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The efficacy of standard and mini-dental implants for mandibular tissue-supported implant retained overdentures

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

by

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THESIS

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Section I

Introduction:

Synopsis:

People who wear full mandibular dentures often experience difficulties with retention, stability, support, mastication and comfort. This causes them to forego use of the denture. With the advent of the osseointegrated dental implant, many of these issues can now be addressed. When the patient desires more retention, two dental implants in the front of the lower jaw can be used to support 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 preventing dislodgment and movement and improving the chewing efficiency of the denture.

Twenty years ago, a miniature-sized dental implant (mini-dental implant) was developed. In the last 5 years, the use of the mini-dental implant (MDI) for denture support has gained acceptance because they may afford the denture wearer several advantages. In most cases the MDI can be placed without reflection of a mucoperiosteal flap, which may cause less post-operative discomfort. Also MDIs can be restored immediately, which may decrease appointment time and cost. Another advantage is that the cost of materials and surgical expenses are significantly less.

Purpose:

The purposes of this clinical study are to: (i) evaluate the differences in clinical success and quality of life when comparing, within the same patient, full lower dentures without dental implant support to those supported by standard-sized dental implants (SDI, the current gold standard) or mini-dental implants (MDI) and after implant placement; (ii) compare the efficacy of standard dental implants and mini-dental implants in their clinical success and contribution to quality of life (iii) compare the pain anticipation and pain experiences prior to, during, and after surgery between standard dental implants and mini-dental implants; and (iv) evaluate effectiveness of pain-control regimens in relieving pain during and after surgery. The null hypothesis of this research is that there will be no difference in long-term clinical success, quality of life, pain anticipation, experience and control between standard dental implants and mini-dental implants placed in the interforaminal region of the anterior mandible. The alternate hypothesis of this research is that there will be differences in long-term clinical success, quality of life, pain anticipation, experience and control between standard dental implants and mini-dental implants placed in the interforaminal region of the anterior mandible.

Section 2:

Literature Review:

Note: In the Literature review following, it is assumed that the implants referred to in individual studies are SDIs, unless otherwise prefaced.

Implant Overdenture Background:

It is widely accepted by both dentists and patients that implant supported/retained mandibular complete prostheses are a significant improvement over conventional removable dentures. The implant prosthesis improves retention, stability, and support in comparison to conventional removable dentures. There are different types of full arch implant prostheses that can be treatment planned. The two main categories of implant prostheses for a full arch rehabilitation are fixed (non-removable) or removable.[1]

The mandibular fixed full arch prosthesis requires an adequate number of implants of sufficient size with enough anterior- posterior spread that cannot be removed by the patient. A fixed prosthesis may be placed on 4 or more implants, and successful long-term results for implant-retained fixed prostheses have been well documented in the literature by several authors.[2-5] 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.[3, 6-15]

The removable full arch 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.[1]

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.[1]

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, but the denture rests on the mucosal tissue in the posterior. 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.[1]

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.[1]

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 mm),

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

When original root-form implants were introduced, they had a diameter of about 3.75 millimeters. An implant of 4 mm in diameter requires at least 1 mm of bone in the buccal and lingual dimension for placement, which means a 4 mm implant would require at least 6 mm of bone in the buccal/lingual dimension. If there is less than six millimeters of bone, additional procedures need to be done either during or in a staged procedure such as particulate bone grafting with or without membranes, ridge expansion, ridge splitting, block grafting, and/or osteoplasty/alveoplasty to allow the placement of the regular diameter implant.

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

diameter (3 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. [16] However, these implants still need approximately 5 mm of bone, which is often not available clinically. 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).

Mini Diameter Implants and Supported Overdentures:

Over the last several years, implants ranging from approximately 1.8 mm to 2.5 mm in diameter have been promoted for use in long-term clinical situations. In 1997, IMTEC (Ardmore, Okla.), which makes the Sendax MDI, received FDA approval for intra-bony and intra-radicular fixation. The first company that received FDA approved for long-term use was IMTEC for Sendax MDI and MDI Plus, in August 2003. In 2004 and 2007, the Dentatus Company and the Intra-Lock mini implant also received approval, respectively.

Historically, mini diameter implants were used successfully to temporarily support or retain fixed and/or removable provisional prostheses while standard implants were integrating, and hence they were thought of as "transitional"[17, 18] The intention was to remove the mini-implants when the larger-diameter implants were fully integrated, 4-6 months later. When the mini-implants were attempted to be removed however, the clinicians found that the mini-implants were also integrated and could not be easily

removed.[17, 18]

Balkin and co-workers (2001) reported the clinical and histological results of two cases demonstrating retrieved MDI (IMTEC Corp.) in two patients. One case was used for a fixed prosthesis while the other was for a removable prosthesis. The MDIs were inserted using the auto-advance technique and loaded immediately. 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, it was shown that bone was in juxaposition to the surface of the implant ("osseointegrated"), and the bone was relatively mature and healthy.[19]

In a prospective study by el Attar and co-workers (1999), twelve edentulous patients received two standard sized implants in the mandibular canine region. At the time of surgery, six patients had two mini-transitional implants placed medially to the standard implants and six patients served as controls. The results of the study indicated that MTIs integrated and provided successful immediate support for the transitional prosthesis and did not interfere with mucosal healing. Two MTIs showed mobility at three months. After loading the standard implants, the two groups had similar bone levels.[17]

In a study by Ahn and co-workers (2004), they reported on 27 mini-implants that were placed to support 11 mandibular complete dentures during integration period of standard diameter implants. According to their protocol, two implants were used to support a

removable implant-retained tissue supported overdenture or 3 to 4 implants were used for 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. During placement one implant fractured due to forceful advancement in very dense bone. During the average of 21 weeks of function, 26 of the 27 mini-implants remained stable. The mini-implants did not demonstrate bone loss and they 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.[18]

Griffitts and co-workers (2005) reported on the efficacy of mini- implants to retain a mandibular implant-retained overdenture. A total of 30 patients were included in this MDI (IMTEC Corp., OK) study. 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 (1=poor and 10=excellent). Another purpose was to analyze success rates, financial impact, and surgical protocol. Each patient received 4 MDIs in the interforaminal mandible. Five months postoperatively, self-reporting questionnaires were sent to the patients. A total of 116 MDIs were placed and113 remained stable, a 97.4% implant success rate. Before implant placement, patients rated their retention at 1.7±0.42 and after MDI placement at 9.6±0.37 (difference of 7.9). Comfort was also improved from 2.2±0.63 to a post-operative rating of 9.4±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. Limitations to this study, however, include the short follow-up period and lack of a control group.[20]

In a multicenter (5 clinics) retrospective study, Bulard and Vance (2005), performed a biometric analysis of the success of 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 long-term prosthesis stabilization.[21]

Mini-implants have also been used to support fixed prostheses. Güler N and coworkers (2005), in a case report on a 15-year-old female with Hypohidrotic Ectodermal Dysplasia was successfully rehabilitated with an implant-retained fixed prosthesis on four MDIs in the mandibular anterior.[22] Flanagan (2006) also presented a case report of a splinted-fixed FPD #24 to #25 on two 1.8 mm X 15 mm MDIs with 2 years of function.[23] Siddiqui and coworkers (2006) presented a case report of two 2.4 mm X 15 mm MDIs to replace #22 and #27 with single units.[24] In a 5-year case series article, Mazor and coworkers (2004), reported on 32 mini-implants that were immediately loaded and restored.[25]

Two widely used mini-implants include MTI (mini-transitional implant from Dentatus) and MDI. Kanie and co-workers (2004), investigated the mechanical and physical properties of these two implants, including flexural properties, surface imaging by SEM with EDX, x-ray analyses were performed. 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 2 devices have similar shapes and dimensions; however, their properties and clinical applications differ.[26]

Mini-implants have shown to integrate and provide adequate soft tissue health. Glauser and coworkers (2005), histologically studied the 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 12 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.[27]

Mandibular Tissue-Supported Implant Retained Overdenture Success:

The mandibular implant retained overdenture has broad acceptance, but has only been investigated with longitudinal studies since 1987.[28] Several authors have reported implant success when using two implants to retain a mandibular overdenture over a five year period.[29-32] One of the first to suggest the use of two implants in the edentulous mandible was van Steenberghe et al with a 98% success rate with up to a 52 month observation.[29]

In a five-year longitudinal study by Mericske-Stern R and coworkers (1994), reported 97% implant survival with 2 implants, irrespective of keratinized tissue, duration of edentulism, or superstructure. In this study, sixty-six ITI implants were placed in edentulous mandibles of thirty-three 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 surrounded by keratinized tissue. Irrespective of adequate or inadequate keratinized mucosa, the peri-implant mucosal tissue was maintained healthy with probing depths averaging approximately 3 mm. 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. They concluded that advanced age, reduced dexterity, and 2 implants with ball or bar overdentures do not represent a higher risk for the development of peri-implantitis or implant failure.[30]

In a five-year multicenter prospective study, Jemt and coworkers (1996) followed a total of 103 patients that received 393 implants in the edentulous mandible. This study included nine worldwide centers with the same protocol. According to their protocol, four mandibular implants were placed, but 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 5-year observation.[31]

In a five-year prospective randomized clinical trial by Naert and coworkers (1999), they reported on 36 fully edentulous patients with 72 implants placed and randomly divided into three groups according to the attachment system they received: 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.[32]

Treatment Considerations for the Mandibular Overdenture:

Number of Implants for the Mandibular Overdenture:

In the following situations, the need for more than 2 implants to retain a mandibular overdenture has been recommended: [28]

- 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

In a study by Meijer and coworkers (1994), they found that 4 implants in the anterior mandible does not seem to reduce implant stresses compared to 2 implants in the anterior mandible.[36]

Batenburg and co-workers (1998) observed no significant differences in peri-implant health between a 2 implant group and a 4 implant group. The aim of their prospective study on sixty edentulous patients was to study the effect of the number of implants supporting a mandibular overdenture on the condition of the peri-implant tissues. Thirty patients were treated with overdentures supported by two implants in the anterior region of the mandible (group A) and thirty patients with overdentures on four implants in the anterior region of the mandible (group B). Standardized clinical and radiographic evaluation was performed 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 of the study concluded that there seems to be no need to insert more

than two implants to support an overdenture.[35]

In the follow-up study by Visser and coworkers (2005), they reported on the same subjects in a five-year prospective comparative study evaluating treatment outcome of mandibular overdentures supported by two or four implants. Standardized clinical and radiographic parameters were evaluated 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, group A had a greater need of prosthetic care; alternatively, group B 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.[36]

In a study by Mericske-Stern (1990), evaluating 67 patients divided into 3 different groups (29 subjects with two implants and a bar, 27 subjects with ball attachments, and 11 subjects with three or four implants and a bar), Mericske-Stern found that occlusal equilibration, retention, and stability of overdentures improved only slightly with increasing the number of implants. Mericske-Stern also reported on the need for keratinized gingiva. In the study population, attached keratinized gingiva (greater than or equal to 2 mm) surrounded approximately 48% of the buccal and 55% of the lingual

implant sites. The conclusion after 6 to 66 months postoperatively suggests that two implants may adequately serve as retention for a mandibular overdenture and that attached gingiva surrounding the implants does not seem to be prerequisite for healthy function.[37]

According to several authors masticatory forces does not seem to differ between the tissue-supported implant overdenture and implant-supported overdenture when opposing a conventional maxillary denture.[38-41]

Fontijn-Tekamp and coworkers (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 prosthese: 1) implant-supported overdenture, 2) tissue-supported implant overdenture on two implants, or 3) 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 conclusion was that tissue-supported overdenture and 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.[38]

In a within-subject crossover clinical trial by van Kampen and coworkers (2004), they examined the hypothesis that greater retention and stability of the overdenture will

improve masticatory function. Eighteen edentulous subjects with 2 implants had 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.[39]

Splinted or Solitary Anchorage Design:

Several authors have stated that it is appropriate to use 2 implants with a round or ovoid bar parallel to the hinge axis and a resilient overdenture.[40-43] The aim is to enhance free rotation during loading and decrease twisting load to implants. Other authors have reviewed mandibular overdenture treatment modalities and have found that these concepts are based on empirical data.[44] The choice of attachments for the mandibular overdenture include but no limited to the following parameters: patient retention, support, stability needs, jaw morphology and anatomy, and compliance to hygiene and maintenance recalls.[28]

In a randomized clinical trial by Naert and coworkers (1997), they studied whether there is a need or 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.[43] Overloading of the implants retaining an overdenture might be more influenced by the superstructure fit and occlusion, rather than the anchorage.[45]

Both solitary attachments and bars have advantages and disadvantages. The solitary attachment is less costly, easier to restore, [46] easier to clean, [47] and causes less gingival hyperplasia.[48] However, bars have greater retention.[49] With regards to maintenance requirements, controversy still remains whether solitary attachments or bars require more maintenance.[50-52]There are several reports of complications with 2 implants retaining an overdenture. The census of many 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). [50-60]

Implant Loading Periods:

A healing period of three to six months is recommended for conventional implant loading. Immediate implant loading has been defined as loading within 24-48 hours after placement. Early loading has been defined as loading in less than 14 days, within the

first 35 days, or within the first 6 weeks after placement. 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). 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.[61]

There are several different loading modes: [62]

- Submerged: flush or subcrestal to 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.[63-68] In a prospectively clinical trial by Chiapasco and Gatti (2003), they studied the survival and success rates of 328 implants (164 Ha-Ti, Mathys Dental, Bettlach, Switzerland; 84 ITI Dental Implant System, Straumann Institute, Waldenburg, Switzerland; 40 Brånemark Conical, Nobel Biocare AB, Gothenburg, Sweden; 40 Frialoc, Friatec, AG Mannheiti, Germany), three to eight-

year after placement in the interforaminal area of edentulous mandibles and immediately loaded overdenture. 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. However, there was a moderate decrease in success rates of implants after longer observation times (88.8 and 90.4% after a seven- to eight-year observation period for Ha-Ti and ITI implants) .[64]

In a 5-year prospective clinical trial by Cooper and coworkers (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 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.[65]

In a prospective evaluation of the early loading of non-splinted Brånemark implants by Payne and coworkers (2001), evaluation of progressive and early loading of 20 unsplinted implants in edentulous mandibles restored with overdentures was studied.

They evaluated ten edentulous patients with 2 implants placed in the anterior mandible with mandatory primary bicortical stability. The ball abutment was placed immediately and the mandibular dentures were temporarily relined with tissue conditioner and worn for the first 2 weeks to allow progressive loading. After 2 weeks, early loading of the implants with solitary attachments and definitive reline was completed. All patients functioned with their mandibular implant overdentures from 2 to 52 weeks postoperatively, however, 40% of the patients had difficulties with the peri-implant mucosa between surgery and 2 weeks after the surgery. They concluded that early loading of non-splinted implants with mandibular overdentures is successful over a 1-year period.[67]

Turkyilmaz and coworkers (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 that time of implant placement without the mandibular denture contacting the healing abutments. During the first 2 years, there was 100% implant success. Clinical and radiographic parameters showed no statistically significant differences between the groups. They concluded that the early loading approach does not effect peri-implant soft tissue, marginal bone resorption, or implant stability.[68]

Anterior and Posterior Mandibular Bone Preservation:

When patients wear a conventional complete denture, there will be alveolar ridge height

reduction over time.[28] In articles presented by Atwood and coworkers (1971) and Tailgren (1972), they both showed an average annual alveolar ridge height reduction of approximately 0.4 mm in the edentulous anterior mandible.[69-70] Implants in the anterior mandible have been shown to increase positive bone remodeling.[28]

In an article by von Wowern and Gotfredsen (2001), they observed load-related positive bone remodeling in the anterior mandible due to the increased function of the alveolar bone when implants were placed. In this five-year study, they placed 2 Astra Tech implants in the mandibular canine area of 22 long-term edentulous (18 women and 4 men from 54 to 78 years of age) patients. Eleven patients received a bar and 11 received ball attachments. Alveolar bone height of the implants was measured on periodically identical intraoral radiographs. They concluded that the implants, which increased function, seem to cause a load-related bone formation that minimizes the physiologic age-related mandibular bone mineral content (BMC) loss. This effect seems to be independent of attachment system.[71]

Several other studies have demonstrated that, on average, anterior mandibular bone may resorb 0.5 mm over a five-year period and long-term resorption usually remains at 0.1 mm annually when the prosthesis is a mandibular implant overdenture.[31, 72-73]

The implant retained overdenture may promote positive bone remodeling and at least impede the negative bone remodeling associated with a conventional complete

mandibular denture; however, the resilient overdenture design may cause posterior mandibular resorption.[28] In a study completed by Jacobs and coworkers (1992), they discovered a two to three fold annual mandibular posterior ridge resorption with implant overdentures compared to a complete denture when patients were edentulous for less than ten years.[74]

In the Jacobs and coworkers (1992) study, three groups of patients with different prosthetic reconstructions were studied as follows: mandibular overdentures supported by two implants connected by a bar (30 patients), mandibular fixed prostheses supported by four-six implants (25 patients), and mandibular complete dentures without implant support as controls (85 patients). The primary aim of this study was to examine on orthopantomograms posterior mandibular ridge resorption differences in the three treatment groups. They found minimal posterior mandibular ridge resorption in patients with fixed implant-supported prostheses. When comparing fixed to removable, were was considerable posterior ridge resorption observed in the complete denture group and overdenture group. For the overdenture group, the annual posterior jawbone resorption after the post-extraction remodeling period of six months, was two- to three-fold that of full denture wearers. However when patients were edentulous for more than 10 years, the difference between the three groups disappeared.[74]

Other researchers have found that fixed implant complete denture may regenerate posterior mandibular bone.[75] In a study by Davis and coworkers (1999), they quantified

the changes in bone height of the posterior edentulous mandible when the denture is supported entirely by implants placed in the anterior. In this study 33 patients with a follow-up visit at least three years later and a mean of 6.6 years were analyzed using panoramic radiographs to measure height in the premolar area. Most subjects showed increases in bone height of 87.9% on the right and 84.9% on the left. The mean change in all subjects was +1.0 mm with a range of -0.8 to +3.3 mm. There was a statistically significant increase bilaterally ($P < .001$) when comparing mandibular height at implant placement to follow-up. They concluded that dentures that are supported totally by implants in the mandibular anterior conserve and may enhance posterior mandible bone height.[75]

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. 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.[28]

Effect of Mandibular Implant Prosthesis on the Maxillary Arch:

Combination syndrome has been reported when a mandibular overdenture opposes a complete maxillary denture.[76-79] Combination syndrome is still considered controversial; however, mandibular overdenture can transfer occlusal forces to the anterior maxilla, and the occlusal forces may cause maxillary soft tissue inflammation and alveolar bone

resorption.[28]

In a study by Barber and coworkers (1990), they studied fifteen edentulous patients that were restored with conventional maxillary dentures opposed by implant-supported removable prostheses. After two to four post surgery, patients were evaluated for maxillary bone loss using radiographic analysis. The findings indicate that vertical bone loss in the anterior maxilla occurs when a maxillary denture is opposed by an implant-supported overdenture, which is similar to complete maxillary denture opposed natural mandibular anterior teeth and a distal extension removable partial denture.[76]

In a study conducted by Jacobs and coworkers (1993), they used radiographs to examine anterior and posterior maxillary ridge resorption in three groups of patients with different mandibular prosthetic reconstructions. The groups were overdentures supported by two implants, fixed prostheses supported by four to six implants, and complete dentures. Their results indicated more annual bone resorption in patients who wore complete dentures compared to both groups with implant-supported prosthesis. They also found that limited and continuing bone resorption was observed for the patients with implant-supported overdentures with a slightly higher annual maxillary bone resorption occurred in the implant-supported fixed prosthesis group.[77]

