A Comparative Study of Three-implant Supported Fixed Dentures and Two-implant Retained Overdentures in Edentulous Mandible: Treatment Efficacy and Patient Satisfaction

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ABSTRACT

KUANG-HAN CHANG: A Comparative Study of Three-implant Supported Fixed Dentures and Two-implant Retained Overdentures in Edentulous Mandible: Treatment Efficacy and Patient Satisfaction
(Under the direction of Lyndon Cooper)

The mandibular two-implant overdentures have been shown to be a highly successful treatment. However, for patients who desire a fixed prosthesis, overdentures may not satisfy their needs. This prospective study is aimed to compare (1) prosthetic outcome, (2) patient satisfaction, and (3) survival rates of Astra Tech implants between two-implant overdentures (2IOD) and three-implant fixed dentures (3IFD). Twenty complete edentulous patients were randomly and equally assigned to two groups. The implants were immediate loaded with a relined denture right after denture delivery and implant surgery. Ball attachments were inserted at 8 weeks and 3IFD delivered at 16 weeks. Patient satisfaction and panoramic radiographic survey were investigated at 6 and 12 months. Both treatments had significant and positive effect in patient satisfaction and quality of life. None of the fifty implants had failed at 6 months follow-up; therefore, implant survival rate was 100%. Prosthetic complications were generally few and easily manageable.
# TABLE OF CONTENTS

LIST OF TABLES..........................................................................................................vii

LIST OF FIGURES...........................................................................................................viii

1 INTRODUCTION......................................................................................................... 1

1.1 Mandibular two-implant overdenture for edentulous patients ......................... 2

1.2 Shortcomings of mandibular two-implant overdenture ................................. 3

1.3 Three-implant fixed complete denture............................................................... 4

1.4 Aim of the study................................................................................................. 6

2 MATERIAL AND METHOD.................................................................................... 7

2.1 Patient Selection................................................................................................. 8

2.2 Inclusion and exclusion criteria........................................................................ 9

2.2.1 Inclusion criteria ......................................................................................... 9

2.2.2 Exclusion criteria......................................................................................... 9

2.3 Procedure for Randomization............................................................................ 10

2.4 Prosthodontic and dental implant treatments .................................................. 10

2.4.1 Visit 1, Screening, informed consent and baseline evaluation .................. 10

2.4.2 Visit 2, Preliminary impression ................................................................. 11
2.4.3 Visit 3, Final impression ................................................................. 12
2.4.4 Visit 4, Maxillomandibular relationship and anterior teeth try-in .... 12
2.4.5 Visit 5, Wax denture try-in ............................................................. 13
2.4.6 Visit 6, Denture delivery and implant placement, P11 (Week 0) ....... 14
2.4.7 Visit 7, Post operative visit, Group I and II (1 week) ................. 18
2.4.8 Visit 8, Post operative visit, Group I and II (3-4 week) ............... 18
2.4.9 Visit 9, Attachment insertion; Group I impression (8 weeks) ....... 19
2.4.10 Visit 10, Follow up; Group I fixed denture delivery (16 weeks) .... 25
2.4.11 Visits 11 and 12: OHIP-49 and VAS questionnaire, P11 .......... 27
2.5 Measurement of outcomes ............................................................... 28
2.6 Statistical analysis ........................................................................... 29
3 RESULTS ................................................................................................. 30
3.1 Implant survival ................................................................................ 31
3.2 Patient satisfaction and oral health related quality of life ............... 31
3.2.1 Visual Analogue Scales (VAS) ....................................................... 31
3.3 Oral Health Impact Profile (OHIP-49) ........................................... 32
3.4 Prosthetic complications ................................................................. 33
4 DISCUSSION .......................................................................................... 35
4.1 Dental implant treatment ................................................................. 35
4.2 Patient satisfaction......................................................................................... 36

4.3 Prosthetic complications ............................................................................... 38

5 CONCLUSION .................................................................................................... 40

APPENDICES...........................................................................................................41

REFERENCES........................................................................................................47
LIST OF TABLES

TABLE 2.1  DEMOGRAPHIC CHARACTERISTICS FOR THE TWO TREATMENT GROUPS ................................................................. 8

TABLE 3.1  PRE- AND POST-TREATMENT MEAN SATISFACTION SCORES USING THE 100-MM VISUAL ANALOGUE SCALES (VAS) FOR THE TWO TREATMENT GROUPS ......................................................... 32

TABLE 3.2. PRE- AND POST-TREATMENT MEAN SCORES ON THE OVERALL ORAL HEALTH IMPACT PROFILE (OHIP) AND ITS SUBSCALES FOR THE TWO TREATMENT GROUPS ........................................... 33

TABLE 3.3. INCIDENTS OF PROSTHETIC COMPLICATIONS IN TWO TREATMENT GROUPS ............................................................. 34
LIST OF FIGURES

FIGURE 2.1 THREE IMPLANTS INSTALLED AND BALL ABUTMENTS PLACED ... 16
FIGURE 2.2 OCCUSAL VIEW ................................................................. 17
FIGURE 2.3 MANDIBULAR COMPLETE DENTURE RELINED AROUND BALL ABUTMENTS ................................................................. 17
FIGURE 2.4 PANORAMIC RADIOGRAPH AFTER IMPLANT PLACEMENT ........ 18
FIGURE 2.5 WAX PATTERN WITH THERMOPLASTIC INDEX. NOTE THAT THE DENTURE TEETH ARE WELL SUPPORTED BY FRAMEWORK ........ 20
FIGURE 2.6 LATERAL VIEW ...................................................................... 20
FIGURE 2.7 CAD/CAM TITANIUM FRAMEWORK ........................................ 21
FIGURE 2.8 CENTRIC RELATION RECORD .................................................. 22
FIGURE 2.9 THREE-IMPLANT FIXED COMPLETE DENTURE. NOTE THE DISTAL INCLINATION OF POSTERIOR IMPLANTS TO INCREASE A-P SPREAD .......................................................... 22
FIGURE 2.10 A TWO-IMPLANT OVERDENTURE PATIENT AFTER 3 MONTHS OF UNEVENTFUL HEALING ................................................................. 23
FIGURE 2.11 CLIX METAL HOUSING ATTACHED TO BALL ABUTMENTS BEFORE INTRAORAL PICK-UP PROCEDURE. NOTE THE BLACK RUBBER RINGS (SPACER) INSERTED BETWEEN BALL ABUTMENT AND CLIX METAL HOUSING ................................................................. 24
FIGURE 2.12 MANDIBULAR TWO-IMPLANT OVERDENTURE. BEFORE AND AFTER ATTACHMENT PICK-UP .................................................. 25
FIGURE 2.13 UNI-ABUTMENTS WERE INSTALLED AND TORQUE TO 15 NCM ..... 26
FIGURE 2.14 THREE-IMPLANT FIXED DENTURE INSERTED ........................................ 26
FIGURE 2.15 OCCLUSAL VIEW ................................................................. 27
FIGURE 2.16 PANORAMIC RADIOGRAPH AT 6 MONTHS FOLLOW-UP ........ 28
1 INTRODUCTION

Edentulism is still a prevalent disability among the older-age group; the percentage has been estimated to be 26% for people more than 65 years of age in the USA. \(^1\) The need for complete denture treatment will be continually increasing in the next twenty years despite an anticipated decreasing percentage of edentulous people. It has been conservatively estimated that the need for complete dentures service will reach 61.0 millions dentures in 2020. \(^2\)

