# UCSF

**UC San Francisco Electronic Theses and Dissertations**

**Title**

The Efficacy of Standard and Mini-Dental Implants for Mandibular Tissue-Supported Implant Retained Overdentures

**Permalink**

https://escholarship.org/uc/item/1z03x0vm

**Author**

Dang, Calvin

**Publication Date**

2011

Peer reviewed|Thesis/dissertation

The Efficacy of Standard and Mini-Dental Implants for Mandibular Tissue-Supported
Implant Retained Overdentures

by

Calvin Triet Dang

THESIS

Submitted in partial satisfaction of the requirements for the degree of

MASTER OF SCIENCE

in

Oral and Craniofacial Sciences

in the

GRADUATE DIVISION

of the

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

**Acknowledgements:**

**The Efficacy of Standard and Mini-Dental Implants for Mandibular Tissue-**

**Supported Implant Retained Overdentures.**

**By**

**Calvin Dang, DDS**

**Abstract**

**Introduction:** Patients with a severely resorbed edentulous mandible suffer with various problems including mucosal pain, poor denture retention, abnormal speech and mastication, altered facial appearance, and loss of soft tissue support. These patients are often not candidates for a conventional denture or a standard dental implant (SDI) retained or supported overdenture. Mini-dental implants (MDI) have gained recent support, especially in these cases, to provide increased tolerance and retention of mandibular conventional dentures. MDIs have been marketed to be placed without mucoperiosteal reflection, loaded immediately, and offer a less expensive alternative treatment option to the edentulous patient.

**Methods:** Patients were evaluated with QOL surveys before and after implant placement and will be followed for a total of 6 years. The QOL surveys were measured using VAS scales filled out by the patients.

**Results:** The results showed that there was no significant difference in patient QOL scores between MDIs and SDIs placed in the interforaminal area of the mandible 3, 6, and 12 months after implant placement for all QOL parameters.

**Conclusions:** There is no difference in long-term quality of life between standard dental implants and mini-dental implants placed in the interforaminal region of the anterior mandible

**Table of Contents:**

**List of Tables:**

**List of Figures:**

**Section 1**

**INTRODUCTION:**

According to the World Health Organization (WHO), millions of people throughout the world are edentulous. They have lost a body part, up to thirty-two body parts to be exact, edentulous people are physically impaired [1]. Loss of all teeth causes disability for most people who wear conventional denture because they often experience difficulties with retention, stability, support, mastication and comfort. These problems can lead to a decreased chewing ability and function which can ultimately affect their general health and emotional well-being. The mandibular conventional denture is more mobile and is easily dislodged more often compared to a maxillary conventional denture. With the advent of the osseointegrated dental implant, many of these issues can now be addressed. When the patient desires more retention, two or more dental implants in the mandibular interforaminal region of the lower jaw can be used to support/retain their denture. Depending on the clinical situation and the patient needs, additional implants and other superstructures can also be employed to increase retention, stability, support, and comfort of the prosthesis. Implants provide a surface to which the denture is secured in place, thus resisting dislodgment and movement and improving the chewing efficiency of the denture.

In patients with edentulous mandible, they suffer from various problems including mucosal pain, poor denture retention, loss of soft tissue support, alteration in speech, mastication, and facial expression. These patients are often not candidates for a conventional denture or a standard implant retained or supported overdenture. These patients who have advanced resorption of the alveolar ridges cannot receive SDI unless

bone augmentation procedures are completed as a prerequisite.  These bone augmentation

procedures are often not indicated for elderly patients with advanced alveolar bone

resorption.  In the past twenty-five years, mini-dental implants (MDI) have gained

support to provide increased tolerance and retention of mandibular conventional dentures

[1].  MDIs have been marketed to be placed without mucoperiosteal reflection, loaded

immediately, and offer a less expensive alternative treatment option to the edentulous

patient.

**Purpose and Hypothesis:**

The purposes of this long-term clinical study are to: (i) evaluate the differences in clinical success and quality of life when comparing complete mucosal supported, well-fitted lower dentures to those supported by standard-sized dental implants (SDI, the current gold standard) or mini-dental implants (MDI) after implant placement within the same patient; and (ii) compare the efficacy of standard dental implants and mini-dental implants in their clinical success and contribution to quality of life. The null hypothesis of this research is that there will be no difference in long-term clinical success and quality of life, between standard dental implants and mini-dental implants placed in the interforaminal region of the anterior mandible for mandibular overdentures.

**Section 2:**

**Literature Review:**

*Implant Overdenture Background*

      Complete edentulism is one of the major oral problems in elderly people; if inadequately compensated for by dentures, it may not only imply impaired oral function and loss of alveolar bone but is also often accompanied by reduced self-confidence. Besides the effect on oral and general health of an individual, it certainly can affect the overall quality of life [2, 3]. The majority of these people are still being rehabilitated with conventional removable complete prostheses. However, most of them, especially those with more mandibular bone resorption, have functional and psychological problems due to the lack of stability and retention and in turn decreased chewing ability [4, 5]. Various factors can influence patient satisfaction such as denture quality, the available denture bearing area, previous experience with dentures, patient's personality, and psychologic well-being [6]. A recent consensus conference stated that an implant-supported mandibular overdenture supported by two unsplinted dental implants was the minimal acceptable standard care for the edentulous mandible [7].

      The fixed full arch prosthesis for the mandible requires a number of implants with enough anterior-posterior spread that cannot be removed by the patient. A fixed prosthesis may be placed on 4 or more implants, and several authors have documented these in their studies in the literature [8-11]. An alternative implant treatment option is the removable implant-supported overdenture, which has also been evaluated in a number of studies and documented in the literature by several authors [9, 12-21].

The prosthesis obtains additional retention, stability, and support from a superstructure that is attached to the implants, and the superstructure defines the type of denture that can be constructed. The three types of implant overdentures are tissue-supported, tissue-implant supported, and implant-supported [22].

The mandibular tissue-supported implant-retained overdenture usually consists of two implants placed in the interforamen area with non-splinted retention mechanism such as ball, locator, or magnet attachment. With the tissue-supported overdenture, the denture rests on the attachments as well as mucosal tissue. The attachments guarantee retention during lateral and extrusive movements only. Significant support and stability is provided by the posterior ridge and mucosal tissues [22].

The mandibular tissue-implant supported overdenture usually consists of two implants placed in the interforamen area with a bar as the splinted retention mechanism that allows for free rotation. With the tissue-implant supported overdenture, the denture rests on the implants and bar in the anterior arch, but the denture rests on the mucosal tissue in the posterior arch. The attachment guarantees retention during lateral and extrusive movements. When intrusive movements occur, the implants and bar carry the occlusal load in the anterior, while the posterior ridge and mucosal tissue carry the load in the posterior [22].

The implant-supported overdenture usually consists of 4 or more implants with a bar or superstructure as the splinted retention mechanism that does not allow free rotation. The attachment guarantees retention during intrusive, lateral, and extrusive movements with minimal to no loading of the mucosal tissue [22].

***Diameter of Implants***

The diameter of implants ranges from approximately 1.8 mm to 6 mm. There are four general categories of implant diameters, with many sizes in between:

1) Mini-implant or small-diameter (1.8 to 2.5 mm),

2) Narrow-sized implant (3.0 to 3.5 mm),

3) Standard-sized implant (3.75 to 4.0 mm),

4) Wide-body implant (5.0 to 6.0 mm).

The size of an implant depends on the existing bone width and bone quality as well as esthetic demands and occlusal force factors. The risk of dental implant failure increases as patient forces increases and bone quality decreases. Distributing functional load over the implant surface is directly affected by implant size. A way to increase functional load and avoid anatomical landmarks may be to increase the width of a dental implant, and by doing this, increasing circumferential bone contact. Functional surface area increases by 30-200% by each millimeter diameter increase[23].

When original root-form Branemark implants were first introduced, they had a diameter of 3.75 mm. All implants require additional 1 mm of surrounding bone. For example, a standard sized 4 mm implant will require 6 mm of bone in the buccal-lingual dimension. Many patients who have lost their teeth for awhile, may not have a wide enough ridge for standard dental implant placement. Additional methods to augment the ridge such as block graft, ridge expansion or alveoplasty is required to prepare the ridge prior to implant placement. Such surgical requirements increase surgical treatments, treatment time, morbidity, and treatment risk.

Several implant companies, such as 3i, Astra, Straumann, and Noble Biocare, have recognized presence of minimal bone and space limitations, and have made implants

6

of slightly smaller diameter (3.0 to 3.5 mm). This minor reduction in diameter has allowed placement of implants into narrow edentulous spaces such as the maxillary lateral incisor and mandibular anterior. These narrow-diameter implants have been successful in many situations [24]. However, these implants still need a minimum of 5 mm of bone, which is often not available clinically. In these edentulous patients with severe space limitations, an alternative to standard and narrow dental implants is necessary. Several other companies, such as IMTEC Corp. and Dentatus, have recognized the presence of severe space limitations, and have designed implants of miniature diameters (1.8 to 2.5 mm). Using multiple miniature dental implants (1.8 to 2.5 mm) in areas of narrow edentulous space can offer increased force distribution over multiple mini-dental implants, often without additional surgical procedures.

### *Mini-Diameter Implants & Supported Overdentures*

Over the last several years, the popularity of mini-dental implants (1.8 - 2.5 mm in diameter) has increased as a long-term options for edentulous patients. In 1997, IMTEC, now 3M (Ardmore, OK), received FDA approval to use Sendax MDI for intra-bony and intra-radicular fixation. This was the first company that received FDA approved for long-term use. Following that, MDI Plus was also approved in August 2003. In 2004 and 2007, the Dentatus Company (New York, NY) and the Intra-Lock (Boca Raton, FL) mini implant also received FDA approval, respectively.

Two widely used mini-implants include MTI (mini-transitional implant from Dentatus) and MDI. Kanie and colleagues, in 2004 [25], investigated the mechanical and physical properties of the two widely used mini-implants (MTI – mini-transitional implant from Dentatus and Sendax MDI. Their study included the analysis of flexural

properties, surface imaging by scanning electron microscopy (SEM) with EDX, x-ray. The results show that the maximum strength and proportion limit for the different implants differed significantly (P <0.01) but, the elastic modulus did not differ significantly (P >0.01). The surface characteristics of the MTI were smooth; however, the MDI had a rough surface. Based on elemental analysis and x-ray diffraction patterns, MTI is composed of pure titanium (Ti), and the MDI is composed of Ti, aluminum, and vanadium. The two devices have similar shapes and dimensions; however, their properties and clinical applications differ [25].

The use of the mini-dental implant, which has been in use in various forms for approximately 20 years, has gradually increased as patients have desired immediate support for the prosthesis preventing transmucosal loads while the standard implants are healing. These were thought as "transitional." The intention was to remove the transitional implants after the standard implants were fully integrated about 4-6 months later. The clinicians found the transitional implants were also integrated and could not be easily removed [26, 27].

In 2001, Balkin and his colleagues reported the clinical and histological results in two patients after retrieving the MDI (IMTEC Corp., Ardmore, OK). The MDIs were inserted using the auto-advance technique and loaded immediately. In one case, the mini-dental implants were used for a fixed prosthesis while the other was for a removable prosthesis. The implants were retrieved at 4 and 5 months following insertion. At the time of removal, the implants had no apparent exudate or bleeding upon probing and no mobility. Histologically, osseointegration was shown as bone appeared to be integrated

to the surface of the implant at the light microscopic level, and the bone was relatively mature and healthy [28].

In a prospective study by el Attar and colleagues reported in 1999, twelve edentulous patients received two SDIs in the mandibular canine region. In the study group, two mini-transitional implants (MTIs) were placed medially to the standard implants in six patients, and the other six patients served as controls. This study showed that MTIs were integrated and provided successful immediate support for the transitional prosthesis and did not interfere with mucosal healing. After the SDIs were loaded, the two groups had similar bone levels [27].

Ahn and colleagues in 2004 evaluated the efficacy of twenty-seven mini-implants that were placed to immediately load the eleven mandibular complete dentures during the healing period of SDIs. When two MDIs were placed, they would support a removable implant-retained tissue supported overdenture. When 3 to 4 MDIs were placed, they would support a fixed prosthesis without tissue support. Twenty-five were MDIs (1.8 mm x 13 to 18 mm, IMTEC Corp., OK) and two were mini drive-lock implants (2.0 mm x 13 to 18 mm, Intra-Lock International Inc., FL). The implants were inserted according to the auto-advance technique like the study reported by Balkin in 2004. During placement one implant fractured due to forceful advancement in very dense bone. Twenty-six out of twenty-seven MDIs remained stable during the 21 weeks of function. The MDIs did not interfere with the final implant integration. All patients reported no pain with the immediate prostheses and were satisfied with the immediate temporary prostheses [26].

Griffitts and colleagues in 2005 reported on the efficacy of mini-implants to retain

a mandibular implant-retained overdenture in thirty patients with four MDIs in the interforaminal mandible. The objective of this study was to examine the success of MDIs by evaluating four subjective measures of patient satisfaction: comfort, retention, chewing ability, and speaking ability from 1 to 10 where 1 is poor and 10 is excellent. This study also analyzed the success rates, financial impact, and surgical protocol. Five months postoperatively, self-reporting questionnaires were sent to the patients. A total of 116 MDIs were placed and 113 remained stable, a 97.4% implant success rate. Patients reported the improvement of their denture retention from $1.7 \pm 0.42$ to $9.6 \pm 0.37$ (difference of 7.9). Comfort was also improved from $2.2 \pm 0.63$ to $9.4 \pm 0.45$ (difference of 7.2). Chewing and speaking ability also improved, with a difference of 7.0 and 3.2, respectfully. They found that overall patient satisfaction was excellent, and that MDIs are a highly successful implant option. The limitations to this study, however, was that it included only the short follow-up period and the lack of a control group [29].

Bulard and Vance 2005 performed a biometric analysis in a multicenter retrospective study with 5 clinics, and they found 1,029 MDIs in service from 5 months to 8 years. The success rate for stabilization was 91%. The authors concluded that MDIs were an adequate fixture for immediate and long-term prosthesis stabilization [30].

Mini-dental implants are also used to support fixed prostheses. Flanagan presented a successful case report in 2006 of a splinted-fixed FPD #24 to #25 on two 1.8 mm x 15 mm MDIs with 2 years of function [31]. Flanagan continued to report on the success and usefulness of small diameter implants in fixed prostheses in twenty-five patients in 2008. These cases demonstrate that single and multiple very small implants may successfully support crowns or fixed partial dentures where there is appropriate bone

and occlusal considerations [32]. In another case report, Siddiqui and colleagues 2006 used two 2.4 mm x 15 mm MDIs to replace #22 and #27 with single units [33]. Güler N and colleagues 2005 successfully rehabilitated a 15-year-old female with Hypohidrotic Ectodermal Dysplasia with an implant-retained fixed prosthesis on four MDIs in the mandibular anterior [34]. In a 5-year case series article, Mazor and colleagues in 2004 reported on 32 mini-implants that were immediately loaded and restored with positive results [35].

Mini-implants have shown to integrate and provide adequate soft tissue health. Glauser and colleagues in 2005, studied the histology of peri-implant soft tissue barrier (PSTB) and characterized the PSTB formed in humans around experimental one-piece mini-implants with different surface topography. In this study, five patients received a total of twelve titanium, one-piece mini-implants with an oxidized (n = 4), an acid-etched (n = 4), or a machined (n = 4) surface distal to definitive implants. After 8 weeks of transmucosal healing and at abutment connection of the regular implants, the mini-implants were removed with a layer of surrounding hard and soft tissue. The results show an overall height of the soft tissue or biologic width of 4 to 4.5 mm, which consisted of an epithelial and a supracrestal connective tissue barrier. There was junctional epithelium attachment to the implant surface, and connective tissue consisting of collagen fibers and fibroblasts that were oriented parallel to the mini-implants. The epithelial attachment was longer in the machined surface group, but there was a longer zone of connective tissue in the oxidized and acid-etched group. The peri-implant soft tissue formed around mini-implants in humans was similar to that described in animal studies for standard diameter implants. The oxidized and acid-etched implants revealed

less epithelial down growth and longer connective tissue seal than machined implants [36].

*Mandibular Tissue-Supported Implant Retained Overdenture Success*

The mandibular implant-retained overdenture has been shown to be a highly successful prosthetic treatment similar to the fixed implant denture. However, controversy persists as to its design and indications. Such design has not been investigated until 1987 with longitudinal studies [37]. Van Steenberghe *et al.,* were among the first authors to propose placement of only two implants in the edentulous mandible. They reported the follow up of 52 months with 98% success rate [38].

Several authors have reported success when using two implants to retain a mandibular overdenture over a five-year period [5, 38-42]. Jemt *et al.,* 1996 followed a total of 103 patients that received 393 implants in the edentulous mandible in a five-year multicenter prospective study. They followed the same protocol in all nine worldwide centers. In this study, four mandibular implants were placed, but only two were used to support the overdenture, leaving the remaining buried implants as backup for future implant failure. They observed a mean marginal bone loss of 0.5 mm with a 94.5% cumulative success rate for two implants and 100% success for overdentures supported by two implants during the five-year observation [5].

In a five-year longitudinal study by Mericske-Stern R *et al.,* 1994, they reported 97% implant survival with two implants, irrespective of keratinized tissue, duration of edentulism, or superstructure. In this study, 66 ITI implants were placed in edentulous mandibles of 33 elderly patients with a mean age of 69 years. The implants were retained by either a connecting bar or ball attachments. Approximately 50% of the implants were

12

surrounded by keratinized tissue. The peri-implant mucosal tissue was maintained healthy with probing depths averaging approximately 3 mm irrespective of adequate or inadequate keratinized mucosa. Small local angular bony defects were detected on 16 implants (22%) in 12 patients at the end of the study period with an associated slight increase in probing depth. This study offered a conclusion that advanced age, reduced dexterity, and two implants with ball or bar overdentures do not represent a higher risk for the development of peri-implantitis or implant failure [39].

Naert *et al.,* 1999, reported a five-year prospective randomized clinical trial on thirty-six fully edentulous patients with seventy-two implants placed and randomly divided into three different overdenture anchorages: magnets, ball attachments or straight bars. After 5 years of observation, none of the implants failed in any of the groups for a 100% implant and overdenture success [40].

Ueda *et al.,* 2011 reported long-term clinical observations of edentulous patients treated with mandibular implant-supported overdentures. The treatment plan was to connect the dentures to only two implants with single ball anchors or bars with the exception in patients with special oral conditions where three implants would be placed. In this study, 314 implants were placed in 147 patients, and they were evaluated for 10 to 24 years. After this period, 101 patients were still available for evaluations. Thirteen implants failed during this period, resulting in a cumulative survival rate of 85.9% after 24 years. Mean crestal bone loss was $0.54 \pm 0.7$ mm per implant site after $16.5 \pm 3.9$ years of observation. This data showed a satisfactory survival rate of implants to support the overdenture [41].

Akoglu *et al.,* 2011 evaluated clinical outcomes, posttreatment care, and patient

satisfaction with two implant-supported mandibular overdentures in the intraforaminal region of 36 edentulous patients with severely resorbed mandible. Seventy-two implants with an even number of three different implants systems were used: 24 ITI, 24 SwissPlus (Zimmer Dental, Warsaw, IN), and 24 Astra (Astra Tech, Waltham, MA). The survival rate after 5 years of loading was 100% and they concluded that mandibular implant overdenture treatment is a successful treatment modality for the severely resorbed mandible [42].

### *Number of Implants for the Mandibular Overdenture*

In 1984, a treatment modality was established that used only two interforaminal implants for denture connections, and studies published in the 1990s have provided evidence of the increasing popularity of this treatment modality [15, 43-46]. However, the number of implants to be placed and the type of retention mechanism for overdenture fixation to be used has remained an object of controversy. The need for more than 2 implants to retain a mandibular overdenture has been recommended by several authors [37, 43, 47].

- Implant length less than 8 mm

- Implant width less than 3.5 mm

- Dentate maxilla

- Patient requests an extraordinarily retentive prosthesis

- V-shaped ridges

- High muscle attachments

- Sharp mylohyoid projections

- Sensitive soft tissue

Meijer and colleagues in 1994 conducted a 3-D finite element study and found that the number of implants (either two or four) placed in the interforaminal region of the mandible does not seem to reduce the stress if more implants are placed. The important part is that the load needs to be uniformly distributed [48].

Batenburg and colleagues in 1998 evaluated 60 patients with implant-supported overdentures in a 12-month study. Patients were randomly divided into two treatment groups with either 2 anterior mandibular implants or 4 mandibular implants to support their overdentures. This prospective study evaluated patients at 0, 6 and 12 months after insertion of the denture. There were no significant differences with regard to any of the studied parameters of the peri-implant tissues. The authors concluded that there is no need to insert more than two implants to support an overdenture [49].

Visser and colleagues (2005) reported a 5 year prospective study on these 60 patients. They followed the same standardized clinical and radiographic parameters at 6 weeks after prosthetic treatment and after one, two, three, four and five years of functional loading. There were no significant differences with regard to any of the parameters of the peri-implant tissues between the groups. No differences in satisfaction were observed between the groups. With regard to aftercare, the group with 2 implants had a greater need of prosthetic care; alternatively, the group with 4 implants needed more correction of soft-tissue problems. The five-year conclusion was that there was no difference in either the clinical or radiographic state of patients treated with an overdenture on two or four implants, and that both groups were equally satisfied with their overdentures [50].