In a study by Lechner and Mammen (1996), they evaluated thirteen patients who had worn a maxillary conventional denture and mandibular implant-supported overdenture

for at least three years. Their findings support the view that this combination of prostheses can result in effects similar to combination syndrome such as perceived loosening of the conventional maxillary denture, loss of posterior occlusion, increased anterior occlusal pressure, and anterior maxillary bone loss.[78]

In a six year randomized prospective study by Närhi and coworkers (2000), they studied how complete denture, transmandibular prosthesis, and single bar overdenture effects the edentulous maxillary ridge and subjective complaints with maxillary complete dentures. Fifty-five subjects were randomly assigned into three groups treated with the following: implant-supported overdentures on a transmandibular implant system (n = 21), implant-mucosa-supported overdentures on two implants (n = 20), or conventional complete dentures (n = 14). The occlusal scheme included a lingual contact occlusion concept with anterior open bite. There was significant reduction in the width of the ridge found in all measurement areas (mean difference = 0.4 to 0.6 mm; P <.0001). These changes were small and not associated with the type of prosthetic restoration. They also found that the complaint of loose maxillary denture was correlated with the reduction of residual ridge width. They concluded that, with time, residual ridge width decreases regardless of the type of mandibular prosthesis.[79]

The occlusal scheme is important to preserve maxillary alveolar bone and several authors have recommended minimal anterior contact during excursive movements and no anterior contact in centric relation position.[80-83] It is also recommend that the patient has regular

recalls to evaluate proper occlusal plane and extension base fit, which may decrease maxillary denture relines.[80]

Problems with the maxillary prosthesis can also occur such as midline fracture of maxillary denture, loss of maxillary denture fit, and need for maxillary denture reline.[84] Maxillary denture relines may be needed in the range of 25% to 33% of the time over a five-year period.[85, 86]

Chewing Ability, Chewing Efficiency, and Bite Force:

In a study by Haraldson and coworkers (1988), nine subjects treated with mandibular implant overdentures were functionally evaluated before and one year after treatment. The bite force 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 to 24.0 N, biting as when chewing increased from on average 24.0 N to 38.7 N, and the maximal bite force increased from on average 74.6 N to 131.5 N. Their chewing efficiency improved from Ci = 4 (Median value) to Ci = 2.8 (Median value). It was concluded that treatment with an overdenture supported by implants in the mandible improves oral function compared to a mandibular conventional denture.[84]

In a within-subject crossover clinical trial by Feine and coworkers (1994), they studied 145 completely edentulous subjects wearing implant-supported mandibular fixed

prostheses and long-bar overdentures to test the hypothesis that fixed prostheses are more efficient implant-supported devices than removable types for edentulous patients. After a two-month adaptation period, they found that the long-bar overdenture appears to be no less efficient than the fixed prosthesis, and patients are capable of adapting to the different prostheses.[87]

Quality of Life:

Problems with Conventional Mandibular Dentures:

Treatment success is determined by more factors than the survival of the implants and restorations. Success is also determined by peri-implant, radiographic parameters, and prosthetic maintenance problems. In addition to clinical outcomes, one of the most important factors in patient treatment is patient satisfaction.

A complete mandibular denture can be hard for the patient to handle. One of the reasons is that a mandibular residual ridge supporting and stabilizing a complete denture provides less than one-quarter of the chewing ability of the natural dentition even with an adequate residual ridge; however, many patients expect the denture to be equivalent their natural dentition in terms of function, esthetics, and comfort.[88]

After the teeth are extracted and a denture is constructed there is unpredictable resorption and remodeling of the residual ridge supporting a conventional denture which will continue over time, [70] resulting in problems with stability, support, and retention of the

denture and problems with the patient's satisfaction and quality of life (QOL). In addition to wearing a denture the loss of teeth can cause permanent and intense disturbances to the patient's psychological health such as disgrace, secrecy, and decline in self-confidence and self-image.[89]

Edentulism can be disabling within the context of appearance, appetite, eating, general health, mood, recreation, weight, and work.[90-91] Eating is difficult for most people who wear conventional dentures. There are also some denture patients that avoid public eating 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 dependant 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.[92]

People want to replace missing teeth and improve QOL when physical pressures such as difficulty to chew foods becomes increasingly evident. In addition, people are motivated to replace missing teeth due to social pressures such as cosmetic reasons that affect self-esteem or self-confidence.[88]

Comparing Implant Overdentures to Conventional Complete Dentures:

Edentulism effects patients and their QOL in at least 4 different dimensions: 1) psychological health, 2) socioeconomic status, 3) life satisfaction, and 4) self-esteem. 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.[88] Socioeconomic status is impacted by edentulism. The edentulous patient is more likely to from a lower economical background because they more often are unable to cope with the financial burdens that health problems invariably incur.[93] 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 QOL.[88] When comparing patients who have implant supported or retained dentures with patients that wear conventional dentures, the implant patients have a higher QOL than patients with conventional dentures, and their higher QOL may be due to the implant prosthesis feeling like a part of their body.[94]

For patients, the three most important qualities of complete dentures are comfort, stability, and ability to chew. Other qualities include esthetics, speech ability, and ease of cleaning.[95] Patient satisfaction and QOL is directly related to those six qualities. Patient satisfaction is an outcome measure that describes the patient's valuation of a specific aspect of treatment. Patient satisfaction is measured using self-administered

questionnaires. For scaling or quantitative purposes, questions are either coupled with multi-step answer categories (Likert scales) or visual analog scales (VAS). [96]

Patient dissatisfaction with complete dentures has been a problem 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.[97-100]

Many authors have addressed patient satisfaction with implant overdentures.[14, 32, 48, 97, 101-116, 118, 125] In Awad MA and coworkers (1998), [97] the aim was to investigate the relationship between patients' ratings of general satisfaction and their perceptions of different aspects of mandibular prostheses. Their methods included 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 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). They concluded that patient satisfaction is highly dependent on gender, appearance, and functionality of the denture.[97]

In another study by Awad MA and coworkers (2000), [101] the aim was to investigate the importance of assessing the impact of treatments for chronic conditions such as edentulism on an individual's quality of life. They also studied oral-health-related quality of life, measured with the Oral Health Impact Profile (OHIP) reported and validated by Slade and Spencer.[117] Their methods included one hundred and two subjects in a randomized controlled clinical trial comparing new conventional dentures (n=48) and implant prostheses (n=54). 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 may suggest that implant prostheses provides a short-term significant improvement compared to conventional dentures in oral-health-related quality of life.[101]

In Boerrigter EM and coworkers (1995),[102] they compared denture chewing ability and satisfaction of edentulous patients treated with implant-retained overdentures or with complete dentures with or without previous preprosthetic surgery. In this randomized controlled clinical trial, thirty-eight men and 52 women were assigned to the three treatment modalities with a 21 (16 to 25 mm) mm mean height of the anterior mandible.

The main outcome measures were chewing ability and denture satisfaction, which were assessed using questionnaires. Their results show that based on the baseline data from denture complaints, overall denture satisfaction, and chewing ability questionnaires, at the one-year evaluation five out of seven factors showed significantly better scores for the implant-retained overdentures and with preprosthetic surgery groups than for the control group. They concluded that at the one-year evaluation implant overdentures or complete dentures constructed after a vestibuloplasty and deepening of the floor of the mouth provide a more denture satisfaction than complete dentures. In addition, the overdenture group showed a significantly better score than the preprosthetic surgery group.[102]

Raghoebar GM and coworkers (2000), [103] followed up on the long-term data initially presented by Boerrigter EM et al 1995. The purpose of this study was to compare denture chewing ability and satisfaction of edentulous patients treated with implant-retained overdentures or with complete dentures with or without previous preprosthetic surgery at five years post treatment. At five years post-treatment, the positive effects of preprosthetic 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.[103]

In a randomized clinical trial, Awad MA and coworkers (2003),[107] studied middle-aged subjects (35 to 65 years) that were assigned to two groups that received either a mandibular conventional denture (n=48) or an overdenture with two implants splinted with a bar (n=54). Patients used a VAS to report their general satisfaction and other features of their original dentures and their new prostheses prior to treatment and two months post delivery. 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.[107]

In a similar randomized clinical trial, Awad MA and coworkers (2003),[108] studied 60 elderly edentulous patients (65 to 75 years) that received a maxillary conventional denture along with either a mandibular conventional denture (n=30) or a two-implant overdenture with ball attachments (n=30). Patients used a VAS to report their general satisfaction and other features of their original dentures and their new prostheses prior to treatment then at two and six months post delivery. 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 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.[108]

Feine and coworkers (1994),[111] reported on a within-subject crossover clinical trial with fixed and long-bar removable implant-supported mandibular prostheses. Fifteen subjects were randomly divided into two groups. One group received the fixed prosthesis first and the other received the removable prosthesis first. After a two-month adaptation period, psychometric measurements of various aspects of the prostheses and physiological tests of masticatory efficiency were completed. The prostheses were then changed, and the procedures repeated. At the end of the study, subjects chose the prosthesis they wished to keep. Eight subjects chose the fixed and seven chose the removable. Both groups rated stability and ability to chew significantly better with the fixed prosthesis. The removable group rated ease of cleaning as the most important factor, followed by esthetics and stability. The fixed group considered stability to be the most important factor, followed by chewing ability and ability to clean. There was a tendency for the removable to be chosen by older subjects (greater than 50 years). These results suggest that the chose of fixed or removable implant-supported prostheses is for patient specific reasons, and that patient's preferences and attitudes need be considered.[111]

de Grandmont P and coworkers (1994),[112] reported on a within-subject crossover clinical trial with fixed and long-bar removable implant-supported mandibular prostheses. Fifteen subjects were randomly divided into two groups. One group received the fixed prosthesis first and the other received the removable prosthesis first. After a two-month adaptation period, psychometric measurements of various aspects of the prostheses and

physiological tests of masticatory efficiency were completed then the prostheses were changed, and the procedures repeated. Using VAS and category scales, patients reported significantly higher scores to both types of implant-supported prostheses than to their original conventional denture; however, no statistically significant differences between the two implant-supported prostheses were detected except for the difficulty chewing harder foods. These results suggest that there is no difference in general satisfaction between fixed and removable prostheses, although patients find the fixed prosthesis to be significantly better for chewing harder foods.[112]

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 and QOL with Preferences and Expectations:

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.[118] 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.[119-124]

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. These preferences should be based on the risks, benefits, and alternatives to treatment. These preferences may impact the patient's satisfaction with treatment and impact their QOL.[125]

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. Patient preferences on satisfaction level and QOL may not be the same based on several issues such as patient expectations.[125]

Patient expectations of the outcome may play an important role in their preferences.[126] 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.[125] Lick et al attempted to explain the mechanism by which expectations can affect the treatment outcome, which includes the following: 1) trigger of a physiologic response, 2) motivation to achieve a better outcome, 3) psychological patient conditioning to observe certain symptoms and ignore others, and 4) changing of

conceptions about the disease.[127]

Patients with positive expectations of treatment tend to ignore adverse symptoms and focus on apparent improvements following therapy.[126] For example, if an edentulous patient expects an implant-supported prostheses to be superior to a complete conventional denture, the patient has realistic expectations. Another example of patient expectations is pain experience during implant surgery. If the patient experiences a high level of anxiety toward the implant placement, the patient could be more sensitive to pain and focus on unfavorable symptoms during and/or after implant surgery. Alternatively, 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.[125]

Pain:

Few articles have reported on the pain experienced during and following implant placement.[128-132] Hashem AA and coworkers (2006),[128] studied pain experience and anxiety following dental implant surgery using questionnaires. Before implant placement, patients kept diaries to assess pain experienced and to record average pain, worst pain, and interfering with activities on a visual analog scale (VAS). Thirty implants were placed in 12 women and six men (18 patients total). On the day of surgery anxiety was highest. After implant placement, most patients reported mild to moderate interference

with daily activities and postoperative pain with no one reporting high levels of any symptoms. Average pain experience decreased significantly with time ($P < .001$), from a VAS score of 24/100 (day 1) to 12/100 (day 3) and 9/100 (day 6). The patients experienced the worst pain ($P < .001$) and highest limitation of daily activities ($P < .001$) on the first postoperative day. By the second or third day postoperative day, pain decreased to about half the maximum level experienced. They concluded that implant surgery is a mild to moderately painful and anxiety-provoking procedure as reported by self-assessment. During the first three postoperative days, patients should expect limitation of daily activities and mild to moderate symptoms.[128]

González-Santana H and coworkers (2005)[129] investigated pain and swelling in the first week after dental implant placement. Forty-one patients (17 males and 24 females) received a total of 131 implants placed under local anesthesia. Pain was scored by means of a verbal and visual analog scale (VAS) and swelling was evaluated by a verbal scale. Most patients who experienced pain reported slight pain. The pain peaked 6 hours after the implant surgery in about 40% of cases. Peak intensity of inflammation was recorded after 48 hours in about 50% of cases with moderate swelling in most patients who reported pain. They observed a significant association between swelling and older patients, placement of more than four implants, and surgery combined with sinus lifts or bone grafts. Posterior implant placement caused greater swelling. Swelling was also greater in completely edentulous patients. Single implant placement between adjacent teeth caused the least inflammation. In conclusion after implant placement, pain

experienced tends to be mild with moderate inflammation.[129]

Eli I and coworkers (2003)[130] examined the inter-relationship between anxiety and pain perception during implant placement. They studied 60 patients who were scheduled for implant placement in a private clinic. Patients completed anxiety and pain VAS questionnaires on three occasions immediately preoperatively (T1), immediately post-operatively (T2), and at four weeks post-operative follow-up (T3). Patient pain and anxiety were highest immediately before the surgical procedure (T1), which significant decrease immediately afterwards (T2). The best predictor of the patient's pain evaluation at each time point was their state of anxiety at that time (T1: $P < 0.001$; T2: $P < 0.001$; T3: $P < 0.005$). They concluded that pain experienced during and following implant placement is best predicted by anxiety at each time point.[130]

Al-Khabbaz AK and coworkers (2007)[131] investigated patient-reported pain during and following implant surgery in a prospective, two-center study. Implant placement was performed by an experienced periodontist or periodontal graduate students. Mean pain scores were evaluated with the use of a zero to ten scale during surgery. The same scale was used 24 hours and one, six, and twelve weeks following implant surgery. Two hundred and thirty-four patients received 510 total implants. Mean pain scores were highest at 24 hours after surgery (2.01 +/- 0.11) and then decreased gradually. The majority of patients had mild pain for at all time-points. A few patients had moderate to severe pain. Pain perception for individuals after one week was significantly correlated

with the severity of pain that the patient reported after 24 hours (OR = 38.69). Several factors were associated with pain such as surgical difficulty, female gender, operator experience, and early pain. They concluded that pain experienced by patients following implant placement was commonly mild, which slowly decreased with time.[131]

Pain Expectation and Anxiety:

Pain is a complex emotional and sensory experience that is associated with stress and anxiety.[130, 133-137] Implant placement causes high levels of anxiety that is related to the pain expected, experienced and remembered during treatment.[130] It has been shown that in a situation involving surgery, there is a significant increase in the subject's anxiety immediately before the surgery.[138] When a patient is anxious before treatment, the patient anticipates the treatment as painful.[139-146] In conclusion, anxiety is significantly associated with the subject's expectation of experiencing pain during the procedure.[130]

Section 3:

METHODS and MATERIALS

Selection Process and Study Population:

Twenty-one completely edentulous subjects were enrolled in a single-center, randomized case-controlled clinical study to compare four mini-dental implants (MDI, Imtec Corporation, Imtec Sendax MDI) or two standard dental implants (SDI, Biomet 3i, Osseotite Internal Hex). Subjects were selected from a list of patients that received full dentures from the San Francisco Veteran's Administration Dental Clinic (SFVADC) within a five period or presented to the SFVADC with complete dentures with a mandibular denture that could be converted to implant retained overdenture. Subjects were screened by telephone interview and those that were eligible and interested were appointed for a clinical and radiographic examination (Table 1). Male 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 2). The inclusion criteria required that participants have the following: recently made maxillary and mandibular complete dentures, mandibular dentures with adequate support and stability that were poorly retained, maxillary dentures with adequate retention, support and stability, with at least one month experience wearing the existing denture, ability to answer the questionnaires, no systemic diseases which could influence the outcome of therapy, good level of oral hygiene and denture care, compliance with the recall and maintenance program, presence of adequate bone quantity

and quality to support dental implants, and dental coverage at SFVADC. Volunteers were excluded from the study if they have the following: bleeding disorders and blood dyscrasias, uncontrolled Diabetes, history of bisphosphonate treatment (oral or IV), history of head and neck radiation, history of chronic hyposalivation or Sjögrens Syndrome, history of disorders affecting the structure and/or healing of the patients bone, or diminished capacity to provide consent.

All subjects received a verbal and written description of the study, including information about the two different implant systems, randomization, risks, and benefits. Informed consent was obtained from all subjects. Characteristics of the two groups are listed in Table 3. The study flowchart 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 Committee on Human Research.

Study Design:

The overdenture treatment was provided by modification of their adequate existing conventional mandibular denture.[110] 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.[112,147,148] Subjects were then randomly assigned (via random permutations, from an Excel spreadsheet) into one of two treatment groups.[147] After a two month period of adaptation,

with the implant retained mandibular overdenture, perception data for their conventional complete maxillary and implant retained mandibular overdenture was obtained using the same VAS based questions.[87,101,107,108,112,148] The same VAS data will be collected at six, 12, 24, 36, and 60 months after implant placement. [87,101,107,108,112,148] See the outline of appointments in Appendix 3 for additional details.

Surgical Procedures:

The surgical treatment was performed under local anesthesia by two periodontal residents (CS and PW) under the supervision of an experienced periodontist and implant surgeon (RN). Patients were anesthetized with 2 percent lidocaine with 1:100,000 epinephrine. Buccal and lingual soft tissue infiltrations followed by crestal injections were used. 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 7mm for the SDI group or 5mm 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 and 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 (Figure 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 11.5 to 13 mm. The surgical protocol for implant placement was performed according to previous research.[153, 154] The Biomet 3i "dense bone protocol" was used for the drilling sequence and implant insertion procedures. In brief, a pilot hole was drilled bilaterally approximately one millimeter from midline or in the area of the mandibular canines, 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. Tissue was closed with 5-0 vicryl and the intaglio surface of the patients denture relieved and relined with soft reliner in the area of the implant fixtures. Occlusion and denture base was checked and adjusted if necessary with articulating paper and pressure indicating paste (PIP), respectively. The patient was given detailed post-operative directions, denture care and usage instructions.

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. The surgical protocol for implant placement was performed according to previous research.[19] Both 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. Next, the plastic friction grip was used as a carrier and the beginning surgical driver. Then, the titanium finger driver was used until noticeable resistance was encountered by rotating clockwise and exerting apical pressure. 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 Ncm) was achieved. At the final stage of placement, the implant was turned ¼ to ½ turn clockwise with a waiting period of 15-30 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 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.

When the implant was delivered to the ideal apical position without significant stability, the implant was removed. Then the implant osteotomy was moved to the mesial or distal. The second osteotomy was prepared at approximately half the original depth or only crestal penetration depending on the amount of initial resistance.