Edentulism comes with anatomical, functional and psychological changes in patients. Reduced chewing ability due to unstable mandibular dentures is a common finding along with deteriorated quality of life in this specific patient group. A contemporary and frequently-used treatment is to place titanium implants in the anterior mandible to retain and support mandibular overdentures or fixed complete dentures. However, the financial limitation is one of the difficulties mostly faced by edentulous patients’ lower socioeconomical status. As a result, a cost-effective treatment modality needs to be determined and we have to define the patient reported outcome.
1.1 Mandibular two-implant overdenture for edentulous patients

Edentulous patients often experience problems with their mandibular dentures. Unlike the maxillary complete dentures, most people have difficulties wearing and functioning with their mandibular dentures. Lack of stability and retention, together with a decreased chewing ability are the main complaints from these patients.³

A wide body of evidence shows that a mandibular two-implant overdenture is superior to a conventional denture.⁴⁸ Implant treatment in the anterior mandible is advantageous because the implant survival is very high in the parasymphysis area and the incidence of surgical complications is low. Recently-established protocols of single stage surgery further shorten the length of time and reduce cost of this highly predictable procedure. The benefits of an implant overdenture include bone preservation, improvement in chewing ability, increased stability and retention, and significantly higher patient satisfaction.⁹

Residual ridge resorption is a multi-factorial condition that will continuously affect complete denture wearers. It has been reported in the literature that the rate of residual ridge resorption is four-time faster in the mandible than in the maxilla after tooth loss.¹⁰ This further complicates the ability of patients to function with their lower denture and presents a prosthodontic challenge in the long term. The bone-maintaining property of dental implants is especially beneficial in the anterior mandible because keeping a stable marginal bone level is important to maintain a healthy status of the edentulous patient.
From the patient’s perspective, an implant overdenture is more stable, and the improved chewing ability allows them to choose more varieties of food and modify their diet, and thus improve their nutritional status. This is extremely important to the elderly because they are particularly vulnerable to malnutrition. There are different mechanisms of retention, for example, ball attachments, bar and clip attachments or magnets. Patient satisfaction has been shown to be significantly higher regardless of the retention mechanism (ball, bar or magnet) when compared to conventional dentures. 11

A two-implant overdenture is a cost-effective alternative to more complex implant prosthodontic procedures. It provides a strong return for the investment in treatment time and expense and is a treatment suited to the lower socioeconomic status of many edentulous patients. The clinical outcome of this treatment is significantly better than that achieved with conventional mandibular dentures, especially when patients are experiencing technical problems due to compromised prosthesis retention or stability. 12 It is a highly successful prosthetic treatment to improve patients’ oral health related quality of life, and it has been suggested by a group of experts to be the first choice of treatment in the edentulous mandible. 13

1.2 Shortcomings of mandibular two-implant overdenture

In reality, a two-implant overdenture is not for every patient. A removable overdenture may not satisfy the specific needs for those who desire a fixed prosthesis or psychologically cannot accept a removable prosthesis. There are also biological
consequences related to an implant-retained, tissue supported prosthesis. The resilient overdenture design may in fact cause more posterior mandibular resorption. Jacobs et al. found a 2- to 3-fold increase in annual posterior mandibular bone resorption when compared to conventional complete dentures if patients were edentulous for less than 10 years. 14 This finding suggests that two-implant overdentures, although cost-effective, should be used cautiously in younger edentulous patients and the potential bone resorption in the posterior mandible needs to be closely monitored in the long-term.

Implant-supported fixed complete dentures, on the other hand, present very little or no posterior bone resorption in the mandible. In fact, it has been found by other investigators that fixed dentures promote posterior mandibular bone apposition. 15, 16

Traditional protocols for implant-supported fixed complete denture require at least 4-6 implants installed between the mental foramina. The additional number of implants rapidly increases the treatment cost. This situation may become a dilemma for those who want a fixed prosthesis but present with financial limitations.

1.3 Three-implant fixed complete denture

Four to six implants have been traditionally considered to be an adequate number to support a mandibular full arch fixed prosthesis. 17. Recently, four implants have commonly been prescribed to the edentulous mandible with great success even with an immediate loading protocol. 18, 19

From the patient’s point of view, cost often plays an important role in choosing or accepting treatments. In order to decrease a patient’s financial burden, the reduction of
surgical interventions and the reduction of the number of implants should be taken into consideration. In 1999, Branemark and colleagues introduced a new system (Branemark Novum, Nobel Biocare) to restore edentulous mandibles. 20 By using a precise surgical guide to predetermine implant positions and a prefabricated titanium framework, patients receive a permanent mandibular fixed denture on three implants on the same day of surgery. The survival rate of implants ranged from 91%-98% at one year and the reported prosthesis survival ranged from 94% to 99%. 20-22 However, the technique-sensitive surgical procedure, the requirements of special components and the lack of flexibility to change implant positions made this new concept lose its popularity among dental practitioners.

In 2001, De Bruyn et al. reported an implant survival rate of 90% when fabricating a fixed mandibular denture on three early-loaded regular platform Branemark implants. 23 This study suggests that three implants, even with an immediate or early loading protocol, could be used to support a mandibular fixed complete denture. With one more implant placed and the extra metal framework to splint three implants together, we can provide patients with an economical fixed prosthesis. Then the choice between a fixed complete denture and a removable overdenture need not be a financial one. Plus there is a psychological advantage since patients often regard the fixed prosthesis as a part of their own body. 24

The mandibular two-implant retained overdenture has been recognized as a superior treatment when compared with the traditional complete denture and has become the standard of care for mandibular edentulism. However, this treatment modality may not satisfy patients’ desire for a fixed prosthesis. If a three implant fixed denture could be
proved to be a successful treatment, it may provide more benefit than two-implant overdenture and become the first choice of treatment for fixed rehabilitation of mandibular edentulism.

1.4 Aim of the study

This prospective randomized controlled study aimed to evaluate (1) one year survival rates of microthreaded/TiOBlast (4.0 diameter Astra Tech Osseospeed) implants immediately loaded in the parasymphyseal mandible, (2) the outcome and complications of prosthetic treatment between two treatment modalities including two-implant overdentures and three-implant fixed complete dentures, and (3) self-reported outcome of oral health related quality of life and patient satisfaction by the use of 49-item oral health impact profile (OHIP-49) questionnaires and visual analog scales (VAS).
2 MATERIAL AND METHOD

This study was a prospective, randomized, controlled study to document the prosthetic performance, patient satisfaction and implant survival rates following three or two AstraTech Osseospeed™ implant placed in the edentulous mandible for the treatment of patients in need of complete dentures. The study population consisted of two groups: three-implant fixed complete denture group (3IFD, group I) and two-implant overdenture group (2IOD, group II). The research protocol was reviewed and approved by the Institutional Review Board of the University of North Carolina at Chapel Hill for the protection of human subjects.
2.1 Patient Selection

All the potential subjects were obtained from the UNC graduate prosthodontic program waiting list for complete denture treatment. Patients who were appointed for evaluation and treatment for complete dentures were identified as potential study subjects. When a patient expressed the interest in participating in the implant denture study, he or she would be scheduled for a screening appointment and asked to sign informed consent before study enrollment.