Mericske-Stern (1990) evaluated 67 subjects with implants supported overdentures. Subjects were divided into 3 different groups (27 subjects with two implants and simple ball-shaped precision attachments, 29 subjects with two implants connected with a clip bar, and 11 subjects with three or four implants, all splinted with a clip bar). All implants were placed in the interforminal area of the mandible. The author found that occlusal equilibration, retention, and stability of overdentures improved only slightly with increasing the number of implants. The author concluded after 6 to 66 months observation that two implants may adequately support a mandibular overdenture in the parameter of retention, stability, and occlusal equilibration [15].

Several authors found no significant differences in masticatory forces between patients having tissue-supported implant overdentures and patients having implant-supported overdenture when opposing a conventional maxillary denture [13, 51-53]. In a systematic review by Fueki in 2007, the author concluded that the benefits in masticatory performance between implant-supported and implant-retained overdenture were superior to conventional dentures [54].

Fontijn-Tekamp and colleagues (1998) evaluated the idea that bite forces with mandibular implant-retained overdentures may depend on the type of implant support. The subjects received new maxillary dentures and one of three different mandibular prostheses: 1) implant-supported overdenture, 2) tissue-supported implant overdenture on two implants, or 3) a new conventional denture. Both unilateral and bilateral bite forces were recorded at different positions with a miniature strain gauge transducer and a mechanical bite fork. The authors concluded that the tissue-supported overdenture and the implant-supported overdenture had significantly higher unilateral and bilateral

maximum bite forces than complete denture wearers.  However, bite forces did not differ between the mainly implant-borne and tissue-supported overdenture [51].

Klemetti's systematic review in 2008 critically looked at 39 articles to determine the ideal number of implants to support an overdenture.  In this review, most articles supported some modality of implant retention or support for mandibular overdenture. The review came with a conclusion that patient satisfaction and function of the prosthesis in the mandible do not seem to depend on the number of implants or type of attachment [52].

Van Kampen and colleagues (2004) examined the hypothesis that greater retention and stability of the overdenture will improve masticatory function.  Eighteen edentulous subjects were studied with 2 implants with 3 different suprastructure modalities: magnet, ball, and bar-clip.  Masticatory function significantly improved after implant treatment with each of the 3 attachments, and there was slightly better masticatory performance with ball and bar-clip than with magnet attachments.  They concluded that significantly better masticatory performance, combined with a slightly smaller number of chewing cycles after implant treatment, results in smaller food particles being swallowed [53].

McGill's Consensus statement in 2002 stated that there is overwhelming evidence that 2-implant overdenture should be the first choice of treatment for the edentulous mandible.  These patients would benefit their nutrition intake as well as social acceptance [55].

***Splinted or Solitary Anchorage Design for the Mandibular Overdenture:***

Several authors agreed that it is appropriate to use 2 implants with a round or

ovoid bar parallel to the hinge axis and a resilient overdenture [13, 56, 57]. This kind of attachment would allow free rotation during loading and would decrease the twisting load to implants. However, Chao in 1995, concluded that the connection of the implants has less influence than the direction of the occlusal forces, and that the difference in stress concentration is not significant with or without the bar [58]. Other authors have reviewed mandibular overdenture treatment modalities and have found that these concepts are based on empirical data [59]. The choice of attachments for the mandibular overdenture includes but is not limited to the following parameters: patient retention, support, stability needs, jaw morphology and anatomy, and compliance to hygiene and maintenance recalls [37].

Naert and colleagues (1997) studied whether there is an advantage to splint two implants to retain a mandibular overdenture. Patient satisfaction was also evaluated for the different attachment systems. Thirty-six patients were randomized into three groups of equal size and treated with magnets, ball attachments, or straight bar. After 3 years of observation no implants were lost in any of the groups. There were no statistically significant differences noted for the peri-implant outcome. The bar group presented the highest retention force; however, the general satisfaction of the patients in the three groups did not differ. The patients with bar retention showed more complications at the level of the denture-supporting mucosa but less prosthetic complications of the retention elements [56].

Bilhan *et al.,* 2009, in a prospective 36 month study, compared mandibular implant-overdentures with either ball or bar attachments and evaluated the marginal bone loss of 51 patients through radiographic analysis. There was no statistical significance

between the marginal mesial and distal bone loss rates of single or splinted attachment types. The bone loss rates were significantly higher in cantilevered overdentures. It was concluded that the implant diameter did not affect marginal bone loss, however, the length of the implant was a critical factor in marginal bone level maintenance. The cantilevering of the bars significantly increased the bone loss, but the attachment type of the overdenture did not influence implant marginal bone loss [60].

Both solitary attachment and bar attachment have its advantages and disadvantages. The solitary attachment is less costly, easier to place and restore [61], easier to clean [62], and causes less gingival hyperplasia [63]. However, bar attachments have greater retention[45]. The controversy still remains whether solitary attachment or bar attachment requires more maintenance [64-66]. Several reports of complications existed with 2 implants retaining an overdenture. The census of these articles is that maintenance requirements of several different implant systems is greatest in the first year and related to contour, matrix (socket/clip), and patrix (ball/bar) [14, 40, 64, 65, 67-72].

***Implant Loading Periods for the Mandibular Overdenture:***

Generally, conventional implant loading is recommended after a healing period of three to six months. Immediate implant loading has been defined as full occlusal loading within 24-48 hours after placement. Early loading has been defined as loading in less than 14 days, within the first 3-5 days, or within the first 6 weeks after placement. In a meta-analysis by Ioannidou and Doufexi (2005), despite several limitations, the data suggests that there is no difference in failure rate between early and conventional loading periods [73]. Progressive loading has been defined as a provisional restoration in and/or out of function, which is later replaced by a definitive restoration (after 6 weeks to 6

months) [74].

There are several different loading modes, and their definitions are as followed: [75]

- Submerged: implant is at or below bone crest and covered with gingiva

- Nonsubmerged: supracrestal and flush or within 1 to 2 mm of gingiva

- Immediate functional loading: temporary or final prosthesis on day of surgery that is in occlusion

- Immediate non-functional loading: temporary or final prosthesis on day of surgery that is not in occlusion

- Early loading: final prosthesis within 3 weeks from placement that is in occlusion

- Anticipated loading: temporary prosthesis within 8 to 10 weeks from surgery

Several authors have reported a success rate of 95% to 100% when 2 to 4 implants are immediately loaded with a mandibular overdenture [76-80].  In a long-term prospective clinical study by Chiapasco *et al* (2003), they evaluated the survival and success rates of 328 implants placed in the interforaminal area of edentulous mandibles and immediately loaded with bar attachment overdenture.  They followed these subjects from three to eight-year.  The success of implants were evaluated every year both clinically and radiographically.  Success was measured  according to the following parameters: absence of clinical mobility of implants tested individually after bar removal, absence of periimplant radiolucency evaluated on panoramic radiographs, absence of pain and radiologic or clinical signs of neural lesion, and periimplant bone resorption mesial and distal to each implant less than 0.2 mm after the first year of prosthetic load. Despite the loss of 7 implants in 6 patients out of 296 implants, all patients maintained

their bars supporting the overdentures. The absolute success and survival rates were 91.6% and 97.6% respectively. The results of this study suggest that survival and success rates of immediately loaded implants rigidly connected with a bar and an overdenture are consistent with delayed loading after three years of loading [76].

In a 5-year prospective clinical trial by Cooper and colleagues (1999), they reported on treatment of mandibular edentulism using single-stage implant placement with immediate replacement of a relieved mandibular overdenture and 3 month retention of the overdenture with ball abutments. Fifty-eight patients were treated with 116 implants placed using a single-stage surgical approach with the mandibular dentures relieved and relined with a tissue conditioning material and placed immediately after implant surgery. Five implants failed at two to four months, resulting in an implant survival rate of 95.69%. Pain and inflammation were not common to all failures, and infection was not reported in any of the 5 failures. They concluded that immediate placement of implants by a single-stage surgical procedure in the mandible, followed by placement of a relined mandibular denture, results in predictable implant success [77].

Turkyilmaz and colleagues (2006) reported on 26 edentulous patients that were treated with two unsplinted dental implants supporting mandibular overdentures that were connected 1 week after surgery (test group) versus three months after surgery in a clinical trial. Healing abutments placed at the time of implant placement, and the mandibular denture was relieved so that there was no contact between the healing abutments and the denture. There was 100% implant success during the 2-year study. Clinical and radiographic parameters showed no statistically significant differences between the groups. The authors concluded that the early loading approach does not affect peri-

implant soft tissue, marginal bone resorption, or implant stability [80].

***Anterior and Posterior Mandibular Bone Preservation:***

The alveolar ridge height is reduced over time when patients wear a conventional complete denture [37], but implants in the anterior mandible have been shown to increase positive bone remodeling and reduce anterior mandibular bone resorption as little as 0.5 mm over a 5-year period and with long-term annual resorption of 0.1 mm [5, 37, 66].  In the longitudinal studies by Atwood and colleagues (1971) and Tallgren (1972), they both showed an average annual alveolar ridge height reduction of approximately 0.4 mm in the edentulous anterior mandible [81, 82].

von Wowern and Gotfredsen (2001) conducted a five-year study on 2 Astra Tech implants in the mandibular canine area of 22 long-term edentulous subjects for mandibular overdentures with ball or bar attachments.  Eleven patients received a bar and 11 received ball attachments.  Alveolar bone height of the implants was measured periodically on identical intraoral radiographs.  They found that the anterior alveolar bone responded to the loaded implants with positive bone remodeling due to its increased function.  They concluded that the implants, which increased function in the alveolar bone, seemed to cause load-related bone formation that minimizes the physiologic age-related mandibular bone mineral content (BMC) loss.  This effect was found independent of attachment system used in this study [83].

Implant-retained overdenture may promote positive bone remodeling and, at least, impede bone resorption associated with a conventional complete mandibular denture; however, the resilient overdenture design may cause posterior mandibular resorption [37].  In a study by Jacobs and colleagues (1992), they followed three groups of patients

with different prosthetic reconstructions using orthopantomograms to evaluate posterior mandibular ridge resorption. Thirty patients, with two implants, were connected by a bar to support the mandibular overdentures and twenty-five patients had four to six implants to support mandibular fixed prostheses and eighty-five patients had conventional mandibular complete dentures. The authors found minimal posterior mandibular ridge resorption in patients with fixed implant-supported prostheses. When comparing fixed to removable, there was considerable posterior ridge resorption observed in the complete denture group and overdenture groups. The annual posterior jawbone resorption after the post-extraction remodeling period of six months, was two- to three-fold greater in the overdenture group than that of full denture wearers. However, when patients were edentulous for more than 10 years, the difference between the three groups disappeared. These results implied that the initial severe bone loss experienced after dental extraction can be avoided with immediate implant placement or placement soon after extraction [84].

For young patients or patients with minimal mandibular posterior ridge height, a two implant overdenture or complete denture may be contraindicated due to the continued resorption process of the mandible. When treatment planning for the edentulous mandible, the surgical and restorative dentist must consider the preserving effect of totally implant-borne prosthesis compared to the continued resorption with the other treatment options [37].

***Chewing Ability, Chewing Efficiency, and Bite Force:***

Patient's chewing ability is a critical factor for a successful prothodontic outcome in edentulous patients. In the study by Muller *et al.,* in 2011, the author found that

chewing ability and chewing efficiency is lowest in subjects with conventional complete denture [85].

The systematic review by Fueki *et al.,* in 2007, found from 18 peer-reviewed articles that a combination of a mandibular implant-supported or retained overdentures and maxillary complete dentures provided significant improvement in masticatory performance compared to complete dentures in both the mandible and maxilla due to severely resorbed mandible. Furthermore, they also found that mandibular fixed implant-supported complete dentures provide significant improvement in masticatory performance compared to mandibular complete dentures in subjects dissatisfied with their complete dentures [54].

In a study by Haraldson and colleagues (1988), nine subjects with mandibular implant overdentures were functionally evaluated before and one year after treatment. The bite force on an almond was measured during gentle biting, biting as when chewing and biting with maximal effort. All subjects improved subjectively and clinically after implant treatment. The bite force during gentle biting increased on average from 17.3 N before treatment to 24.0 N one year after treatment. A corresponding improvement of biting was also found, from an average 24.0 N before to 38.7 N after treatment. The maximal bite force increased from on average 74.6 N at baseline to 131.5 N at a 1-year follow up. Their chewing efficiency improved dramatically. It was concluded that treatment with an overdenture supported by implants in the mandible improves oral function compared to a mandibular conventional denture [86].

*Problems with Conventional Mandibular Dentures:*

Since the time of the American Revolution, disease prevention and health care

have been improving, but this had little impact on the average denture wearer. The appearance of conventional denture has improved vastly since the time of George Washington's denture, but the mandibular denture is still a horseshoe-shaped structure with no retention and, over the years, it gradually destroys the mucoperiosteum and underlying bone [87].

The residual ridge supporting a complete denture is inherently unstable due to unpredictable resorption and remodeling of the alveolar bone when natural teeth are removed [82]. Consequently, resorption of the residual ridge disturbs the comfort and retention of a denture, which, in turn, can irritate the peripheral mucosa to produce an epulis fissuratum [88]. The influence of dentures on the supporting jawbone is unclear. Denture base pressure, especially if it is unevenly distributed on the residual ridge, infected, or structurally defective, can precipitate a low-grade inflammation on the supporting mucosa and the underlying bone, but usually the damage is reversible. Clinical experience reveals that the discomfort of an ill-fitting complete denture, especially in the mandible, can be very difficult for the denture wearer to manage. A mandibular residual ridge provides a complete denture with less than one quarter of the support offered by the periodontium to natural teeth, yet some patients expect the prosthesis to replace natural teeth in every respect in terms of function, esthetics, and comfort. Obviously, this expectation is unrealistic, and many denture wearers cannot cope with their dentures, no matter how well they have been made [89].

Edentulism can be disabling in today's society within the context of appearance, appetite, eating, general health, mood, recreation, weight, and work. It can be psychologically disruptive with its social stigma and a significant esthetic problem [90-

92]. It has been shown that some edentulous patients with existing conventional dentures experienced difficulty in eating some foods specifically due to difficulty in chewing. However, many of these patients learn to adapt to their inefficient prostheses instead of seeking more supportive and stable prosthetic options. This adaptation affects the dietary habits of such edentulous older adults. They tend to avoid some healthy and fibrous foods like fruit, vegetables and other dietary fibers. These poor dietary habits are revealed in blood tests with lower levels of plasma ascorbate and plasma retinol compared to patients with a higher chewing function [93].

Besides the problem of learning to adapt to their newly acquired, inefficient prosthesis, there are also some denture patients who avoid eating in public due to their prosthesis. The satisfaction of eating is highly dependent on a functional dentition. If the dentition is inadequate, it can negatively influence diet and nutrition. Digestion is not dependent on teeth, but a reduced number of teeth or reduction chewing ability may make mastication difficult that may lead to avoidance of foods that require rigorous chewing. When the dentition is inadequate, patients may be forced to eat highly processed foods, which are easy to chew, swallow, and digest. However, these foods may lead to dietary intake deficiencies in protein, fiber, vitamins, and minerals. These dietary changes may be associated with increased risk for cerebrovascular accidents, cardiovascular diseases, and colon cancer[94].

In addition to general health issue of having conventional denture, edentulism carries a list of problems with it including stigma of social embarrassment of having a prosthesis falling out. This embarrassment could lead to social avoidance and isolation that are characteristic of chronic illness. This stigma includes dentures as being

unesthetic and a sign of low socioeconomic status. Patients learning to adapt and cope with unstable, esthetic dentures made them suffer substantially from chronic dysfunction, low self-esteem, and reduced quality of life [95, 96].

***Implant-Supported/Retained Overdentures vs. Conventional Complete Dentures:***

Edentulism affects patients and their quality of life in at least four prominent dimensions: 1) psychological health and function, 2) socioeconomic status, 3) life satisfaction, and 4) self-esteem [97]. When considering psychological health most patients who wear complete conventional dentures are able to adapt to sometimes painful and unstable dentures, but some edentulous patients are embarrassed and believe that complete dentures is a sign of personal decline or neglect. Socioeconomic status is impacted by edentulism. The edentulous patient is more likely belong to a lower economical background because they are more likely to face the financial burdens that health problems invariably incur [95]. Edentulism has also been shown to negatively affect life satisfaction and self-esteem. Often patients who are very concerned with their complete dentures are likely to experience a poor quality of life. When comparing patients who have implant supported or retained dentures with patients that wear conventional dentures, the implant patients have a higher quality of life than patients with conventional dentures, and their higher quality of life may be due to the implant prosthesis feeling like a part of their body [98].

For most patients with complete dentures, comfort, stability, and ability to chew are the three most important qualities they seek. Other qualities include esthetics, speech ability, and ease of cleaning [99, 100]. Patient satisfaction and quality of life are directly related to those six qualities. Patient satisfaction is an outcome measure that describes

the patient's evaluation of a specific aspect of treatment; it is usually measured by self-administered questionnaires.  For scaling or quantitative purposes, questions are either coupled with multi-step answer categories (Likert scales) or visual analog scales (VAS) [101].

Patient with complete dentures have dealt with prosthesis disatisfaction for many years.  The main reasons for dissatisfaction among complete denture wears are discomfort, poor fit, and inadequate retention.  Patients also experience pain and soreness under complete dentures.  The mandibular denture causes more patient dissatisfaction and many more problems than maxillary dentures [99, 102-104].

Multiple authors have addressed patient satisfaction with implant overdentures [6, 17, 40, 63, 99, 103, 105-108].  Awad MA and colleagues, in 1998, investigated the relationship between patients' ratings of general satisfaction and their perceptions of different aspects of mandibular prostheses.  In this study, they randomized one hundred and twenty subjects in a randomized controlled clinical trial comparing conventional dentures and implant prostheses.  At baseline, they were asked to rate on 100 mm visual analog scales (VAS) factors that were important to them such as comfort, ability to chew, stability, esthetics, speech, and ease of cleaning.  Subjects were also asked to rate their general satisfaction and one quality of their denture that they considered to be the most important.  They found that gender, comfort, stability, esthetics, ability to chew and ability to speak contributed significantly to general satisfaction (F<0.0001).  They also found that 89% of the variation in ratings of general satisfaction was explained by the above factors.  In addition, when patients considered the ability to chew as the most important factor, they rated their general satisfaction significantly higher than the other

subjects (P=0.0003).   The authors concluded that patient satisfaction is highly dependent on gender, appearance, and functionality of the denture [99].

Awad MA and colleagues continued to investigate the importance of assessing the impact of treatments for chronic conditions such as edentulism on an individual's quality of life.  In this study, they incorporated the oral-health-related quality of life, measured with the Oral Health Impact Profile (OHIP) reported and validated by Slade and Spencer [109].  They compared the new conventional dentures in forty-eight patients to the implant prostheses in fifty-four patients in a randomized controlled clinical trial. Assessments were performed pre-treatment and two months post prostheses delivery, which showed that implant treatment was significantly associated with lower post-treatment OHIP scores (p = 0.0002), indicating a better quality of life.  These results suggest that implant prostheses provides a short-term significant improvement compared to conventional dentures in oral-health-related quality of life [105].

In a randomized clinical trial, Awad MA and colleagues studied middle-aged subjects (35 to 65 years old) that were randomnly assigned to either a group receiving mandibular conventional denture (n=48) or a group receiving overdenture with two implants splinted with a bar (n=54).  Data was collected at baseline and two months post delivery using VAS.   The results indicate that the mean post-treatment general satisfaction, comfort, esthetics, stability, and ease of chewing were significantly higher in the implant overdenture group.   They concluded that the mandibular two-implant overdenture opposed by a maxillary conventional denture is a more effective treatment for middle-aged adults than conventional treatment [106].

Similarly, Awad MA and colleagues 2003 extended their study to older

population in the same fashion.  Sixty elderly edentulous patients (65 to 75 years old) who received a maxillary conventional denture along with either a mandibular conventional denture (n=30) or a two-implant overdenture with ball attachments (n=30). Data was collected at baseline, two month and six month post delivery using VAS to report their general satisfaction and other features of the dentures. Their study showed the mean post-treatment general satisfaction, comfort, esthetics, stability, and ease of chewing were significantly higher in the implant overdenture group.  They concluded that the mandibular two-implant overdenture retained by ball attachments opposed by a maxillary conventional denture is a more effective treatment for seniors than conventional treatment at two and six months post-treatment [107].

Boerrigter EM and colleagues 1995, compared patient satisfaction and chewing ability of edentulous patients treated with implant-retained overdentures or with complete dentures with or without vestibuloplasty.  In this randomized controlled clinical trial, thirty patients had mandibular conventional dentures, thirty patients had vestibuloplasty prior to obtaining conventional denture and thirty patients had two-implant supported mandibular overdenture.  The main outcome measures were chewing ability and denture satisfaction, which were assessed using patient-administered questionnaires. Their results showed that at the one-year evaluation, implant overdentures or complete dentures constructed after vestibuloplasty provide a more denture satisfaction than complete dentures alone [6].  Raghoebar GM and colleagues 2000, followed up on the long-term data initially presented by Boerrigter EM *et al* 1995.  At five-year post-treatment, the positive effects of vestibuloplasty surgery had disappeared and the difference with conventional denture treatment alone was no longer significant.  The implant overdenture

group consistently produced significantly higher general satisfaction scores compared to both alternative treatments. They concluded that implant-retained overdentures are a satisfactory treatment modality for patients with problems with their lower complete denture [108].