All MDI implants were placed with significant (i.e., rock-like) 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 reliner per manufactures instructions. Occlusion and denture base was checked and adjusted if necessary with articulating paper and PIP, respectively. The patient was given detailed post-operative directions, denture care and usage instructions.

Postoperative Care:

All subjects received postoperative analgesia (Vicodin 5 mg/500 mg, q6h for 1 week, as needed for pain) and antibiotics (Amoxicillin 500 mg TID for 1 week). The subjects were instructed to 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 three times a day for 1 week, as needed for pain was substituted for Vicodin. 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, respectively.

Prosthodontic Procedures:

Introduction:

The accurate placement of the implant attachment into an overdenture is important for function, comfort, and tissue maintenance. If the overdenture is not accurately attached to the implants, excessive forces can be placed on the denture and implants causing 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 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[155] (Figure 1-24).

Prosthodontic Protocol:

The prosthodontic treatment was performed by two periodontal residents (CS and PW) under the supervision of an experienced implant prosthodontist (PK). The prosthodontic protocol for attachment placement and overdenture modification was performed according to previous research.[155] See Appendix 3 for additional details.

MDI retrofit:

The intaglio surface of the patient's denture was relieved by excavating an approximate 5mm hole that would allow the denture to be fully seated 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. An elastomeric shim (i.e., spacer) was cut to size and placed over the cervical half of the abutment while allowing the O-Ball half of the abutment to protrude uncovered. The shim was used 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 then placed over the implant fixtures with the keeper caps and shims in place to verify that clearance was completely passive by checking with PIP, articulating paper, and bite registration material. A vent hole was placed from the housing hole completely through the cameo surface of the denture to allow excess acrylic to escape when the housing was attached to the O-ball attachment. 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 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 seven minutes. 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.

SDI retrofit:

The intaglio surface of the patient's denture was relieved and relined with silicone reliner 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 with the lower denture for 3 weeks.

After the four month healing period, the cover screws were removed and the locator abutments of appropriate height were torqued to 25 N-cm. After the soft reline material was removed, 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 was used 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 then placed over the implant fixtures with the keeper caps and rubber dam in place to verify that clearance was completely passive by checking with PIP, articulating paper, and bite registration material. A vent hole was placed from the housing hole completely through the cameo surface of the denture to allow excess acrylic to escape when the housing was attached to the locator attachment. 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. 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 rubber dam pieces were removed. The black elastomers were removed and final elastomers were inserted according to the patient's desire of retention and finger strength. The final step of the retrofit was to check the denture with PIP and articulating paper.

The patient was instructed how to insert and remove the overdenture properly. The patient was told to demonstrate in front of a mirror that the denture could be inserted and removed properly. The patient also received oral hygiene and denture cleaning instructions.

Statistical Analyses:

Enrollment of 100 subjects was calculated for good statistical power to detect a difference between the four mini-dental implants and two standard dental implants groups in the following: (i) differences in clinical success and quality of life when comparing full lower dentures without dental implant support with lower dentures supported by standard dental implants (SDI, the current gold standard) or mini-dental implants (MDI) in the same patient before and after implant placement; and (ii) compare the efficacy of standard dental implants and mini-dental implants in their clinical success and contribution to quality of life. The statistician was masked to the group assignment until all subjects completed the data collection. Data were analyzed using the non-

parametric tests considering the small sample size,[156] and the mixed model considering the correlated data structure within each subject ($\alpha = 0.05$).[157] An effect size of 10 mm was used when analyzing the median differences between pre and post-implant variables regardless of group and median pre and post-implant within group variables as described previously.[112,148]

Results:

Out of twenty-three subjects that participated in the study, ten subjects completed the 6-month follow-up (**Table 1**). Six subjects in the MDI group and four subjects in the SDI group completed the quality of life questionnaire at six months after implant placement and two months after denture conversion to the implant-retained overdenture. Ten subjects completed the questionnaire at the time the statistics were completed. The other 13 subjects are waiting restorations or have not been restored for the two month time period. Two subjects in each group dropped out of the study. For the MDI group, one subject dropped out due to health problems, and the other subject had four implants fail to integrate, and chose to exit the study. For the SDI group, both subjects had both implants fail to integrate, and they chose to exit the study.

The baseline characteristics of the subjects were similar in each group (Table 4). There was no significant difference (P=0.8302) between the mean ages of the two groups. The mean age of group one was 56 (range 52-61) and the mean age of group two was 58 (range 48-71). There was no significant difference (P=0.4951) between the numbers of

smokers in the two groups. The percentage of non-smokers in group one was 67%, and 75% of group two. There was no significant difference (P=0.5000) between the number of subjects that consumed alcohol in the two groups. The percentage of alcohol consumption in group one was 83%, and 50% of group two. Denture characteristics of the subjects are shown in Table 5 and 6. The average age of dentures was 3.1 years for group one and 2.7 years for group two (p-value: 0.9391). The number of maxillary dentures for group one was 1.5, and 1.4 for group two (P=0.5545). The number of mandibular dentures for group one was 1.4 and 1.1 for group two (P=0.4242). Both maxillary and mandibular denture baseline characteristics of the study participants are shown in Table 7, which includes stability, retention, support, and the amount of acrylic. There was no significant difference between the two groups, except the support of the mandibular denture that is approaching significance (P=0.0506).

VAS scales—Explanatory Variables:

Maxillary Denture VAS Ratings Comparing Before and After Implants, Regardless of Group

(Table 8 and 9):

- General Satisfaction
    - The median VAS scores for the difference between pre and post implant placement in regards to general satisfaction were significantly different (P=0.0028). The median general satisfaction difference between pre and post

implant placement was 15.5 (range: -13, 60 and standard error: 5.5598). The data suggests that the subjects were more satisfied with the maxillary denture before implants were placed in the mandible.

- Overall function
    - The median VAS scores for the difference between pre and post implant placement in regards to overall function were significantly different (P=0.0164). The median overall function difference between pre and post implant placement was 14.5 (range: -19, 60 and standard error: 7.3648). The data suggests that the subjects were more satisfied with the overall function of the maxillary denture before implants were placed in the mandible.

- Stability
    - The median VAS scores for the difference between pre and post implant placement in regards to stability were not significantly different (P=0.9689). The median stability difference between pre and post implant placement was 4 (range: -27, 15 and standard error: 4.1794). The data suggests that the subjects were equally satisfied with the stability of the maxillary denture before implants were placed in the mandible.

- Retention
    - The median VAS scores for the difference between pre and post implant placement in regards to retention were significantly different (P=0.0280). The median retention difference between pre and post implant placement was 10 (range: -14, 58 and standard error: 6.6231). The data suggests that the subjects were more satisfied with the retention of the maxillary denture before implants were placed in the mandible.

- Fit
    - The median VAS scores for the difference between pre and post implant placement in regards to fit were not significantly different (P=0.9689). The median fit difference between pre and post implant placement was 10 (range: -44, 59 and standard error: 9.6250). The data suggests that the subjects were equally satisfied with the fit of the maxillary denture before implants were placed in the mandible.

- Appearance
    - The median VAS scores for the difference between pre and post implant placement in regards to appearance were significantly different (P=0.0456). The median appearance difference between pre and post implant placement was 10 (range: -15, 52 and standard error: 5.7320). The data suggests that the

subjects were more satisfied with the appearance of the maxillary denture before implants were placed in the mandible.

- Speech ability
    - The median VAS scores for the difference between pre and post implant placement in regards to speech ability were significantly different (P=0.0480). The median speech ability difference between pre and post implant placement was 9 (range: -15, 34 and standard error: 3.8755). The data suggests that the subjects were more satisfied with the speech ability of the maxillary denture before implants were placed in the mandible.

- Overall chewing ability
    - The median VAS scores for the difference between pre and post implant placement in regards to overall chewing ability were significantly different (P=0.0063). The median overall chewing ability difference between pre and post implant placement was 13 (range: -15, 40 and standard error: 4.7546). The data suggests that the subjects were more satisfied with the overall chewing ability of the maxillary denture before implants were placed in the mandible.

- Chewing hard foods
    - The median VAS scores for the difference between pre and post implant placement in regards to chewing hard foods were not significantly different (P=0.4860). The median chewing hard foods difference between pre and post implant placement was 17 (range: -78, 64 and standard error: 12.8317). The data suggests that the subjects were equally satisfied with the chewing hard foods of the maxillary denture before implants were placed in the mandible.

- Chewing tough foods
    - The median VAS scores for the difference between pre and post implant placement in regards to chewing tough foods were not significantly different (P=0.0818). The median chewing tough foods difference between pre and post implant placement was 17.5 (range: -40, 34 and standard error: 6.4389). The data suggests that the subjects were equally satisfied with the chewing tough foods of the maxillary denture before implants were placed in the mandible.

- Chewing crisp foods
    - The median VAS scores for the difference between pre and post implant placement in regards to chewing crisp foods were not significantly different (P=0.6620). The median chewing crisp foods difference between pre and post implant placement was 2 (range: -41, 49 and standard error: 6.6788). The

data suggests that the subjects were equally satisfied with the chewing crisp foods of the maxillary denture before implants were placed in the mandible.

- Chewing whole fruits
    - The median VAS scores for the difference between pre and post implant placement in regards to chewing whole fruits were not significantly different (P=0.3828). The median chewing whole fruits difference between pre and post implant placement was 15 (range: -62, 60 and standard error: 10.7253). The data suggests that the subjects were equally satisfied with the chewing whole fruits of the maxillary denture before implants were placed in the mandible.

- Chewing fruit pieces with peels
    - The median VAS scores for the difference between pre and post implant placement in regards to chewing fruit pieces with peels were not significantly different (P=0.5982). The median chewing fruit pieces with peels difference between pre and post implant placement was 9.5 (range: -74, 72 and standard error: 11.5182). The data suggests that the subjects were equally satisfied with the chewing fruit pieces with peels of the maxillary denture before implants were placed in the mandible.

- Chewing fruit with out peels
    - The median VAS scores for the difference between pre and post implant placement in regards to chewing fruit pieces with out peels were not significantly different (P=0.2127). The median chewing fruit pieces with out peels difference between pre and post implant placement was 8 (range: -40, 85 and standard error: 9.4488). The data suggests that the subjects were equally satisfied with the chewing fruit pieces with out peels of the maxillary denture before implants were placed in the mandible.

- Chewing soft/dry foods
    - The median VAS scores for the difference between pre and post implant placement in regards to chewing soft and dry were not significantly different (P=0.1662). The median chewing soft and dry difference between pre and post implant placement was 12.5 (range: -42, 84 and standard error: 11.4660). The data suggests that the subjects were equally satisfied with the chewing soft and dry of the maxillary denture before implants were placed in the mandible.

- Chewing soft/wet foods
    - The median VAS scores for the difference between pre and post implant placement in regards to chewing soft and wet food were not significantly different (P=0.2580). The median chewing soft and wet food difference

between pre and post implant placement was 8.5 (range: -40, 66 and standard error: 6.7761). The data suggests that the subjects were equally satisfied with the chewing soft and wet food of the maxillary denture before implants were placed in the mandible.

- Chewing flat vegetables
    - The median VAS scores for the difference between pre and post implant placement in regards to chewing flat vegetables were not significantly different (P=0.0866). The median chewing flat vegetables difference between pre and post implant placement was 10.5 (range: -42, 84 and standard error: 9.1661). The data suggests that the subjects were equally satisfied with the chewing flat vegetables of the maxillary denture before implants were placed in the mandible.

Mandibular Denture VAS Ratings Comparing Before and After Implants, Regardless of Group (Table 10 and 11):

- General Satisfaction
    - The median VAS scores for the difference between pre and post implant placement in regards to general satisfaction were significantly different (P=0.0022). The median general satisfaction difference between pre and post implant placement was -32 (range: -70, 12 and standard error: 7.7278). The

data suggests that the subjects were more satisfied with the mandibular denture after implants were placed in the mandible.

- Overall function
    - The median VAS scores for the difference between pre and post implant placement in regards to overall function were significantly different (P=0.0090). The median overall function difference between pre and post implant placement was -27.5 (range: -77, 12 and standard error: 8.7086). The data suggests that the subjects were more satisfied with the overall function of the mandibular denture after implants were placed in the mandible.

- Stability
    - The median VAS scores for the difference between pre and post implant placement in regards to stability were significantly different (P=0.0082). The median stability difference between pre and post implant placement was -48.5 (range: -66, 14 and standard error: 9.4035). The data suggests that the subjects were more satisfied with the stability of the mandibular denture after implants were placed in the mandible.

- Retention
    - The median VAS scores for the difference between pre and post implant placement in regards to retention were significantly different (P=<.0001). The

median retention difference between pre and post implant placement was -50 (range: -78, 5 and standard error: 7.3097). The data suggests that the subjects were more satisfied with the retention of the mandibular denture after implants were placed in the mandible.

- Fit
    - The median VAS scores for the difference between pre and post implant placement in regards to fit were significantly different (P=0.0029). The median fit difference between pre and post implant placement was -39 (range: -65, 9 and standard error: 7.7101). The data suggests that the subjects were more fit with the retention of the mandibular denture after implants were placed in the mandible.

- Appearance
    - The median VAS scores for the difference between pre and post implant placement in regards to appearance were not significantly different (P=0.9314). The median appearance difference between pre and post implant placement was 8 (range: -37, 18and standard error: 4.7314). The data suggests that the subjects were equally satisfied with the appearance of the mandibular denture before implants were placed in the mandible.

- Speech ability
    - The median VAS scores for the difference between pre and post implant placement in regards to speech ability were not significantly different (P=0.0871). The median speech ability difference between pre and post implant placement was -4 (range: -64, 14 and standard error: 8.4359). The data suggests that the subjects were equally satisfied with the speech ability of the mandibular denture before implants were placed in the mandible.

- Overall chewing ability
    - The median VAS scores for the difference between pre and post implant placement in regards to overall chewing ability were significantly different (P=0.0011). The median overall chewing ability difference between pre and post implant placement was -31.5 (range: -68, 8and standard error: 7.1556). The data suggests that the subjects were more satisfied with the overall chewing ability of the mandibular denture after implants were placed in the mandible.

- Chewing hard foods
    - The median VAS scores for the difference between pre and post implant placement in regards to chewing hard foods were significantly different (P=0.0026). The median chewing hard foods difference between pre and post implant placement was -43 (range: -78, 24and standard error: 9.7769). The

data suggests that the subjects were more satisfied with chewing hard foods with the mandibular denture after implants were placed in the mandible.

- Chewing tough foods
    - The median VAS scores for the difference between pre and post implant placement in regards to chewing tough foods were significantly different (P=0.0006). The median chewing tough foods difference between pre and post implant placement was -44.5 (range: -78, 24 and standard error: 8.3489). The data suggests that the subjects were more satisfied with chewing tough foods with the mandibular denture after implants were placed in the mandible.

- Chewing crisp foods
    - The median VAS scores for the difference between pre and post implant placement in regards to chewing crisp foods were significantly different (P=0.0044). The median chewing crisp foods difference between pre and post implant placement was -38.5 (range: -78, 8 and standard error: 8.3770). The data suggests that the subjects were more satisfied with the chewing crisp foods with the mandibular denture after implants were placed in the mandible.

- Chewing whole fruits
    - The median VAS scores for the difference between pre and post implant placement in regards to chewing whole fruits were significantly different

(P=0.0008). The median chewing whole fruits difference between pre and post implant placement was -40.5 (range: -69, 22 and standard error: 7.8615). The data suggests that the subjects were more satisfied with chewing whole fruits with the mandibular denture after implants were placed in the mandible.

- Chewing fruit pieces with peels
    - The median VAS scores for the difference between pre and post implant placement in regards to chewing fruit pieces with peels were significantly different (P=0.0358). The median chewing fruit pieces with peels difference between pre and post implant placement was -35.5 (range: -73, 43 and standard error: 9.8315). The data suggests that the subjects were more satisfied with chewing fruit pieces with peels with the mandibular denture after implants were placed in the mandible.

- Chewing fruit with out peels
    - The median VAS scores for the difference between pre and post implant placement in regards to chewing fruit with out peels were significantly different (P=0.0213). The median chewing fruit with out peels difference between pre and post implant placement was -17.0 (range: -42, 17 and standard error: 6.5256). The data suggests that the subjects were more satisfied with chewing fruit with out peels with the mandibular denture after implants were placed in the mandible.

- Chewing soft/dry foods
    - The median VAS scores for the difference between pre and post implant placement in regards to chewing soft and dry foods were significantly different (P=0.0352). The median chewing soft and dry foods difference between pre and post implant placement was -16.5 (range: -54, 17 and standard error: 7.7063). The data suggests that the subjects were more satisfied with chewing soft and dry foods with the mandibular denture after implants were placed in the mandible.

- Chewing soft/wet foods
    - The median VAS scores for the difference between pre and post implant placement in regards to chewing soft and wet foods were not significantly different (P=0.0989). The median chewing soft and wet foods difference between pre and post implant placement was -6.5 (range: -59, 14 and standard error: 7.3038). The data suggests that the subjects were equally satisfied with chewing soft and wet foods with the mandibular denture after implants were placed in the mandible.

- Chewing flat vegetables
    - The median VAS scores for the difference between pre and post implant placement in regards to chewing flat vegetables were significantly different (P=0.0084). The median chewing flat vegetables difference between pre and

post implant placement was -30.0 (range: -61, 12 and standard error: 7.3294). The data suggests that the subjects were more satisfied with chewing flat vegetables with the mandibular denture after implants were placed in the mandible.

Maxillary Denture VAS Ratings Comparing MDI and SDI Groups (Table 12 and 13, Figure 25-29):

- General Satisfaction
    - The baseline characteristics of the subjects were similar in each group. There was no significant differences (P=0.3359) between the median general satisfaction of the two groups. The median general satisfaction of group one was 84.5 (range 38 to 100) and the median general satisfaction of group two was 64 (range 2 to 90).
    - After implant placement the median VAS scores for general satisfaction were similar in each group. There was no significant difference (P=0.2864) between the median general satisfactions of the two groups post implant placement. The median general satisfaction of group one was 63 (range 38 to 94) and the median general satisfaction of group two was 91 (range 64 to 98).
    - The median VAS scores for the difference between pre and post implant placement in regards to general satisfaction were similar in each group (pre-implant minus post-implant). There was no significant difference (P=0.7484) between the median general satisfaction. The median general satisfaction

difference between pre and post implant placement of group one was 9 (range -4 to 53) and the median general satisfaction of group two was 5.5 (range -23 to 27).

- Overall function
    - The baseline characteristics of the subjects were similar in each group. There was no significant difference (P=0.3938) between the median overall function of the two groups. The median overall function of group one was 89.5 (range 10 to 100) and the median general satisfaction of group two was 67.5 (range 25 to 89).
    - After implant placement the median VAS scores for overall function were similar in each group. There was no significant difference (P=0.1344) between the median overall function of the two groups post implant placement. The median overall function of group one was 61.5 (range 39 to 95) and the median overall function of group two was 33 (range 25 to 91).
    - The median VAS scores for the difference between pre and post implant placement in regards to overall function were similar in each group (pre-implant minus post-implant). There was no significant difference (P=0.5224) between the median overall function. The median overall function difference between pre and post implant placement of group one was 11 (range -29 to 50) and the median overall function of group two was 15 (range -2 to 39).