A total of twenty complete edentulous patients fulfilling all inclusion criteria and none of the exclusion criteria were selected (9 men, 11 women; mean age 62 years, range from 47-76.) Demographic characteristics such as age, sex and average mandibular height were shown in Table 2.1. They were randomly and equally assigned to two treatment groups (Group I, 3IFD, N=10; Group II, 2IOD, N=10) in the study.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Statistic</th>
<th>Group 1 (N = 10)</th>
<th>Group 2 (N = 10)</th>
<th>Total (N = 20)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>Mean (SD)</td>
<td>62.4 (9.88)</td>
<td>62.6 (7.31)</td>
<td>62.5 (8.46)</td>
</tr>
<tr>
<td></td>
<td>Min, Max</td>
<td>47, 76</td>
<td>55, 73</td>
<td>47, 76</td>
</tr>
<tr>
<td>MAD Height</td>
<td>Mean (SD)</td>
<td>19.2 (4.73)</td>
<td>16.4 (5.25)</td>
<td>17.8 (5.07)</td>
</tr>
<tr>
<td></td>
<td>Min, Max</td>
<td>12, 25</td>
<td>11, 27</td>
<td>11, 27</td>
</tr>
<tr>
<td>Gender</td>
<td>Males</td>
<td>N (%)</td>
<td>5 (50%)</td>
<td>4 (40%)</td>
</tr>
<tr>
<td></td>
<td>Females</td>
<td>N (%)</td>
<td>5 (50%)</td>
<td>6 (60%)</td>
</tr>
</tbody>
</table>

a There is no significant difference between two treatment groups for baseline characteristics
2.2 Inclusion and exclusion criteria

2.2.1 Inclusion criteria

The inclusion criteria required that subjects: be age between 18-80, have good physical health (ASA CL I or II), be completely edentulous for at least 3 months, possess mandibular bone height of at least 10 mm in parasympysis area, no history of radiotherapy in the head and neck region, be non-smokers, and be willing to give informed consent.

2.2.2 Exclusion criteria

Participants were excluded from the study if they had: a history of radiotherapy in head and neck region; smoke habits; bone height less than 10 mm in parasympysis area; severe Angle’s class II or III jaw relationship; psychological problems for accepting a removable prosthesis (unwilling to wear dentures; severe gag reflex); pregnancy; steroid use; ASA Class III or IV patients; uncontrolled diabetes; known alcohol and/or drug abuse and those with Bruxism; patients who took medication that might interfere with coagulation (e.g. Aspirin, Coumadin) and/or subjects with bleeding disorders (e.g. liver disease; patient with unrealistic esthetic expectations; any condition that contraindicated dental implant therapy.
2.3 Procedure for Randomization

The randomization procedure was implemented in two steps. In step 1, a computer program was written to generate a sequence of randomization ID numbers and treatment assignments. The assignment key was securely stored in a blinded manner prior to the randomization. Step 1 was completed before enrollment begins. In Step 2, each new eligible patient was assigned to a randomization ID number.

Step 2 used an "envelope system" -- implemented as follows. Upon completing Step 1, the principle investigator prepared a set of sealed envelopes, each bearing a "randomization ID number" inside the envelope. These envelopes were sent to the clinic administrator for use, one-by-one, according to the numbered sequence. The clinician then opened the envelope whenever an eligible patient was enrolled and needed to be randomized.

This ongoing study is a 12-month follow-up study with 16-17 hours of treatment time which involves 12 visits over one year with 10 visits occurring in the first 8 weeks. Primary analysis is based on 12 months data. An interim analysis was performed on the 6 months data and presented in this thesis.

2.4 Prosthodontic and dental implant treatments

2.4.1 Visit 1, Screening, informed consent and baseline evaluation

After the study was thoroughly explained the study, each patient was given the opportunity to read the consent form, had all questions answered, and signed the consent form.
The screening procedure included a clinical and radiographic assessment. All potential subjects were screened using panoramic radiographs (P11). This is the standard screening x-ray for all edentulous patients. If it was determined necessary at the screening visits, patients were also evaluated by computerized tomography to identify a possible malpositioned lingual artery or inferior alveolar nerve. Medical and dental histories were taken followed by extraoral and intraoral examinations.

Prosthodontic planning followed guidelines suggested in Boucher’s textbook of complete dentures. Pre-surgical planning followed the guidelines described in the Astra Tech Manual ‘Surgical Procedures Fixture MicroThread™ OsseoSpeed™. Patients in need of complete dentures with implants in the mandible were enrolled and allocated randomly into treatment groups I (3IFD) or II (2IOD). Once the consent form was signed, the patient was asked to answer a 49-item Oral Health Impact Profile (OHIP-49) questionnaire to evaluate oral health related quality of life as baseline before treatment started. Patients’ opinion about current dentures, in terms of general satisfaction, retention and stability of dentures, chewing, oral hygiene, comfort, speech and esthetics, were also evaluated by a 14-item Visual analogue scale (VAS) questionnaire. Each scale used a 100-mm line to represent a continuum of feelings, with complete dissatisfaction at one end of the line and complete satisfaction at the other.

2.4.2 Visit 2, Preliminary impression

A preliminary impression was made using irreversible hydrocolloid (Jeltrate Alginate, Dentsply) and stock trays. Appropriate stock trays were selected according to patient’s jaw size. After a try-in procedure, alginate adhesive was sprayed on the stock
tray. Alginate powder and water was measured and mixed according to manufacturer’s instructions.

The impression material was seated and left in the patient’s mouth for 3 minutes. After the impressions were removed from the patient’s mouth, the impressions were disinfected and left undisturbed for 10 minutes. Impressions were poured in type III dental stone (Microstone, Whipmix). The resulting casts were used to fabricate an individual custom tray using light cured acrylic tray material. (Triad, Dentsply)

2.4.3 Visit 3, Final impression

Custom acrylic resin (Triad, Dentsply) trays made from preliminary casts were tried-in and adjusted to the movable mucosa. Polyvinal siloxane (PVS) adhesive was applied to the individual trays. Heavy body PVS material (Imprint III, 3M ESPE) was applied to the tray border and seated in the patient’s mouth to obtain functional border registration for complete dentures. A modified Halperin impression technique was used according to methods described by Felton, Cooper and Scurria. 25

Complete, refined impressions subject to wash impressions were made with 3M Imprint II quick step wash or regular body PVS material. The impressions were poured in microstone (Whipmix). Occlusion rims and stabilized record bases were made on master casts using Triad light cured acrylic denture base material and baseplate wax.

2.4.4 Visit 4, Maxillomandibular relationship and anterior teeth try-in
Stabilized record bases were tried in the patient’s mouth to determine the occlusal plane, midline, and vertical dimension of occlusion. Maxillary anterior denture teeth (SR Vivodent DCL, Ivoclar Vivadent) were set to verify esthetics.

A centric relation record was made using PVS bite registration material (Regisil, Dentsply). A face-bow transfer record was also obtained to orient the maxillary cast to the articulator. After both maxillary and mandibular casts were mounted on the articulator, Ivoclar blueline Ortholigual denture teeth were used to set up posterior teeth using a lingualized occlusion concept.

2.4.5 Visit 5, Wax denture try-in

At this visit, final wax dentures were evaluated for occlusal vertical dimension, esthetics, phonetics, and centric relations. The maxillary and mandibular trial dentures were placed in the patient’s mouth. The patient was guided to close into centric relation (CR) position. Any errors in CR were identified and corrected by obtaining a new bite registration record, remounting mandibular cast, and resetting the denture teeth.

Occlusal vertical dimension, phonetics and esthetics of the denture were reevaluated and modifications of tooth set up were made at this stage. Patients were given the opportunity to observe and approve the final denture teeth arrangement before denture processing.

The wax dentures were then festooned and processed in heat-cure denture acyclic resin (Lucitone 199, Dentsply) using a long curing program (8 hours at 165 degree F), followed by trimming and polishing.
2.4.6 Visit 6, Denture delivery and implant placement, P11 (Week 0)

At this visit, complete dentures were tried in and delivered to patients in both groups followed by implant surgery. Group 1 (3IFD) received 3 implants; one in the mandibular symphysis, two as distally as possible but keeping a minimum of 5 mm anterior to the metal foramina. Group 2 (2IOD) received 2 implants approximately at the canine areas.