The 2002 McGill consensus report draw the conclusion that implant overdentures are superior to conventional dentures. The conclusion was made after reviewing and discussing fifteen papers with experienced patients and clinicians described their overdenture and conventional denture experiences. Bone loss in edentulous patients is expected, and bone loss occurs more rapidly and more significantly in the mandible which leads frequently to a mobile mandibular denture. With a mobile denture, experienced patients have noticed that they cannot function at a normal level which, in turn, forces them to change their diets that often leads to worse nutrition than people with natural teeth [55].

In conclusion, the reviewed randomized clinical trials suggest that implant overdentures provide patients with better outcomes than conventional dentures. These positive outcomes include satisfaction, oral health-related QOL, and functional improvements, which should be based on the patient's preferences and expectations.

*Patient Satisfaction, Preferences, Expectations and QOL:*

When evaluating the benefits of any therapeutic intervention involves consideration of three distinct types of outcomes: survival/longevity, physiologic/physical, and behavioral/psychosocial. These relate to mortality, morbidity, health status and quality of life. While the first two types of outcomes are almost always addressed in clinical trials of health interventions, the third often is not. This is also the

case with respect to evaluations of implant procedures. The clinical outcome, including implant success and overdenture fit, is an important factor in the assessment of implant overdentures treatment; however, the patient's opinion and satisfaction with the improvement in function and quality of life is another important factor that must be considered when treating the edentulous patient. There is a weak association between clinical evaluation of denture fit by the clinician and the patient's satisfaction with the prosthesis. However there is a stronger association between the patient's perception of the prosthesis and patient satisfaction [110-114].

Researchers have recently argued that treatment evaluation should be based on patients' own ratings of treatment success, rather than on traditional clinical estimates [115-117]. Patient-based measures are an important outcome of implant and prosthodontic treatment. Patient centered care and informed consent must include the patient preferences into the treatment planning process. Patient preferences are a complex phenomena and the strength of those preferences may be different, even for patients who prefer the same treatment. The preference of a specific treatment should include a clear explanation of the prostheses and what the prostheses includes, such as implant surgery, maintenance of the implants, and maintenance of the prostheses. They also should be based on the risks, benefits, and alternatives to treatment. Patient preferences on satisfaction level and QOL may not be the same based on several issues such as patient expectations. These preferences may impact the patient's satisfaction with treatment and impact their QOL [112].

Patient expectations of the outcome may play an important role in their preferences. Unrealistic expectations may cause patient disappointment with the

prostheses. This may lead to disappointment with the treatment outcome, which may lead to low treatment satisfaction. For example, if an edentulous patient expects an implant-supported prostheses to be identical or even superior to a full dentition, this patient has unrealistic expectations. However, patients with positive expectations of treatment tend to lower the adverse symptoms and focus on apparent improvements following therapy. For example, if an edentulous patient expects an implant-supported prostheses to be better than a complete conventional denture, the patient has realistic expectations. Positive expectations may cause a reduction in apprehension and unpleasant symptoms. If the patient has realistic expectations of the implant-supported prostheses, the patient may be pleased with the treatment outcome, which may lead to high treatment satisfaction [118].

**Section 3:**

**MATERIALS and METHODS**

**Selection Process and Study Population**

Forty-three completely edentulous subjects were enrolled in a single-center, case-controlled clinical study to compare four mini-dental implants (MDI, Imtec Corporation, Imtec Sendax MDI, Ardmore, OK) or two standard dental implants (SDI, Biomet 3i, Osseotite Internal Hex, Palm Beach Gardens, FL). Most of the subjects were either selected from a list of patients that received full dentures from the San Francisco Veteran's Administration Dental Clinic (SFVADC) within a five-year period or presented to the SFVADC with complete dentures with a mandibular denture that they considered inadequate. Some patients were also referred from other Veteran's Administrations or from other healthcare providers within the SFVADC. Subjects were screened by telephone interview, and those that were eligible and interested were appointed for a clinical and radiographic examination. Many patients of record at the SFVADC with complete dentures that had persistent problems with stability, comfort, and/or retention were examined and enrolled based on inclusion and exclusion criteria (**Table 1**).

The inclusion criteria required that participants have the following: 1) recently made maxillary and mandibular complete dentures; 2) mandibular dentures with adequate support and stability that are poorly retained; 3) maxillary dentures with adequate retention, support and stability, with at least one month experience wearing the existing denture; 4) ability to answer the questionnaires; 5) no systemic diseases which could influence the outcome of therapy; 6) good level of oral hygiene and denture care; 7) compliance with the recall and maintenance program; 8) presence of adequate bone

quantity and quality to support dental implants; and 9) dental coverage at SFVADC.

Volunteers were excluded from the study if they have the following: 1) bleeding disorders and blood dyscrasias; 2) uncontrolled diabetes; 3) history of having either oral or IV bisphosphonate treatment; 4) history of head and neck radiation; 5) history of chronic hyposalivation or Sjögrens Syndrome; 6) history of disorders affecting the structure and/or healing of the patient's bone; or 7) diminished capacity to provide consent. Four equilibrated periodontal residents completed all enrollment and treatment for the study patients under the guidance and supervision of an attending Periodontist and Prosthodontist.

All subjects received a verbal and written description, and time-line of the study, including information about the two different implant systems, their risks and benefits. Informed consent was obtained from all subjects. The study flowchart that was provided to all subjects is available in **Appendix 1** for additional detail. The treatments were provided at no charge to all the subjects. The research protocol, recruitment procedures, exclusion/inclusion criteria, and the informed consent were approved by UCSF and SFVAMC Committees on Human Research. No monetary incentives were exchanged between patients, providers or implant companies.

**Study Design**

The overdenture treatment was provided by modification of the well-fitting existing conventional mandibular denture [119]. The conventional dentures of both upper and lower were ensured to fit well or they were to be relined/remade prior to

enrollment into the study.  Each patient received a new panoramic or cone-beam CT scan prior to or at the time of evaluation/consent.  Each patient received an extra-oral and intra-oral exam to exclude any pathology and confirm adequate vestibular depth, keratinized tissue, and frenum attachments.  A House Classification (Philosophical, Exacting, Indifferent, Hysterical) was obtained for each patient.  Prior to implant placement and denture alternation, baseline perception data for their conventional complete maxillary and mandibular dentures were obtained using a visual analog scale (VAS) given in **Appendix 2** [120-122]. Subjects were then randomly assigned (via random permutations, from an Excel spreadsheet) into one of two treatment groups. After implant placement and healing period, the mandibular dentures were modified, and attachments were placed into the intaglio of the mandibular dentures to engage the implants.  A two month period of adaptation was given to all subjects, with the implant retained mandibular overdenture, followed with perception data for their conventional complete maxillary and implant retained mandibular overdenture.  The perception data was obtained using the same VAS based questions as given to subjects at baseline [105-107, 120, 122, 123].  The same VAS data would be collected at 6, 12, 24, 36, and 60 months after implant placement [105-107, 120, 122, 123].  See the outline of appointments in **Appendix 3** for additional details.  During the 60 month follow-up, subjects were treated for any problems that arise with the overdentures including any necessary denture adjustments, relines, retention male replacements, housing replacements or even explant and possible implant replacement in the case of implant failures.

Forty-three patients were enrolled in the study. Surgical consents and HIPAA forms were obtained. Eighteen patients belonged to SDI group and twenty-five patients belonged to MDI group. Out of eighteen patients in the SDI group, 1 patient had 1 failed implant, 1 patient had both implants failed and 2 patients passed away before the surgical appointment. Out of twenty-five patients in the MDI group, one patient had two failed implants. All patients who had failed implants decided that they did not want to continue with the study.

**Surgical Procedures**

The surgical treatment was performed under local anesthesia by one of four periodontal residents (CS, PW, NS and CD) under the supervision of an experienced periodontist and implant surgeon (RN) as well as input from an experienced prosthodontist (K). Oral sedation (0.125 – 0.250 mg of Triazolam) was given to anxious patients prior to surgery for dental anxiety. Patients were anesthetized with 2 percent Lidocaine with 1:100,000 epinephrine. Buccal and lingual soft tissue infiltrations followed by crestal injections were used. Some patients received lingual and inferior-alveolar block injections with the same anesthetic. After adequate anesthesia, the tissue of the anterior mandible was probed to determine the condition of the alveolus of the anterior mandible, particularly for those patients with thin, spiny ridges or large lingual undercuts. If osteoplasty was required to increase buccal/lingual width to approximate 7 mm for the SDI group or 5 mm for the MDI group, a crestal incision from left mental foramen to right mental foramen, and a full-thickness flap was elevated to expose the ridge and the mental foramina. A large round bur in a slow speed handpiece with copious saline irrigation was

used to flatten the ridge to create sufficient bone width to allow approximately 1.5 mm of bone on the buccal and lingual aspects of the implants. If patients did not require osteoplasty, the SDI group received full-thickness bilateral semilunar flaps for implant placement. If the MDI patients did not require osteoplasty or visualization of the ridge, the implant fixtures were placed trans-gingivally **(Figures 1-24).**

**SDI Group**

For the SDI group, all patients received two dual acid-etched cylindrical screw-type Full Osseotite Certain Parallel-Walled Implants (Biomet *3i*, West Palm Beach, FL, USA) with a standard diameter of 4 mm, and a length ranging from 10 to 13 mm. The surgical protocol for implant placement was performed according to previous research[124, 125]. The Biomet *3i* "dense bone protocol" was used for the drilling sequence and implant insertion procedures. In brief, a pilot hole was drilled bilaterally equidistant from midline in the area of the mandibular canines and in an adequate distance from the mental foramen, with a round bur, followed by sequential use of twist drills to reach a final osteotomy diameter of 3.5 mm. All implants were placed with primary stability in a two-stage procedure. The SDIs were placed as parallel as possible with the fixture platforms at approximate equal heights. If needed, a guide pin was placed at the midline to help with paralleling the two implants to each other. Primary closure of the tissue was achieved with 5-0 vicryl. The intaglio surface of the patient's denture was relieved and relined with soft reline material in the area of the implant fixtures. Patients were advised to not wear the denture for one week. Occlusion and denture base were checked and adjusted if necessary with articulating paper and pressure indicating paste (PIP). Patients

were given detailed post-operative directions, denture care and usage instructions. A post-operative panoramic radiograph was taken at the end of the surgical treatment.

**MDI Group**

For the MDI group, all patients received four Sendax IMTEC Collard Thread Design, O-Ball Prosthetic Head Mini-Dental Implants (IMTEC Corp., Ardmore, OK, USA) with a standard diameter and length of 1.8 mm and 13 mm, respectively. Some patients received 10 mm or 15 mm length implants if appropriate for their bony vertical dimension. The surgical protocol for implant placement was performed according to previous research [28]. All clinicians followed the IMTEC instructions for implant site and implant insertion instructions. In detail, four 1.1 mm pilot holes were drilled with the MDI 1.1 mm surgical drill (single patient use only) approximately 6 mm and 12 mm from midline, bilaterally. With copious saline, the pilot drill was lightly pumped up and down until the cortical plate was penetrated, approximately one-third to one-half the threaded length of the implant. In dense bone, the osteotomy was prepared deeper as described in the dense bone protocol. Next, the plastic friction grip was used as an implant carrier and the initial surgical driver. Then, the titanium finger driver rotated the implant clockwise while exerting apical pressure until noticeable resistance was encountered. The titanium finger driver was followed by the winged thumb wrench, which was used until noticeable resistance was encountered by rotating clockwise and exerting apical pressure. The ratchet wrench and adapter was used next, also using clockwise rotation and apical pressure until significant stability (30-45 N/cm$^2$) was achieved. At the final stage of placement, the implant was turned ¼ to ½ turn clockwise with a waiting period of 15-30

39

seconds between turns to ensure small, incremental, and carefully controlled turns for final seating. The implant was delivered until the collared portion was at the level of the marginal gingiva and the O-ball prosthetic head was coronal to the marginal gingiva. The four MDI were placed as parallel as possible with the restorative platforms of approximately equal heights.

When a force of more than 45 N/cm$^2$ was encountered, the implant was turned ½ turn counter-clockwise, followed by ¼ to ½ turn clockwise and apical pressure with a waiting period of 30 seconds and repeated as necessary. When the counter-clockwise, followed by ¼ to ½ turn clockwise technique failed to deliver the implant to the ideal depth, the implant was removed, and the 1.1 mm pilot drill was used to increase the osteotomy depth by the length discrepancy. If the implant was delivered to the ideal apical position without significant stability, the implant was removed. The implants' osteotomy was either moved mesially or distally. The second osteotomy was prepared at approximately half the original depth or only with crestal penetration depending on the amount of initial resistance and bone quality.

All MDI implants were placed with significant primary stability. After fixture placement, the intaglio surface of the denture was relieved, with a minimum of 2 mm of clearance and relined with silicone soft-reline material per manufactures instructions. Occlusion and denture base was checked and adjusted if necessary with articulating paper and pressure indicating paste (PIP). The patient was given detailed post-operative

directions, denture care, and usage instructions. A post-operative panoramic radiograph was taken at the end of the surgical treatment.

**Postoperative Care**

All subjects received postoperative analgesia (Vicodin 5 mg/500 mg, q4-6h for 1 week and Ibuprofen 600mg tid for 1 week as needed for pain) and antibiotics (Amoxicillin 500 mg TID for 1 week). The subjects were instructed to gently rinse with Peridex (Chlorhexidine Gluconate 0.12%) BID for 3 weeks. In the event of an allergy to any of the medications, Hydrocodone/ASA was substituted for Vicodin, and Clindamycin 300 mg TID for one week was substituted for Amoxicillin. In the event of previous drug abuse or narcotic dependency, postoperative analgesia Ibuprofen 600mg, was recommended three times a day for 1 week, as needed for pain and substituted for Vicodin. All patients were advised to use Ibuprofen as initial analgesia for pain and Vicodin only when necessary. Sutures were removed 1-3 weeks after the surgery depending on wound healing. Occlusion and denture base was checked and adjusted if necessary with articulating paper and PIP. Patients were instructed to swab implants with Peridex rinse or start gently brushing implants at 1-3 weeks after surgery depending on wound healing. Patients were instructed to avoid chewing hard foods, biting into food without wearing their dentures and functioning on their implants during healing.

**Prosthodontic Procedures**

**Introduction**

The accurate placement of the implant attachment into an overdenture is important for function, comfort, attachment maintenance, and tissue maintenance. If the overdenture does not attach accurately to the implants, excessive and uneven forces can be placed on the denture and could lead to tissue and bone trauma, early wear of the attachments, and possible loss of implant integration. Implant attachments can be incorporated into the denture by an indirect laboratory procedure or directly at chairside. The direct denture retrofit conversion of a denture to an overdenture has advantage over the lab process because the chairside procedure requires minimal chair time, does not require lab fees, and can be completed at the time of prosthesis or implant insertion. It is critical that the denture is positioned and stabilized properly while the keyway component of the attachment is bonded to the denture with an auto-polymerizing acrylic resin [126]. **(Figures 1-24)**

**Prosthodontic Protocol**

The prosthodontic treatment was performed by four periodontal residents (CS, PW, NS and CD) under the supervision of an experienced implant prosthodontist (PK). The prosthodontic protocol for attachment placement and overdenture modification was performed according to previous research [126].

**MDI retrofit**

Since the MDI is a one piece implant with an O-ball attachment, the intaglio surface of the patient's denture was relieved by excavating a hole that would allow the denture to be fully seated with at least 2 mm of clearance between the denture and

implant and without acrylic impinging on the fixture head. After the denture was confirmed to be seated properly by using pressure indicting paste (PIP) and articulating paper, a soft reliner was inserted into the relieved denture used per manufactures instructions.

After the four months of healing, the soft reline material was removed. The denture was tested again to confirm seating during maximum intercuspation. A 9 mm by 9 mm piece of rubber dam was placed over the cervical half of the abutment while allowing the O-Ball half of the abutment to protrude uncovered. The shim was an important step to prevent auto-polymerizing acrylic resin from curing to the implant fixture. The keeper caps (*i.e.,* O-ring attachment housings) with the rubber elastomer (*i.e.,* O-rings) were placed over the O-Ball until they were fully seated and could easily rotate. The denture was relieved further to allow for a passive fit over the implant housings, and a vent hole were placed over each housing to allow for excess acrylic material to escape upon denture engagement. The denture was then placed over the implant fixtures with the housings and rubber dam in place to verify that clearance was completely passive by checking with PIP, articulating paper, bite registration material and visually checking clearance through the vent holes. The denture was then washed and dried, and petroleum jelly was used to cover portions of the denture that did not require acrylic. Next, pink auto-polymerizing acrylic resin was placed into the denture holes. The denture was stabilized, and the patient was gently guided into centric occlusion with light contact. The auto-polymerizing acrylic resin was allowed to fully cure for at least seven minutes while the patient remained in centric occlusion. The

denture was then removed and any flash trimmed and voids filled with additional acrylic. The denture was smoothed and polished to a higher luster. The blockout shims were removed. The final step of the retrofit was to check the denture with PIP and articulating paper. Removal and replacement of denture was demonstrated and reviewed with the patients until clear. The patient also received oral hygiene and denture cleaning instructions.

**SDI retrofit**

Since the SDI is a two-piece implant with a cover screw placed at the time of surgery, the intaglio surface of the patient's denture was relieved and relined with silicone reline material in the area of the implant fixtures. After the soft reline, the denture was confirmed to be seated properly by using PIP and articulating paper. The patient was advised to avoid wearing the lower denture for 1 week and avoid chewing hard with the lower denture during the healing phase.

After three months, the cover screws were removed, and the locator abutments of appropriate height were torqued to 25 N-cm. The denture was relieved and soft-reline material was placed to avoid loading the locator abutments. After the four month healing period, the soft reline material was removed, and the denture was tested again to confirm seating during maximum intercuspation. A 9 mm by 9 mm rubber dam piece was placed over the cervical half of the abutment while allowing the locator portion to protrude uncovered. The rubber dam is an important step to prevent auto-polymerizing acrylic resin from curing to the implant fixture. The locator caps (*i.e.,* locator attachment

housings) with the black elastomers were placed over the locator until they were fully seated and could easily rotate. The denture was relieved further to allow for a passive fit over the implant housings, and a vent hole were placed over each housing to allow for excess acrylic material to escape upon denture engagement. The denture was then placed over the implant fixtures with the implant housings and rubber dam in place. The clearance was at least 2 mm between the housing and denture and completely passive by checking with PIP, articulating paper, bite registration material and visually checking clearance through the vent holes. The denture was then washed and dried, and petroleum jelly was used to cover portions of the denture that did not require acrylic. Next, acrylic glue was placed then pink auto-polymerizing acrylic resin was placed into the denture holes and then placed over the locator attachments. The denture was stabilized and the patient was gently guided into centric occlusion with light contact. The auto-polymerizing acrylic resin was allowed to fully cure for at least 7 minutes while the patient remained in centric occlusion. The rubber dam pieces were removed. The denture was removed and any flash trimmed and voids filled with additional acrylic. The denture was smoothed and polished to a higher luster. The black elastomers were removed and final elastomers were inserted according to the patient's desire of retention and finger strength. The black elastomers were left in the housings for one patient with minimal manual dexterity and satisfactory denture retention. The final step of the retrofit was to check the denture with PIP and articulating paper. Removal and replacement of denture was demonstrated and reviewed with the patients until clear. The patient also received oral hygiene and denture cleaning instructions.

**Statistical Analysis**

The statistical data were collected for the MDI and SDI groups at pre-implant placement, $3^{rd}$ month, $6^{th}$ month, and $12^{th}$ month post-implant placements. The groups were compared to each other for lower arch at each time points through an unpaired t-test. Each group was evaluated by comparing pre-implant placement to $6^{th}$ month and $12^{th}$ month post-implant placement through an unpaired t-test. Statistical significance was found with a p-value less than 0.05.

**RESULTS:**

*QOL Variables in VAS Scale*

❖ General Satisfaction:

➢ At baseline, the characteristics of the subjects were similar in each group. There was no statistically significant differences (p = 0.6076) in the mean general satisfaction between SDI and MDI groups before implant placement. The mean general satisfaction of SDI group is 43.47 and the mean general satisfaction of MDI group is 37.39 (Table 2).

➢ At 3 months after implant placement, there was no statistically significant differences (p = 0.4585) in the mean general satisfaction between the 2 groups. The mean general satisfaction of SDI group is 81.14 and the mean general satisfaction of MDI group is 71.87 (Table 3).

➢ At 6 months after implant placement, there was no statistically significant differences (p = 0.2214) in the mean general satisfaction between the 2 groups. The mean general satisfaction of SDI group is 70.50 and the mean general satisfaction of MDI group is 84.11 (Table 4).

➢ At 12 months after implant placement, there was no statistically significant differences (p = 0.5026) in the mean general satisfaction between the 2 groups. The mean general satisfaction of SDI group is 84.50 and the mean general satisfaction of MDI group is 74.20 (Table 5).