- Stability
    - The baseline characteristics of the subjects were similar in each group. There was no significant difference (P=0.2864) between the median stability of the two groups. The median stability of group one was 70 (range 38 to 100) and the median stability of group two was 54 (range 26 to 93).
    - After implant placement the median VAS scores for stability were similar in each group. There was no significant difference (P=0.1356) between the median stability of the two groups post implant placement. The median stability of group one was 57.5 (range 38 to 100) and the median stability of group two was 36.5 (range 25 to 91).
    - The median VAS scores for the difference between pre and post implant placement in regards to stability were similar in each group (pre-implant minus post-implant). There was no significant difference (P=0.8307) between the median stability. The median stability difference between pre and post implant placement of group one was 10 (range -3 to 22) and the median stability of group two was 1.5 (range -2 to 37).

- Retention
    - The baseline characteristics of the subjects were similar in each group. There was no significant difference (P=0.4542) between the median retention of the

two groups. The median retention of group one was 86.5(range 12 to 100) and the median retention of group two was 63.5 (range 26 to 91).

- After implant placement the median VAS scores for retention were similar in each group. There was no significant difference (P=1.0000) between the median retention of the two groups post implant placement. The median retention of group one was 54.5 (range 36 to 100) and the median retention of group two was 59 (range 37 to 90).
- The median VAS scores for the difference between pre and post implant placement in regards to retention were similar in each group (pre-implant minus post-implant). There was no significant difference (P=0.4528) between the median stability. The median retention difference between pre and post implant placement of group one was 0 (range -24 to 40) and the median retention of group two was -3 (range -24 to 26).

- Fit
  - The baseline characteristics of the subjects were similar in each group. There was no significant difference (P=0.5224) between the median fit of the two groups. The median fit of group one was 88.5 (range 13 to 100) and the median fit of group two was 68 (range 51 to 88).
  - After implant placement the median VAS scores for fit were similar in each group. There was no significant difference (P=0.5212) between the median fit

of the two groups post implant placement. The median fit of group one was 77 (range 58 to 100) and the median fit of group two was 66 (range 2 to 90).

- The median VAS scores for the difference between pre and post implant placement in regards to fit were similar in each group (pre-implant minus post-implant). There was no significant difference (P=0.1995) between the median fit. The median fit difference between pre and post implant placement of group one was -8 (range -54 to 40) and the median fit of group two was 2 (range -2 to 49).

- Appearance
  - The baseline characteristics of the subjects were not similar in each group. There was a significant difference (P=0.0330) between the median appearance of the two groups. The median appearance of group one was 94 (range 86 to 100) and the median appearance of group two was 80.5 (range 67 to 90).
  - After implant placement the median VAS scores for appearance were similar in each group. There was no significant difference (P=0.5173) between the median appearance of the two groups post implant placement. The median appearance of group one was 94.5 (range 67 to 100) and the median appearance of group two was 91 (range 64 to 98).
  - The median VAS scores for the difference between pre and post implant placement in regards to appearance were similar in each group (pre-implant minus post-implant). There was no significant difference (P=0.3880) between

the median appearance. The median appearance difference between pre and post implant placement of group one was 0 (range -14 to 31) and the median appearance of group two was -10.5 (range -25 to 20).

- Speech ability
    - The baseline characteristics of the subjects were similar in each group. There was no significant difference (P=0.7963) between the median speech ability of the two groups. The median speech ability of group one was 87 (range 13 to 100) and the median speech ability of group two was 87 (range 25 to 90).
    - After implant placement the median VAS scores for speech ability were similar in each group. There was no significant difference (P=0.1151) between the median speech ability of the two groups post implant placement. The median speech ability of group one was 97.5 (range 38 to 100) and the median speech ability of group two was 63 (range 26 to 91).
    - The median VAS scores for the difference between pre and post implant placement in regards to speech ability were similar in each group (pre-implant minus post-implant). There was no significant difference (P=0.1930) between the median speech ability. The median speech ability difference between pre and post implant placement of group one was -4.5 (range -25 to 0) and the median speech ability of group two was -1 (range -1 to 24).

- Overall chewing ability
    - The baseline characteristics of the subjects were similar in each group. There was no significant difference (P=0.8307) between the median overall chewing ability of the two groups. The median overall chewing ability of group one was 73 (range 38 to 100) and the median general satisfaction of group two was 66.5 (range 25 to 89).
    - After implant placement the median VAS scores for overall chewing ability were similar in each group. There was no significant difference (P=0.3938) between the median overall chewing ability of the two groups post implant placement. The median overall chewing ability of group one was 60.5 (range 38 to 100) and the median overall chewing ability of group two was 44 (range 27 to 91).
    - The median VAS scores for the difference between pre and post implant placement in regards to overall chewing ability were similar in each group (pre-implant minus post-implant). There was no significant difference (P=0.6660) between the median overall chewing ability. The median overall chewing ability difference between pre and post implant placement of group one was 8 (range -25 to 27) and the median overall chewing ability of group two was 6.5 (range -2 to 30).

- Chewing hard foods
    - The baseline characteristics of the subjects were similar in each group. There was no significant difference (P=0.8307) between the median chewing hard foods of the two groups. The median chewing hard foods of group one was 80.5 (range 12 to 100) and the median general satisfaction of group two was 69.5 (range 51 to 90).
    - After implant placement the median VAS scores for chewing hard foods were similar in each group. There was no significant difference (P=0.1995) between the median chewing hard foods of the two groups post implant placement. The median chewing hard foods of group one was 77.5 (range 39 to 100) and the median chewing hard foods of group two was 38.5 (range 0 to 89).
    - The median VAS scores for the difference between pre and post implant placement in regards to chewing hard foods were similar in each group (pre-implant minus post-implant). There was no significant difference (P=0.1645) between the median chewing hard foods. The median chewing hard foods difference between pre and post implant placement of group one was 3 (range –88 to 48) and the median chewing hard foods of group two was 29.5 (range 1 to 54).

- Chewing tough foods
    - The baseline characteristics of the subjects were similar in each group. There was no significant difference (P=0.9146) between the median chewing tough

foods of the two groups. The median chewing tough foods of group one was 71.5 (range 13 to 100) and the median general satisfaction of group two was 63.5 (range 26 to 97).

- After implant placement the median VAS scores for chewing tough foods were similar in each group. There was no significant difference (P=0.5224) between the median chewing tough foods of the two groups post implant placement. The median chewing tough foods of group one was 62 (range 39 to 100) and the median chewing tough foods of group two was 36.5 (range 3 to 92).
- The median VAS scores for the difference between pre and post implant placement in regards to chewing tough foods were similar in each group (pre-implant minus post-implant). There was no significant difference (P=0.5929) between the median chewing tough foods. The median chewing tough foods difference between pre and post implant placement of group one was 5 (range –50 to 24) and the median chewing tough foods of group two was 12 (range -1 to 23).

- Chewing crisp foods
  - The baseline characteristics of the subjects were similar in each group. There was no significant difference (P=0.2864) between the median chewing crisp foods of the two groups. The median chewing crisp foods of group one was

91.5 (range 12 to 100) and the median general satisfaction of group two was 67 (range 26 to 88).

- After implant placement the median VAS scores for chewing crisp foods were similar in each group. There was no significant difference (P=0.6679) between the median chewing crisp foods of the two groups post implant placement. The median chewing crisp foods of group one was 88.5 (range 58 to 100) and the median chewing crisp foods of group two was 86.5 (range 26 to 90).
- The median VAS scores for the difference between pre and post implant placement in regards to chewing crisp foods were similar in each group (pre-implant minus post-implant). There was no significant difference (P=0.7484) between the median chewing crisp foods. The median chewing crisp foods difference between pre and post implant placement of group one was -7 (range –51 to 39) and the median chewing crisp foods of group two was -9.5 (range -22 to 0).

- Chewing whole fruits
  - The baseline characteristics of the subjects were similar in each group. There was no significant difference (P=0.8312) between the median chewing whole fruits of the two groups. The median chewing whole fruits of group one was 43 (range 10 to 100) and the median general satisfaction of group two was 62 (range 50 to 91).

- After implant placement the median VAS scores for chewing whole fruits were similar in each group. There was no significant difference (P=0.2864) between the median chewing whole fruits of the two groups post implant placement. The median chewing whole fruits of group one was 54.5 (range 5 to 69) and the median chewing whole fruits of group two was 64.5 (range 26 to 88).
- The median VAS scores for the difference between pre and post implant placement in regards to chewing whole fruits were similar in each group (pre-implant minus post-implant). There was no significant difference (P=0.6698) between the median chewing whole fruits. The median chewing whole fruits difference between pre and post implant placement of group one was 10.5 (range –53 to 50) and the median chewing whole fruits of group two was 3.5 (range -9 to 24).

- Chewing fruit pieces with peels
  - The baseline characteristics of the subjects were similar in each group. There was no significant difference (P=0.5212) between the median chewing fruit pieces with peels of the two groups. The median chewing fruit pieces with peels of group one was 92 (range 13 to 100) and the median general satisfaction of group two was 65 (range 26 to 91).
  - After implant placement the median VAS scores for chewing fruit pieces with peels were similar in each group. There was no significant difference

(P=0.0842) between the median chewing fruit pieces with peels of the two groups post implant placement. The median chewing fruit pieces with peels of group one was 99 (range 37 to 100) and the median chewing fruit pieces with peels of group two was 46.5 (range 0 to 88).

- The median VAS scores for the difference between pre and post implant placement in regards to chewing fruit pieces with peels were similar in each group (pre-implant minus post-implant). There was no significant difference (P=0.0325) between the median chewing fruit pieces with peels. The median chewing fruit pieces with peels difference between pre and post implant placement of group one was -8 (range –49 to 0) and the median chewing fruit pieces with peels of group two was 3.5 (range -1 to 60).

- Chewing fruit with out peels
  - The baseline characteristics of the subjects were similar in each group. There was no significant difference (P=1.0000) between the median chewing fruit with out peels of the two groups. The median chewing fruit with out peels of group one was 92 (range 13 to 100) and the median general satisfaction of group two was 81 (range 58 to 100).
  - After implant placement the median VAS scores for chewing fruit with out peels were similar in each group. There was no significant difference (P=0.0521) between the median chewing fruit with out peels of the two groups post implant placement. The median chewing fruit with out peels of

group one was 98.5 (range 63 to 100) and the median chewing fruit with out peels of group two was 50.5 (range 26 to 90).

- The median VAS scores for the difference between pre and post implant placement in regards to chewing fruit with out peels were similar in each group (pre-implant minus post-implant). There was no significant difference (P=0.0550) between the median chewing fruit with out peels. The median chewing fruit with out peels difference between pre and post implant placement of group one was -8 (range –50 to 1) and the median chewing fruit with out peels of group two was 18 (range -7 to 75).

- Chewing soft/dry foods
  - The baseline characteristics of the subjects were similar in each group. There was no significant difference (P=0.9148) between the median chewing soft dry foods of the two groups. The median chewing soft dry foods of group one was 93 (range 13 to 100) and the median general satisfaction of group two was 92.5 (range 11 to 100).
  - After implant placement the median VAS scores for chewing soft dry foods were similar in each group. There was no significant difference (P=0.6689) between the median chewing soft dry foods of the two groups post implant placement. The median chewing soft dry foods of group one was 72 (range 39 to 100) and the median chewing soft dry foods of group two was 75.5 (range 26 to 92).

- The median VAS scores for the difference between pre and post implant placement in regards to chewing soft dry foods were similar in each group (pre-implant minus post-implant). There was no significant difference (P=0.9148) between the median chewing soft dry foods. The median chewing soft dry foods difference between pre and post implant placement of group one was 9 (range –52 to 39) and the median chewing soft dry foods of group two was 2.5 (range -52 to 74).

- Chewing soft/wet foods
  - The baseline characteristics of the subjects were similar in each group. There was no significant difference (P=0.7484) between the median chewing soft wet foods of the two groups. The median chewing soft wet foods of group one was 93 (range 15 to 100) and the median general satisfaction of group two was 88 (range 60 to 100).
  - After implant placement the median VAS scores for chewing soft wet foods were similar in each group. There was no significant difference (P=0.3284) between the median chewing soft wet foods of the two groups post implant placement. The median chewing soft wet foods of group one was 96.5 (range 65 to 100) and the median chewing soft wet foods of group two was 92 (range 65 to 97).
  - The median VAS scores for the difference between pre and post implant placement in regards to chewing soft wet foods were similar in each group

(pre-implant minus post-implant). There was no significant difference (P=1.0000) between the median chewing soft wet foods. The median chewing soft wet foods difference between pre and post implant placement of group one was -1.5 (range –50 to 6) and the median chewing soft wet foods of group two was -2.5 (range -8 to 3).

- Chewing flat vegetables
  - The baseline characteristics of the subjects were similar in each group. There was no significant difference (P=0.9148) between the median chewing flat vegetables of the two groups. The median chewing flat vegetables of group one was 88 (range 12 to 100) and the median general satisfaction of group two was 87 (range 61 to 100).
  - After implant placement the median VAS scores for chewing flat vegetables were similar in each group. There was no significant difference (P=0.5918) between the median chewing flat vegetables of the two groups post implant placement. The median chewing flat vegetables of group one was 79.5 (range 61 to 100) and the median chewing flat vegetables of group two was 73.5 (range 26 to 92).
  - The median VAS scores for the difference between pre and post implant placement in regards to chewing flat vegetables were similar in each group (pre-implant minus post-implant). There was no significant difference (P=0.5929) between the median chewing flat vegetables. The median chewing

flat vegetables difference between pre and post implant placement of group one was -0.5 (range –52 to 22) and the median chewing flat vegetables of group two was 5 (range -14 to 74).

Mandibular Denture VAS Ratings Comparing MDI and SDI Groups (Table 14 and 15, Figure 30-34):

- General Satisfaction
    - The baseline characteristics of the subjects were similar in each group. There was no significant difference (P=0.8312) between the median general satisfaction of the two groups. The median general satisfaction of group one was 53.5 (range 13 to 88) and the median general satisfaction of group two was 56 (range 10 to 90).
    - After implant placement the median VAS scores for general satisfaction were similar in each group. There was no significant difference (P=0.0649) between the median general satisfaction of the two groups post implant placement. The median general satisfaction of group one was 96 (range 88 to 100) and the median general satisfaction of group two was 82.5 (range 72 to 99).
    - The median VAS scores for the difference between pre and post implant placement in regards to general satisfaction were similar in each group (pre-implant minus post-implant). There was no significant difference (P=0.5929) between the median general satisfaction. The median general satisfaction difference between pre and post implant placement of group one was -42.5

(range -47 to -7) and the median general satisfaction of group two was -32 (range -62 to 2).

- Overall function
  - The baseline characteristics of the subjects were similar in each group. There was no significant difference (P=0.8312) between the median overall function of the two groups. The median overall function of group one was. 43 (range 8 to 99) and the median general satisfaction of group two was 56 (range 16 to 91).
  - After implant placement the median VAS scores for overall function were similar in each group. There was no significant difference (P=0.3880) between the median overall function of the two groups post implant placement. The median overall function of group one was 98.5 (range 40 to 100) and the median overall function of group two was 81 (range 39 to 99).
  - The median VAS scores for the difference between pre and post implant placement in regards to overall function were similar in each group (pre-implant minus post-implant). There was no significant difference (P=0.5224) between the median overall function. The median overall function difference between pre and post implant placement of group one was -41 (range -29 to 50) and the median overall function of group two was -29.5 (range -75 to 2).

- Stability
    - The baseline characteristics of the subjects were similar in each group. There was no significant difference (P=0.2864) between the median stability of the two groups. The median stability of group one was 60 (range 33 to 99) and the median stability of group two was 41 (range 33 to 95).
    - After implant placement the median VAS scores for stability were similar in each group. There was no significant difference (P=0.1356) between the median stability of the two groups post implant placement. The median stability of group one was 92 (range 40 to 100) and the median stability of group two was 81 (range 39 to 99).
    - The median VAS scores for the difference between pre and post implant placement in regards to stability were similar in each group (pre-implant minus post-implant). There was no significant difference (P=1.0000) between the median stability. The median stability difference between pre and post implant placement of group one was -32 (range -73 to 1) and the median stability of group two was -40 (range -72 to 4).

- Retention
    - The baseline characteristics of the subjects were similar in each group. There was no significant difference (P=1.0000) between the median retention of the two groups. The median retention of group one was 37 (range 12 to 84) and the median retention of group two was 28 (range 16 to 89).

- After implant placement the median VAS scores for retention were similar in each group. There was no significant difference (P=0.1308) between the median retention of the two groups post implant placement. The median retention of group one was 98.5 (range 85 to 100) and the median retention of group two was 83 (range 69 to 99).
- The median VAS scores for the difference between pre and post implant placement in regards to retention were similar in each group (pre-implant minus post-implant). There was no significant difference (P=0.2864) between the median stability. The median retention difference between pre and post implant placement of group one was -61.5 (range -88 to -13) and the median retention of group two was -47 (range -74 to -5).

- Fit
  - The baseline characteristics of the subjects were similar in each group. There was no significant difference (P=0.3359) between the median fit of the two groups. The median fit of group one was 68 (range 11 to 92) and the median fit of group two was 30.5 (range 11 to 90).
  - After implant placement the median VAS scores for fit were similar in each group. There was no significant difference (P=0.1724) between the median fit of the two groups post implant placement. The median fit of group one was 100 (range 86 to 100) and the median fit of group two was 82 (range 67 to 100).

- The median VAS scores for the difference between pre and post implant placement in regards to fit were similar in each group (pre-implant minus post-implant). There was no significant difference (P=0.5224) between the median fit. The median fit difference between pre and post implant placement of group one was -31 (range -74 to -8) and the median fit of group two was -53 (range -62 to -11).

- Appearance
  - The baseline characteristics of the subjects were not similar in each group. There was a significant difference (P=0.0136) between the median appearances of the two groups. The median appearance of group one was 94.5 (range 88 to 100) and the median appearance of group two was 80.5 (range 64 to 88).
  - After implant placement the median VAS scores for appearance were similar in each group. There was no significant difference (P=0.5883) between the median appearances of the two groups post implant placement. The median appearance of group one was 96.5 (range 86 to 100) and the median appearance of group two was 90 (range 87 to 100).
  - The median VAS scores for the difference between pre and post implant placement in regards to appearance were not similar in each group (pre-implant minus post-implant). There was a significant difference (P=0.0187) between the median appearances. The median appearance difference between

pre and post implant placement of group one was 0.5 (range -12 to 31) and the median appearance of group two was -22.5 (range -24 to -4).

- Speech ability
    - The baseline characteristics of the subjects were similar in each group. There was no significant difference (P=0.7954) between the median speech ability of the two groups. The median speech ability of group one was 64 (range 39 to 87) and the median speech ability of group two was 82 (range 26 to 92).
    - After implant placement the median VAS scores for speech ability were similar in each group. There was no significant difference (P=0.6924) between the median speech ability of the two groups post implant placement. The median speech ability of group one was 94.5 (range 65 to 100) and the median speech ability of group two was 90 (range 87 to 100).
    - The median VAS scores for the difference between pre and post implant placement in regards to speech ability were similar in each group (pre-implant minus post-implant). There was no significant difference (P=0.6056) between the median speech ability. The median speech ability difference between pre and post implant placement of group one was -22 (range -51 to -1) and the median speech ability of group two was -5 (range -74 to 2).