A thin layer of pressure indicator paste was applied onto intaglio surfaces of maxillary and mandibular dentures and the dentures were inserted in the patient’s mouth to locate pressure spots. Pressure spots, overextended denture flanges and sharp area were trimmed and relieved for patient comfort.

Patients were guided to close into CR position and errors in CR were identified and corrected by a clinical remount procedure. Subsequent denture occlusal adjustments were made extraorally on the articulator.

One hour before implant surgery, patients were given 800mg Ibuprofen and 1 gram Amoxicillin (300 mg Clindamycin if the patient was allergic to penicillin). Before surgery, patients were instructed to rinse with 0.12% chlorohexidine digluconate solution for one minute. The patient’s torso, head and neck region was covered with a sterile drape.

Topical anesthetic was applied to oral mucosa in the parasympysis area and maintained for one minute. Infiltration anaesthesia using 2% lidocaine with epinephrine
1/100,000 was provided in the anterior mandible. Generally 3 to 4 carpules (5.4 to 7.2 cc) were used.

The mandibular complete denture was used as a surgical stent, and the proposed implant positions were marked on the mucosa with the surgical stent and indelible marker. For Group I, 3 implants were placed, one in the mid-symphysis area and the other two were placed 5mm anteriorly to mental foramen in the premolar area. For Group II, 2 implants were placed bilaterally at the canine areas. Standard implant surgical procedures were used according to manufacturer’s recommendation.

A mid-crestal incision was made with a #15 blade and a full thickness mucoperiosteal flap raised. Alveolectomies were performed if necessary to provide at least 15mm from bone level to occlusal plane. Site preparation was accomplished using an electric motor with a maximum speed of 1500 rpm and external irrigation of sterile water through a sideport on the handpiece according to the AstraTech surgical manual.

The preparation of the osteotomy for all implants used included the use of the guide drill, the 2.5 Tiger drill and the 3.2 pilot drill. The guide drill established the faciolingual and mesiodistal position of the implant. Care was taken throughout all site preparation to maintain proper angulation for prosthetic accessibility. The osteotomies were made sequentially through the 3.2 Tiger drill, the 3.7 pilot drill, and the final osteotomy preparation was done by a single pass of the 3.7 Tiger drill. 4.0 cortical was also used if patient had type I bone quality.

Using a handpiece at 20 rpm and 50 Ncm of torque without irrigation, implants were placed level with the facial crest of bone. Alternatively, hand placement employing the ratchet wrench may be done, also without irrigation. Assessment of stability was
made to exclude lateral or axial implant movement. The mucosal flap was primarily closed with 4.0 chromic gut sutures. The dimensions of all the implants placed are 4.0 mm diameter with 11 or 13 mm in length.

Appropriate Astra Tech ball abutments were selected according to the thickness of soft tissue and hand tightened (Figures 2.1 and 2.2.) Denture base area above the implants was relieved and relined with PVS resilient denture lining material (GC Reline Soft, GC America) (Fig. 2.3.) Patients were given oral hygiene, post operative instructions and a prescription of amoxicillin 500mg 3 times a day for one week. Patients were also given instruction to use 0.12% chlorohexidine digluconate mouth rinse twice daily for two weeks.

A panoramic radiograph (P11) was obtained as baseline reference to monitor future bone level changes (Fig. 2.4.) This radiograph is standard procedure in evaluating implants following surgery.

Figure 2.1 Three implants installed and ball abutments placed
Figure 2.2 Occusal view

Figure 2.3 Mandibular complete denture relined around ball abutments
2.4.7 Visit 7, Post operative visit, Group I and II (1 week)

Seven days after denture delivery and implant placement, patients were scheduled for a follow-up examination. A thorough intraoral examination was performed and denture adjustments were made if needed.

2.4.8 Visit 8, Post operative visit, Group I and II (3-4 week)

Three to four weeks after surgery, patients were scheduled for another follow-up visit. An intraoral examination was performed and denture adjustments were made if deemed necessary. Implants and abutments were evaluated for stability.
2.4.9 Visit 9, Attachment insertion; Group I impression (8 weeks)

2.4.9.1 Group I (3IFD) Patients

Ball abutments were removed and impression copings inserted and hand tightened. A proper sized tray was selected and modified to allow the impression screw to protrude. A fixture level impression was made with PVS impression material (Imprint III, 3M ESPE). This impression was used to fabricate the metal framework for the fixed denture. Patients were recalled 3-4 weeks later for metal framework try-in and bite registration.

Ball abutments were hand tightened back on to the implants and clix attachments were picked up intraorally using cold-cured acrylic resin.

2.4.9.1.1 Fabrication of Mandibular 3IFD, Group I

After the master cast was made, uni-abutments of adequate height were selected and placed on the implant analog. The wax pattern for the metal framework was designed with a vacuum-formed thermoplastic index made from an impression of the mandibular denture to insure that proper dimension and support of denture teeth could be achieved without encroaching on the tongue space (Figures 2.5 and 2.6.)
Figure 2.5 Wax pattern with thermoplastic index. Note that the denture teeth are well supported by framework

Figure 2.6 Lateral View

After the wax up was made, using a CAD/CAM technique including optical scanning and a Computer Numeric Control (CNC) milling procedure, a titanium framework was made as the exact duplicate of the wax pattern (U-best Dental Technology, Anaheim, CA.) This technique ensured a homogeneous, precise, passive fitting metal framework without the distortion and voids that usually come with a traditional casting technique (Fig. 2.7.)
Patients were then scheduled for metal framework try-in. The fit was verified by clinical examination as well as the single screw test. The wax rim was built up on the metal framework and a centric relation record was made at the same occlusal vertical dimension as the current dentures (Fig. 2.8.)

The same tooth mold was used for the mandibular fixed complete denture. After a try-in procedure, the mandibular fixed denture was processed and ready to be delivered at 16 weeks after implant placement (Fig.2.9.)

Figure 2.7 CAD/CAM Titanium Framework
Figure 2.8 Centric relation record

Figure 2.9 Three-implant Fixed Complete Denture. Note the distal inclination of posterior implants to increase A-P spread
2.4.9.2 Group II (2IOD) patients

Ball abutments were torqued to 25 Ncm using AstraTech torque controller. Soft reline material underneath the denture was removed and relieved to provide space for the clix attachment metal housing (Figures 2.10 and 2.11.)

Figure 2.10 A two-implant overdenture patient after 3 months of uneventful healing
Black spacers were placed on the ball abutments and metal housings for clix attachments were attached to the ball abutments. After adequate clearance between the metal housing and denture base was verified, vent holes were drilled in the lingual side of the denture to allow excess acrylic resin to flow.

Clix attachments were picked up intraorally using denture base repair material (Repair resin, Dentsply). Patients were instructed to close lightly into CR with the maxillary denture at all time while repair material was setting (Fig. 2.12.)