➢ The mean VAS scores between the pre and 6 month post mini-implant placement in regards to general satisfaction were significantly different (p = 0.0001). The mean VAS scores between the pre and 12 month post implant

placement in regards to general satisfactions were significantly different as well (p = 0.0181).  The data suggests that the subjects were more satisfied after getting the MDIs (Tables 6 & 7).

❖ Overall Function:

➢ At baseline, the characteristics of the subjects were similar in each group. There was no statistically significant differences (p = 0.6036) in the mean overall function between SDI and MDI groups before implant placement.  The mean overall function of SDI group is 39.67 and the mean overall function of MDI group is 34.00 (Table 2).

➢ At 3 months after implant placement, there was no statistically significant differences (p = 0.9674) in the mean overall function between the 2 groups. The mean overall function of SDI group is 72.00 and the mean overall function of MDI group is 71.47 (Table 3).

➢ At 6 months after implant placement, there was no statistically significant differences (p = 0.3909) in the mean overall function between the 2 groups. The mean overall function of SDI group is 69.25 and the mean overall function of MDI group is 81.22 (Table 4).

➢ At 12 months after implant placement, there was no statistically significant differences (p = 0.4922) in the mean overall function between the 2 groups. The mean overall function of SDI group is 83.75 and the mean overall function of MDI group is 76.50 (Table 5).

➢ The mean VAS scores between the pre and 6 month post mini-implant placement in regards to overall function were significantly different (p =

0.0004).  The mean VAS scores between the pre and 12 month post implant placement in regards to overall function were significantly different as well (p = 0.0150).  The data suggests that the subjects were more satisfied after getting the MDIs (Tables 6 & 7).

- ❖ Overall Chewing Ability:
  - ➢ At baseline, the characteristics of the subjects were similar in each group. There was no statistically significant differences (p = 0.4752) in the mean overall chewing ability between SDI and MDI groups before implant placement.  The mean overall chewing ability of SDI group is 38.50 and the mean overall chewing ability of MDI group is 31.28 (2).
  - ➢ At 3 months after implant placement, there was no statistically significant differences (p = 0.7825) in the mean overall chewing ability between the 2 groups.  The mean speech ability of SDI group is 68.43 and the mean speech ability of MDI group is 64.27 (Table 3).
  - ➢ At 6 months after implant placement, there was no statistically significant differences (p = 0.2387) in the mean overall chewing ability between the 2 groups.  The mean overall chewing ability of SDI group is 66.25 and the mean overall chewing ability of MDI group is 83.22 (Table 4).
  - ➢ At 12 months after implant placement, there was no statistically significant differences (p = 0.5769) in the mean overall chewing ability between the 2 groups.  The mean overall chewing ability of SDI group is 81.00 and the mean overall chewing ability of MDI group is 71.50 (Table 5).

- The mean VAS scores between the pre and 6 month post mini-implant placement in regards to overall chewing ability were significantly different (p = 0.0001). The mean VAS scores between the pre and 12 month post implant placement in regards to overall chewing ability were significantly different as well (p = 0.0142). The data suggests that the subjects were more satisfied with their overall chewing ability after getting the MDIs (Tables 6 & 7).

- ❖ Speech Ability:
    - At baseline, the characteristics of the subjects were similar in each group. There was no statistically significant differences (p = 0.7275) in the mean speech ability between SDI and MDI groups before implant placement. The mean speech ability of SDI group is 56.29 and the mean speech ability of MDI group is 52.44 (Table 2).

    - At 3 months after implant placement, there was no statistically significant differences (p = 0.4694) in the mean speech ability between the 2 groups. The mean speech ability of SDI group is 83.33 and the mean speech ability of MDI group is 75.67 (Table 3).

    - At 6 months after implant placement, there was no statistically significant differences (p = 0.6061) in the mean speech ability between the 2 groups. The mean speech ability of SDI group is 87.00 and the mean speech ability of MDI group is 80.89 (Table 4).

    - At 12 months after implant placement, there was no statistically significant differences (p = 0.1836) in the mean speech ability between the 2 groups. The

mean speech ability of SDI group is 91.75 and the mean speech ability of MDI group is 68.60 (Table 5).

➢ The mean VAS scores between the pre and 6 month post mini-implant placement in regards to speech ability were significantly different (p = 0.0143). The mean VAS scores between the pre and 12 month post implant placement in regards to speech ability were not significantly different (p = 0.2782). The data suggests that the subjects were more satisfied with their speech ability within the first 6 months after getting the MDIs but at 12 months, they are as satisfied with their speech ability as before getting the MDIs (Tables 6 & 7).

❖ Stability:

➢ At baseline, the characteristics of the subjects were similar in each group. There was no statistically significant differences (p = 0.3910) in the mean stability between SDI and MDI groups before implant placement. The mean stability of SDI group is 41.21 and the mean stability of MDI group is 31.67 (Table 2).

➢ At 3 months after implant placement, there was no statistically significant differences (p = 0.7137) in the mean stability between the 2 groups. The mean stability of SDI group is 68.29 and the mean stability of MDI group is 62.93 (Table 3).

➢ At 6 months after implant placement, there was no statistically significant differences (p = 0.4824) in the mean stability between the 2 groups. The

mean stability of SDI group is 66.00 and the mean stability of MDI group is 77.56 (Table 4).

➢ At 12 months after implant placement, there was no statistically significant differences (p = 0.8222) in the mean stability between the 2 groups. The mean stability of SDI group is 71.75 and the mean stability of MDI group is 67.20 (Table 5).

➢ The mean VAS scores between the pre and 6 month post mini-implant placement in regards to stability were significantly different (p = 0.0002). The mean VAS scores between the pre and 12 month post implant placement in regards to stability were significantly different as well (p = 0.0157). The data suggests that the subjects were more satisfied with their denture stability after getting the MDIs (Tables 6 & 7).

❖ Retention:

➢ At baseline, the characteristics of the subjects were similar in each group. There was no statistically significant differences (p = 0.4202) in the mean retention between SDI and MDI groups before implant placement. The mean retention of SDI group is 36.71 and the mean retention of MDI group is 28.47 (Table 2).

➢ At 3 months after implant placement, there was no statistically significant differences (p = 0.5629) in the mean retention between the 2 groups. The mean retention of SDI group is 74.43 and the mean retention of MDI group is 66.20 (Table 3).

➢ At 6 months after implant placement, there was no statistically significant differences (p = 0.4566) in the mean retention between the 2 groups. The mean retention of SDI group is 64.00 and the mean retention of MDI group is 77.00 (Table 4).

➢ At 12 months after implant placement, there was no statistically significant differences (p = 0.1041) in the mean retention between the 2 groups. The mean retention of SDI group is 82.50 and the mean retention of MDI group is 77.60 (Table 5).

➢ The mean VAS scores between the pre and 6 month post mini-implant placement in regards to retention were significantly different (p = 0.0001). The mean VAS scores between the pre and 12 month post implant placement in regards to retention were significantly different as well (p = 0.0001). The data suggests that the subjects were more satisfied with their denture retention after getting the MDIs (Tables 6 & 7).

❖ Appearance:

➢ At baseline, the characteristics of the subjects were similar in each group. There was no statistically significant differences (p = 0.6583) in the mean appearance between SDI and MDI groups before implant placement. The mean appearance of SDI group is 76.20 and the mean appearance of MDI group is 71.94 (Table 2).

➢ At 3 months after implant placement, there was no statistically significant differences (p = 0.4507) in the mean appearance between the 2 groups. The

mean appearance of SDI group is 89.00 and the mean appearance of MDI group is 81.20 (Table 3).

➢ At 6 months after implant placement, there was no statistically significant differences (p = 0.3153) in the mean appearance between the 2 groups. The mean appearance of SDI group is 68.25 and the mean appearance of MDI group is 84.00 (Table 4).

➢ At 12 months after implant placement, there was no statistically significant differences (p = 0.2807) in the mean appearance between the 2 groups. The mean appearance of SDI group is 93.25 and the mean appearance of MDI group is 72.20 (Table 5).

➢ The mean VAS scores between the pre and 6 month post mini-implant placement in regards to appearance were not significantly different (p = 0.2887). The mean VAS scores between the pre and 12 month post implant placement in regards to appearance were not significantly different as well (p = 0.9875). The data suggests that the subjects were as satisfied with their denture appearance after getting the MDIs (Tables 6 & 7).

❖ Fit:

➢ At baseline, the characteristics of the subjects were similar in each group. There was no statistically significant differences (p = 0.4743) in the mean fit between SDI and MDI groups before implant placement. The mean fit of SDI group is 51.00 and the mean fit of MDI group is 43.11 (Table 2).

➢ At 3 months after implant placement, there was no statistically significant differences (p = 0.5099) in the mean fit between the 2 groups. The mean fit of SDI group is 81.43 and the mean fit of MDI group is 73.00 (Table 3).

➢ At 6 months after implant placement, there was no statistically significant differences (p = 0.1501) in the mean fit between the 2 groups. The mean fit of SDI group is 64.25 and the mean fit of MDI group is 84.22 (Table 4).

➢ At 12 months after implant placement, there was no statistically significant differences (p = 0.3373) in the mean fit between the 2 groups. The mean fit of SDI group is 93.67 and the mean fit of MDI group is 77.60 (Table 5).

➢ The mean VAS scores between the pre and 6 month post mini-implant placement in regards to fit were significantly different (p = 0.0008). The mean VAS scores between the pre and 12 month post implant placement in regards to fit were significantly different as well (p = 0.0301). The data suggests that the subjects were more satisfied with their denture fit after getting the MDIs (Tables 6 & 7).

❖ Chewing Hard Food:

➢ At baseline, the characteristics of the subjects were similar in each group. There was no statistically significant differences (p = 0.2855) in the mean regarding to ability to chewing hard food between SDI and MDI groups before implant placement. The mean regarding to ability to chewing hard food of SDI group is 32.93 and the mean regarding to ability to chewing hard food of MDI group is 22.65 (Table 2).

➢ At 3 months after implant placement, there was no statistically significant differences (p = 0.2583) in the mean regarding to ability to chewing hard food between the 2 groups.  The mean regarding to ability to chewing hard food of SDI group is 81.67 and the mean regarding to ability to chewing hard food of MDI group is 64.71 (Table 3).

➢ At 6 months after implant placement, there was no statistically significant differences (p = 0.3834) in the mean regarding to ability to chewing hard food between the 2 groups.  The mean regarding to ability to chewing hard food of SDI group is 69.25 and the mean regarding to ability to chewing hard food of MDI group is 81.22 (Table 4).

➢ At 12 months after implant placement, there was no statistically significant differences (p = 0.6535) in the mean regarding to ability to chewing hard food between the 2 groups.  The mean regarding to ability to chewing hard food of SDI group is 78.33 and the mean regarding to ability to chewing hard food of MDI group is 67.75 (Table 5).

➢ The mean VAS scores between the pre and 6 month post mini-implant placement in regards to ability to chewing hard food were significantly different (p = 0.0001).  The mean VAS scores between the pre and 12 month post implant placement in regards to ability to chewing hard food were significantly different as well (p = 0.0058).  The data suggests that the subjects were more satisfied with their ability to chewing hard food after getting the MDIs (Tables 6 & 7).

❖ Chewing Tough Food:

➢ At baseline, the characteristics of the subjects were similar in each group. There was no statistically significant differences (p = 0.5201) in the mean regarding to ability to chewing tough food between SDI and MDI groups before implant placement. The mean regarding to ability to chewing tough food of SDI group is 34.07 and the mean regarding to ability to chewing tough food of MDI group is 27.67 (Table 2).

➢ At 3 months after implant placement, there was no statistically significant differences (p = 0.3406) in the mean regarding to ability to chewing tough food between the 2 groups. The mean regarding to ability to chewing tough food of SDI group is 77.29 and the mean regarding to ability to chewing tough food of MDI group is 63.33 (Table 3).

➢ At 6 months after implant placement, there was no statistically significant differences (p = 0.1716) in the mean regarding to ability to chewing tough food between the 2 groups. The mean regarding to ability to chewing tough food of SDI group is 66.25 and the mean regarding to chewing tough food of MDI group is 82.33 (Table 4).

➢ At 12 months after implant placement, there was no statistically significant differences (p = 0.2324) in the mean regarding to ability to chewing tough food between the 2 groups. The mean regarding to ability to chewing tough food of SDI group is 96.50 and the mean regarding to ability to chewing tough food of MDI group is 77.50 (Table 5).

➢ The mean VAS scores between the pre and 6 month post mini-implant placement in regards to ability to chewing tough food were significantly

different (p = 0.0001). The mean VAS scores between the pre and 12 month post implant placement in regards to ability to chewing tough food were significantly different as well (p = 0.0021). The data suggests that the subjects were more satisfied with their ability to chew tough food after getting the MDIs (Tables 6 & 7).

❖ Chewing Crisp Food:

➢ At baseline, the characteristics of the subjects were similar in each group. There was no statistically significant differences (p = 0.5675) in the mean regarding to ability to chewing crisp food between SDI and MDI groups before implant placement. The mean regarding to ability to chewing crisp food of SDI group is 41.87 and the mean regarding to ability to chewing crisp food of MDI group is 35.44 (Table 2).

➢ At 3 months after implant placement, there was no statistically significant differences (p = 0.2028) in the mean regarding to ability to chewing crisp food between the 2 groups. The mean regarding to ability to chewing crisp food of SDI group is 83.14 and the mean regarding to ability to chewing crisp food of MDI group is 65.27 (Table 3).

➢ At 6 months after implant placement, there was no statistically significant differences (p = 0.4693) in the mean regarding to ability to chewing crisp food between the 2 groups. The mean regarding to ability to chewing crisp food of SDI group is 75.33 and the mean regarding to ability to chewing crisp food of MDI group is 83.44 (Table 4).

➢ At 12 months after implant placement, there was no statistically significant differences (p = 0.2062) in the mean regarding to ability to chewing crisp food between the 2 groups.  The mean regarding to ability to chewing crisp food of SDI group is 95.67 and the mean regarding to ability to chewing crisp food of MDI group is 78.50 (Table 5).

➢ The mean VAS scores between the pre and 6 month post mini-implant placement in regards to ability to chewing crisp food were significantly different (p = 0.0003).  The mean VAS scores between the pre and 12 month post implant placement in regards to ability to chewing crisp food were significantly different as well (p = 0.0177).  The data suggests that the subjects were more satisfied with their ability to chew crisp food after getting the MDIs (Tables 6 & 7).

❖ Chewing Whole Fruit:

➢ At baseline, the characteristics of the subjects were similar in each group. There was no statistically significant differences (p = 0.4929) in the mean regarding to ability to chewing whole fruit between SDI and MDI groups before implant placement.  The mean regarding to ability to chewing whole fruit of SDI group is 29.50 and the mean regarding to ability to chewing whole fruit of MDI group is 22.82 (Table 2).

➢ At 3 months after implant placement, there was no statistically significant differences (p = 0.0934) in the mean regarding to ability to chewing whole fruit between the 2 groups.  The mean regarding to ability to chewing whole

fruit of SDI group is 78.29 and the mean regarding to ability to chewing whole fruit of MDI group is 56.14 (Table 3).

➢ At 6 months after implant placement, there was no statistically significant differences (p = 0.9137) in the mean regarding to ability to chewing whole fruit between the 2 groups. The mean regarding to ability to chewing whole fruit of SDI group is 70.75 and the mean regarding to ability to chewing whole fruit of MDI group is 72.11 (Table 4).

➢ At 12 months after implant placement, there was no statistically significant differences (p = 0.7379) in the mean regarding to ability to chewing whole fruit between the 2 groups. The mean regarding to ability to chewing whole fruit of SDI group is 70.00 and the mean regarding to ability to chewing whole fruit of MDI group is 60.75 (Table 5).

➢ The mean VAS scores between the pre and 6 month post mini-implant placement in regards to ability to chewing whole fruit were significantly different (p = 0.0001). The mean VAS scores between the pre and 12 month post implant placement in regards to ability to chewing whole fruit were significantly different as well (p = 0.0218). The data suggests that the subjects were more satisfied with their ability to chew whole fruit after getting the MDIs (Tables 6 & 7).

❖ Chewing Fruits with peels:

➢ At baseline, the characteristics of the subjects were similar in each group. There was no statistically significant differences (p = 0.8170) in the mean regarding to ability to chewing fruits with peels between SDI and MDI groups

before implant placement. The mean regarding to ability to chewing fruits with peels of SDI group is 42.43 and the mean regarding to ability to chewing fruits with peels of MDI group is 39.88 (Table 2).

➤ At 3 months after implant placement, there was no statistically significant differences (p = 0.4489) in the mean regarding to ability to chewing fruits with peels between the 2 groups. The mean regarding to ability to chewing fruits with peels of SDI group is 75.33 and the mean regarding to ability to chewing fruits with peels of MDI group is 62.96 (Table 3).

➤ At 6 months after implant placement, there was no statistically significant differences (p = 0.1158) in the mean regarding to ability to chewing fruits with peels between the 2 groups. The mean regarding to ability to chewing fruits with peels of SDI group is 55.25 and the mean regarding to ability to chewing fruits with peels of MDI group is 79.56 (Table 4).

➤ At 12 months after implant placement, there was no statistically significant differences (p = 0.7577) in the mean regarding to ability to chewing fruits with peels between the 2 groups. The mean regarding to ability to chewing fruits with peels of SDI group is 78.25 and the mean regarding to ability to chewing fruits with peels of MDI group is 71.75 (Table 5).

➤ The mean VAS scores between the pre and 6 month post mini-implant placement in regards to ability to chewing fruits with peels were significantly different (p = 0.0027). The mean VAS scores between the pre and 12 month post implant placement in regards to ability to chewing fruits with peels were not significantly different (p = 0.0943). The data suggests that the subjects

61

were more satisfied with their ability to chew fruits with peels at the 6 month period and they are as satisfied with their ability to chew fruits with peels at the 12 month period after getting the MDIs (Tables 6 & 7).

❖ Chewing Fruits without peels:

➢ At baseline, the characteristics of the subjects were similar in each group. There was no statistically significant differences (p = 0.2736) in the mean regarding to ability to chewing fruits without peels between SDI and MDI groups before implant placement. The mean regarding to ability to chewing fruits without peels of SDI group is 53.13 and the mean regarding to ability to chewing fruits without peels of MDI group is 41.67 (Table 2).

➢ At 3 months after implant placement, there was no statistically significant differences (p = 0.6922) in the mean regarding to ability to chewing fruits without peels between the 2 groups. The mean regarding to ability to chewing fruits without peels of SDI group is 77.14 and the mean regarding to ability to chewing fruits without peels of MDI group is 71.93 (Table 3).

➢ At 6 months after implant placement, there was no statistically significant differences (p = 0.0909) in the mean regarding to ability to chewing fruits without peels between the 2 groups. The mean regarding to ability to chewing fruits without peels of SDI group is 61.50 and the mean regarding to ability to chewing fruits without peels of MDI group is 84.33 (Table 4).

➢ At 12 months after implant placement, there was no statistically significant differences (p = 0.2242) in the mean regarding to ability to chewing fruits without peels between the 2 groups. The mean regarding to ability to chewing

fruits without peels of SDI group is 92.75 and the mean regarding to ability to chewing fruits without peels of MDI group is 71.75 (Table 5).

➢ The mean VAS scores between the pre and 6 month post mini-implant placement in regards to ability to chewing fruits without peels were significantly different (p = 0.0005). The mean VAS scores between the pre and 12 month post implant placement in regards to ability to chewing fruits without peels were not significantly different (p = 0.0791). The data suggests that the subjects were more satisfied with their ability to chew fruits without peels at the 6 month period and they are as satisfied with their ability to chew fruits without peels at the 12 month period after getting the MDIs (Tables 6 & 7).

❖ Chewing Soft, Dry Food:

➢ At baseline, the characteristics of the subjects were similar in each group. There was no statistically significant differences (p = 0.2804) in the mean regarding to ability to chewing soft, dry food between SDI and MDI groups before implant placement. The mean regarding to ability to chewing soft, dry food of SDI group is 56.20 and the mean regarding to ability to chewing soft, dry food of MDI group is 44.33 (Table 2).

➢ At 3 months after implant placement, there was no statistically significant differences (p = 0.2087) in the mean regarding to ability to chewing soft, dry food between the 2 groups. The mean regarding to ability to chewing soft, dry food of SDI group is 83.86 and the mean regarding to ability to chewing soft, dry food of MDI group is 68.53 (Table 3).

➢ At 6 months after implant placement, there was no statistically significant differences (p = 0.2186) in the mean regarding to ability to chewing soft, dry food between the 2 groups. The mean regarding to ability to chewing soft, dry food of SDI group is 70.75 and the mean regarding to ability to chewing soft, dry food of MDI group is 84.78 (Table 4).

➢ At 12 months after implant placement, there was no statistically significant differences (p = 0.3494) in the mean regarding to ability to chewing soft, dry food between the 2 groups. The mean regarding to ability to chewing soft, dry food of SDI group is 88.25 and the mean regarding to ability to chewing soft, dry food of MDI group is 71.75 (Table 5).

➢ The mean VAS scores between the pre and 6 month post mini-implant placement in regards to ability to chewing soft, dry food were significantly different (p = 0.0011). The mean VAS scores between the pre and 12 month post implant placement in regards to ability to chewing soft, dry food were not significantly different (p = 0.1177). The data suggests that the subjects were more satisfied with their ability to chew soft, dry food at the 6 month period and they are as satisfied with their ability to chew soft, dry food at the 12 month period after getting the MDIs (Tables 6 & 7).