- Overall chewing ability
    - The baseline characteristics of the subjects were similar in each group. There was no significant difference (P=0.8312) between the median overall chewing ability of the two groups. The median overall chewing ability of group one was 52 (range 9 to 83) and the median general satisfaction of group two was 28.5 (range 11 to 91).
    - After implant placement the median VAS scores for overall chewing ability were similar in each group. There was no significant difference (P=0.3774) between the median overall chewing ability of the two groups post implant placement. The median overall chewing ability of group one was 99 (range 35 to 100) and the median overall chewing ability of group two was 82 (range 35 to 100).
    - The median VAS scores for the difference between pre and post implant placement in regards to overall chewing ability were similar in each group (pre-implant minus post-implant). There was no significant difference (P=0.3938) between the median overall chewing ability. The median overall chewing ability difference between pre and post implant placement of group one was -44 (range -78 to -15) and the median overall chewing ability of group two was -32.5 (range -73 to -2).

- Chewing hard foods
    - The baseline characteristics of the subjects were similar in each group. There was no significant difference (P=0.5212) between the median chewing hard foods of the two groups. The median chewing hard foods of group one was 22.5 (range 12 to 97) and the median general satisfaction of group two was 35 (range 14 to 88).
    - After implant placement the median VAS scores for chewing hard foods were similar in each group. There was no significant difference (P=0.3344) between the median chewing hard foods of the two groups post implant placement. The median chewing hard foods of group one was 93.5 (range 56 to 100) and the median chewing hard foods of group two was 81.5 (range 0 to 98).
    - The median VAS scores for the difference between pre and post implant placement in regards to chewing hard foods were similar in each group (pre-implant minus post-implant). There was no significant difference (P=0.0881) between the median chewing hard foods. The median chewing hard foods difference between pre and post implant placement of group one was -62 (range -88 to 1) and the median chewing hard foods of group two was -25.5 (range -52 to 14).

- Chewing tough foods
    - The baseline characteristics of the subjects were similar in each group. There was no significant difference (P=0.5224) between the median chewing tough

foods of the two groups. The median chewing tough foods of group one was 33.5 (range 12 to 95) and the median general satisfaction of group two was 35 (range 10 to 88).

- After implant placement the median VAS scores for chewing tough foods were similar in each group. There was no significant difference (P=0.4528) between the median chewing tough foods of the two groups post implant placement. The median chewing tough foods of group one was 93 (range 41 to 100) and the median chewing tough foods of group two was 80 (range 65 to 98).
- The median VAS scores for the difference between pre and post implant placement in regards to chewing tough foods were similar in each group (pre-implant minus post-implant). There was no significant difference (P=0.8307) between the median chewing tough foods. The median chewing tough foods difference between pre and post implant placement of group one was -38 (range –88 to -3) and the median chewing tough foods of group two was -54.5 (range -72 to 2).

- Chewing crisp foods
  - The baseline characteristics of the subjects were similar in each group. There was no significant difference (P=0.3938) between the median chewing crisp foods of the two groups. The median chewing crisp foods of group one was 74

(range 10 to 97) and the median general satisfaction of group two was 30.5 (range 18 to 89).

- After implant placement the median VAS scores for chewing crisp foods were similar in each group. There was no significant difference (P=0.3923) between the median chewing crisp foods of the two groups post implant placement. The median chewing crisp foods of group one was 94.5 (range 66 to 100) and the median chewing crisp foods of group two was 88 (range 82 to 98).
- The median VAS scores for the difference between pre and post implant placement in regards to chewing crisp foods were similar in each group (pre-implant minus post-implant). There was no significant difference (P=0.2864) between the median chewing crisp foods. The median chewing crisp foods difference between pre and post implant placement of group one was -17.5 (range –56 to 1) and the median chewing crisp foods of group two was -58 (range -72 to 0).

- Chewing whole fruits
  - The baseline characteristics of the subjects were similar in each group. There was no significant difference (P=0.1995) between the median chewing whole fruits of the two groups. The median chewing whole fruits of group one was 11 (range 6 to 96) and the median general satisfaction of group two was 35.5 (range 15 to 89).

- After implant placement the median VAS scores for chewing whole fruits were similar in each group. There was no significant difference (P=0.2850) between the median chewing whole fruits of the two groups post implant placement. The median chewing whole fruits of group one was 54.5 (range 50 to 100) and the median chewing whole fruits of group two was 85 (range 62 to 98).
- The median VAS scores for the difference between pre and post implant placement in regards to chewing whole fruits were similar in each group (pre-implant minus post-implant). There was no significant difference (P=0.8312) between the median chewing whole fruits. The median chewing whole fruits difference between pre and post implant placement of group one was -50.5 (range –62 to 12) and the median chewing whole fruits of group two was -44.5 (range -67 to 1).

- Chewing fruit pieces with peels
  - The baseline characteristics of the subjects were similar in each group. There was no significant difference (P=0.8312) between the median chewing fruit pieces with peels of the two groups. The median chewing fruit pieces with peels of group one was 61 (range 9 to 99) and the median general satisfaction of group two was 29 (range 21 to 93).
  - After implant placement the median VAS scores for chewing fruit pieces with peels were similar in each group. There was no significant difference

(P=0.1236) between the median chewing fruit pieces with peels of the two groups post implant placement. The median chewing fruit pieces with peels of group one was 100 (range 60 to 100) and the median chewing fruit pieces with peels of group two was 74.5 (range 0 to 99).

- The median VAS scores for the difference between pre and post implant placement in regards to chewing fruit pieces with peels were similar in each group (pre-implant minus post-implant). There was no significant difference (P=0.5212) between the median chewing fruit pieces with peels. The median chewing fruit pieces with peels difference between pre and post implant placement of group one was -39 (range –51 to -1) and the median chewing fruit pieces with peels of group two was -17.5 (range -74 to 33).

- Chewing fruit with out peels
  - The baseline characteristics of the subjects were similar in each group. There was no significant difference (P=0.6698) between the median chewing fruit with out peels of the two groups. The median chewing fruit with out peels of group one was 67 (range 12 to 97) and the median general satisfaction of group two was 67 (range 21 to 100).
  - After implant placement the median VAS scores for chewing fruit with out peels were similar in each group. There was no significant difference (P=0.1593) between the median chewing fruit with out peels of the two groups post implant placement. The median chewing fruit with out peels of

group one was 99 (range 63 to 100) and the median chewing fruit with out peels of group two was 88.5 (range 39 to 98).

- The median VAS scores for the difference between pre and post implant placement in regards to chewing fruit with out peels were similar in each group (pre-implant minus post-implant). There was no significant difference (P=0.2008) between the median chewing fruit with out peels. The median chewing fruit with out peels difference between pre and post implant placement of group one was -27 (range –51 to -1) and the median chewing fruit with out peels of group two was -9 (range -47 to 7).

- Chewing soft/dry foods
  - The baseline characteristics of the subjects were similar in each group. There was no significant difference (P=0.7484) between the median chewing soft dry foods of the two groups. The median chewing soft dry foods of group one was 76.5 (range 15 to 98) and the median general satisfaction of group two was 62 (range 13 to 98).
  - After implant placement the median VAS scores for chewing soft dry foods were similar in each group. There was no significant difference (P=0.7476) between the median chewing soft dry foods of the two groups post implant placement. The median chewing soft dry foods of group one was 92.5 (range 69 to 100) and the median chewing soft dry foods of group two was 89.5 (range 77 to 99).

- The median VAS scores for the difference between pre and post implant placement in regards to chewing soft dry foods were similar in each group (pre-implant minus post-implant). There was no significant difference (P=0.5929) between the median chewing soft dry foods. The median chewing soft dry foods difference between pre and post implant placement of group one was -15.5 (range –54 to 7) and the median chewing soft dry foods of group two was -27.5 (range -64 to -1).

- Chewing soft/wet foods
  - The baseline characteristics of the subjects were similar in each group. There was no significant difference (P=0.8302) between the median chewing soft wet foods of the two groups. The median chewing soft wet foods of group one was 86.5 (range 15 to 100) and the median general satisfaction of group two was 62 (range 60 to 100).
  - After implant placement the median VAS scores for chewing soft wet foods were similar in each group. There was no significant difference (P=0.7406) between the median chewing soft wet foods of the two groups post implant placement. The median chewing soft wet foods of group one was 97.5 (range 67 to 100) and the median chewing soft wet foods of group two was 90.5 (range 90 to 100).
  - The median VAS scores for the difference between pre and post implant placement in regards to chewing soft wet foods were similar in each group

(pre-implant minus post-implant). There was no significant difference (P=0.6698) between the median chewing soft wet foods. The median chewing soft wet foods difference between pre and post implant placement of group one was -8.5 (range –53 to 4) and the median chewing soft wet foods of group two was -26 (range -69 to -1).

- Chewing flat vegetables
    - The baseline characteristics of the subjects were similar in each group. There was no significant difference (P=0.6698) between the median chewing flat vegetables of the two groups. The median chewing flat vegetables of group one was 58 (range 14 to 99) and the median general satisfaction of group two was 62 (range 21 to 100).
    - After implant placement the median VAS scores for chewing flat vegetables were similar in each group. There was no significant difference (P=0.7476) between the median chewing flat vegetables of the two groups post implant placement. The median chewing flat vegetables of group one was 93.5 (range 62 to 100) and the median chewing flat vegetables of group two was 89 (range 75 to 99).
    - The median VAS scores for the difference between pre and post implant placement in regards to chewing flat vegetables were similar in each group (pre-implant minus post-implant). There was no significant difference (P=1.0000) between the median chewing flat vegetables. The median chewing

flat vegetables difference between pre and post implant placement of group one was -34 (range –50 to 0) and the median chewing flat vegetables of group two was -26.5 (range -56 to 2).

Discussion:

Although there may or may not be differences in quality of life variables tested, the statistical power to detect a difference among or between groups was low based on the small sample size (MDI group=6 and SDI group=4). The data presented was preliminary, and the sample size will continue to increase in size as the study continues.

This was the first attempt to directly compare the efficacy of mini-dental implants to standard-dental implants for mandibular tissue-supported implant retained overdentures in a prospective randomized clinical study. The results suggest that mini-dental implants and standard-dental implants were more efficient than removable mandibular complete dentures. Furthermore, the results suggest that there was no difference between groups in quality of life after the implants were restored. Also, there was no difference between groups in quality of life before implants were placed, except appearance. When the post-implant VAS ratings were subtracted from the pre-implant VAS ratings, there was no difference between groups in quality of life before implants were placed, except appearance.

The difference in appearance between the groups may not be clinically important because the baseline appearance of the groups was 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.

In the present study, implant retained mandibular overdentures led to a large increase in quality of life in the tested variables, which support the findings in many other studies.[14, 20, 39, 43, 48, 84, 94, 95 97, 101-116, 118, 125, 147] Both MDI and SDI retained mandibular overdentures significantly improved masticatory function, which was in agreement with other studies.[38-41] There was no significant difference between the two groups. The MDI group tended to have a larger improvement in chewing hard food, which was approaching significance.

When the data was analyzed regardless of group, the mandibular denture satisfaction increased significantly for most variables tested; however, the maxillary denture satisfaction decreased significantly or most variables tested.

In the present study, when implants are used to retain a mandibular overdenture, the efficacy and satisfaction of the maxillary denture declined, which was contrast to other studies[147] and supports the findings in other studies.[78, 79] In several studies [20, 39, 101, 110-112, 148] 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 several reasons that the maxillary denture satisfaction decreased. One reason was that when the ill-retained and supported mandibular denture was improved, the patient's attention was switched from the mandibular denture to the maxillary denture parameters.

Another reason that the maxillary denture satisfaction declined was that the implant retained mandibular overdenture will cause an increase in amount of bite force generated.[84,87] It was not surprising that when the bite force increases there will be more force directed to the maxillary denture, which causes the patient to perceive inadequacy or decline in the maxillary prosthesis.

It could also be argued that the implant retained mandibular overdenture decreased the efficacy and satisfaction of the maxillary denture because the maxillary denture was not newly constructed. The current prostheses were closely analyzed to ensure adequate complete denture parameters including but not limited to, occlusion, support, stability, and age of prosthesis. All complete dentures were considered to be adequate before implant placement was initiated. Since implants were used to retain their current mandibular denture, the increase in satisfaction should indicate the specific improvements of the mandibular implants and not be confounded by a new prosthesis.

There was a large range and standard deviation between the subjects VAS ratings. This large variation was 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.[125] In addition to preferences, patient expectations of the outcome may play an important role.[126] Unrealistic expectations may cause patient disappointment with the prostheses. This may have lead to disappointment with the treatment outcome of the maxillary prosthesis, which may have lead to low treatment satisfaction. For example, if an edentulous patient expects their 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 tend to ignore adverse symptoms and focus on apparent improvements following therapy.[126]

There are several weaknesses to the current study. First of all, there was a small sample size to analyze. Since there was a small sample size, the statistical power and analysis was weak and needs to be interpreted with caution. Another weakness was the study population. The study population consisted of only male patients, which weakened the correlation to women. Another weakness was a short follow-up period. 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. Another weakness was different attachment systems. The best analysis would be

comparing the same style of attachments. Since the MDI was only available as a ball attachment, the SDI should have been a ball attachment. The internal connection was the implant designs of choice, but the ball attachment for the 3i Biomet system was only available for the external connection. In addition, the locator was chosen for the SDI group because of larger amount of divergence between implants that was tolerated, amount and variable retention strength, and the small size, since we needed to work within the confines of the existing denture base. Another weakness was that two clinicians completed the treatment. It would have been better with less variation between patients if there was only one clinician. Finally, a prosthodontist or prosthodontic resident should have done the prosthodontic work rather than 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.

Further direction of this project would be to include more patients. Ideally having 40-50 patients in each group, which would dramatically improve the power of the statistics and clinical study. Currently another clinicians have been trained and will be continuing to recruit new patients and collecting future data. Another future direction would be to place maxillary implants to analyze the possible improvement with satisfaction of the current maxillary prosthesis. Another future direction could include constructing a new maxillary and mandibular prosthesis to analyze the satisfaction of the new maxillary prosthesis, and then decide if implants will help with patient satisfaction.

Conclusions:

This randomized controlled clinical trial evaluated the satisfaction and contribution to quality of life, using VAS ratings of 10 subjects with an implant-retained tissue supported mandibular overdenture using standard dental implants and mini-dental implants. The null hypothesis has been confirmed within the limitations of the study that there was 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. The following conclusions were drawn:

1. There was low satisfaction in general at baseline with the mandibular denture; however, after implants were placed, regardless of group, the subjects' overall satisfaction improved significantly.
2. There was high satisfaction in general at baseline with the maxillary denture; however, after implants were placed, regardless of group, the subjects' overall satisfaction of the maxillary denture decreased significantly.

Section 4 Written by Parker Workman, DMD, MS and Caton State, DDS

Materials and Methods

Study Design

At the surgical appointment, subjects were trained on the use of a visual analog scale (VAS) by one of the periodontal residents (CJS), presented in appendix 4. Immediately prior to the beginning of the procedure, subjects were asked to score their anticipation of pain on a 100 mm VAS with the left endpoint marked "no pain" and the right endpoint marked "worst pain imaginable." Immediately post-procedure, subjects were asked to score the amount of pain experienced during the procedure using the same VAS system. Twenty-four hours after the placement of the dental implants, subjects were telephoned and asked to rate the amount of pain they were experiencing one day post-procedure. Because this was a phone interview, a five point verbal rating scale ranging from 0 – 4 (0 = no pain, 1 = mild, 2 = moderate, 3 = severe and 4 = worst pain ever) was used. At the one-week and three week post-operative evaluations, subjects were again asked to score the amount of pain experienced post-operatively in the preceding time interval using the 100 mm VAS.

Surgical Procedures

See pages 44-46.

Data Analysis:

Statistical analyses and data management were performed using SAS version 9.1 (SAS Institute, Cary, NC). The level of statistical significance was set at 0.05, assuming two-tailed distribution. Subjects were used as the unit of analysis in this study. The primary outcome variables were the VAS measures at different time points, while the exposure variables include the VAS measure at baseline (pre-surgery), age, gender and smoking status. Descriptive summary statistics were produced for each of the two treatment groups, including means and standard deviations for continuous variables (VAS at different time points and age) and proportions for categorical variables (gender or baseline, age, gender, and smoking, indicated the need for possible covariate adjustment in models for treatment comparisons. Differences between the two treatment groups with regard to continuous variables were examined with the one-way Analysis of Variance (ANOVA) following the normality test of the data, whereas differences in the categorical variables were examined using the Chi-Square test or Fisher's Exact test. If the assumption of the normal distribution could not be held, the Wilcoxon-Mann-Whitney test will be used as a nonparametric method. Furthermore, the correlations of VAS at different time points with VAS at baseline, age, gender and smoking status were examined with Pearson correlation coefficients.

As a longitudinal study, statistical methods for treatment group comparisons (SDI vs. MDI) accounted for with intra-person correlation of subject level variables. In order to investigate the difference of the VAS measures over time between two treatment groups,

specific mathematic models were used. For continuous response variables, such as the VAS scores at different study points, a repeated measures analysis was performed with mixed linear models using PROC MIX (SAS 9.1). The repeated measures analysis (i.e., VAS measures) was performed with the generalized estimating equation multinomial or binomial method using PROC GENMOD (SAS 9.1). Bias-corrected variance estimation were used with the GEE approach due to its superior performance over robust variance estimation in smaller samples (less than 50 clusters or persons).

Overall, four models were applicable to the pain-related VAS data: 1) Proportional Odds Model for univariate response (POM); 2) Partial Proportional Odds Model for univariate response (PPOM); 3) Proportional Odds Model for Multivariate Responses (RMPOM); and 4) Partial Proportional Odds Model For Multivariate Responses (RMPPOM). Each model included baseline VAS value and the design stratification factors such gender and smoking status, as well as the primary explanatory variable, the type of procedures (SDI or MDI). The POM and PPOM included univariate VAS measure at each visit, whereas RMPOM and RMPPOM included multivariate VAS measures at different visits. Reference cell parameterization was used with the SDI group at the most recent recall as the reference levels. In this parameterization, the p value for the main effect of implant placement was the comparison of the two treatment groups at the most recent recall. For those VAS measures for which the time (recall visit) by treatment group interaction was statistically significant, an estimate statement was used to compare the two treatments at other recall visits. The calculated odds ratios indicated the odds of subjects in the MDI

group reporting lower problem levels related to the pain experience issues than those in the SDI group.

The reason that four models were applied in this study was to test the proportion assumption of the VAS categories, and also to examine the time (visit) effect on the VAS measures. The data from 24-hour post-surgery's phone-call survey (Appendix 4) was treated separately from VAS measures using only POM and PPOM.

Results

Baseline Subject Characteristics/Demographics

Baseline subject characteristics of the treatment groups are presented in Table 16. Overall, there were no differences in the baseline characteristics of either the SDI group or the MDI group with respect to parameters considered to affect healing or pain perception (Kruskal-Wallis and Fisher's Exact test revealed no statistical difference for any characteristic) suggesting that the randomization was effective in maintaining a balance among the groups in potential non-surgical risk factors considered in this study.

Pain Anticipation and Experience

Pre-operative pain anticipation: Prior to implant surgery, subjects were asked to report that amount of pain they anticipated experiencing during the surgical placement of the implant fixtures. As shown in Table 17 subjects in both treatment groups had

anticipation of pain measured approximately 50 on the visual analog scale and there was no statistical difference between the groups (Kruskal-Wallis $p \geq 0.5970$). Also shown in Table 17, is the post-operative pain experienced at 24-hours after surgery measured through telephone interview. Subjects were asked to rate the amount of pain was being experienced. There was no significant difference between MDI and SDI subjects in responses to each category (Kruskal-Wallis $p \geq 0.8787$).

