your teeth, mouth or dentures?

☐ never ☐ hardly ever ☐ occasionally ☐ fairly often ☐ very often