❖ Chewing Soft, Wet Food:

➢ At baseline, the characteristics of the subjects were similar in each group. There was no statistically significant differences (p = 0.3631) in the mean regarding to ability to chewing soft, dry food between SDI and MDI groups before implant placement. The mean regarding to ability to chewing soft, dry

food of SDI group is 67.40 and the mean regarding to ability to chewing soft, dry food of MDI group is 58.56 (Table 2).

➤ At 3 months after implant placement, there was no statistically significant differences (p = 0.1251) in the mean regarding to ability to chewing soft, dry food between the 2 groups. The mean regarding to ability to chewing soft, dry food of SDI group is 89.57 and the mean regarding to ability to chewing soft, dry food of MDI group is 71.80 (Table 3).

➤ At 6 months after implant placement, there was no statistically significant differences (p = 0.9551) in the mean regarding to ability to chewing soft, dry food between the 2 groups. The mean regarding to ability to chewing soft, dry food of SDI group is 85.50 and the mean regarding to chewing soft, dry food of MDI group is 86.00 (Table 4).

➤ At 12 months after implant placement, there was no statistically significant differences (p = 0.2593) in the mean regarding to ability to chewing soft, dry food between the 2 groups. The mean regarding to ability to chewing soft, dry food of SDI group is 94.25 and the mean regarding to ability to chewing soft, dry food of MDI group is 82.25 (Table 5).

➤ The mean VAS scores between the pre and 6 month post mini-implant placement in regards to ability to chewing soft, dry food were significantly different (p = 0.0019). The mean VAS scores between the pre and 12 month post implant placement in regards to ability to chewing soft, dry food were not significantly different (p = 0.1589). The data suggests that the subjects were more satisfied with their ability to chew soft, wet food at the 6 month period

and they are as satisfied with their ability to chew soft, wet food at the 12 month period after getting the MDIs (Tables 6 & 7).

- ❖ Chewing Flat Vegetable:
  - ➢ At baseline, the characteristics of the subjects were similar in each group. There was no statistically significant differences (p = 0.4931) in the mean regarding ability to chew flat vegetable between SDI and MDI groups before implant placement. The mean regarding ability to chew flat vegetable of SDI group is 49.27 and the mean regarding ability to chew flat vegetable of MDI group is 41.06 (Table 2).

  - ➢ At 3 months after implant placement, there was no statistically significant differences (p = 0.1269) in the mean regarding ability to chew flat vegetable between the 2 groups. The mean regarding ability to chew flat vegetable of SDI group is 85.43 and the mean regarding ability to chew flat vegetable of MDI group is 65.36 (Table 3).

  - ➢ At 6 months after implant placement, there was no statistically significant differences (p = 0.5749) in the mean regarding ability to chew flat vegetable between the 2 groups. The mean regarding ability to chew flat vegetable of SDI group is 75.50 and the mean regarding ability to chew flat vegetable of MDI group is 82.56 (Table 4).

  - ➢ At 12 months after implant placement, there was no statistically significant differences (p = 0.9288) in the mean regarding ability to chew flat vegetable between the 2 groups. The mean regarding ability to chew flat vegetable of

SDI group is 70.50 and the mean regarding ability to chew flat vegetable of MDI group is 72.00 (Table 5).

➢ The mean VAS scores between the pre and 6 month post mini-implant placement in regards to ability to chew flat vegetable were significantly different (p = 0.0019).  The mean VAS scores between the pre and 12 month post implant placement in regards to ability to chew flat vegetable were significantly different as well (p = 0.0791).   The data suggests that the subjects were more satisfied with their ability to chew flat vegetable at the 6 month period and they are as satisfied with their ability to chew flat vegetable at the 12 month period after getting the MDIs (Tables 6 & 7).

**DISCUSSION**

MDIs have recently seen a significant increase in interest as a result of the considerable amount of literature reporting high success rates for orthodontic anchorage, transitional fixation, narrow interdental spaces, knife edge ridges, and immediately loaded implant-supported overdentures. With the success rates of 97.4% reported by Griffitts, these are certainly proving to be much more than temporary implants [29].

To have statistical power of 0.8 for a long-term study, 30 patients are needed in each group. In this current study, there are less than 30 patients in each group, therefore, it has a lower statistical power required to obtain power of 0.8. The data presented is still preliminary, and the sample size will continue to increase in size as the study continues. This is the first study attempting to compare directly the efficacy of mini-dental implants to standard-dental implants for mandibular tissue-support implant-retained overdentures in a prospective randomized clinical study. This data confirms the data presented from previous studies regarding the need for anchorage in the lower mandible to support/retain the lower denture. This suggests that overdentures supported by mini-dental implants or standard-dental implant are superior over conventional removable dentures for the mandible. Furthermore, the results suggest that there is no difference between groups in quality of life before and after implants were placed, except for the appearance of the denture.

The difference in the appearance of the denture between groups may not be clinically important because the baseline appearance of the groups was already significantly different. Since the baseline VAS ratings were different and the post-

implant appearance between the two groups was not statistically different, the difference between the two groups showed a statistical difference. Moreover, when patients are satisfied with the retention of the denture, they probably want a better looking denture to fit with their newly retentive prostheses. In addition to this, these dentures were retrofitted to the implants. In order to create enough space for the housings, a large amount of space is created in the mandibular denture and, thus significantly weakens the denture. This weakening cannot be avoided, yet, the denture can be improved with metal stabilization with metal wire upon repair. Most of these dentures do not have metal framework; but with the retention of the implants, most of these dentures require a little strength from patients to remove the denture. In some occasions, if the dentures are not lifted bilaterally at the same time, the uneven torque applied on the denture may cause denture fatigue. This would lead to different VAS ratings.

Many other studies' findings have provided supports for implant retained mandibular overdentures to increase patients' quality of life [6, 17, 29, 53, 56, 63, 98, 99, 105-108, 112, 119, 121, 127, 128]. Both SDI- and MDI-retained mandibular overdentures significantly improved masticatory function, as pointed out in other studies [13, 51, 53]. There was no significant difference between the SDI and MDI groups. The MDI group tended to have a bigger improvement in chewing hard food. This is due to the fact that most of patients belonging to MDI group had a knife-edge ridge. Patients truly appreciated getting their dentures retrofitted.

In this study, when implants were used to retain a mandibular overdenture, the efficacy and satisfaction of the maxillary denture declined, which is different from some studies [121] but supports other studies [129, 130]. In other studies [29, 53, 105, 119,

120, 131], the VAS ratings of the maxillary dentures were not analyzed, which weakens the overall conclusions and comparisons that can be made of the overall satisfaction of the patient. There are some possible reasons that the maxillary denture satisfaction is decreased. One reason is that when the ill-retained mandibular denture was improved, the patient's attention was switched from the mandibular denture to the maxillary denture. Another reason is that the implant-retained mandibular overdenture is now more retentive, which would increase the amount of bite force mentioned in some studies [86, 131]. It is not a surprise to see when the bite force increases, there would be more force directed to the maxillary denture, and patients may perceive the maxillary denture as inadequate or decline in the retention of the maxillary denture.

There was a wide range and standard deviation between subjects' VAS ratings. This large variation is based on the patient preferences. Patient preferences are a complex phenomena, and the strength of those preferences may be different, even for patients who prefer the same treatment [110-114]. In addition to patient preference phenomena, patients' unrealistic expectations may play a crucial role in perceiving less satisfaction with the prostheses easily. This may have led to disappointment with the treatment outcome of the maxillary prosthesis, which may have led to low treatment satisfaction. For example, if an edentulous patient expects his/her new implant-supported mandibular prostheses to allow them to eat all foods without practice or limitations, this patient has unrealistic expectations. However, if the patient has a positive expectation of treatment, they tend to ignore adverse symptoms and focus on apparent improvements following therapy.

There are several weaknesses to the current study. Firstly, the sample size did not reach its statistical power. Since there was a small sample size, the statistical power and analysis was weak and needs to be interpreted with caution. Secondly, the study population consisted of only male patients, which weakened any correlation to women. Thirdly, the follow-up is not completed. Even though there was no differences between the groups in most variables, there might be more differences as time continues, such as implant failure, peri-implant parameters, amount of retention, number and frequency of new attachments needed, and the number of denture repairs. It was noticed that as the study progressed, the MDI group with ball attachments needed less adjustment and replacement of the O-rings than the SDI group. After 6 months, the SDI group needed more replacement of their retention males, which is equivalent to the O-ring part in the ball attachment device. The ball-attachment apparatus seemed to have more flexibility and corrected for a discrepancy in angulation of the implants. Therefore, there was little wear in the O-ring over time. Furthermore, the retention males for the SDI had more precise fit and were made of plastic, unlike rubber material in the O-rings. This may cause patients in the SDI group to return more often to change their retention males. This, in turn, may not make some patients satisfied and could affect the VAS.

As mentioned in the previous paragraph, the best analysis would be comparing the same style of attachments. Since the MDI is only available as a ball attachment, the SDI should have been a ball attachment. The internal connection was the implant design of choice, but the ball attachment for the *3i* Biomet system is only available for the external connection. In addition, the locator was chosen for the SDI group because of the larger amount of divergence between implants that is tolerated, amount and variable

retention strength, and the small size, since we needed to work within the confines of the existing denture base.

To address the issue with denture repair or relining, a prosthodontist or prosthodontic resident should have done the prosthodontic work rather than the periodontal residents. The surgeons worked closely with the prosthodontist. However, some might argue that the outcome of the denture modification would have been better if a restorative dentist was more closely involved especially with that many denture adjustments, maintenance, and abutment maintenance overtime.

Often the implant housings protrude from the confines of the denture and are contained with additional acrylic. The dentures are, therefore, more bulky on the occluso-lingual aspect in the anterior. Patients with a smaller denture and/or smaller oral cavity sometimes have difficulty tolerating the excessive bulk.

Some patients expect indefinite retention with overdentures. This is an unrealistic expectation since implant overdentures increase retention but do not absolutely prevent denture dislodgement. Denture rocking and food entrapment under the denture is unavoidable with the implant overdentures. This may lead to disappointment, and thus, affect the QOL results. In addition, we had difficulty bringing patients back on regular recall basis since most patients live far away and depend on VA buses to take them to SFVA. When they come in, they either have some problems with the denture or a complaint; this would negatively affect the VAS in our QOL survey.

Lastly, all patients who came to our study were screened by dentists mostly in the VA system. When the dentists at these sites cannot place implants on these patients due to the narrow ridge, they would refer these patients to us. Selection bias already took

place before the patient even entered our study.  We would like to randomize all patients but the randomization process did not succeed.

Further continuation of this study includes admitting more subjects to increase the statistical power, at least 40-50 patients per group to anticipate some patients dropping out due to the long term study.  The follow-up should be continued to achieve more long-term results comparing MDIs to SDIs in tissue-supported implant-retained overdentures.

**Conclusions:**

This clinical trial evaluated the satisfaction and contribution to quality of life, using VAS ratings, in patients who had implant-retained tissue-supported mandibular overdentures using either standard dental implants or mini-dental implants.  The null hypothesis has been confirmed within the limitations of the study that there is no difference in long-term quality of life between the standard dental implants and mini-dental implants placed in the interforaminal region of the anterior mandible.  There was low satisfaction, in general, at baseline with the mandibular denture.  However, after implants were placed, regardless of the group, the subjects' overall satisfaction improved significantly.

**REFERENCES:**

1. World Health Organization., *International classification of functioning, disability and health : ICF.* 2001, Geneva: World Health Organization. iii, 299 p.
2. GIFT, H.R., M., *Oral health and the quality of life.* Clinical Geriatric Medicine, 1992. **27**: p. 120-132.
3. Marcus, P.A., et al., *Complete edentulism and denture use for elders in New England.* J Prosthet Dent, 1996. **76**(3): p. 260-6.
4. Zarb, G.A. and A. Schmitt, *Implant prosthodontic treatment options for the edentulous patient.* J Oral Rehabil, 1995. **22**(8): p. 661-71.
5. Jemt, T., et al., *A 5-year prospective multicenter follow-up report on overdentures supported by osseointegrated implants.* Int J Oral Maxillofac Implants, 1996. **11**(3): p. 291-8.
6. Boerrigter, E.M., et al., *Patient satisfaction and chewing ability with implant-retained mandibular overdentures: a comparison with new complete dentures with or without preprosthetic surgery.* J Oral Maxillofac Surg, 1995. **53**(10): p. 1167-73.
7. Thomason, J.M., *The McGill Consensus Statement on Overdentures. Mandibular 2-implant overdentures as first choice standard of care for edentulous patients.* Eur J Prosthodont Restor Dent, 2002. **10**(3): p. 95-6.
8. Adell, R., *Clinical results of osseointegrated implants supporting fixed prostheses in edentulous jaws.* J Prosthet Dent, 1983. **50**(2): p. 251-4.
9. Adell, R., et al., *Long-term follow-up study of osseointegrated implants in the treatment of totally edentulous jaws.* Int J Oral Maxillofac Implants, 1990. **5**(4): p. 347-59.
10. Adell, R., et al., *A 15-year study of osseointegrated implants in the treatment of the edentulous jaw.* Int J Oral Surg, 1981. **10**(6): p. 387-416.
11. Albrektsson, T., et al., *Edentulousness--an oral handicap. Patient reactions to treatment with jawbone-anchored prostheses.* J Oral Rehabil, 1987. **14**(6): p. 503-11.
12. Bosker, H. and L. van Dijk, *The transmandibular implant: a 12-year follow-up study.* J Oral Maxillofac Surg, 1989. **47**(5): p. 442-50.
13. Engquist, B., et al., *A retrospective multicenter evaluation of osseointegrated implants supporting overdentures.* Int J Oral Maxillofac Implants, 1988. **3**(2): p. 129-34.
14. Johns, R.B., et al., *A multicenter study of overdentures supported by Branemark implants.* Int J Oral Maxillofac Implants, 1992. **7**(4): p. 513-22.
15. Mericske-Stern, R., *Clinical evaluation of overdenture restorations supported by osseointegrated titanium implants: a retrospective study.* Int J Oral Maxillofac Implants, 1990. **5**(4): p. 375-83.
16. Naert, I., et al., *Overdentures supported by osseointegrated fixtures for the edentulous mandible: a 2.5-year report.* Int J Oral Maxillofac Implants, 1988. **3**(3): p. 191-6.
17. Wismeijer, D., J.I. Vermeeren, and M.A. van Waas, *Patient satisfaction with overdentures supported by one-stage TPS implants.* Int J Oral Maxillofac Implants, 1992. **7**(1): p. 51-5.

18.     Wismeyer, D., M.A. van Waas, and J.I. Vermeeren, *Overdentures supported by ITI implants: a 6.5-year evaluation of patient satisfaction and prosthetic aftercare.* Int J Oral Maxillofac Implants, 1995. **10**(6): p. 744-9.

19.     Zarb, G.A. and A. Schmitt, *The longitudinal clinical effectiveness of osseointegrated dental implants: the Toronto study. Part III: Problems and complications encountered.* J Prosthet Dent, 1990. **64**(2): p. 185-94.

20.     Zarb, G.A. and A. Schmitt, *The longitudinal clinical effectiveness of osseointegrated dental implants: the Toronto Study. Part II: The prosthetic results.* J Prosthet Dent, 1990. **64**(1): p. 53-61.

21.     Zarb, G.A. and A. Schmitt, *The longitudinal clinical effectiveness of osseointegrated dental implants: the Toronto study. Part I: Surgical results.* J Prosthet Dent, 1990. **63**(4): p. 451-7.

22.     Feine, J.S. and G.E. Carlsson, *Implant overdentures : the standard of care for edentulous patients.* 2003, Chicago: Quintessence Pub. Co. ix, 162 p.

23.     Misch, C.E., *Contemporary Implant Dentistry.* 2nd ed. 1999, St. Louis (MO): Mosby.

24.     Vigolo, P., et al., *Clinical evaluation of small-diameter implants in single-tooth and multiple-implant restorations: a 7-year retrospective study.* Int J Oral Maxillofac Implants, 2004. **19**(5): p. 703-9.

25.     Kanie, T., M. Nagata, and S. Ban, *Comparison of the mechanical properties of 2 prosthetic mini-implants.* Implant Dent, 2004. **13**(3): p. 251-6.

26.     Ahn, M.R., et al., *Immediate loading with mini dental implants in the fully edentulous mandible.* Implant Dent, 2004. **13**(4): p. 367-72.

27.     el Attar, M.S., et al., *Study of the effect of using mini-transitional implants as temporary abutments in implant overdenture cases.* Implant Dent, 1999. **8**(2): p. 152-8.

28.     Balkin, B.E., D.E. Steflik, and F. Naval, *Mini-dental implant insertion with the auto-advance technique for ongoing applications.* J Oral Implantol, 2001. **27**(1): p. 32-7.

29.     Griffitts, T.M., C.P. Collins, and P.C. Collins, *Mini dental implants: an adjunct for retention, stability, and comfort for the edentulous patient.* Oral Surg Oral Med Oral Pathol Oral Radiol Endod, 2005. **100**(5): p. e81-4.

30.     Bulard, R.A. and J.B. Vance, *Multi-clinic evaluation using mini-dental implants for long-term denture stabilization: a preliminary biometric evaluation.* Compend Contin Educ Dent, 2005. **26**(12): p. 892-7.

31.     Flanagan, D., *Implant-supported fixed prosthetic treatment using very small-diameter implants: a case report.* J Oral Implantol, 2006. **32**(1): p. 34-7.

32.     Flanagan, D., *Fixed partial dentures and crowns supported by very small diameter dental implants in compromised sites.* Implant Dent, 2008. **17**(2): p. 182-91.

33.     Siddiqui, A.A., M. Sosovicka, and M. Goetz, *Use of mini implants for replacement and immediate loading of 2 single-tooth restorations: a clinical case report.* J Oral Implantol, 2006. **32**(2): p. 82-6.

34.     Guler, N., et al., *Hypohidrotic ectodermal dysplasia with bilateral impacted teeth at the coronoid process: a case rehabilitated with mini dental implants.* Oral Surg Oral Med Oral Pathol Oral Radiol Endod, 2005. **99**(5): p. E34-8.

35. Mazor, Z., et al., *Mini-implants to reconstruct missing teeth in severe ridge deficiency and small interdental space: a 5-year case series.* Implant Dent, 2004. **13**(4): p. 336-41.

36. Glauser, R., et al., *Periimplant soft tissue barrier at experimental one-piece mini-implants with different surface topography in humans: A light-microscopic overview and histometric analysis.* Clin Implant Dent Relat Res, 2005. **7 Suppl 1**: p. S44-51.

37. Sadowsky, S.J., *Mandibular implant-retained overdentures: a literature review.* J Prosthet Dent, 2001. **86**(5): p. 468-73.

38. van Steenberghe, D., et al., *A Prospective evaluation of the fate of 697 consecutive intra-oral fixtures ad modum Branemark in the rehabilitation of edentulism.* J Head Neck Pathol, 1987. **6**: p. 53-58.

39. Mericske-Stern, R., et al., *Peri-implant mucosal aspects of ITI implants supporting overdentures. A five-year longitudinal study.* Clin Oral Implants Res, 1994. **5**(1): p. 9-18.

40. Naert, I., et al., *A 5-year prospective randomized clinical trial on the influence of splinted and unsplinted oral implants retaining a mandibular overdenture: prosthetic aspects and patient satisfaction.* J Oral Rehabil, 1999. **26**(3): p. 195-202.

41. Ueda, T., et al., *Long-term results of mandibular implants supporting an overdenture: implant survival, failures, and crestal bone level changes.* Int J Oral Maxillofac Implants. **26**(2): p. 365-72.

42. Akoglu, B., et al., *Five-year treatment outcomes with three brands of implants supporting mandibular overdentures.* Int J Oral Maxillofac Implants, 2011. **26**(1): p. 188-94.

43. Batenburg, R.H., et al., *Treatment concept for mandibular overdentures supported by endosseous implants: a literature review.* Int J Oral Maxillofac Implants, 1998. **13**(4): p. 539-45.

44. Cune, M.S., C. de Putter, and J. Hoogstraten, *Treatment outcome with implant-retained overdentures: Part I--Clinical findings and predictability of clinical treatment outcome.* J Prosthet Dent, 1994. **72**(2): p. 144-51.

45. Naert, I., et al., *A comparative prospective study of splinted and unsplinted Branemark implants in mandibular overdenture therapy: a preliminary report.* J Prosthet Dent, 1994. **71**(5): p. 486-92.

46. Spiekermann, H., V.K. Jansen, and E.J. Richter, *A 10-year follow-up study of IMZ and TPS implants in the edentulous mandible using bar-retained overdentures.* Int J Oral Maxillofac Implants, 1995. **10**(2): p. 231-43.

47. Mericske-Stern, R.D., T.D. Taylor, and U. Belser, *Management of the edentulous patient.* Clin Oral Implants Res, 2000. **11 Suppl 1**: p. 108-25.

48. Meijer, H.J., et al., *A three-dimensional finite element study on two versus four implants in an edentulous mandible.* Int J Prosthodont, 1994. **7**(3): p. 271-9.