Post-operative pain experienced, immediate: Table 18 presents subject assessment of pain during the procedure, evaluated immediately post-implant placement. There was no statistical difference between groups with respect to intra-operative pain experience (Kruskal-Wallis $p \geq 0.2440$).

Post-operative pain experienced, delayed: Subjects were also asked to score the amount of pain they experienced at the 1-week and 3-weeks post-operative appointments using the VAS system. The data are presented in Table 18. There was no significant difference in pain between groups at the 1-week appointment (Kruskal-Wallis $p \geq 0.5024$); however, subjects in the MDI group experienced statistically less pain than the SDI group (Kruskal-Wallis $p \geq 0.0422$) at four weeks.

Mean Pain Experienced

Subject pain experience during the first week and first month post-implant placement was measured at the one-week post-operative appointment, and again four weeks later. The

questions elicited the amount of pain each subject had experienced, on average, since their previous visit. This distinguished the measurements from the amount of pain subjects were currently experiencing at the time of the post-operative appointment. Data are shown in Table 19 along with anticipated pain for comparison. There were no differences between groups at either time point (Kruskal-Wallis $p \geq 0.3240$ and 0.7910, respectively).

Change in Post-operative Pain Experience

The amount of change in pain experienced during each visit was compared to pain reported at previous appointments. The difference in pain between immediate post-op and one-week post-operative visit, one-week post-operative and four week post-operative visit, and immediate post-operative and four week post-operative visit were considered. Though the MDI group reported an increase in pain from immediate post-operative to the one-week post-operative visit, there was no statistical difference between the groups at any time point (Kruskal-Wallis $p \geq 0.8325$, 0.3239 and 0.1808, respectively).

Potential Pain Modifiers and Medication-based Pain Control

Variation in the use of local anesthetics during procedures and post-operative pain medications were investigated for potential effect on pain perception of subjects. The number of carpules of 2 percent lidocaine with 1:100,000 epinephrine used is reported in Table 20. There was no difference between groups in amount of anesthetic used during surgery (Kruskal-Wallis $p \geq 0.4886$). Subjects also reported how many days they

required the prescribed pain medication. There were no differences between groups for days of medication usage (Kruskal-Wallis $p \geq 0.9149$). Additionally, at the one-week and three-week post-operative appointments, subjects were asked to evaluate how well the prescribed pain medication controlled post-operative pain (Table 20.), No significant differences were noted between groups (Kruskal-Wallis $p \geq 0.5725$ and 1.0000, respectively).

Post-operative swelling

Swelling is an important determinate of post-operative healing and pain, increased swelling indicating a more severe post-operative course of healing. The amount of swelling was assessed for each subject at each post-operative appointment by a single investigator (CS) using a VAS scale. Table 21 presents the investigator assessments of amount of swelling present. There were no differences identified in the amount of swelling between groups at either time point (Kruskal-Wallis 0.8323 and 0.5725, respectively.)

Post-operative wound healing

Wound healing was assessed at each post-operative appointment to identify possible influences of post-operative pain and pain control. A single investigator (CS) assessed the level of wound healing for all subjects at each time point. There was no difference in the amount of swelling between groups at either time point (Kruskal-Wallis 0.6214 and

0.7473, respectively.) Table 22 presents the amount of wound healing measured on VAS scales for every subject.

Discussion

This is a preliminary report of data from a small sample of subjects receiving different types of implants. Analysis of this small sample was unlikely to identify differences between groups (MDI group=11 and SDI group=10) but it provides important information regarding subject perceptions and healing. This information gained will inform further investigations as the sample size continues to increase in size.

This preliminary study was the first to compare pain anticipated by subjects and pain experienced during the placement of mini-dental implants and standard-dental implants. Postoperative pain experience was also evaluated in a prospective randomized clinical trial. The results suggested that subjects expected moderate pain during implant placement surgery (approximately 50 mm on a 100 mm VAS). However, on average subjects experienced milder pain (approximately 15 mm on a 100 mm VAS) than anticipated during the procedure.

The results also suggested that the subjects experienced mild pain 24-hours after placement of both mini-dental implants and standard-dental implants, although some subjects experienced moderate levels of pain. The results also suggest that subjects pain experience can vary from feeling no pain to severe pain 24-hours after surgery. Subjects

in this sample experiences pain that decrease slowly over time, but some continued to experience mild to moderate pain for up to four weeks.

The results also suggested that there was no difference between groups in terms of pain experienced, swelling, or wound healing variables after treatment with the exception of the SDI group at 28-days post implant placement. At 28 days, the groups had similar mean post surgery pain ratings (12 MDI and 13 SDI) however, there was a large difference when evaluating the medians of the two groups.

In the present study, implant placement caused mild to moderate pain, which supports the findings in other studies.[128,129,131] The present study also supported the finding that subjects experience mild to moderate swelling after implant surgery.[129] However, in the present study, pain was not predicted by anxiety, which does not support the findings of Eli I and coworkers (2003).[130]

There were several limitations to the current study. There was a small sample size reducing the statistical power of the analysis so that the results must be interpreted with caution. Most comparisons showed no differences between groups, and this will continue to be evaluated as the study continues and the sample size increases.

The study population also consisted only of male subjects, not permitting inferences to be drawn regarding female subjects.

In addition, the study design used a combination of VAS variables and categorical variables. This was done to facilitate the collection of assessment data 24 hours after surgery, but subjects could have been asked to complete VAS forms at home and return them at the one-week post operative appointment, which could have strengthened the statistical analysis.

Another possible weakness in this study was variation in the surgical procedures and techniques that were preformed, Extensive flap procedures and osteoplasty increase the difficulty of the surgeries, and have been shown to affect the amount and duration of pain experienced by subjects. [131]

In the brief duration of a residency program, two clinicians were required to complete the treatment in order to include a sufficient number of subjects. Having one clinician performing the implant placement would reduce the risk of variation between subject responses due to surgical technique. In addition, Al-Khabbaz AK and coworkers (2007)[131] reported that subjects experienced different levels of pain when implant surgeries were performed by experienced periodontists compared to periodontal graduate students. Both surgeons conducting the procedures for this study were periodontal residents so any results may not be generalizable to experienced implant surgeons.

In order to maximize the power of this study and better understand the differences between types of implants, surgical placement, and course of healing 40 to 50 subjects

must be included in each group, including females. Currently another clinician has been recruited and will be continuing the study.

Conclusions:

This randomized controlled clinical trial evaluated pain anticipated by subjects receiving implants, and pain experienced during surgery and post operatively. Subjects received either mini-dental implants or standard-dental implants in the anterior mandible, and variables were assessed using questionnaires for the 21 subjects. Within the limitations of the study, including small sample size, no differences in pain perception were reported between groups of subjects receiving standard dental implants or mini-dental implants placed in the interforaminal region of the anterior mandible.

Section 5:

Implant Survival

During the course of the study there were 10 total implant failures out of a total of 64 implants placed. A total of five patients had failures. Smoking and Diabetes mellitus type 2 history of the patients is shown in table 16. There was no significant difference (P=0.2705) between smoking and nonsmoking. Also there was no significant difference (P=0.0666) between Diabetes mellitus type 2 diagnosis and without diabetes. The overall success rate for both implant systems was 85%.

There were five MDIs that failed. In the MDI group, two subjects had implant failure. One subject had all four implants fail to integrate. The other subject had one implant fail. Both subjects had symptoms of pain at three months. During the 3 month examination the failing implants were clinically mobile and were removed easily. Both subjects have Diabetes mellitus type 2, and one subject was a current smoker. Eleven subjects received four implants each for a total of 44 implants, five of which failed. MDI success rate was 89%.

There were five SDIs that failed. In the SDI group, three subjects had implant failure. Two subjects had both implants fail to integrate, and one patient had one implant fail to integrate. There was no abnormal pain or symptoms during the first three months. At second stage, the cover screws were removed and replaced with 3mm healing abutments. During the torque test to 35Ncm at the four- month retrofit appointment, all subjects had pain and implants that did not resist the torque test and were removed during that appointment. The two subjects that had both implants fail decided to exit from the study. The subject had had one implant fail decided to continue with the study and had another implant placed at the four- month appointment, which four months later was successfully restored. One subject was a current smoker and one subject was a former smoker. Nine subjects received two implants and one patient received three implants for a total of 21 implants, five of which failed. SDI success rate was 76%.

Peri-implant parameters

The mean clinical peri-implant parameters at 6 months after placement is shown in table 17. There was no significant difference between the two groups. Four sites per implant had peri-implant parameters completed, and the indexes used are shown in table 18.[156,157] The indexes during the first 6 months was low in both groups, which indicates that the subjects practiced excellent to good oral hygiene. The subjects received oral hygiene instructions at every appointment to reinforce plaque control and the importance of proper oral hygiene to maintain healthy peri-implant tissues.

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TABLES:

Table 1: Section Process

• 139 Total referred.
• 59 Unable to contact by telephone.
• 80 Interviewed by telephone.
• 44 Did not meet telephone criteria.
• 9 Not interested by telephone.
• 25 Screened in clinic.
• 1 Did not meet screening criteria.
• 24 Accepted.
• 21 Participated in study.
• 10 Completed 6 month Follow-up

Table 2: Selection Criteria

Inclusion Criteria:
Recently made maxillary and mandibular complete dentures.
Mandibular dentures with adequate support and stability that are poorly retained.
Maxillary dentures with adequate retention, support and stability.
The minimum length that the patient must wear the existing denture is one month.
Ability to answer the questionnaire.
No systemic diseases which could influence the outcome of therapy.
Good level of oral hygiene and/or denture care.
Compliance with the recall and maintenance program.
Presence of adequate bone quantity and quality to support dental implants.
Full dental coverage at SFVADC.
Exclusion Criteria:
Bleeding disorders and blood dyscrasias.
Uncontrolled Diabetes.
History of use of any bisphosphonates (oral or IV).
History of head and neck radiation.
Current history of chronic hyposalivation or Sjögrens Syndrome.
History of disorders affecting the structure and/or healing of the patients bone including primary or metastatic bone cancers.
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 or person well acquainted with the subject, 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 interacting with the individual).

Table 3: Characteristics of the groups at the baseline of the study

ID	GROUP	AGE	RACE	SMOKING	PTSD
1	1	61	AA	Former	yes
2	2	56	Cauc	Yes	yes
3	1	57	Cauc	No	yes
4	2	48	AA	Mari	yes
5	2	89	Cauc	No	no
6	2	58	AA	Mari	no
7	1	78	Cauc	Former	no
8	1	52	Cauc	Mari, 1pk /week	no
9	1	59	Hispan	Former	yes
10	1	67	AA	Yes	yes
11	1	80	Cauc	No	no
12	2	58	Cauc	No	yes
13	2	71	Cauc	yes, 1/4 pack/day	yes
14	1	61	Cauc	No	yes
15	2	58	Hispan	No	yes
16	2	79	AA	Former	no
17	1	54	Cauc	No	no
18	1	55	Cauc	Former	yes
19	1	58	Cauc	Yes	yes
20	2	75	Cauc	Yes	yes
21	2	59	Cauc	No, smokeless	yes
22	2	55	Cauc	Former	yes
23	2	85	Cauc	No	no

1=MDI Group, 2=SDI Group, PTSD= Posttraumatic Stress Disorder, AA= African

American, Cauc=Caucasian, Hispan=Hispanic

Table 3 (continued): Characteristics of the groups at the baseline of the study continued

ID	GROUP	Hyperglycemia	Diabetes Type II	Previous drug abuse	ALCOHOL
1	1	yes	no	yes	Yes
2	2	no	no	no	Yes
3	1	no	no	no	Yes
4	2	no	no	yes	No
5	2	no	no	no	No
6	2	no	no	no	Yes
7	1	no	no	no	Yes
8	1	no	no	yes	Yes
9	1	no	no	no	Yes
10	1	no	yes	yes, current	Yes
11	1	no	no	no	Yes
12	2	yes	no	no	Yes
13	2	yes	no	no	No
14	1	no	yes	yes	Yes
15	2	no	no	no	No
16	2	no	no	no	No
17	1	no	no	no	No
18	1	no	no	yes	Yes
19	1	no	no	no	Yes
20	2	yes	no	no	Yes
21	2	no	yes	no	Yes
22	2	no	no	yes	Yes

23	2	no	no	no	Yes

Table 3(continued): Characteristics of the groups at the baseline of the study continued

ID	GROUP	Hyperglycemia	HIV	HEP C	warfarin	functional reline
1	1	yes	no	Yes	no	no
2	2	no	no	yes	no	no
3	1	no	no	no	no	no
4	2	no	yes	no	no	no
5	2	no	no	no	no	no
6	2	no	no	no	no	yes
7	1	no	no	no	yes	no
8	1	no	no	no	no	no
9	1	no	no	yes	no	yes
10	1	no	no	no	no	no
11	1	no	no	no	no	no
12	2	yes	no	no	no	no
13	2	yes	no	no	no	no
14	1	no	no	no	no	no
15	2	no	no	no	no	yes
16	2	no	no	no	no	no
17	1	no	no	no	no	no
18	1	no	no	no	no	no
19	1	no	no	no	no	no
20	2	yes	no	no	no	no
21	2	no	no	no	yes	no
22	2	no	no	no	no	no

23	2	no	no	no	yes	no

Table 4: Demographic Characteristics of Study Participants at Baseline

Baseline Characteristics	**Group1**	**Group2**	p-value
AGE (years)			
N	6	4	
Mean (SD)	56 (3)	58 (10)	0.8302 *
Median	56	57	
Min, Max	52, 61	48, 71	
Smoking			
No	4 (66.67%)	3 (75.00%)	0.4951 **
Yes	1 (16.67%)	0 (0.00%)	
Mari	1 (16.67%)	1 (25.00%)	
Alcohol Consumption			
No	1 (16.67%)	2 (50.00%)	0. 5000 **
Yes	5 (83.33%)	2 (50.00%)	
Race			
AA	1 (16.67%)	2 (50.00%)	0.5000**
Caucasian	5 (83.33%)	2 (50.00%)	

* p-value based on Kruskal-Wallis Test; **p-value based on Fisher's Exact test

Table 5: Denture Characteristics of Study Participants at Baseline

	Mean	**p-value**
AOD: Group 1	**3.1 yrs**	
AOD: Group 2	**2.7 yrs**	**0.9391 ***
NMaxD: Group 1	**1.5**	
NMaxD: Group 2	**1.4**	**0.5545 ***
NManD: Group 1	**1.4**	
NManD: Group 2	**1.1**	**0.4242 ***

* *p*-value based on Kruskal-Wallis Test

AOD: Age of current complete dentures. NMaxD: Number of complete maxillary dentures. NManD: Number of complete mandibular dentures

Table 6: Characteristics of Study Participants at Baseline

Baseline Characteristics	**Group1**	**Group2**	p-value
N	11	10	
Mandibular Ridge			
Flat	0 (0%)	1 (10%)	
Round	4 (36.3%)	5 (50%)	0.2007 *
Spiny	7 (63.7%)	4 (40%)	
Mandibular Anterior Keratinized Gingiva			
Adequate	11 (100%)	7 (70%)	0.0902 **
Inadequate	0 (0%)	3 (30%)	
Mandibular Vestibular Depth			
Adequate	11 (100%)	7 (70%)	0.0902 **
Inadequate	0 (0%)	3 (30%)	
House Classification			
Philosophical	3 (27.2%)	4 (40%)	
Exacting	0 (0%)	1 (10%)	0. 8877 *
Indifferent	7 (63.7%)	5 (50%)	
Hysterical	1 (9.1%)	0 (0%)	

* *p*-value based on Mantel-Haenszel Chi-Square; *******p*-value based on Fisher's Exact test

Table 7: Additional Denture Characteristics of Study Participants at Baseline

Baseline Characteristics	**Group1**	**Group2**	*p*-value
N	11	10	
Stability of Maxillary Denture			
0	0	0	0.3906 *
1	1 (9.0%)	3 (30%)	
2	6 (54.6%)	4 (40%)	
3	4 (36.4%)	3 (30%)	
Stability of Mandibular Denture			
0	2 (18.2%)	3 (30%)	
1	8 (72.7%)	4 (40%)	0.5727 *
2	1 (9.1%)	2 (20%)	
3	0 (0%)	1 (10%)	
Retention of Maxillary Denture			
0	0 (0%)	0 (0%)	
1	2 (18.2%)	3 (30%)	0. 3834 *
2	5 (45.5%)	5 (50%)	
3	4 (36.3%)	2 (20%)	
Retention of Mandibular Denture			
0	8 (72.7%)	6 (60%)	
1	2 (18.2%)	4 (40%)	0. 8877 *
2	1 (9.1%)	0 (0%)	
3	0 (0%)	0 (0%)	
Support of Maxillary Denture			
0	0 (0%)	0 (0%)	
1	2 (18.2%)	0 (0%)	0.2575 *
2	6 (54.6%)	6 (60%)	
3	3 (27.2%)	4 (40%)	
Support of Mandibular Denture			
0	0 (0%)	0 (0%)	
1	0 (0%)	4 (40%)	0.0506 *
2	10 (90.9%)	6 (60%)	
3	1 (9.1%)	0 (0%)	
Mandibular Acrylic Thickness (height)			
Adequate	10 (90.9%)	9 (90%)	0.3685 *
Inadequate	1 (9.1%)	1 (10%)	
Mandibular Acrylic Thickness (width)			
Adequate	8 (72.7%)	9 (90%)	0.1824 *
Inadequate	3 (27.2%)	1 (10%)	
* p-value based on Mantel-Haenszel Chi-Square			

Table 8: Maxillary Denture QOL Pre--Post Implant Placement: Regardless of Group

	Median (Pre-Post)	Range (Min, Max)	Standard Error	p-value
GS	15.5	60, -13	5.5598	0.0028*
OF	14.5	60, -19	7.3648	0.0164*
S	4.0	15, -27	4.1794	0.9689
R	10.0	58, -14	6.6231	0.0280*
F	10.0	59, -44	9.6250	0.1833
A	10.0	52, -15	5.7320	0.0456*
SA	9.0	34, -15	3.8755	0.0480*

QOL VAS Scales (1-100) Pre-Implant, 6 months Post-Implant
GS. General Satisfaction, OF. Overall function, S. Stability, R. Retention, F. Fit, A. Appearance, SA. Speech ability

Table 9: Maxillary Denture QOL Pre--Post Implant Placement: Regardless of Group

	Median (Pre-Post)	Range (Min, Max)	Standard Error	p-value
OCA	13.0	40, -15	4.7546	0.0063*
CHF	17.0	64, -78	12.8317	0.4860
CTF	17.5	34, -40	6.4389	0.0818
CCF	2.0	49, -41	6.6788	0.6620
CWF	15.0	60, -62	10.7253	0.3828
CFP	9.5	72, -74	11.5182	0.5982
CFNP	8.0	85, -40	9.4488	0.2127
CSD	12.5	84, -42	11.4660	0.1662
CSW	8.5	66, -40	6.7761	0.2580
CFV	10.5	84, -42	9.1661	0.0866

QOL VAS Scales (1-100) Pre-Implant, 6 months Post-Implant
OCA. Overall chewing ability, CHF. Chewing hard foods, CTF. Chewing tough foods, CCF. Chewing crisp foods, CWF. Chewing whole fruits, CFP. Chewing fruit pieces with peels, CFNP. Chewing fruit with out peels, CSD. Chewing soft/dry foods, CSW. Chewing soft/wet foods, CFV. Chewing flat vegetables