After repair material had cured completely, the mandibular denture was removed from the patient’s mouth. The excess material was removed and the denture was polished and returned to the patient.
2.4.10 Visit 10, Follow up; Group I fixed denture delivery (16 weeks)

2.4.10.1 Group I (3IFD) patients

Ball abutments were removed. Uni-abutments were inserted and torqued to 15 Ncm (Fig. 2.13.) A new mandibular fixed denture supported by three implants was delivered and the occlusion was adjusted (Figures 2.14 and 2.15.) After all necessary adjustments were made, bridge screws were hand-tightened and the screw channels were sealed with a cotton pellet and Cavit.
Figure 2.13 Uni-abutments were installed and torque to 15 Ncm

Figure 2.14 Three-implant fixed denture inserted
2.4.11 Visits 11 and 12: OHIP-49 and VAS questionnaire, P11

The patients were scheduled for follow-up visits at 6, and 12 months after implant placement. An oral examination evaluating status of soft tissue, implant stability and treatment related complications were performed at follow-up visits. Panoramic radiographs and clinical photographs were also obtained (Fig. 2.16.) At these visits, patient satisfaction and opinions about their dentures and were evaluated by the OHIP-49 and VAS questionnaire.
2.5 Measurement of outcomes

The primary outcomes of this study are listed as follows:

(1) Implant survival rates of Astra Tech 4.0 implants placed in the parasympysis area. Implants are deemed surviving if they are functional intraorally without any pain and mobility at follow-up visits. A panoramic radiograph examination was ordered at 6 and 12 months to monitor bone level around the implants.

(2) Patient satisfaction and oral health related quality of life evaluated by VAS and OHIP-49 questionnaires. The VAS scale questionnaires were used specifically to evaluate patients’ opinions about general satisfaction, comfort, speech, chewing and esthetics of their dentures. The Oral Health Impact Profile (OHIP), a self-administered instrument that was specifically designed to measure the impact of oral health on psychosocial well-being, was used to measure quality of life. This questionnaire
consists of 49 items that cover seven domains: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap. The 5 categories of choice per item are: never (code=0), hardly ever (code=1), occasionally (code=2), fairly often (code=3), very often (code=4). The codes for these categories range from 0 for never to 4 for very often, with higher scores indicating more serious problems. Internal reliability, test/re-test reliability, and validity were previously established by Slade and Spencer.

(3) Prosthetic complications in the two treatment groups; incidents of denture adjustments, repair, reline, abutment and bridge screw loosening were tabulated by means of a chart review by the primary investigator.

2.6 Statistical analysis

Demographic characteristics and implant survival were classified by treatment groups using descriptive tabular methods. An independent T-test was used to compare the post-treatment mean scores on the total OHIP scores as well as subscale scores on each of the 7 domains of the OHIP between the two treatment groups. Within each treatment group, we carried out paired T-test to compare the mean scores between pre- and post-treatments. For these analyses, the responses, each ranging from 0 for never to 4 for very often, for all items per domain were summed. Similar methods were used in the analyses of each question in the questionnaire based on a VAS. Data analyses were performed using SAS system software (version 9.1.3, SAS Institute, Cary, NC).
3 RESULTS

Healthy men (n = 9) and women (n = 13) were recruited for a protocol approved by the Institutional Review Board at the University of North Carolina at Chapel Hill (informed consent was obtained from all participants). Of the initially recruited 22 subjects, 20 subjects completed the study per protocol. One patient dropped out because there was no enough bone thickness for implant placement although she seemed to have adequate mandibular height on the pre-operative panoramic x-ray. Another subject was excluded from the study because she desired conscious sedation during the implant surgery. Therefore the regular surgery protocol was violated. The primary statistical analyses were conducted on data from the remaining per-protocol study population of 20 subjects (9 men and 11 women). They ranged in age from 47 to 76 years, with the mean of 62.5. There was no significant difference in the pre-treatment demographic characteristics in terms of age, sex and anterior mandibular height. Ten subjects were assigned to three-implant fixed complete denture group (3IFD) and 10 to the two-implant overdenture (2IOD) group. The 6 months data presented in this thesis is the preliminary result of this ongoing study.
3.1 Implant survival

At the 6 months follow-up, all of the 50 implants placed (30 in group I, 3IFD; 20 in group II, 2IOD) remained functional, healthy and without pain and mobility. Therefore, the implant survival rate was 100% for both groups.

3.2 Patient satisfaction and oral health related quality of life

3.2.1 Visual Analogue Scales (VAS)

A 14-item VAS questionnaire was used to evaluate patient satisfaction, as well as comfort, retention, stability, speech, ease of cleaning and esthetics. Mean VAS scores at baseline evaluation did not differ between groups. Within each treatment group, at 6 months follow-up visit, a significant difference was observed in all the categories between pre- and post-treatment VAS scales (Table 3.1.) As for between group comparisons, there was no statistical difference in the post treatment scores except for ease of cleaning of lower denture, which indicated that a removable two-implant overdenture was easier to clean than a three-implant fixed denture.
Table 3.1 Pre- and Post-treatment Mean Satisfaction Scores using the 100-mm Visual Analogue Scales (VAS) for the Two Treatment Groups

<table>
<thead>
<tr>
<th>Satisfaction relating to:</th>
<th>Group 1 (N = 10)</th>
<th>Group 2 (N = 10)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre Mean (SD)</td>
<td>Post Mean (SD)</td>
</tr>
<tr>
<td>General Satisfaction</td>
<td>36.8 (28.8)</td>
<td>95.1 (7.03)</td>
</tr>
<tr>
<td>Upper Denture</td>
<td>57.3 (36.4)</td>
<td>91.4 (12.2)</td>
</tr>
<tr>
<td>Lower Denture</td>
<td>18.3 (27.0)</td>
<td>96.0 (5.62)</td>
</tr>
<tr>
<td>Ease of Cleaning:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper Denture</td>
<td>67.0 (35.9)</td>
<td>96.7 (3.56)</td>
</tr>
<tr>
<td>Lower Denture</td>
<td>61.3 (36.6)</td>
<td>89.4 (8.81)</td>
</tr>
<tr>
<td>Stability:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper Denture</td>
<td>58.6 (37.5)</td>
<td>90.4 (9.68)</td>
</tr>
<tr>
<td>Lower Denture</td>
<td>17.1 (28.8)</td>
<td>96.4 (4.06)</td>
</tr>
<tr>
<td>Retention:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper Denture</td>
<td>55.4 (36.9)</td>
<td>92.0 (8.00)</td>
</tr>
<tr>
<td>Lower Denture</td>
<td>16.5 (29.0)</td>
<td>97.0 (3.43)</td>
</tr>
<tr>
<td>Comfort:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper Denture</td>
<td>61.1 (33.7)</td>
<td>93.5 (9.17)</td>
</tr>
<tr>
<td>Lower Denture</td>
<td>21.1 (30.7)</td>
<td>97.5 (3.69)</td>
</tr>
<tr>
<td>Ease of Chewing</td>
<td>32.2 (30.1)</td>
<td>94.3 (9.20)</td>
</tr>
<tr>
<td>Ease of Speaking</td>
<td>42.0 (31.4)</td>
<td>88.9 (9.72)</td>
</tr>
<tr>
<td>Esthetics</td>
<td>48.5 (35.6)</td>
<td>97.5 (3.60)</td>
</tr>
</tbody>
</table>

|                   | Pre Mean (SD)    | Post Mean (SD)   |
|                   | 29.2 (14.3)      | 93.6 (8.41)      |
|                   | 47.9 (26.9)      | 87.2 (20.2)      |
|                   | 28.5 (34.5)      | 95.6 (5.89)      |
|                   | 73.7 (20.6)      | 98.8 (2.30)      |
|                   | 72.1 (21.4)      | 96.8 (6.25)      |
|                   | 45.3 (38.2)      | 87.6(18.9)       |
|                   | 24.9 (32.5)      | 93.7 (7.53)      |
|                   | 48.8 (34.2)      | 89.3 (15.8)      |
|                   | 24.5 (27.3)      | 95.0 (5.60)      |
|                   | 64.2 (21.8)      | 90.7 (15.2)      |
|                   | 29.1 (31.1)      | 95.0 (5.52)      |
|                   | 34.0 (27.6)      | 91.7 (12.9)      |
|                   | 46.8 (22.2)      | 91.4 (8.41)      |
|                   | 37.1 (39.2)      | 94.9 (9.95)      |

\( ^a \) Significant difference between pre-treatment and post-treatment OHIP scores within each treatment group by paired T test (p < 0.05).
\( ^b \) Significant difference between Groups 1 and 2 according to post-treatment OHIP scores by independent T test (p < 0.05).