49. Batenburg, R.H., et al., *Mandibular overdentures supported by two or four endosteal implants. A prospective, comparative study.* Int J Oral Maxillofac Surg, 1998. **27**(6): p. 435-9.

50.	Visser, A., et al., *Mandibular overdentures supported by two or four endosseous implants. A 5-year prospective study.* Clin Oral Implants Res, 2005. **16**(1): p. 19-25.

51.	Fontijn-Tekamp, F.A., et al., *Bite forces with mandibular implant-retained overdentures.* J Dent Res, 1998. **77**(10): p. 1832-9.

52.	Klemetti, E., *Is there a certain number of implants needed to retain an overdenture?* J Oral Rehabil, 2008. **35 Suppl 1**: p. 80-4.

53.	van Kampen, F.M., et al., *Masticatory function with implant-supported overdentures.* J Dent Res, 2004. **83**(9): p. 708-11.

54.	Fueki, K., et al., *Effect of implant-supported or retained dentures on masticatory performance: a systematic review.* J Prosthet Dent, 2007. **98**(6): p. 470-7.

55.	*The McGill consensus statement on overdentures.* Quintessence Int, 2003. **34**(1): p. 78-9.

56.	Naert, I.E., et al., *A randomised clinical trial on the influence of splinted and unsplinted oral implants in mandibular overdenture therapy. A 3-year report.* Clin Oral Investig, 1997. **1**(2): p. 81-8.

57.	Wright, P.S. and R.M. Watson, *Effect of prefabricated bar design with implant-stabilized prostheses on ridge resorption: a clinical report.* Int J Oral Maxillofac Implants, 1998. **13**(1): p. 77-81.

58.	Chao, Y.L., et al., *The incomprehensible success of the implant stabilised overdenture in the edentulous mandible: a literature review on transfer of chewing forces to bone surrounding implants.* Eur J Prosthodont Restor Dent, 1995. **3**(6): p. 255-61.

59.	Burns, D.R., *Mandibular implant overdenture treatment: consensus and controversy.* J Prosthodont, 2000. **9**(1): p. 37-46.

60.	Bilhan, H., E. Mumcu, and S. Arat, *The comparison of marginal bone loss around mandibular overdenture-supporting implants with two different attachment types in a loading period of 36 months.* Gerodontology, 2009. **28**(1): p. 49-57.

61.	Naert, I., et al., *Prosthetic aspects of osseointegrated fixtures supporting overdentures. A 4-year report.* J Prosthet Dent, 1991. **65**(5): p. 671-80.

62.	Cune, M.S., C. de Putter, and J. Hoogstraten, *Treatment outcome with implant-retained overdentures: Part II--Patient satisfaction and predictability of subjective treatment outcome.* J Prosthet Dent, 1994. **72**(2): p. 152-8.

63.	Krennmair, G. and C. Ulm, *The symphyseal single-tooth implant for anchorage of a mandibular complete denture in geriatric patients: a clinical report.* Int J Oral Maxillofac Implants, 2001. **16**(1): p. 98-104.

64.	Bergendal, T. and B. Engquist, *Implant-supported overdentures: a longitudinal prospective study.* Int J Oral Maxillofac Implants, 1998. **13**(2): p. 253-62.

65.	Gotfredsen, K. and B. Holm, *Implant-supported mandibular overdentures retained with ball or bar attachments: a randomized prospective 5-year study.* Int J Prosthodont, 2000. **13**(2): p. 125-30.

66.	Naert, I., et al., *A 5-year randomized clinical trial on the influence of splinted and unsplinted oral implants in the mandibular overdenture therapy. Part I: Peri-implant outcome.* Clin Oral Implants Res, 1998. **9**(3): p. 170-7.

67.	Davis, D.M., J.O. Rogers, and M.E. Packer, *The extent of maintenance required by implant-retained mandibular overdentures: a 3-year report.* Int J Oral Maxillofac Implants, 1996. **11**(6): p. 767-74.

68.	den Dunnen, A.C., et al., *Professional hygiene care, adjustments and complications of mandibular implant-retained overdentures: a three-year retrospective study.* J Prosthet Dent, 1997. **78**(4): p. 387-90.

69.	Hemmings, K.W., A. Schmitt, and G.A. Zarb, *Complications and maintenance requirements for fixed prostheses and overdentures in the edentulous mandible: a 5-year report.* Int J Oral Maxillofac Implants, 1994. **9**(2): p. 191-6.

70.	Payne, A.G. and Y.F. Solomons, *Mandibular implant-supported overdentures: a prospective evaluation of the burden of prosthodontic maintenance with 3 different attachment systems.* Int J Prosthodont, 2000. **13**(3): p. 246-53.

71.	Walton, J.N. and M.I. MacEntee, *Problems with prostheses on implants: a retrospective study.* J Prosthet Dent, 1994. **71**(3): p. 283-8.

72.	Watson, R.M., et al., *Prosthodontic treatment, patient response, and the need for maintenance of complete implant-supported overdentures: an appraisal of 5 years of prospective study.* Int J Prosthodont, 1997. **10**(4): p. 345-54.

73.	Ioannidou, E. and A. Doufexi, *Does loading time affect implant survival? A meta-analysis of 1,266 implants.* J Periodontol, 2005. **76**(8): p. 1252-8.

74.	Payne, A.G., et al., *Loading Strategies for Mandibular Implant Overdentures*, in *Implant overdentures : the standard of care for edentulous patients*, J.S. Feine and G.E. Carlsson, Editors. 2003, Quintessence Pub. Co.: Chicago. p. 111-128.

75.	Degidi, M. and A. Piattelli, *Immediate functional and non-functional loading of dental implants: a 2- to 60-month follow-up study of 646 titanium implants.* J Periodontol, 2003. **74**(2): p. 225-41.

76.	Chiapasco, M. and C. Gatti, *Implant-retained mandibular overdentures with immediate loading: a 3- to 8-year prospective study on 328 implants.* Clin Implant Dent Relat Res, 2003. **5**(1): p. 29-38.

77.	Cooper, L.F., et al., *Treatment of edentulism using Astra Tech implants and ball abutments to retain mandibular overdentures.* Int J Oral Maxillofac Implants, 1999. **14**(5): p. 646-53.

78.	Gatti, C., W. Haefliger, and M. Chiapasco, *Implant-retained mandibular overdentures with immediate loading: a prospective study of ITI implants.* Int J Oral Maxillofac Implants, 2000. **15**(3): p. 383-8.

79.	Roynesdal, A.K., B. Amundrud, and H.R. Hannaes, *A comparative clinical investigation of 2 early loaded ITI dental implants supporting an overdenture in the mandible.* Int J Oral Maxillofac Implants, 2001. **16**(2): p. 246-51.

80.	Turkyilmaz, I., et al., *A 2-year clinical report of patients treated with two loading protocols for mandibular overdentures: early versus conventional loading.* J Periodontol, 2006. **77**(12): p. 1998-2004.

81.	Atwood, D.A. and W.A. Coy, *Clinical, cephalometric, and densitometric study of reduction of residual ridges.* J Prosthet Dent, 1971. **26**(3): p. 280-95.

82.	Tallgren, A., *The continuing reduction of the residual alveolar ridges in complete denture wearers: a mixed-longitudinal study covering 25 years.* J Prosthet Dent, 1972. **27**(2): p. 120-32.

83. von Wowern, N. and K. Gotfredsen, *Implant-supported overdentures, a prevention of bone loss in edentulous mandibles? A 5-year follow-up study.* Clin Oral Implants Res, 2001. **12**(1): p. 19-25.

84. Jacobs, R., et al., *Posterior jaw bone resorption in osseointegrated implant-supported overdentures.* Clin Oral Implants Res, 1992. **3**(2): p. 63-70.

85. Muller, F., et al., *Masseter muscle thickness, chewing efficiency and bite force in edentulous patients with fixed and removable implant-supported prostheses: a cross-sectional multicenter study.* Clin Oral Implants Res, 2011.

86. Haraldson, T., et al., *Oral function in subjects with overdentures supported by osseointegrated implants.* Scand J Dent Res, 1988. **96**(3): p. 235-42.

87. Lund, J.P., *It Is Time to Tackle Denture Disability*, in *Implant overdentures : the standard of care for edentulous patients*, J.S. Feine and G.E. Carlsson, Editors. 2003, Quintessence Pub. Co.: Chicago. p. 1.

88. MacEntee, M.I., *The prevalence of edentulism and diseases related to dentures--a literature review.* J Oral Rehabil, 1985. **12**(3): p. 195-207.

89. Zarb, G.A., et al., *Boucher's prosthodontic treatment for edentulous patients*. 11th ed. 1997, St. Louis: Mosby. xii, 558 p., [4] p. of plates.

90. Anttila, S.S., M.L. Knuuttila, and T.K. Sakki, *Relationship of depressive symptoms to edentulousness, dental health, and dental health behavior.* Acta Odontol Scand, 2001. **59**(6): p. 406-12.

91. MacEntee, M.I., R. Hole, and E. Stolar, *The significance of the mouth in old age.* Soc Sci Med, 1997. **45**(9): p. 1449-58.

92. Locker, D., *Disability and disadvantage : the consequences of chronic illness.* Social science paperbacks. 1983, London New York: Tavistock Publications. ix, 211 p.

93. Sheiham, A. and J. Steele, *Does the condition of the mouth and teeth affect the ability to eat certain foods, nutrient and dietary intake and nutritional status amongst older people?* Public Health Nutr, 2001. **4**(3): p. 797-803.

94. Boushey, C.J., et al., *A quantitative assessment of plasma homocysteine as a risk factor for vascular disease. Probable benefits of increasing folic acid intakes.* JAMA, 1995. **274**(13): p. 1049-57.

95. MacEntee, M.I., E. Stolar, and N. Glick, *Influence of age and gender on oral health and related behaviour in an independent elderly population.* Community Dent Oral Epidemiol, 1993. **21**(4): p. 234-9.

96. Scheff, T.J., *The labelling theory of mental illness.* Am Sociol Rev, 1974. **39**(3): p. 444-52.

97. George, L.K. and L.B. Bearon, *Quality of life in older persons : meaning and measurement*. 1980, New York: Human Sciences Press. xii, 238 p.

98. MacEntee, M.I. and J.N. Walton, *The economics of complete dentures and implant-related services: a framework for analysis and preliminary outcomes.* J Prosthet Dent, 1998. **79**(1): p. 24-30.

99. Awad, M.A. and J.S. Feine, *Measuring patient satisfaction with mandibular prostheses.* Community Dent Oral Epidemiol, 1998. **26**(6): p. 400-5.

100. Kent, G., *Effects of osseointegrated implants on psychological and social well-being: a literature review.* J Prosthet Dent, 1992. **68**(3): p. 515-8.

101. Feine, J.S. and G. Heydecke, *Implant Overdentures Versus Conventional Dentures*, in *Implant overdentures : the standard of care for edentulous patients*, J.S. Feine and G.E. Carlsson, Editors. 2003, Quintessence Pub. Co.: Chicago. p. 37-45.

102. Bergman, B. and G.E. Carlsson, *Review of 54 complete denture wearers. Patients' opinions 1 year after treatment.* Acta Odontol Scand, 1972. **30**(4): p. 399-414.

103. Carlsson, G.E., et al., *Patient factors in appreciation of complete dentures.* J Prosthet Dent, 1967. **17**(4): p. 322-8.

104. Pietrokovski, J., et al., *Oral findings in elderly nursing home residents in selected countries: quality of and satisfaction with complete dentures.* J Prosthet Dent, 1995. **73**(2): p. 132-5.

105. Awad, M.A., et al., *Measuring the effect of intra-oral implant rehabilitation on health-related quality of life in a randomized controlled clinical trial.* J Dent Res, 2000. **79**(9): p. 1659-63.

106. Awad, M.A., et al., *Comparing the efficacy of mandibular implant-retained overdentures and conventional dentures among middle-aged edentulous patients: satisfaction and functional assessment.* Int J Prosthodont, 2003. **16**(2): p. 117-22.

107. Awad, M.A., et al., *Oral health status and treatment satisfaction with mandibular implant overdentures and conventional dentures: a randomized clinical trial in a senior population.* Int J Prosthodont, 2003. **16**(4): p. 390-6.

108. Raghoebar, G.M., et al., *Effectiveness of three treatment modalities for the edentulous mandible. A five-year randomized clinical trial.* Clin Oral Implants Res, 2000. **11**(3): p. 195-201.

109. Slade, G.D. and A.J. Spencer, *Development and evaluation of the Oral Health Impact Profile.* Community Dent Health, 1994. **11**(1): p. 3-11.

110. Berg, E., *The influence of some anamnestic, demographic, and clinical variables on patient acceptance of new complete dentures.* Acta Odontol Scand, 1984. **42**(2): p. 119-27.

111. Heyink, J., J. Heezen, and R. Schaub, *Dentist and patient appraisal of complete dentures in a Dutch elderly population.* Community Dent Oral Epidemiol, 1986. **14**(6): p. 323-6.

112. Locker, D., *Patient-based assessment of the outcomes of implant therapy: a review of the literature.* Int J Prosthodont, 1998. **11**(5): p. 453-61.

113. Magnusson, T., *Signs and symptoms of mandibular dysfunction in complete denture wearers five years after receiving new dentures.* Cranio, 1985. **3**(3): p. 267-72.

114. Smith, M., *Measurement of personality traits and their relation to patient satisfaction with complete dentures.* J Prosthet Dent, 1976. **35**(5): p. 492-503.

115. Feine, J.S., M.A. Awad, and J.P. Lund, *The impact of patient preference on the design and interpretation of clinical trials.* Community Dent Oral Epidemiol, 1998. **26**(1): p. 70-4.

116. Hlatky, M.A., *Patient preferences and clinical guidelines.* JAMA, 1995. **273**(15): p. 1219-20.

117. Laine, C. and F. Davidoff, *Patient-centered medicine. A professional evolution.* JAMA, 1996. **275**(2): p. 152-6.

118. Flood, A.B., et al., *The role of expectations in patients' reports of post-operative outcomes and improvement following therapy.* Med Care, 1993. **31**(11): p. 1043-56.

119. Burns, D.R., et al., *Prospective clinical evaluation of mandibular implant overdentures: Part II--Patient satisfaction and preference.* J Prosthet Dent, 1995. **73**(4): p. 364-9.

120. de Grandmont, P., et al., *Within-subject comparisons of implant-supported mandibular prostheses: psychometric evaluation.* J Dent Res, 1994. **73**(5): p. 1096-104.

121. MacEntee, M.I., J.N. Walton, and N. Glick, *A clinical trial of patient satisfaction and prosthodontic needs with ball and bar attachments for implant-retained complete overdentures: three-year results.* J Prosthet Dent, 2005. **93**(1): p. 28-37.

122. Tang, L., et al., *A within-subject comparison of mandibular long-bar and hybrid implant-supported prostheses: psychometric evaluation and patient preference.* J Dent Res, 1997. **76**(10): p. 1675-83.

123. Feine, J.S., et al., *Within-subject comparisons of implant-supported mandibular prostheses: evaluation of masticatory function.* J Dent Res, 1994. **73**(10): p. 1646-56.

124. Davarpanah, M., H. Martinez, and J.F. Tecucianu, *Apical-coronal implant position: recent surgical proposals. Technical note.* Int J Oral Maxillofac Implants, 2000. **15**(6): p. 865-72.

125. Lazzara, R.J., et al., *A human histologic analysis of osseotite and machined surfaces using implants with 2 opposing surfaces.* Int J Periodontics Restorative Dent, 1999. **19**(2): p. 117-29.

126. Dominici, J.T., K.E. Kinderknecht, and E. Patella-Clark, *Clinical procedure for stabilizing and connecting O-ring attachments to a mandibular implant overdenture.* J Prosthet Dent, 1996. **76**(3): p. 330-3.

127. Meijer, H.J., et al., *Implant-retained mandibular overdentures compared with complete dentures; a 5-years' follow-up study of clinical aspects and patient satisfaction.* Clin Oral Implants Res, 1999. **10**(3): p. 238-44.

128. Wismeijer, D., et al., *Patient satisfaction with implant-supported mandibular overdentures. A comparison of three treatment strategies with ITI-dental implants.* Int J Oral Maxillofac Surg, 1997. **26**(4): p. 263-7.

129. Narhi, T.O., et al., *Changes in the edentulous maxilla in persons wearing implant-retained mandibular overdentures.* J Prosthet Dent, 2000. **84**(1): p. 43-9.

130. Thiel, C.P., D.B. Evans, and R.R. Burnett, *Combination syndrome associated with a mandibular implant-supported overdenture: a clinical report.* J Prosthet Dent, 1996. **75**(2): p. 107-13.

131. Feine, J.S., et al., *Within-subject comparisons of implant-supported mandibular prostheses: choice of prosthesis.* J Dent Res, 1994. **73**(5): p. 1105-11.

**Table 1**

**Selection Criteria:**

| Inclusion Criteria |
| --- |
| <ul><li>Recently made maxillary and mandibular complete dentures.</li><li>Mandibular dentures with adequate support and stability that are poorly retained.</li><li>Maxillary dentures with adequate retention, support and stability.</li><li>Patient must wear the existing denture at least one month.</li><li>Ability to answer the questionnaire.</li><li>No systemic diseases which could influence the outcome of therapy.</li><li>Good level of oral hygiene and/or denture care.</li><li>Compliance with the recall and maintenance program.</li><li>Presence of adequate bone quantity and quality to support dental implants.</li><li>Full dental coverage at SFVADC.</li></ul> |
| **Exclusion Criteria** |
| <ul><li>Bleeding disorders and blood dyscrasias.</li><li>Uncontrolled Diabetes.</li><li>History of use of any bisphosphonates (oral or IV).</li><li>History of head and neck radiation.</li><li>Current history of chronic hyposalivation or Sjögrens Syndrome.</li><li>History of disorders affecting the structure and/or healing of the patients' bone including primary or metastatic bone cancers.</li><li>Diminished capacity to consent (a diagnosis of dementia or cognitive impairment; presenting for an evaluation of dementia or cognitive impairment; a report in medical records or from a family member, that the subject has symptoms of dementia or cognitive impairment; psychotic symptoms, bizarre or abnormal behavior exhibited by the individual; an abnormal degree of confusion, forgetfulness, or difficulties in communication that is observed in the course of interaction).</li></ul> |

**Table 2: Comparison between SDI and MDI at baseline for mandibular QOL**

| | PRE-IMPLANT | | | | | | |
| | Mean | | SD | | SEM | | p |
| | SDI | MDI | SDI | MDI | SDI | MDI | |
|---|---|---|---|---|---|---|---|
| General Satisfaction | 43.47 | 37.39 | 38.23 | 29.06 | 9.87 | 6.85 | 0.6076 |
| Overall Function | 39.67 | 34.00 | 31.22 | 30.64 | 8.06 | 7.22 | 0.6036 |
| Overall Chewing Ability | 38.50 | 31.28 | 29.54 | 26.81 | 7.90 | 6.32 | 0.4752 |
| Speech Ability | 56.29 | 52.44 | 33.37 | 28.39 | 8.92 | 6.69 | 0.7275 |
| Stability | 41.21 | 31.67 | 35.65 | 26.46 | 9.53 | 6.24 | 0.3910 |
| Retention | 36.71 | 28.47 | 34.06 | 21.72 | 9.10 | 5.27 | 0.4202 |
| Appearance | 76.20 | 71.94 | 21.82 | 31.02 | 5.63 | 7.31 | 0.6583 |
| Fit | 51.00 | 43.11 | 32.25 | 30.13 | 8.35 | 7.10 | 0.4743 |
| Chewing Hard Food | 32.93 | 22.65 | 28.29 | 24.34 | 7.56 | 5.90 | 0.2855 |
| Chewing Tough Food | 34.07 | 27.67 | 28.80 | 26.68 | 7.70 | 6.29 | 0.5201 |
| Chewing Crisp Food | 41.87 | 35.44 | 31.92 | 31.68 | 8.24 | 7.47 | 0.5675 |
| Chewing Whole Fruit | 29.50 | 22.82 | 29.50 | 24.07 | 7.88 | 5.84 | 0.4929 |
| Chewing Fruits, Peels | 42.43 | 39.88 | 26.37 | 33.01 | 7.05 | 8.01 | 0.8170 |
| Chewing Fruits, No Peels | 53.13 | 41.67 | 29.63 | 29.26 | 7.65 | 6.90 | 0.2736 |
| Chewing Soft, Dry | 56.20 | 44.33 | 31.26 | 30.60 | 8.07 | 7.21 | 0.2804 |
| Chewing Soft, Wet | 67.40 | 58.56 | 22.56 | 30.83 | 5.82 | 7.27 | 0.3631 |
| Chewing Flat Vegetable | 49.27 | 41.06 | 36.04 | 31.97 | 9.31 | 7.53 | 0.4931 |