Table 10: Mandibular Denture QOL Pre--Post Implant Placement: Regardless of Group

	Median (Pre-Post)	Range (Min, Max)	Standard Error	p-value
GS	-32.0	12, -70	7.7278	0.0022*
OF	-27.5	12, -77	8.7086	0.0090*
S	-48.5	14, -66	9.4035	0.0082*
R	-50.0	5, -78	7.3097	<.0001*
F	-39.0	9, -65	7.7101	0.0029*
A	8.0	18, -37	4.7314	0.9314
SA	-4.0	14, -64	8.4359	0.0871

QOL VAS Scales (1-100) Pre-Implant, 6 months Post-Implant
GS. General Satisfaction, OF. Overall function, S. Stability, R. Retention, F. Fit, A. Appearance, SA. Speech ability

Table 11: Mandibular Denture QOL Pre--Post Implant Placement: Regardless of Group

	Median (Pre-Post)	Range (Min, Max)	Standard Error	p-value
OCA	-31.5	8, -68	7.1556	0.0011*
CHF	-43.0	24, -78	9.7769	0.0026*
CTF	-44.5	8, -78	8.3489	0.0006*
CCF	-38.5	11, -63	8.3770	0.0044*
CWF	-40.5	22, -69	7.8615	0.0008*
CFP	-35.5	43, -73	9.8315	0.0358*
CFNP	-17.0	17, -42	6.5256	0.0213*
CSD	-16.5	17, -54	7.7063	0.0352*
CSW	-6.5	14, -59	7.3038	0.0989
CFV	-30.0	12, -61	7.3294	0.0084*

QOL VAS Scales (1-100) Pre-Implant, 6 months Post-Implant
OCA. Overall chewing ability, CHF. Chewing hard foods, CTF. Chewing tough foods, CCF. Chewing crisp foods, CWF. Chewing whole fruits, CFP. Chewing fruit pieces with peels, CFNP. Chewing fruit with out peels, CSD. Chewing soft/dry foods, CSW. Chewing soft/wet foods, CFV. Chewing flat vegetables

Table 12: Maxillary Denture QOL Pre, Post, and Difference Between Pre and Post Implant Placement

	Pre Median (Min, Max)		p-value *	Post Median (Min, Max)		p-value*	Difference (Pre-Post) Median (Min, Max)		p-value*
	Group1 (n=6)	Group2 (n=4)		Group1 (n=6)	Group2 (n=4)		Group1 (n=6)	Group2 (n=4)	
GS	84.5 (38,100)	64 (2,90)	0.3359	63 (38,94)	91 (64,98)	0.2864	9 (-4,53)	5.5 (-23,27)	0.7484
OF	89.5 (10,100)	67.5 (25,89)	0.3938	61.5 (39,95)	33 (25,91)	0.1344	11 (-29,50)	15 (-2,39)	0.5224
S	70 (38,100)	54 (26,93)	0.2864	57.5 (38,100)	36.5 (25, 91)	0.1356	10 (-3,22)	1.5 (-2,37)	0.8307
R	86.5 (12,100)	63.5 (26,91)	0.4542	54.5 (36,100)	59 (37,90)	1.0000	0 (-24,40)	-3 (-24, 26)	0.4528
F	88.5 (13,100)	68 (51,88)	0.5224	77 (58,100)	66 (2,90)	0.5212	-8 (-54,40)	2 (-2,49)	0.1995
A	94 (86,100)	80.5 (67,90)	0.0330*	94.5 (67,100)	91 (64,98)	0.5173	0 (-14, 31)	-10.5 (-25,20)	0.3880
SA	87 (13,100)	87 (25, 90)	0.7963	97.5 (38,100)	63 (26,91)	0.1151	-4.5 (-25,0)	-1 (-1,24)	0.1930

*p-value based on Kruskal-Wallis Test

QOL VAS Scales (1-100) Pre-Implant, 6 months Post-Implant, and difference. GS. General Satisfaction, OF. Overall function, S. Stability, R. Retention, F. Fit, A. Appearance, SA. Speech ability

Table 13: Additional Maxillary Denture QOL Pre, Post, and Difference Between Pre and Post Implant Placement

	Pre Median (Min, Max)		p-value*	Post Median (Min, Max)		p-value*	Difference (Pre-Post) Median (Min, Max)		p-value*
	Group1 (n=6)	Group2 (n=4)		Group1 (n=6)	Group2 (n=4)		Group1 (n=6)	Group2 (n=4)	
OCA	73 (38,100)	66.5 (25,89)	0.8307	60.5 (38,100)	44 (27,91)	0.3938	8 (-25,27)	6.5 (-2,30)	0.6660
CHF	80.5 (12,100)	69.5 (51,90)	0.8307	77.5 (39,100)	38.5 (0,89)	0.1995	3 (-88,48)	29.5 (1,54)	0.1645
CTF	71.5 (13,100)	63.5 (26,97)	0.9146	62 (39,100)	36.5 (3, 92)	0.5224	5 (-50,24)	12 (-1,23)	0.5929
CCF	91.5 (12,100)	67 (26,88)	0.2864	88.5 (58,100)	86.5 (26,90)	0.6679	-7 (-51,39)	-9.5 (-22,0)	0.7484
CWF	43 (10,100)	62 (50,91)	0.8312	54.5 (5,69)	64.5 (26,88)	0.2864	10.5 (-53,50)	3.5 (-9,24)	0.6698
CFP	92 (13,100)	65 (26,91)	0.5212	99 (37,100)	46.5 (0,88)	0.0842	-8 (-49,0)	3.5 (-1,60)	0.0325*
CFNP	92 (13,100)	81 (58,100)	1.0000	98.5 (63,100)	50.5 (26,90)	0.0521	-8 (-50,1)	18 (-7,75)	0.0550
CSD	93 (13,100)	92.5 (11,100)	0.9148	72 (39,100)	75.5 (26,92)	0.6689	9 (-52,39)	2.5 (-52,74)	0.9148
CSW	93 (15,100)	88 (60,100)	0.7484	96.5 (65,100)	92 (65,97)	0.3284	-1.5 (-50,6)	-2.5 (-8,3)	1.0000
CFV	88 (12,100)	87 (61,100)	0.9148	79.5 (61,100)	73.5 (26,92)	0.5918	-0.5 (-52,22)	5 (-14,74)	0.5929

* p-value based on Kruskal-Wallis Test

QOL VAS Scales (1-100) Pre-Implant, 6 months Post-Implant, and difference. OCA. Overall chewing ability, CHF. Chewing hard foods, CTF. Chewing tough foods, CCF. Chewing crisp foods, CWF. Chewing whole fruits, CFP. Chewing fruit pieces with peels, CFNP. Chewing fruit with out peels, CSD. Chewing soft/dry foods, CSW. Chewing soft/wet foods, CFV. Chewing flat vegetables

Table 14: Mandibular Denture QOL Pre, Post, and Difference Between Pre and Post Implant Placement

	Pre Median (Min, Max)		p-value *	Post Median (Min, Max)		p-value*	Difference (Pre-Post) Median (Min, Max)		p-value*
	Group1 (n=6)	Group2 (n=4)		Group1 (n=6)	Group2 (n=4)		Group1 (n=6)	Group2 (n=4)	
GS	53.5 (13,88)	56 (10,90)	0.8312	96 (88,100)	82.5 (72,99)	0.0649	-42.5 (-75,-7)	-32 (-62,2)	0.5929
OF	43 (8,99)	56 (16,91)	0.8312	98.5 (40,100)	83 (32,100)	0.3880	-41 (-29,50)	-29.5 (-75,2)	0.5224
S	60 (33,99)	41 (33,95)	0.2864	92 (40,100)	81 (39, 99)	0.1356	-32 (-73,1)	-40 (-72,4)	1.0000
R	37 (12,84)	28 (16,89)	1.0000	98.5 (85,100)	83 (69,99)	0.1308	-61.5 (-88,-13)	-47 (-74,-5)	0.2864
F	68 (11,92)	30.5 (11,90)	0.3359	100 (86,100)	82 (67,100)	0.1724	-31 (-74,-8)	-53 (-62,-1)	0.5224
A	94.5 (88,100)	80.5 (64,88)	0.0136*	96.5 (86,100)	90 (87,100)	0.5883	0.5 (-12,31)	-22.5 (-24,-4)	0.0187*
SA	64 (39,87)	82 (26, 92)	0.7954	94.5 (65,100)	90 (87,100)	0.6924	-22 (-51,-1)	-5 (-74,2)	0.6056

*p-value based on Kruskal-Wallis Test

QOL VAS Scales (1-100) Pre-Implant, 6 months Post-Implant, and difference. GS. General Satisfaction, OF. Overall function, S. Stability, R. Retention, F. Fit, A. Appearance, SA. Speech ability

Table 15: Additional Mandibular Denture QOL Pre, Post, and Difference Between Pre and Post Implant Placement

	Pre Median (Min, Max)		p-value*	Post Median (Min, Max)		p-value*	Difference (Pre-Post) Median (Min, Max)		p-value*
	Group1 (n=6)	Group2 (n=4)		Group1 (n=6)	Group2 (n=4)		Group1 (n=6)	Group2 (n=4)	
OCA	52 (9,83)	28.5 (11,91)	0.8312	99 (35,100)	82 (35,100)	0.3774	-44 (-78,-15)	-32.5 (-73,-2)	0.3938
CHF	22.5 (12,97)	35 (14,88)	0.5212	93.5 (65,100)	81.5 (0,98)	0.3344	-62 (-88,1)	-25.5 (-52,14)	0.0881
CTF	33.5 (12,95)	35 (10,88)	0.5224	93 (41,100)	80 (65, 98)	0.4528	-38 (-88,-3)	-54.5 (-72,-2)	0.8307
CCF	74 (10,97)	30.5 (18,89)	0.3938	94.5 (66,100)	88 (82,98)	0.3923	-17.5 (-56,1)	-58 (-72,0)	0.2864
CWF	11 (6,96)	35.5 (15,89)	0.1995	64.5 (50,100)	85 (62,98)	0.2850	-50.5 (-62,12)	-44.5 (-67,1)	0.8312
CFP	61 (9,99)	29 (21,93)	0.8312	100 (60,100)	74.5 (0,99)	0.1236	-39 (-51,-1)	-17.5 (-74,33)	0.5212
CFNP	67 (12,97)	67 (21,100)	0.6698	99 (63,100)	88.5 (39,98)	0.1593	-27 (-51,-1)	-9 (-47,7)	0.2008
CSD	76.5 (15,98)	62 (13,98)	0.7484	92.5 (69,100)	89.5 (77,99)	0.7476	-15.5 (-54,7)	-27.5 (-64,-1)	0.5929
CSW	86.5 (15,100)	62 (60,100)	0.8302	97.5 (67,100)	90.5 (90,100)	0.7406	-8.5 (-53,4)	-26 (-69,-1)	0.6698
CFV	58 (14,99)	62 (21,100)	0.6698	93.5 (62,100)	89 (75,99)	0.7476	-34 (-50,0)	-26.5 (-56,2)	1.0000

*p-*value* based on Kruskal-Wallis Test

QOL VAS Scales (1-100) Pre-Implant, 6 months Post-Implant, and difference. OCA. Overall chewing ability, CHF. Chewing hard foods, CTF. Chewing tough foods, CCF. Chewing crisp foods, CWF. Chewing whole fruits, CFP. Chewing fruit pieces with peels, CFNP. Chewing fruit with out peels, CSD. Chewing soft/dry foods, CSW. Chewing soft/wet foods, CFV. Chewing flat vegetables

Table 16: Demographic Characteristics of Study Participants at Baseline

Baseline Characteristics	MDI (n=11)	SDI (n=10)	p-value
AGE (years)			
N	11	10	
Mean (SD)	62 (9)	64 (12)	0.8320 *
Median	59	58	
Min, Max	52, 80	48, 85	
Smoking			
No	9 (81.82%)	8 (80.00%)	1.0000 **
Yes	2 (18.18%)	2 (20.00%)	
Alcohol Consumption			
No	1 (9.09%)	4 (40.00%)	0. 1486 **
Yes	10 (90.91%)	6 (60.00%)	
Chronic Analgesia Usage			
No	6 (54.55%)	7 (70.00%)	0. 6594**
Yes	5 (45.45%)	3 (30.00%)	
Race			
AA	2 (18.18%)	3 (30.00%)	
Caucasian	8 (72.73%)	6 (60.00%)	0.6631**
Hispanics	1 (9.09%)	1 (10.00%)	

* *p*-value based on Kruskal-Wallis test; ***P*-value based on Fisher's Exact test

Table 17: Anticipated Pain at Baseline and Experience Pain One-Day Post-surgery

	MDI (n=11)	SDI (n=10)	*p*-value
Anticipated Pain before Surgery (Baseline VAS)			
N	11	10	
Mean (SD)	50 (22)	54 (35)	
Median	48	60	0.5970 *
Min, Max	7, 89	5, 92	
Experiencing Pain at 24-hour Post-surgery			
None	1 (9.09%)	0 (0.00%)	
MIld	6 (54.54%)	7 (70.00%)	
Moderate	2 (18.18%)	3 (30.00)	0.8787 **
Severe	1 (9.09%)	0 (0.00%)	
Worst pain ever experienced	1 (9.09%)	0 (0.00%)	

* p-value based on Kruskal-Wallis test; ** *P*-value based on Mantel-Haenszel Chi-square test

Table 18: Experiencing pain

	MDI (n=11)	SDI (n=10)	*p*-value
Experiencing Pain Immediately Post-surgery			
N	11	10	
Mean (SD)	24 (22)	16 (16)	
Median	15	11.5	0. 2440 *
Min, Max	5, 66	1, 41	
Experiencing Pain at 7 Day Post-surgery			
N	11	10	
Mean (SD)	25 (32)	14 (14)	
Median	10	8	0.5024 *
Min, Max	0, 100	1, 38	
Experiencing Pain at 28 Day Post-surgery			
N	10	10	
Mean (SD)	12 (31)	13 (100)	
Median	1.5	11	**0.0422 ***
Min, Max	0, 100	1, 27	
* *p*-value based on Kruskal-Wallis test			

Table 19: Experienced pain

	MDI (n=11)	SDI (n=10)	*p*-value
Experienced Pain within first week post-surgery			
N	11	10	
Mean (SD)	44 (34)	27 (14)	
Median	38	30	0. 3240 *
Min, Max	5, 99	6, 50	
Experienced Pain within first month post-surgery			
N	10	10	
Mean (SD)	33 (37)	21 (12)	
Median	15	19	0.7910 *
Min, Max	1, 100	6, 44	
* *p*-value based on Kruskal-Wallis test			

Table 20: Potential Pain Modifiers during and after Implant's Placement Surgery.

	MDI (n=11)	SDI (n=10)	p-value
Local Anesthesia usage (Carpules)			
N	11	10	
Mean (SD)	5 (1)	5 (1)	
Median	6	5	0. 4886 *
Min, Max	3, 6	3, 6	
Analgesics Taken Post-surgery (Days)			
N	11	10	
Mean (SD)	4 (4)	4 (2)	
Median	4	4	0.9149 *
Min, Max	0, 14	0, 7	
Wellness of Medication Control at 1 Week Post-surgery (VAS)			
N	11	10	
Mean (SD)	77 (26)	85 (11)	
Median	86	88.5	0.5725 *
Min, Max	10, 100	64, 97	
Wellness of Medication Control at 28-days Post-surgery (VAS)			
N	11	10	
Mean (SD)	73 (40)	91 (8)	
Median	96	89.5	1.0000 *
Min, Max	0, 100	77, 100	
* *p*-value based on Kruskal-Wallis test			

Table 21: Swelling

	MDI (n=11)	SDI (n=10)	p-value
Swelling within first week post-surgery			
N	11	10	
Mean (SD)	19 (20)	14 (12)	
Median	11	13.5	0. 8323 *
Min, Max	4, 64	1, 40	
Swelling within first month post-surgery			
N	11	10	
Mean (SD)	3 (3)	6 (8)	
Median	1	1	0.5725 *
Min, Max	1, 11	1, 25	
* p-value based on Kruskal-Wallis test			

Table 22: Wound Healing

	MDI (n=11)	SDI (n=10)	*p*-value
Wound healing within first week post-surgery			
N	11	10	
Mean (SD)	79 (22)	81 (24)	
Median	85	87.5	0. 6214 *
Min, Max	30, 99	21, 100	
Wound healing within 28-days post-surgery			
N	11	10	
Mean (SD)	96 (6)	95 (7)	
Median	97	98	0.7473 *
Min, Max	81, 100	80, 100	
* *p*-value based on Kruskal-Wallis test			

Table 23: Implant Failures and Study Participants

	Success	Failure	p-value
Smoking			
No	15 (79%)	2 (50%)	
Yes	4 (21%)	2 (50%)	0.2705 *
Diabetes Type II			
No	18 (95%)	2 (50%)	
Yes	1 (5%)	2 (50%)	0.0666 *

*p-value based on Fisher's Exact Test

Table 24: Clinical Implant parameters at 6 month evaluation

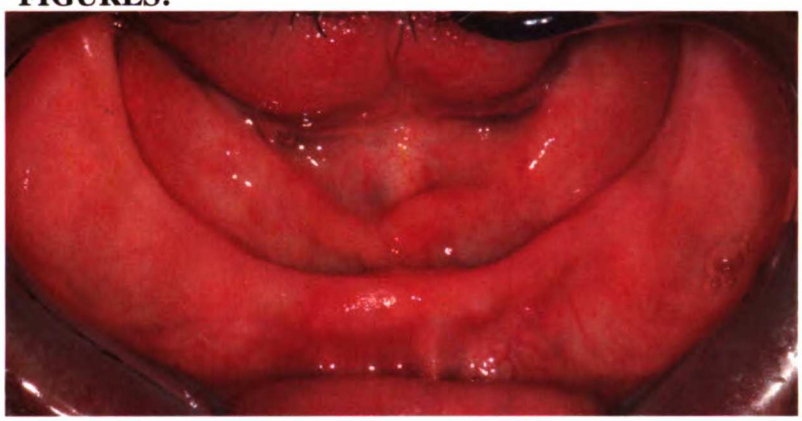
	MDI (n=7)	SDI (n=5)	p-value
Mean plaque index (min,max)	0.6 (0,2)	0.7 (0,2)	0.7940
Mean gingival index (min,max)	0.1 (0,1)	0.1 (0,1)	1.0000
Mean bleeding index (min,max)	0.0 (0,0)	0.0 (0,0)	1.0000
Mean probing depth (min,max)	1.4 (1,2)	1.9 (1,3)	0.1007
*p-value based on Kruskal-Wallis Test			

Table 25: Definitions of Plaque*, Bleeding*, and Gingival Index**

Score	Plaque Index	Bleeding Index	Gingival Index
0	No detection of plaque	No bleeding when a periodontal probe is passed along the gingival margin adjacent to the implant	Normal mucosa
1	Plaque recognized only by running a probe across the smooth marginal surface of the implant	Isolated bleeding spots visible	Mild inflammation; slight change in color; slight edema
2	Plaque can be seen by the naked eye	Blood forms a confluent red line on margin	Moderate inflammation; redness, edema, and glazing
3	Abundance of soft matter	Heavy or profuse bleeding	Severe inflammation; marked redness and edema; ulceration

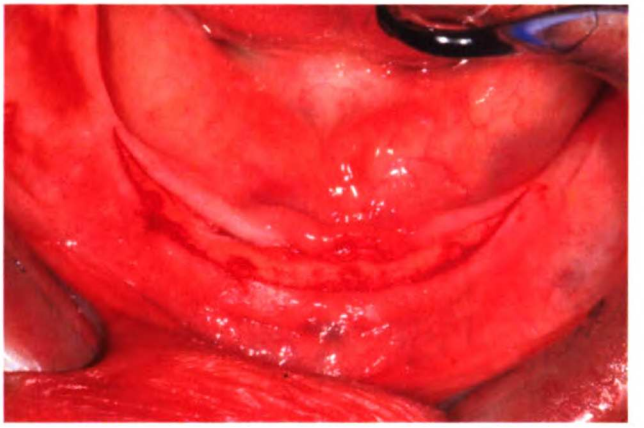
*Mombelli et al, 1987,[158] **Löe and Silness, 1963 [159]

FIGURES:

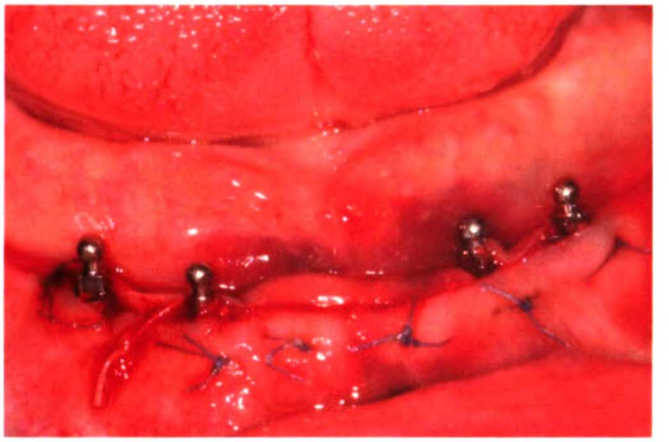


Case 1: Figure 1: Typical pre-surgical case randomized to MDI, which requires full thickness flap.