### 3.3 Oral Health Impact Profile (OHIP-49)

In Table 3.2, the mean scores on the 7 subscales for pre- and post-treatments were presented according to group assignment. No significant differences were observed on any of the individual pre-treatment OHIP domains between groups. Within each group, mean post-treatment scores at 6 months on all subscales were significantly lower than it
at baseline. There was no significant difference in the post-treatment scores between the two treatment groups.

Table 3.2. Pre- and Post-treatment Mean Scores on the Overall Oral Health Impact Profile (OHIP) and Its Subscales for the Two Treatment Groups

<table>
<thead>
<tr>
<th>Domain</th>
<th>Group 1 (N = 10)</th>
<th>Group 2 (N = 10)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre Mean (SD)</td>
<td>Post Mean (SD)</td>
</tr>
<tr>
<td>Total OHIP scores</td>
<td>99.1 (69.3)</td>
<td>18.9 (20.5)a</td>
</tr>
<tr>
<td>Functional limitations</td>
<td>21.7 (14.0)</td>
<td>5.60 (4.14)a</td>
</tr>
<tr>
<td>Physical pain</td>
<td>18.8 (12.3)</td>
<td>3.00 (3.17)a</td>
</tr>
<tr>
<td>Psychological discomfort</td>
<td>12.5 (8.17)</td>
<td>2.40 (3.17)a</td>
</tr>
<tr>
<td>Physical disability</td>
<td>19.0 (13.6)</td>
<td>3.70 (4.03)a</td>
</tr>
<tr>
<td>Psychological disability</td>
<td>9.90 (9.37)</td>
<td>1.60 (2.91)a</td>
</tr>
<tr>
<td>Social disability</td>
<td>8.10 (7.75)</td>
<td>1.20 (2.30)a</td>
</tr>
<tr>
<td>Handicap</td>
<td>9.10 (9.85)</td>
<td>1.40 (2.50)a</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Domain</th>
<th>Pre Mean (SD)</th>
<th>Post Mean (SD)</th>
<th>Pre Mean (SD)</th>
<th>Post Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Functional limitations</td>
<td>21.7 (14.0)</td>
<td>5.60 (4.14)a</td>
<td>23.4 (8.78)</td>
<td>7.10 (3.96)a</td>
</tr>
<tr>
<td>Physical pain</td>
<td>18.8 (12.3)</td>
<td>3.00 (3.17)a</td>
<td>21.1 (8.21)</td>
<td>4.40 (3.34)a</td>
</tr>
<tr>
<td>Psychological discomfort</td>
<td>12.5 (8.17)</td>
<td>2.40 (3.17)a</td>
<td>15.4 (3.81)</td>
<td>1.40 (2.22)a</td>
</tr>
<tr>
<td>Physical disability</td>
<td>19.0 (13.6)</td>
<td>3.70 (4.03)a</td>
<td>21.5 (8.48)</td>
<td>4.40 (3.60)a</td>
</tr>
<tr>
<td>Psychological disability</td>
<td>9.90 (9.37)</td>
<td>1.60 (2.91)a</td>
<td>12.7 (5.54)</td>
<td>1.20 (1.99)a</td>
</tr>
<tr>
<td>Social disability</td>
<td>8.10 (7.75)</td>
<td>1.20 (2.30)a</td>
<td>5.60 (6.06)</td>
<td>0.20 (0.63)a</td>
</tr>
<tr>
<td>Handicap</td>
<td>9.10 (9.85)</td>
<td>1.40 (2.50)a</td>
<td>9.90 (6.17)</td>
<td>1.50 (2.12)a</td>
</tr>
</tbody>
</table>

a Significant difference between pre-treatment and post-treatment OHIP scores within each treatment group by paired T test (p < 0.05).
b Significant difference between Groups 1 and 2 according to post-treatment OHIP scores by independent T test (p < 0.05)

3.4 Prosthetic complications

In general, the prosthetic complications were few and manageable at the recall visits. Non-scheduled appointments were also given to patients by request to address pain and discomfort but rarely needed. The frequencies of all prosthetic complications were summarized in Table 3.3. Denture adjustments related to patient comfort was the most common occurrence (83.33%); a great majority of them were related to removable prostheses, including maxillary complete dentures and mandibular two or three-implant
overdentures. Only one three-implant fixed denture adjustment was made because the patient complained that the lingual contour was bulky and she needed more space for her tongue. Ball abutment loosening and bridge screw loosening were rare. Denture relines were made when patients complained about loss of retention and stability and a clinical examination revealed that a reline procedure would improve this situation. Most relines were made on the maxillary dentures and the timing was around 3-4 months after denture delivery. Three incidents of denture tooth fracture happened; they were all anterior teeth in the three-implant fixed denture group.

Table 3.3 Incidents of prosthetic complications in two treatment groups.

<table>
<thead>
<tr>
<th>Prosthetic Complication</th>
<th>Group 1 (N = 10)</th>
<th>Group 2 (N = 10)</th>
<th>Total (%)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dental Adjustments</td>
<td>25</td>
<td>30</td>
<td>55 (83.33 %)</td>
</tr>
<tr>
<td>Ball Abutments Loosening</td>
<td>1</td>
<td>1</td>
<td>2 (3.03 %)</td>
</tr>
<tr>
<td>Bridge Screw Loosening</td>
<td>1</td>
<td>N/A</td>
<td>1 (1.52 %)</td>
</tr>
<tr>
<td>Repair of Denture Teeth</td>
<td>3</td>
<td>0</td>
<td>3 (4.55 %)</td>
</tr>
<tr>
<td>Reline</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper Denture</td>
<td>2</td>
<td>2</td>
<td>4 (6.05 %)</td>
</tr>
<tr>
<td>Lower Denture</td>
<td>0</td>
<td>1</td>
<td>1 (1.52 %)</td>
</tr>
<tr>
<td>Total</td>
<td>32</td>
<td>34</td>
<td>66</td>
</tr>
</tbody>
</table>

* The percentage was calculated based on the total number of incidences of prosthetic complications.
4 DISCUSSION

4.1 Dental implant treatment

The implant survival rate was 100% at 6 months. However, the length of time for
evaluation was too short to make any solid interpretations. Because implant failures tend
to happen in the first year, the report of implant survival at 12 months, although still
preliminary, will be more meaningful.

Marginal bone level evaluation is best accomplished with a radiographic stent and
a long cone parallel technique with periapical radiographs. However, the shallow
vestibule of completely edentulous patients could make this procedure very difficult, if
not impossible. Therefore, a panoramic radiograph evaluation was used instead at implant
placement, 6 and 12 months. Since precise bone level changes cannot be measured,
implant success is not reported here.
4.2 Patient satisfaction

In this randomized controlled clinical trial, the oral health related quality of life of subjects who received a mandibular three-implant fixed denture or a two-implant overdenture was compared using Oral Health Impact Profile (OHIP-49). Both treatment modalities statistically significantly improved patients’ quality of life in all the subcategories at 6 months recall. VAS questionnaires evaluating patient satisfaction also demonstrated the same result that the post treatment quality of life did improve significantly. However, between groups comparisons failed to show any significant difference, which suggests that both treatments provide a significant and similar improvement in patient satisfaction and oral health related quality of life. Whether this improvement can be maintained over the long term is still to be investigated.