**Table 3: Comparison between SDI and MDI at 3 month after implants placement for mandibular QOL**

| | 3 MONTH | | | | | | |
|---|---|---|---|---|---|---|---|
| | Mean | | SD | | SEM | | p |
| | SDI | MDI | SDI | MDI | SDI | MDI | |
| General Satisfaction | 81.14 | 71.87 | 13.75 | 30.75 | 5.20 | 7.94 | 0.4585 |
| Overall Function | 72.00 | 71.47 | 26.93 | 28.68 | 10.18 | 7.41 | 0.9674 |
| Overall Chewing Ability | 68.43 | 64.27 | 23.37 | 35.70 | 8.83 | 9.22 | 0.7825 |
| Speech Ability | 83.33 | 75.67 | 12.71 | 23.86 | 5.19 | 6.16 | 0.4694 |
| Stability | 68.29 | 62.93 | 21.01 | 34.94 | 7.94 | 9.02 | 0.7137 |
| Retention | 74.43 | 66.20 | 16.30 | 34.92 | 6.16 | 9.02 | 0.5629 |
| Appearance | 89.00 | 81.20 | 9.83 | 25.68 | 3.72 | 6.63 | 0.4507 |
| Fit | 81.43 | 73.00 | 12.69 | 31.73 | 4.80 | 8.19 | 0.5099 |
| Chewing Hard Food | 81.67 | 64.71 | 15.13 | 35.91 | 6.18 | 9.60 | 0.2583 |
| Chewing Tough Food | 77.29 | 63.33 | 17.79 | 35.46 | 6.72 | 9.15 | 0.3406 |
| Chewing Crisp Food | 83.14 | 65.27 | 13.33 | 34.35 | 5.04 | 8.87 | 0.2028 |
| Chewing Whole Fruit | 78.29 | 56.14 | 12.97 | 31.53 | 4.90 | 8.43 | 0.0934 |
| Chewing Fruits, Peels | 75.33 | 62.96 | 17.45 | 37.10 | 7.13 | 9.91 | 0.4489 |
| Chewing Fruits, No Peels | 77.14 | 71.93 | 19.69 | 31.13 | 7.44 | 8.32 | 0.6922 |
| Chewing Soft, Dry | 83.86 | 68.53 | 9.28 | 30.20 | 3.51 | 7.80 | 0.2087 |
| Chewing Soft, Wet | 89.57 | 71.80 | 9.00 | 28.38 | 3.40 | 7.33 | 0.1251 |
| Chewing Flat Vegetable | 85.43 | 65.36 | 8.81 | 32.29 | 3.33 | 8.63 | 0.1269 |

**Table 4: Comparison between SDI and MDI at 6 month after implants placement for mandibular QOL**

| | 6 MONTH | | | | | | |
| | Mean | | SD | | SEM | | p |
| | SDI | MDI | SDI | MDI | SDI | MDI | |
|---|---|---|---|---|---|---|---|
| General Satisfaction | 70.50 | 84.11 | 22.88 | 14.95 | 11.44 | 4.98 | 0.2214 |
| Overall Function | 69.25 | 81.22 | 21.55 | 22.59 | 10.77 | 7.53 | 0.3909 |
| Overall Chewing Ability | 66.25 | 83.22 | 24.06 | 22.12 | 12.03 | 7.37 | 0.2387 |
| Speech Ability | 87.00 | 80.89 | 8.76 | 21.81 | 4.38 | 7.27 | 0.6061 |
| Stability | 66.00 | 77.56 | 32.59 | 23.74 | 16.29 | 7.91 | 0.4824 |
| Retention | 64.00 | 77.00 | 35.15 | 24.85 | 17.57 | 8.28 | 0.4566 |
| Appearance | 68.25 | 84.00 | 39.32 | 16.54 | 19.66 | 5.51 | 0.3153 |
| Fit | 64.25 | 84.22 | 31.69 | 16.06 | 15.84 | 5.35 | 0.1501 |
| Chewing Hard Food | 69.25 | 81.22 | 22.08 | 21.89 | 11.04 | 7.30 | 0.3834 |
| Chewing Tough Food | 66.25 | 82.33 | 21.85 | 16.78 | 10.93 | 5.59 | 0.1716 |
| Chewing Crisp Food | 75.33 | 83.44 | 13.05 | 16.87 | 7.54 | 5.62 | 0.4693 |
| Chewing Whole Fruit | 70.75 | 72.11 | 16.40 | 21.74 | 8.20 | 7.25 | 0.9137 |
| Chewing Fruits, Peels | 55.25 | 79.56 | 35.51 | 17.29 | 17.75 | 5.76 | 0.1158 |
| Chewing Fruits, No Peels | 61.50 | 84.33 | 27.62 | 17.10 | 13.81 | 5.70 | 0.0909 |
| Chewing Soft, Dry | 70.75 | 84.78 | 22.57 | 15.78 | 11.29 | 5.26 | 0.2186 |
| Chewing Soft, Wet | 85.50 | 86.00 | 8.54 | 16.11 | 4.27 | 5.37 | 0.9551 |
| Chewing Flat Vegetable | 75.50 | 82.56 | 13.28 | 22.39 | 6.64 | 7.46 | 0.5749 |

**Table 5: Comparison between SDI and MDI at 12 month after implants placement for mandibular QOL**

| | 12 MONTH | | | | | | |
|---|---|---|---|---|---|---|---|
| | Mean | | SD | | SEM | | p |
| | SDI | MDI | SDI | MDI | SDI | MDI | |
| General Satisfaction | 84.50 | 74.20 | 15.42 | 25.45 | 7.71 | 11.38 | 0.5026 |
| Overall Function | 83.75 | 76.50 | 12.15 | 15.67 | 6.07 | 7.84 | 0.4922 |
| Overall Chewing Ability | 81.00 | 71.50 | 14.76 | 28.64 | 7.38 | 14.32 | 0.5769 |
| Speech Ability | 91.75 | 68.60 | 8.66 | 30.02 | 4.33 | 13.43 | 0.1836 |
| Stability | 71.75 | 67.20 | 30.59 | 27.88 | 15.29 | 12.47 | 0.8222 |
| Retention | 82.50 | 77.60 | 4.20 | 15.31 | 2.10 | 6.85 | 0.1041 |
| Appearance | 93.25 | 72.20 | 7.63 | 34.89 | 3.82 | 15.60 | 0.2807 |
| Fit | 93.67 | 77.60 | 4.16 | 22.68 | 2.40 | 11.48 | 0.3373 |
| Chewing Hard Food | 78.33 | 67.75 | 19.04 | 34.13 | 10.99 | 17.07 | 0.6535 |
| Chewing Tough Food | 96.50 | 77.50 | 0.71 | 18.01 | 0.50 | 9.00 | 0.2324 |
| Chewing Crisp Food | 95.67 | 78.50 | 7.51 | 19.02 | 4.33 | 9.51 | 0.2062 |
| Chewing Whole Fruit | 70.00 | 60.75 | 21.66 | 40.49 | 12.50 | 20.25 | 0.7379 |
| Chewing Fruits, Peels | 78.25 | 71.75 | 26.75 | 30.07 | 13.38 | 15.04 | 0.7577 |
| Chewing Fruits, No Peels | 92.75 | 71.75 | 6.70 | 30.26 | 3.35 | 15.13 | 0.2242 |
| Chewing Soft, Dry | 88.25 | 71.75 | 15.04 | 28.84 | 7.52 | 14.42 | 0.3494 |
| Chewing Soft, Wet | 94.25 | 82.25 | 6.18 | 18.25 | 3.09 | 9.12 | 0.2593 |
| Chewing Flat Vegetable | 70.50 | 72.00 | 26.90 | 17.72 | 13.45 | 8.86 | 0.9288 |

**Table 6: Comparison for MDI group between pre-implants and 6 month after implants placement for mandibular QOL**

| | PRE-IMPLANT VS. 6 MONTH MDI | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| | Mean | | SD | | SEM | | p |
| | PRE | 6 MO | PRE | 6 MO | PRE | 6 MO | |
| General Satisfaction | 37.39 | 84.11 | 29.06 | 14.95 | 6.85 | 4.98 | 0.0001 |
| Overall Function | 34.00 | 81.22 | 30.64 | 22.59 | 7.22 | 7.53 | 0.0004 |
| Overall Chewing Ability | 31.28 | 83.22 | 26.81 | 22.12 | 6.32 | 7.37 | 0.0001 |
| Speech Ability | 52.44 | 80.89 | 28.39 | 21.81 | 6.69 | 7.27 | 0.0143 |
| Stability | 31.67 | 77.56 | 26.46 | 23.74 | 6.24 | 7.91 | 0.0002 |
| Retention | 28.47 | 77.00 | 21.72 | 24.85 | 5.27 | 8.28 | 0.0001 |
| Appearance | 71.94 | 84.00 | 31.02 | 16.54 | 7.31 | 5.51 | 0.2887 |
| Fit | 43.11 | 84.22 | 30.13 | 16.06 | 7.10 | 5.35 | 0.0008 |
| Chewing Hard Food | 22.65 | 81.22 | 24.34 | 21.89 | 5.90 | 7.30 | 0.0001 |
| Chewing Tough Food | 27.67 | 82.33 | 26.68 | 16.78 | 6.29 | 5.59 | 0.0001 |
| Chewing Crisp Food | 35.44 | 83.44 | 31.68 | 16.87 | 7.47 | 5.62 | 0.0003 |
| Chewing Whole Fruit | 22.82 | 72.11 | 24.07 | 21.74 | 5.84 | 7.25 | 0.0001 |
| Chewing Fruits, Peels | 39.88 | 79.56 | 33.01 | 17.29 | 8.01 | 5.76 | 0.0027 |
| Chewing Fruits, No Peels | 41.67 | 84.33 | 29.26 | 17.10 | 6.90 | 5.70 | 0.0005 |
| Chewing Soft, Dry | 44.33 | 84.78 | 30.60 | 15.78 | 7.21 | 5.26 | 0.0011 |
| Chewing Soft, Wet | 58.56 | 86.00 | 30.83 | 16.11 | 7.27 | 5.37 | 0.0198 |
| Chewing Flat Vegetable | 41.06 | 82.56 | 31.97 | 22.39 | 7.53 | 7.46 | 0.0019 |

**Table 7: Comparison for MDI group between pre-implants and 12 month after implants placement for mandibular QOL**

| | PRE-IMPLANT VS. 12 MO MDI | | | | | | |
|---|---|---|---|---|---|---|---|
| | Mean | | SD | | SEM | | p |
| | PRE | 12 MO | PRE | 12 MO | PRE | 12 MO | |
| General Satisfaction | 37.39 | 74.20 | 29.06 | 25.45 | 6.85 | 11.38 | 0.0181 |
| Overall Function | 34.00 | 76.50 | 30.64 | 15.67 | 7.22 | 7.84 | 0.0150 |
| Overall Chewing Ability | 31.28 | 71.50 | 26.81 | 28.64 | 6.32 | 14.32 | 0.0142 |
| Speech Ability | 52.44 | 68.60 | 28.39 | 30.02 | 6.69 | 13.43 | 0.2782 |
| Stability | 31.67 | 67.20 | 26.46 | 27.88 | 6.24 | 12.47 | 0.0157 |
| Retention | 28.47 | 77.60 | 21.72 | 15.31 | 5.27 | 6.85 | 0.0001 |
| Appearance | 71.94 | 72.20 | 31.02 | 34.89 | 7.31 | 15.60 | 0.9875 |
| Fit | 43.11 | 77.60 | 30.13 | 25.68 | 7.10 | 11.48 | 0.0301 |
| Chewing Hard Food | 22.65 | 67.75 | 24.34 | 34.13 | 5.90 | 17.07 | 0.0058 |
| Chewing Tough Food | 27.67 | 77.50 | 26.68 | 18.01 | 6.29 | 9.00 | 0.0021 |
| Chewing Crisp Food | 35.44 | 78.50 | 31.68 | 19.02 | 7.47 | 9.51 | 0.0177 |
| Chewing Whole Fruit | 22.82 | 60.75 | 24.07 | 40.49 | 5.84 | 20.25 | 0.0218 |
| Chewing Fruits, Peels | 39.88 | 71.75 | 33.01 | 30.07 | 8.01 | 15.04 | 0.0943 |
| Chewing Fruits, No Peels | 41.87 | 71.75 | 29.26 | 30.26 | 6.90 | 15.13 | 0.0791 |
| Chewing Soft, Dry | 44.33 | 71.75 | 30.60 | 28.84 | 7.21 | 14.42 | 0.1177 |
| Chewing Soft, Wet | 58.56 | 82.25 | 30.83 | 18.25 | 7.27 | 9.12 | 0.1589 |
| Chewing Flat Vegetable | 41.06 | 72.00 | 31.97 | 17.72 | 7.53 | 8.86 | 0.0791 |
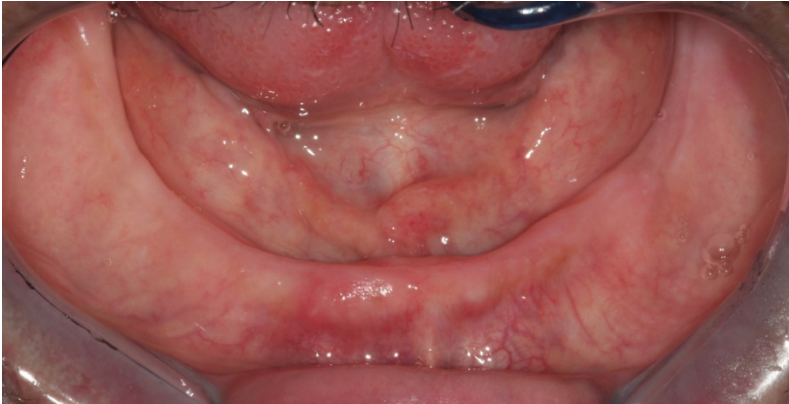
Figure 1: Typical pre-surgical case randomized to MDI, which requires full thickness flap.



Figure 2: Pre-surgical panographic radiograph

Figure 3: Full thickness flap reveals the need for osteoplasty to increase buccal-lingual width to approximate 5 mm
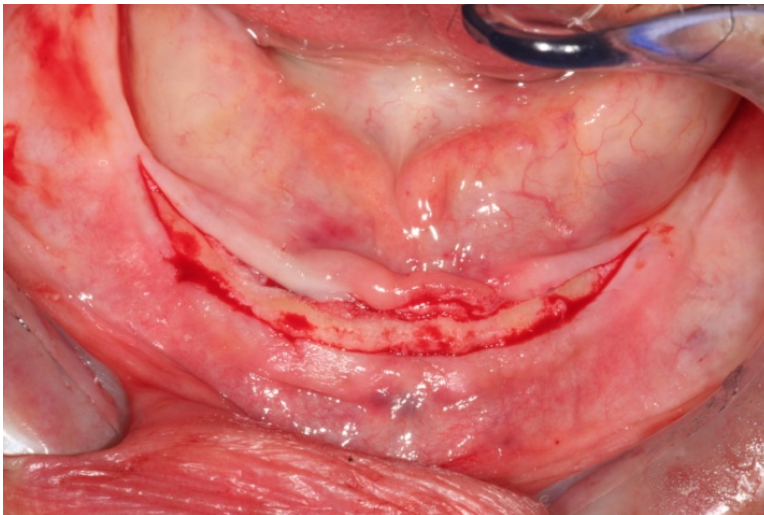


Figure 4: Completion of osteoplasty and osteotomy for MDI (1.8 X 13 mm) at sites #22, #24, #25, and #27.
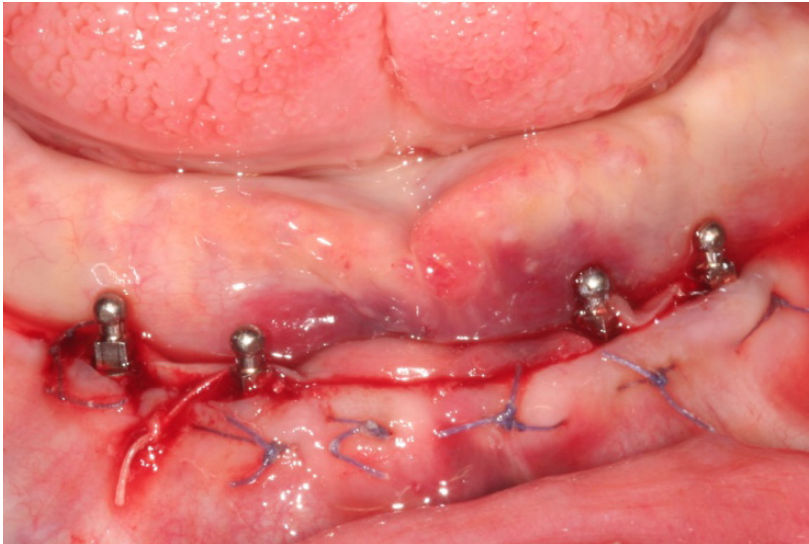
Figure 5: Completion of MDI (1.8 X 13 mm) #22, #24, #25, and #27.
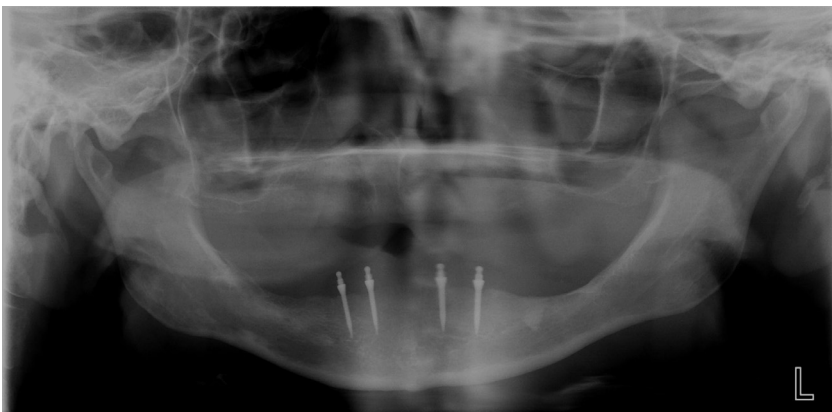


Figure 6: Post-surgical panographic radiograph

Figure 7: 1 week post-op



Figure 8: 3 week post-op

**Case 2:**



Figure 9: Typical pre-surgical case randomized to SDI, which requires full thickness flap.
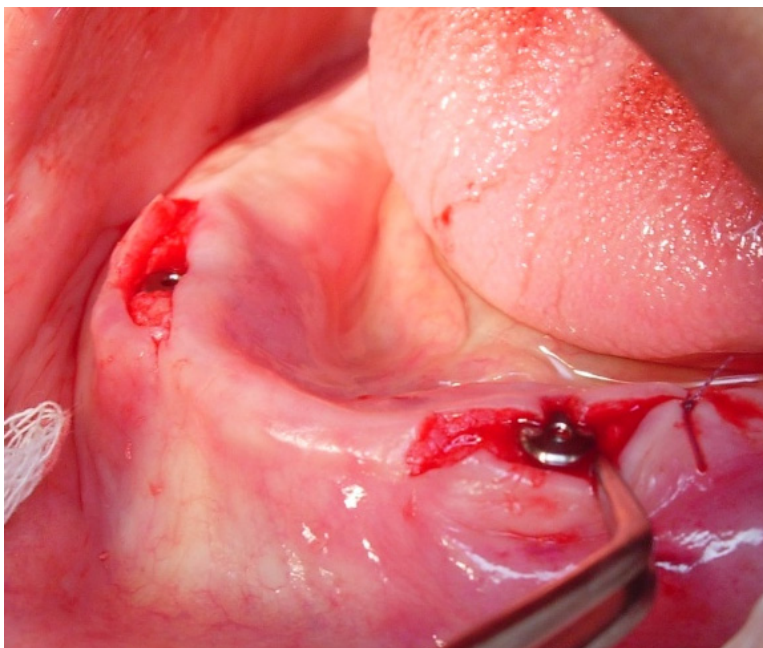


Figure 10: Implants at sites #22 & 27 with cover screws in place
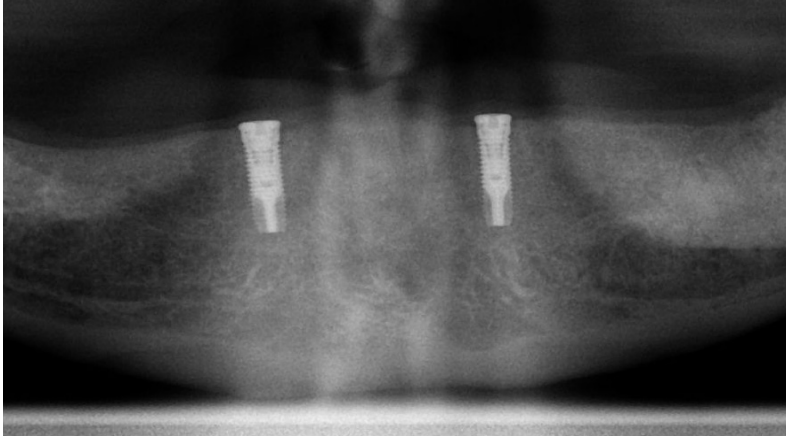
Figure 11: 3 month post-surgical panographic radiograph



Figure 12: 4 month post-op
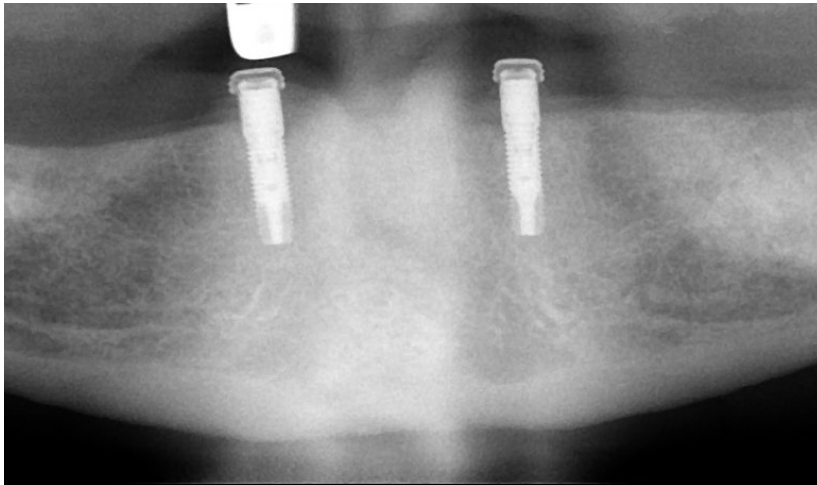
Figure 13: Post-retrofit panographic radiograph with locator abutments



Figure 14: Additional auto-polymerizing acrylic resin needed to increase the height of acrylic in the area of #23 and #26.