A limitation of the study is that we did not measure the effect of receiving new dentures. Therefore, a part of the improvement in patient satisfaction and quality of life could simply be due to renewal of the prosthesis instead of the implant treatment itself. Fortunately, a lot of studies have compared the two-implant overdenture and the conventional complete denture in the edentulous mandible.\textsuperscript{6, 7, 28, 29} The common findings are significant improvement of general satisfaction, chewing and quality of life in the two-implant overdenture group but not with conventional dentures. Therefore, we could safely assume that the implant treatment in the mandible, either with two-implant overdenture or three-implant fixed denture, is the main reason for improvement in patient satisfaction.

Feine and her colleagues evaluated patient preference for the fixed or the removable prosthesis in the edentulous mandible.\textsuperscript{30} It was a cross-over study with a total
of 15 subjects, who tried each prosthesis for two months. At the end of study, eight patients chose a fixed implant supported prosthesis and seven chose a removable long bar overdenture; both were an implant-supported prosthesis. They concluded that patients do not always prefer fixed prosthesis and, instead, they chose fixed or removable for their own specific reasons.

Our study compares differences between implant-tissue born (2IOD) prosthesis and purely implant-born (3IOD) prosthesis. Our finding at 6 months is consistent with Feine’s group\(^{30-32}\) that patients in both groups had significant improvement in terms of satisfaction and oral health related quality of life after treatment but this improvement, although higher in the 3IFD group, is not significantly different between treatments modalities.

Wismeijer et al. compared three treatment modalities for mandibular overdentures: two implants with ball abutments, two implants connected with a bar and four implants connected with three bars. When general satisfaction was evaluated at 19 months and 8 years after treatment, there was no difference between these three groups.\(^{33, 34}\)

Contrary to the mandibular prosthesis, a maxillary implant overdenture prosthesis did not significantly improve patient satisfaction when compared with conventional dentures even with reduced palatal coverage.\(^{35}\) A similar cross-over study further showed that after patients experienced both removable long bar overdenture and fixed complete denture in the edentulous maxilla, most patients would choose removable prosthesis, possibly due to better cleansability and fewer speech problems that often happened with maxillary implant fixed complete dentures.\(^{36}\) It seems that for a completely edentulous patient, a maxillary conventional complete denture and a
mandibular two-implant overdenture would achieve the functional threshold so that oral health related quality of life can be maintained at an adequate level. A three-implant fixed complete denture would be an economic option for those who wish to have a fixed prosthesis in mandible.

### 4.3 Prosthetic complications

In our study, the prosthetic complications were generally few and easily manageable. Denture adjustments related to patient comfort were the most common occurrence and usually they happened in the first 2 or 3 post-op visits. The great majority of them were related to a removable prosthesis. This result concurs with Walton and MacEntee. However, the common findings in the literature, including repair or adjustment of retention mechanism, ball abutment loosening, or the gold screw loosening, have not been observed in our study possibly due to the short observation time or the stable abutment-implant interface in the Astra Tech implants system.

Several patients requested a reline of their maxillary denture. The instability of a maxillary denture with a lower implant-supported prosthesis has been reported by other researchers. This could be the result of changes in soft tissue after functioning with the improved chewing ability of their mandibular dentures. Another possibility is that when the patients achieved a certain level of function of their lower denture, they start to pursue better stability and retention of maxillary dentures. A similar finding was reported by Narhi and colleagues. Based on their study, maxillary edentulous ridge resorption and
the change of its dimension is a continuous process, irrespective of the mandibular prosthesis, either conventional full denture or implant supported prosthesis.
5 CONCLUSION

Within the limitation of this study, the following conclusions can be drawn.

1. Both the treatment modalities, three-implant fixed complete denture and two implant overdenture, significantly and similarly improved patient satisfaction and oral health related quality of life.

2. Two-implant overdenture is easier to clean than a three-implant fixed denture.

3. Three implants can be used to support a mandibular fixed prosthesis; however, a longer observation period is needed to validate this treatment modality.

4. Prosthetic complications are relatively few for both treatments. Patients might request a reline for the opposing maxillary conventional dentures.
APPENDIX A:

VAS Questionnaire

1. How do you find your prosthesis in general?

   Unsatisfied 0 %  1  2  3  4  5  6  7  8  9  10  Satisfied 100 %

2. Are you satisfied with your upper denture?

   Unsatisfied 0 %  1  2  3  4  5  6  7  8  9  10  Satisfied 100 %

3. Are you satisfied with your lower denture?

   Unsatisfied 0 %  1  2  3  4  5  6  7  8  9  10  Satisfied 100 %

4. Ease of chewing: How well can you eat with your prosthesis?

   Can’t chew 0 %  1  2  3  4  5  6  7  8  9  10  Very well 100 %

5. Ease of speaking: How well can you talk with your prosthesis?

   Can’t speak 0 %  1  2  3  4  5  6  7  8  9  10  Speak very well 100 %

6. Ease of cleaning: Is it difficult to clean your upper denture?

   Very difficult 0 %  1  2  3  4  5  6  7  8  9  10  Very easy 100 %

7. Ease of cleaning: Is it difficult to clean your lower denture?

   Very difficult 0 %  1  2  3  4  5  6  7  8  9  10  Very easy 100 %

8. Stability: Are you satisfied with the stability of your upper denture?

   Unsatisfied 0 %  1  2  3  4  5  6  7  8  9  10  Satisfied 100 %

9. Stability: Are you satisfied with the stability of your lower denture?

   Unsatisfied 0 %  1  2  3  4  5  6  7  8  9  10  Satisfied 100 %

10. Retention: Are you satisfied with the retention of your upper denture?

    Unsatisfied 0 %  1  2  3  4  5  6  7  8  9  10  Satisfied 100 %

11. Retention: Are you satisfied with the retention of your lower denture?

    Unsatisfied 0 %  1  2  3  4  5  6  7  8  9  10  Satisfied 100 %
12. **Comfort: Is your upper denture comfortable?**

Uncomfortable 0 %  |  |  |  |  |  |  |  |  |  | Comfortable 100 %

13. **Comfort: Is your lower denture comfortable?**

Uncomfortable 0 %  |  |  |  |  |  |  |  |  |  | Comfortable 100 %

14. **Esthetics: How do you find the appearance of your prosthesis?**

Very bad 0 %  |  |  |  |  |  |  |  |  |  | Excellent 100 %
## APPENDIX B:

Because of problems with your teeth, denture, or mouth have you…

*(Oral Health Impact Profile—49)*

<table>
<thead>
<tr>
<th>Question</th>
<th>Never or not applicable</th>
<th>Hardly ever</th>
<th>Occasionally</th>
<th>Fairly often</th>
<th>Very often</th>
<th>Don’t know</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Have you had difficulty chewing any foods because of problems with your teeth, mouth, or dentures?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>2. Have you had trouble pronouncing any words because of problems with your teeth, mouth, or dentures?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>3. Have you noticed a tooth which doesn’t look right?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>4. Have you felt that your appearance has been affected because of problems with your teeth, mouth, or dentures?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>5. Have you felt that your breath has been stale because of problems with your teeth, mouth, or dentures?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>6. Have you felt that your sense of taste has worsened because of problems with your teeth, mouth, or dentures?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>7. Have you had food catching in your teeth or dentures?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>8. Have you felt that your digestion has worsened because of problems with your teeth, mouth, or dentures?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>9. Have you felt that your dentures have not been fitting properly?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>10. Have you had painful aching in your mouth?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>11. Have you had a sore jaw?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>12. Have you had headaches because of problems with your teeth, mouth, or dentures?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>13. Have you had sensitive teeth, for example, due to hot or cold foods or drinks?</td>
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<td>14. Have you had tooth ache?</td>
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<td>15. Have you had painful gums?</td>
<td>Never or not applicable</td>
<td>Hardly ever</td>
<td>Occasionally</td>
<td>Fairly often</td>
<td>Very often</td>
<td>Don't know</td>
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<td>16. Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth, or dentures?</td>
<td>Never or not applicable</td>
<td>Hardly ever</td>
<td>Occasionally</td>
<td>Fairly often</td>
<td>Very often</td>
<td>Don't know</td>
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<td>17. Have you had sore spots in your mouth?</td>
<td>Never or not applicable</td>
<td>Hardly ever</td>
<td>Occasionally</td>
<td>Fairly often</td>
<td>Very often</td>
<td>Don't know</td>
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<tr>
<td>18. Have you had uncomfortable dentures?</td>
<td>Never or not applicable</td>
<td>Hardly ever</td>
<td>Occasionally</td>
<td>Fairly often</td>
<td>Very often</td>
<td>Don't know</td>
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<td>19. Have you been worried by dental problems?</td>
<td>Never or not applicable</td>
<td>Hardly ever</td>
<td>Occasionally</td>
<td>Fairly often</td>
<td>Very often</td>
<td>Don't know</td>
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<tr>
<td>20. Have you been self conscious because of your teeth, mouth, or dentures?</td>
<td>Never or not applicable</td>
<td>Hardly ever</td>
<td>Occasionally</td>
<td>Fairly often</td>
<td>Very often</td>
<td>Don't know</td>
</tr>
<tr>
<td>21. Have dental problems made you miserable?</td>
<td>Never or not applicable</td>
<td>Hardly ever</td>
<td>Occasionally</td>
<td>Fairly often</td>
<td>Very often</td>
<td>Don't know</td>
</tr>
<tr>
<td>22. Have you felt uncomfortable about the appearance of your teeth, mouth, or dentures?</td>
<td>Never or not applicable</td>
<td>Hardly ever</td>
<td>Occasionally</td>
<td>Fairly often</td>
<td>Very often</td>
<td>Don't know</td>
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<tr>
<td>23. Have you felt tense because of problems with your teeth, mouth, or dentures?</td>
<td>Never or not applicable</td>
<td>Hardly ever</td>
<td>Occasionally</td>
<td>Fairly often</td>
<td>Very often</td>
<td>Don't know</td>
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<td>24. Has your speech been unclear because of problems with your teeth, mouth, or dentures?</td>
<td>Never or not applicable</td>
<td>Hardly ever</td>
<td>Occasionally</td>
<td>Fairly often</td>
<td>Very often</td>
<td>Don't know</td>
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<tr>
<td>25. Have people misunderstood some of your words because of problems with your teeth, mouth, or dentures?</td>
<td>Never or not applicable</td>
<td>Hardly ever</td>
<td>Occasionally</td>
<td>Fairly often</td>
<td>Very often</td>
<td>Don't know</td>
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<tr>
<td>26. Have you felt that there has been less flavour in your food because of problems with your teeth, mouth, or dentures?</td>
<td>Never or not applicable</td>
<td>Hardly ever</td>
<td>Occasionally</td>
<td>Fairly often</td>
<td>Very often</td>
<td>Don't know</td>
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<td>27. Have you been unable to brush your teeth properly because of problems with your teeth, mouth, or dentures?</td>
<td>Never or not applicable</td>
<td>Hardly ever</td>
<td>Occasionally</td>
<td>Fairly often</td>
<td>Very often</td>
<td>Don't know</td>
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<td>28. Have you had to avoid eating some foods because of problems with your teeth, mouth, or dentures?</td>
<td>Never or not applicable</td>
<td>Hardly ever</td>
<td>Occasionally</td>
<td>Fairly often</td>
<td>Very often</td>
<td>Don't know</td>
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<td>29. Has your diet been unsatisfactory because of problems with your teeth, mouth, or dentures?</td>
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<td>30. Have you been unable to eat with your dentures because of problems with them?</td>
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<td>31. Have you avoided smiling because of problems with your teeth, mouth, or dentures?</td>
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<td>32. Have you had to interrupt meals because of problems with your teeth, mouth, or dentures?</td>
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<td>33. Has your sleep been interrupted because of problems with your teeth, mouth, or dentures?</td>
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<td>34. Have you been upset because of problems with your teeth, mouth, or dentures?</td>
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<td>35. Have you found it difficult to relax because of problems with your teeth, mouth, or dentures?</td>
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<td>36. Have you felt depressed because of problems with your teeth, mouth, or dentures?</td>
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<td>37. Has your concentration been affected because of problems with your teeth, mouth, or dentures?</td>
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<td>38. Have you been a bit embarrassed because of problems with your teeth, mouth, or dentures?</td>
<td>☐</td>
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<td>39. Have you avoided going out because of problems with your teeth, mouth, or dentures?</td>
<td>☐</td>
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<td>40. Have you been less tolerant of your spouse or family because of problems with your teeth, mouth, or dentures?</td>
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<td>41. Have you had trouble getting on with other people because of problems with your teeth, mouth, or dentures?</td>
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<td>42. Have you been a bit irritable with other people because of problems with your teeth, mouth, or dentures?</td>
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<td>43. Have you had difficulty doing your usual jobs because of problems with your teeth, mouth, or dentures?</td>
<td>☐ 0 Never or not applicable, ☐ 1 Hardly ever, ☐ 2 Occasionally, ☐ 3 Fairly often, ☐ 4 Very often, ☐ 5 Don’t know</td>
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<td>44. Have you felt that your general health has worsened because of problems with your teeth, mouth, or dentures?</td>
<td>☐ 0 Never or not applicable, ☐ 1 Hardly ever, ☐ 2 Occasionally, ☐ 3 Fairly often, ☐ 4 Very often, ☐ 5 Don’t know</td>
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<td>45. Have you suffered any financial loss because of problems with your teeth, mouth, or dentures?</td>
<td>☐ 0 Never or not applicable, ☐ 1 Hardly ever, ☐ 2 Occasionally, ☐ 3 Fairly often, ☐ 4 Very often, ☐ 5 Don’t know</td>
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<td>46. Have you been unable to enjoy other people’s company as much because of problems with your teeth, mouth, or dentures?</td>
<td>☐ 0 Never or not applicable, ☐ 1 Hardly ever, ☐ 2 Occasionally, ☐ 3 Fairly often, ☐ 4 Very often, ☐ 5 Don’t know</td>
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<td>47. Have you felt that life in general was less satisfying because of problems with your teeth, mouth, or dentures?</td>
<td>☐ 0 Never or not applicable, ☐ 1 Hardly ever, ☐ 2 Occasionally, ☐ 3 Fairly often, ☐ 4 Very often, ☐ 5 Don’t know</td>
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<td>48. Have you been totally unable to eat foods because of problems with your teeth, mouth, or dentures?</td>
<td>☐ 0 Never or not applicable, ☐ 1 Hardly ever, ☐ 2 Occasionally, ☐ 3 Fairly often, ☐ 4 Very often, ☐ 5 Don’t know</td>
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<td>49. Have you been totally unable to work to your full capacity because of problems with your teeth, mouth, or dentures?</td>
<td>☐ 0 Never or not applicable, ☐ 1 Hardly ever, ☐ 2 Occasionally, ☐ 3 Fairly often, ☐ 4 Very often, ☐ 5 Don’t know</td>
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REFERENCES