**Case 3:**
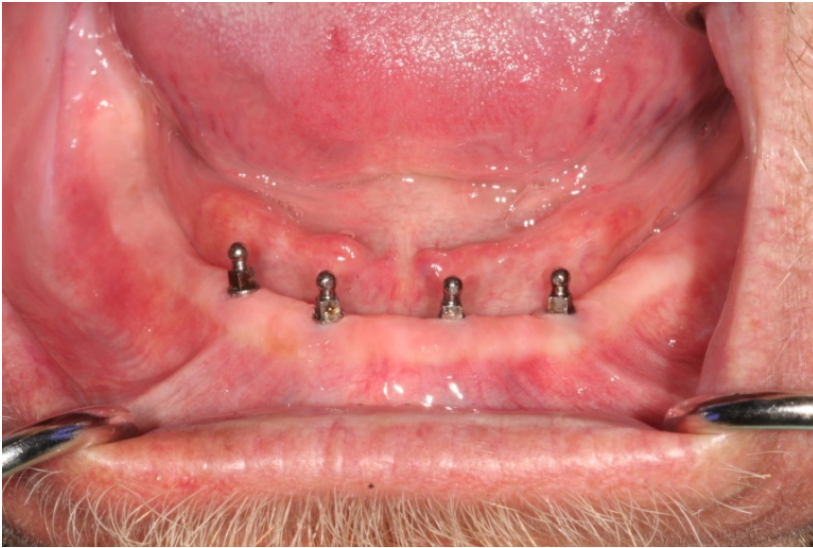


Figure 15: Typical MDI, which does not require full thickness flap.



Figure 16: 4 month post-op

Figure 17: Adequate width of acrylic

**Case 4:**
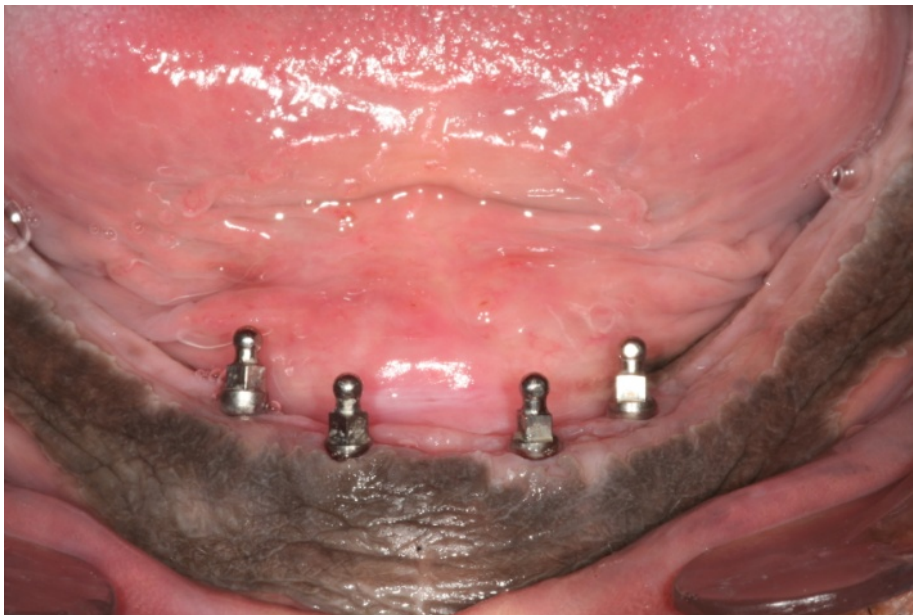


Figure 18: 4 month post-op for retrofit

Figure 19: Placement of housings over block-out shims



Figure 20: Removal of adequate acrylic for housing pick-up. Lingual placement of

implant #27 required removal of lingual flange in that area with placement of acrylic vent

holes on lingual

Figure 21: Completion of housing pick-up using auto-polymerizing acrylic resin

**Case 5:**
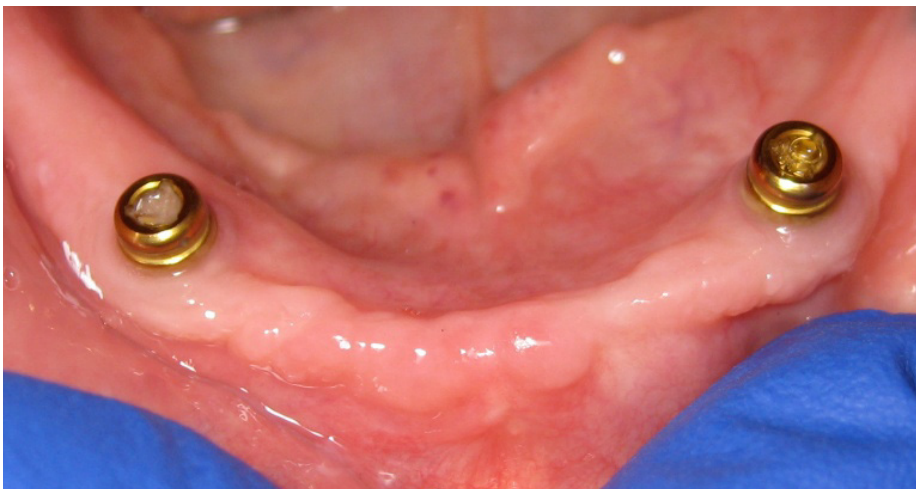


Figure 22: Typical SDI 4 month post-op for retrofit
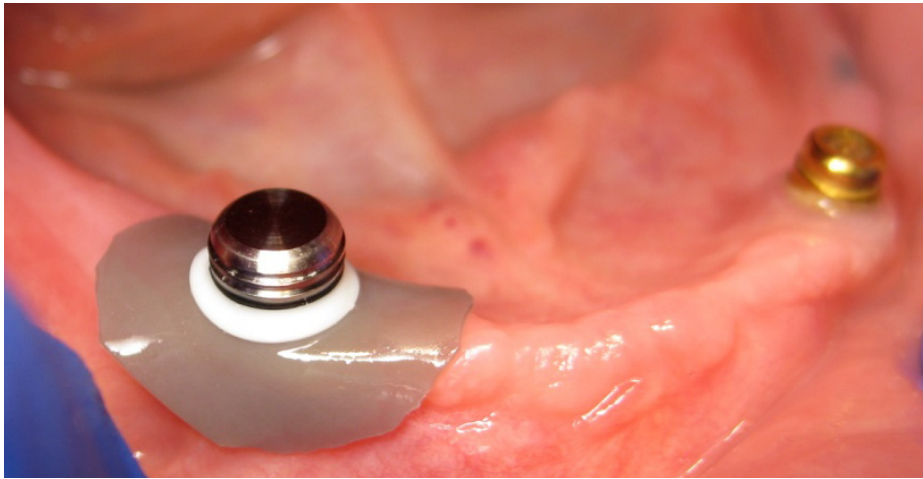
Figure 23: SDI Locator with rubber dam and block-out shim



Figure 24: Completion of locator housing pick-up using auto-polymerizing acrylic resin

**Appendix A: Flow chart of study**



SDI
Arm A

MDI
Arm B

Consent and Enrollment for lower

Examination

Randomization:
Assigned group:
**A, B**

Implant Placement Surgery

**A.** 2 SDI implants in front

**B.** 4 MDI implants in front

Post-operative Appointments:
(1 and 3 weeks)

Post-operative Appointments:
(1 and 3 weeks)

3 Months Healing

4 Months Healing

Implant Uncovering Surgery

1 Month Healing

Denture Modification
(4 months)

Denture Modification
(4 months)

Long-term Follow-up
(6, 12, 24, 36, 60 months)

Long-term Follow-up
(6, 12, 24, 36, 60 months)

**Appendix B: VAS Clinical Evaluations**

**1. General satisfaction:**

In general, are you satisfied with your lower denture?

**Not at all**　　　　　　　　　　　　　　　　　　　　　　　**Totally**
**Satisfied** |_____|_____|_____|_____| **Satisfied**

In general, are you satisfied with your upper denture?

**Not at all**　　　　　　　　　　　　　　　　　　　　　　　**Totally**
**Satisfied** |_____|_____|_____|_____| **Satisfied**

**2. Overall function:**

In general, are you satisfied with the function of your lower denture?

**Not at all**　　　　　　　　　　　　　　　　　　　　　　　**Totally**
**Satisfied** |_____|_____|_____|_____| **Satisfied**

In general, are you satisfied with the function of your upper denture?

**Not at all**　　　　　　　　　　　　　　　　　　　　　　　**Totally**
**Satisfied** |_____|_____|_____|_____| **Satisfied**

**3. Overall chewing ability:**

In general, are you satisfied with the chewing ability of your lower denture?

**Not at all**　　　　　　　　　　　　　　　　　　　　　　　**Totally**
**Satisfied** |_____|_____|_____|_____| **Satisfied**

In general, are you satisfied with the chewing ability of your upper denture?

**Not at all**　　　　　　　　　　　　　　　　　　　　　　　**Totally**
**Satisfied** |_____|_____|_____|_____| **Satisfied**

## 4. Speech ability:

In general, are you satisfied with the way you speak while wearing your lower denture?

**Not at all**                                               **Totally**
**Satisfied** |_____|_____|_____|_____| **Satisfied**

In general, are you satisfied with the way you speak while wearing your upper denture?

**Not at all**       **Totally**
**Satisfied** |_____|_____|_____|_____| **Satisfied**

## 5. Stability (rocking side to side):

In general, are you satisfied with the stability of your lower denture?

**Not at all**       **Totally**
**Satisfied** |_____|_____|_____|_____| **Satisfied**

In general, are you satisfied with the stability of your upper denture?

**Not at all**       **Totally**
**Satisfied** |_____|_____|_____|_____| **Satisfied**

## 6. Retention (dislodging):

In general, are you satisfied with the retention of your lower denture?

**Not at all**       **Totally**
**Satisfied** |_____|_____|_____|_____| **Satisfied**

In general, are you satisfied with the retention of your upper denture?

**Not at all**       **Totally**
**Satisfied** |_____|_____|_____|_____| **Satisfied**

## 7. Appearance:

In general, are you satisfied with the appearance of your lower denture?

**Not at all**                                          **Totally**
**Satisfied** |_____|_____|_____|_____| **Satisfied**

In general, are you satisfied with the appearance of your upper denture?

**Not at all**                                          **Totally**
**Satisfied** |_____|_____|_____|_____| **Satisfied**

## 8. Fit (comfort):

In general, are you satisfied with the fit of your lower denture?

**Not at all**                                          **Totally**
**Satisfied** |_____|_____|_____|_____| **Satisfied**

In general, are you satisfied with the fit of your upper denture?

**Not at all**                                            **Totally**
**Satisfied** |_____|_____|_____|_____| **Satisfied**

## 9. Chewing hard foods (examples: raw carrots, nuts):

Are you satisfied with chewing hard foods while wearing your lower denture?

**Not at all**                                          **Totally**
**Satisfied** |_____|_____|_____|_____| **Satisfied**

Are you satisfied with chewing hard foods while wearing your upper denture?

**Not at all**                                          **Totally**
**Satisfied** |_____|_____|_____|_____| **Satisfied**

## 10. Chewing tough foods (examples: beef):

Are you satisfied with chewing tough foods while wearing your lower denture?

**Not at all**
**Satisfied** |_____|_____|_____|_____| **Totally**
**Satisfied**

Are you satisfied with chewing tough foods while wearing your upper denture?

**Not at all**
**Satisfied** |_____|_____|_____|_____| **Totally**
**Satisfied**

## 11. Chewing crisp foods (examples: chips):

Are you satisfied with chewing crisp foods while wearing your lower denture?

**Not at all**
**Satisfied** |_____|_____|_____|_____| **Totally**
**Satisfied**

Are you satisfied with chewing crisp foods while wearing your upper denture?

**Not at all**
**Satisfied** |_____|_____|_____|_____| **Totally**
**Satisfied**

## 12. Chewing whole fruits (examples: raw apples, pears):

Are you satisfied with chewing whole fruits while wearing your lower denture?

**Not at all**
**Satisfied** |_____|_____|_____|_____| **Totally**
**Satisfied**

Are you satisfied with chewing whole fruits while wearing your upper denture?

**Not at all**
**Satisfied** |_____|_____|_____|_____| **Totally**
**Satisfied**

### 13. Chewing fruit with peels (examples: raw apples, pears):

Are you satisfied with chewing fruit with peels while wearing your lower denture?

**Not at all**
**Satisfied** |_____|_____|_____|_____| **Totally**
                                                                **Satisfied**

Are you satisfied with chewing fruit with peels while wearing your upper denture?

**Not at all**
**Satisfied** |_____|_____|_____|_____| **Totally**
                                                                **Satisfied**

### 14. Chewing fruit with out peels (examples: peeled raw apples, pears):

Are you satisfied with chewing fruit without peels while wearing your lower denture?

**Not at all**
**Satisfied** |_____|_____|_____|_____| **Totally**
                                                                **Satisfied**

Are you satisfied with chewing fruit without peels while wearing your upper denture?

**Not at all**
**Satisfied** |_____|_____|_____|_____| **Totally**
                                                                **Satisfied**

### 15. Chewing soft/dry foods (examples: bread, cheese):

Are you satisfied with the chewing soft/dry foods while wearing your lower denture?

**Not at all**
**Satisfied** |_____|_____|_____|_____| **Totally**
                                                                **Satisfied**

Are you satisfied with the chewing soft/dry foods while wearing your upper denture?

**Not at all**
**Satisfied** |_____|_____|_____|_____| **Totally**
                                                                **Satisfied**

**16. Chewing soft/wet foods (examples: mashed potatoes with gravy, apple sauce):**

Are you satisfied with the chewing soft/wet foods while wearing your lower denture?

**Not at all**                                                                 **Totally**
**Satisfied** |_____|_____|_____|_____| **Satisfied**


Are you satisfied with the chewing soft/wet foods while wearing your upper denture?

**Not at all**                                                                 **Totally**
**Satisfied** |_____|_____|_____|_____| **Satisfied**


**17. Chewing flat vegetables (examples: lettuce, spinach):**

Are you satisfied with the chewing flat vegetables while wearing your lower denture?

**Not at all**                                                                 **Totally**
**Satisfied** |_____|_____|_____|_____| **Satisfied**


Are you satisfied with the chewing flat vegetables while wearing your upper denture?

**Not at all**                                                                 **Totally**
**Satisfied** |_____|_____|_____|_____| **Satisfied**

**Appendix C: Outline of Subject Appointments:**

**Phone Screening and Appointment 1 scheduled:**

- **Inclusion and Exclusion Criteria determined**

**Appointment 1:**

**Consent, Examination, and Enrollment**

- **Consent form completed**

- **Medical and dental chart review**

- **Head and Neck Exam**

- **Panographic radiograph or CBCT**

- **Existing Denture, Patient, and Anatomical**

- **Final Inclusion and Exclusion Criteria determined**

- **VAS on pain & quality of life questionnaires**

- **Randomization**: Random number generator (Microsoft Excel) places subject in
  Group A or B.

  o **Group 1 ("Arm A").** Two 3i full Osseotite internal hex 4X11.5-13 mm
    dental implants in the mandibular canine area

  o **Group 2 ("Arm B").** Four IMTEC MDI Sendax1.8-2.2X10-13 mm,
    collared thread design, O-ball prosthetic head, mini dental implants placed
    in the interforaminal region

**Appointment 2:**

**Implant surgery and lower denture modification**

**Surgical Forms and Summary completed:**

- o Amount and type of local anesthesia: buccal, lingual, and crestal locals only

- o Sedation

- o Type of bone quality and quantity

- o Type, size, and location of implants

- o Amount of stability

- o Type of incisions, if needed

- o Degree of soft tissue closure

- o Type and number of sutures, if needed

- o Surgical complications

- o Amount and type of analgesics prescribed, if needed

- o Amount and type of antibiotics, if needed

- o Amount, duration, and frequency of chlorhexidine

- **Panographic radiograph**

- **Denture modification**

  - o Intaglio of denture relieved and relined with soft-reliner

  - o Occlusion and denture base checked and adjusted if necessary with articulating paper and PIP paste, respectively

- **Post-operation directions**

- **Denture care and usage instructions**

**Phone call 24 hrs after surgery:**

- Five point verbal scale ranging from 0 – 4 (0=no pain, 1=mild, 2=moderate, 3=severe, and 4=worst pain ever experienced)

**Appointment 3:**

**1 week post-operation**

- **Removal of sutures if needed**

- **Post-operation directions**

- **Denture care and usage instructions**

- **Occlusion and denture base checked and adjusted if necessary**

- **Questionnaire:**

  - Pain experiencing, pain experienced, and pain medication usage, effectiveness, and side effects at 1 week post-op on VAS scale

- **Clinical evaluation:**

  - Swelling, ecchymosis, infection, wound healing on VAS

  - Pain medication effectiveness on VAS

  - Other complications recorded

**Appointment 4:**

**3 week post-operation**

- **Removal of sutures if needed**

- **Post-operation directions**

- **Denture care and usage instructions**

- **Occlusion and denture base checked and adjusted if necessary**

- **Questionnaire:**

  o Pain experiencing, pain experienced, and pain medication usage,

    effectiveness, and side effects at 1 week post-op on VAS scale

- **Clinical evaluation:**

  o Swelling, ecchymosis, infection, wound healing on VAS

  o Pain medication effectiveness on VAS

  o Other complications recorded

**Appointment 5 (for Group 1 only):**

**3-month second stage implant surgery and additional lower denture modification**

- **Surgical Forms and Summary completed:**

  o Amount and type of local anesthesia: buccal, lingual, and crestal locals only

  o Type of incisions, if needed

  o Type and number of sutures, if needed

  o Implant torque test to 35Ncm

    - Implant(s) not integrated, implant removal

    - If implant failure additional implant(s) placed depending on patient's

      desires

  o Size of healing abutment

  o Amount and type of analgesics prescribed, if needed

  o Amount and type of antibiotics, if needed

  o Amount, duration, and frequency of chlorhexidine

- **Panographic radiograph**

- **Denture modification**

  - Intaglio of denture relieved and relined with soft-reliner

  - Occlusion and denture base checked and adjusted if necessary with articulating paper and PIP paste, respectively

- **Post-operation directions**

- **Denture care and usage instructions**


**Appointment 6:**

**4 month Mandibular denture conversion to mandibular retained overdenture**

- **Peri-implant evaluation**

  - Probing depth

  - Plaque index

  - Gingival index

  - Bleeding index

- **Implant prophylaxis**

- **Denture modification and housing placement**

  - Occlusion and denture base checked and adjusted if necessary with articulating paper and PIP, respectively

  - Rubber dam and/or block shims placed

  - Housings (2 or 4) placed

  - Occlusion and denture base checked and adjusted if necessary with articulating paper, PIP, and/or bite registration material

- Acrylic vent holes placed on lingual

- Vaseline coated on denture where new acrylic is not needed

- Cold cure/hard reline adhesive where new acrylic is needed

- Cold cure/hard reline placed

- Patient lightly occludes for 10 minutes

- Excess acrylic removed and denture polished

- Occlusion and denture base checked and adjusted if necessary with articulating paper and PIP, respectively

- Denture care and usage instructions


**Appointment 7, 8, 9, 10, and 11:**

**Long-term follow-up (6, 12, 24, 36, 60 months)**

- **Quality of Life Questionnaires:**

  - After implant placement regarding your satisfaction with your lower and upper denture.

- **Panographic radiograph**

- **Denture modification**

  - Occlusion and denture base checked and adjusted if necessary with articulating paper and PIP paste and/or reline, respectively

- **Denture care and usage instructions**

- **Peri-implant evaluation**

  - Probing depth

  - Plaque index

- o Gingival index

- o Bleeding index

- **Implant prophylaxis**

**<u>Additional appointments</u>:**

**As needed for follow-up and/or adjustments to the implants or dentures**

**Publishing Agreement**

*It is the policy of the University to encourage the distribution of all theses, dissertations, and manuscripts. Copies of all UCSF theses, dissertations, and manuscripts will be routed to the library via the Graduate Division. The library will make all theses, dissertations, and manuscripts accessible to the public and wil preserve these to the best of their abilities, in perpetuity.*

**Please sign the following statement:**

*I hereby grant permission to the Graduate Division of the University of California, San Francisco to release copies of my thesis, dissertation, or manuscript to the Campus Library to provide access and preservation, in whole or in part, in perpetuity.*

_____          08. 29. 2011

Author Signature                                                        Date