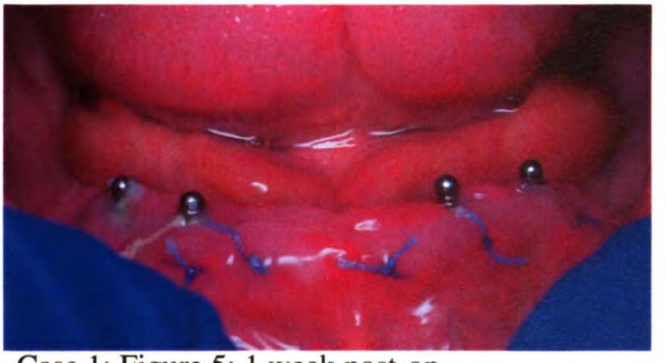
Case 1: Figure 2: Full thickness flap reveals the need for osteoplasty to increase buccal/lingual width to approximate 5mm



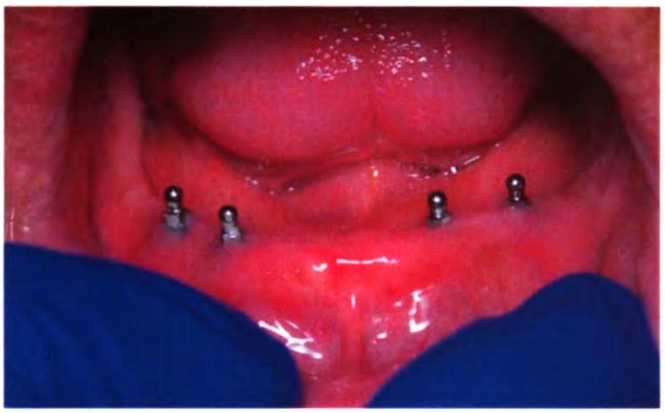
Case 1: Figure 3: Completion of osteoplasty and osteotomy for MDI (1.8X13mm) #22, #24, #25, and #27.



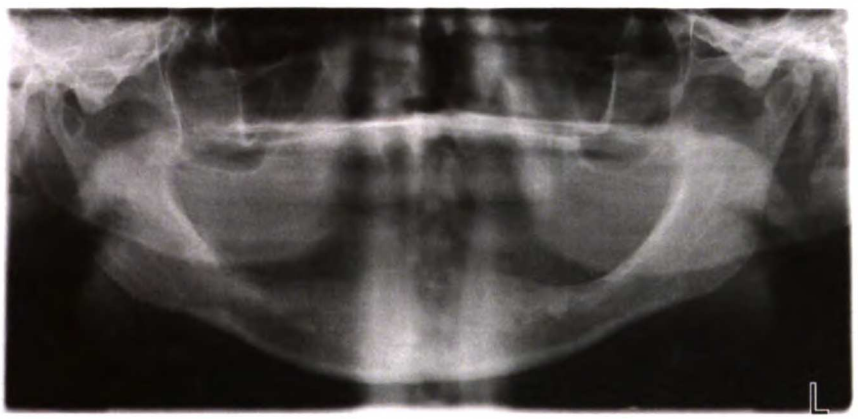
Case 1: Figure 4: Completion of MDI (1.8X13mm) #22, #24, #25, and #27.



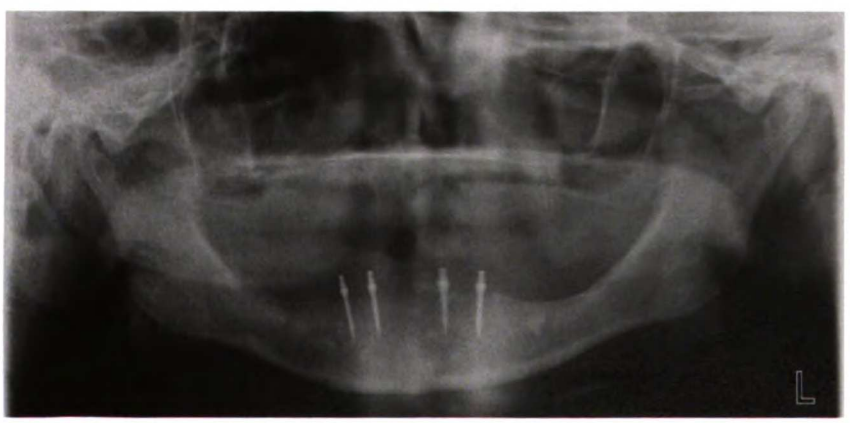
Case 1: Figure 5: 1 week post-op



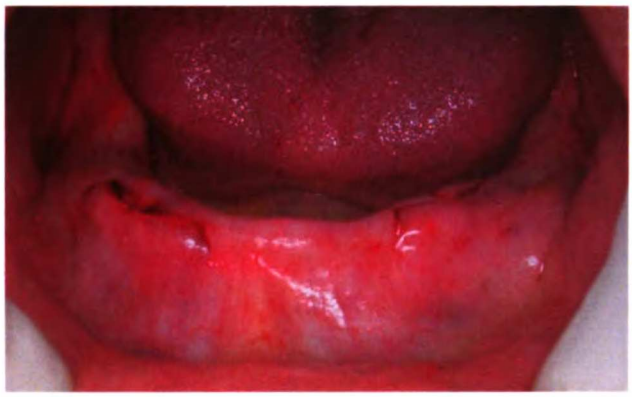
Case 1: Figure 6: 3 week post-op



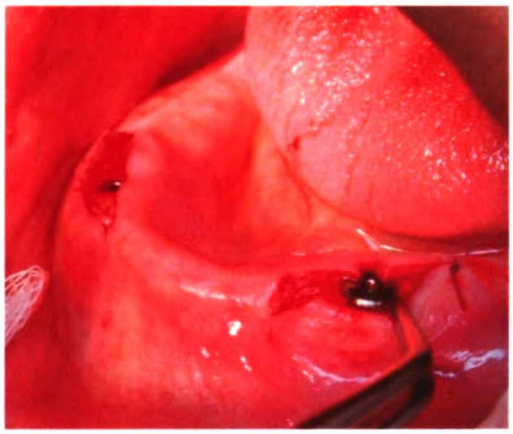
Case 1: Figure 7: Pre-surgical panographic radiograph



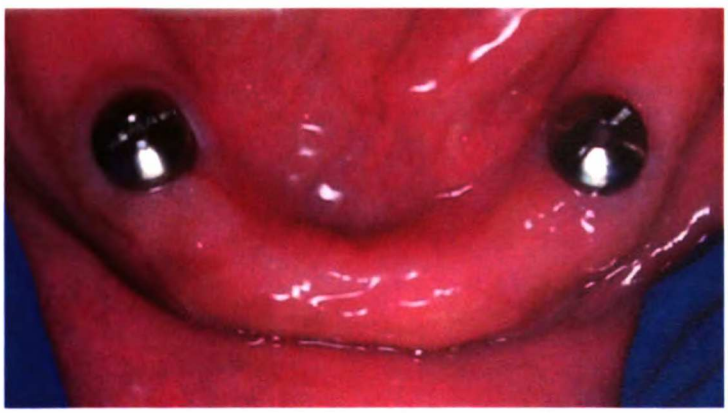
Case 1: Figure 8: Post-surgical panographic radiograph



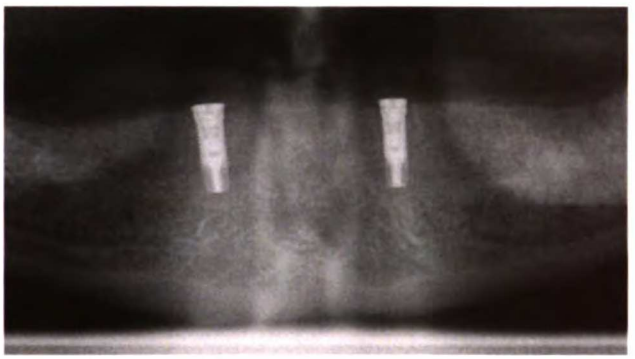
Case 2: Figure 9: Typical pre-surgical case randomized to SDI, which requires full thickness flap.



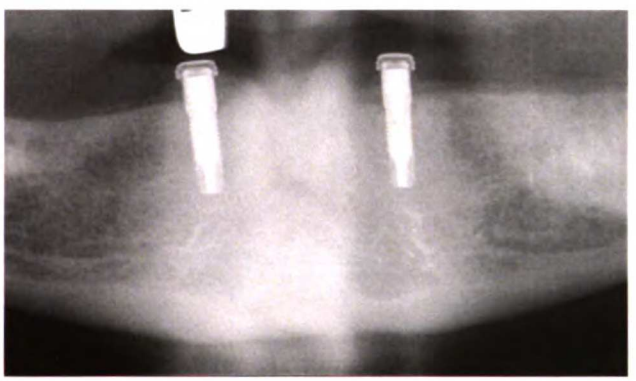
Case 2: Figure 10: Implants with cover screw placement #22 and #27



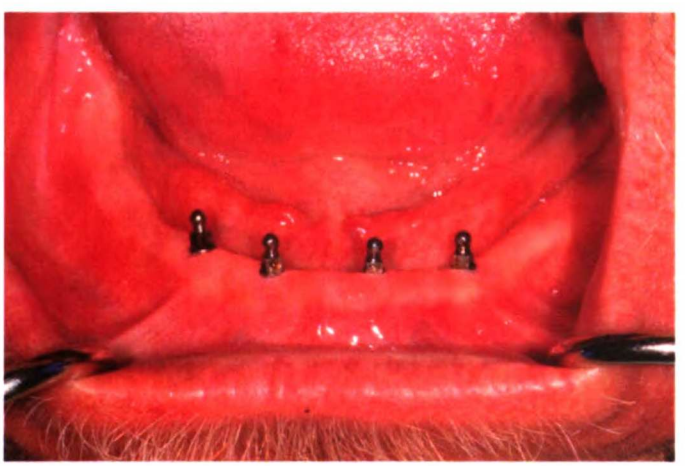
Case 2: Figure 11: 4 month post-op



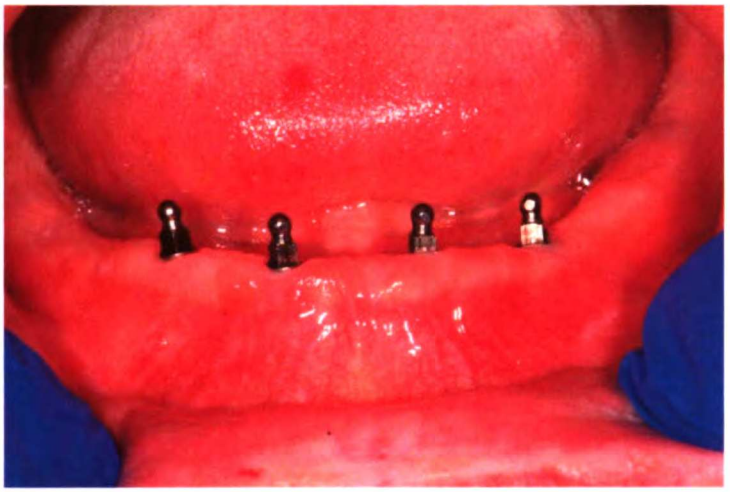
Case 2: Figure 12: 3 month post-surgical panographic radiograph



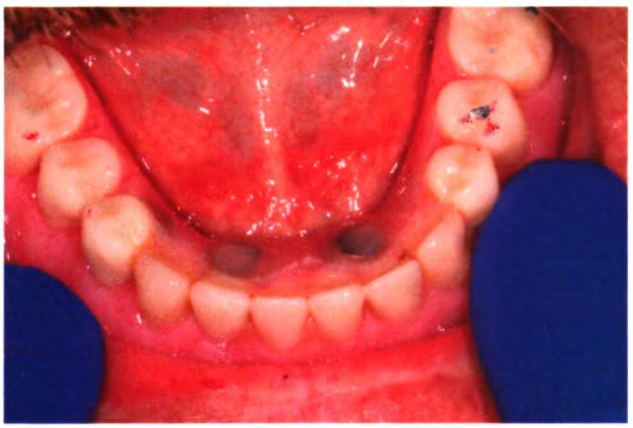
Case 2: Figure 13: Post-retrofit panographic radiograph with Locator abutments



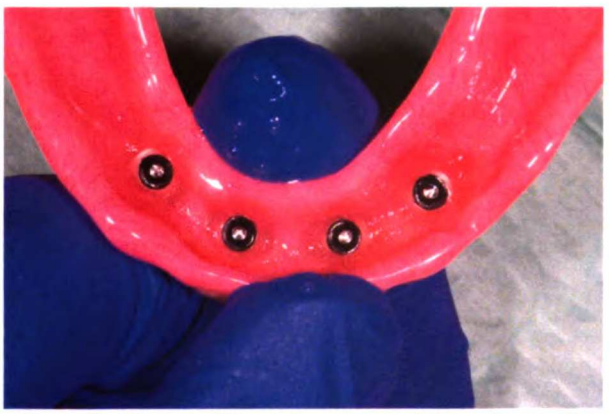
Case 3: Figure 14: Typical MDI, which does not require full thickness flap.



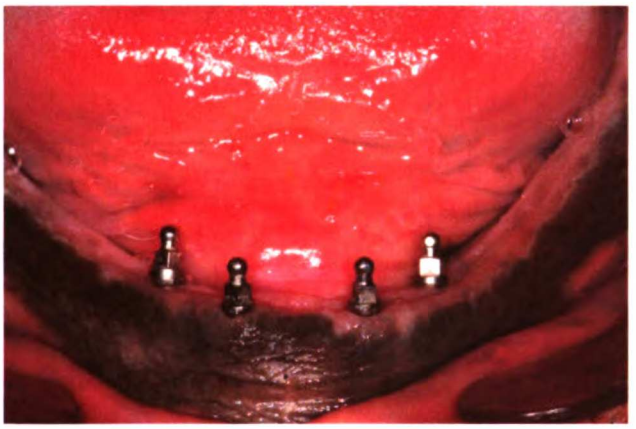
Case 3: Figure 15: 4 month post-op



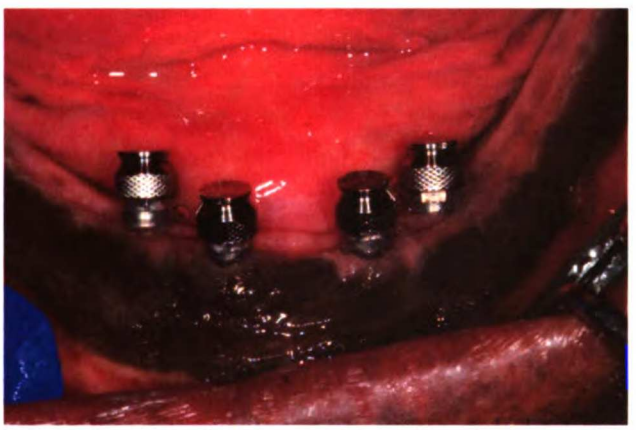
Case 3: Figure 16: Additional auto-polymerizing acrylic resin needed to increase the height of acrylic in the area of #23 and #26.



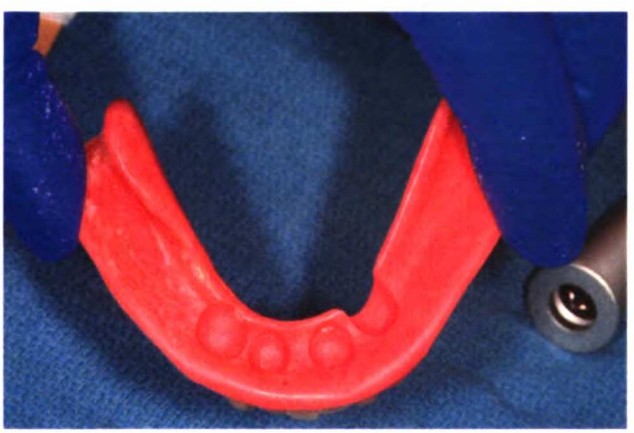
Case 3: Figure 17: Adequate width of acrylic



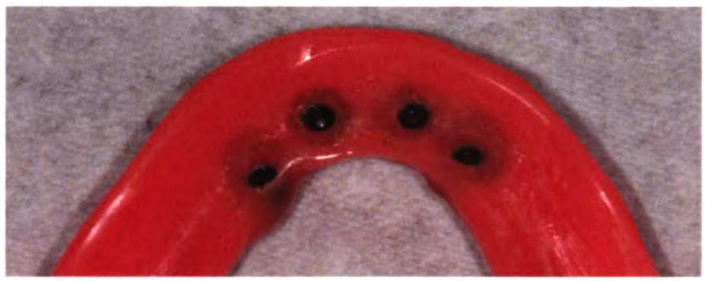
Case 4: Figure 18: 4 month post-op for retrofit



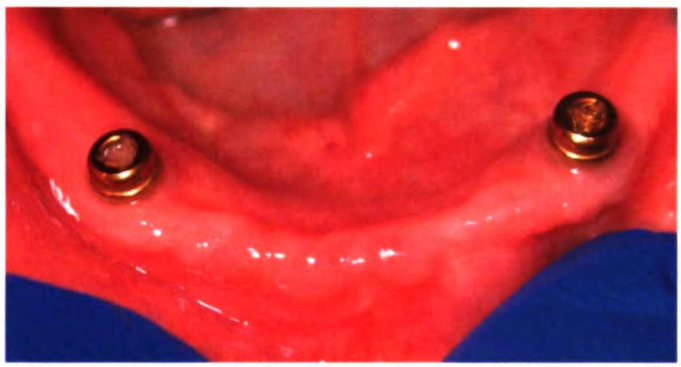
Case 4: Figure 19: Placement of housings over block-out shims



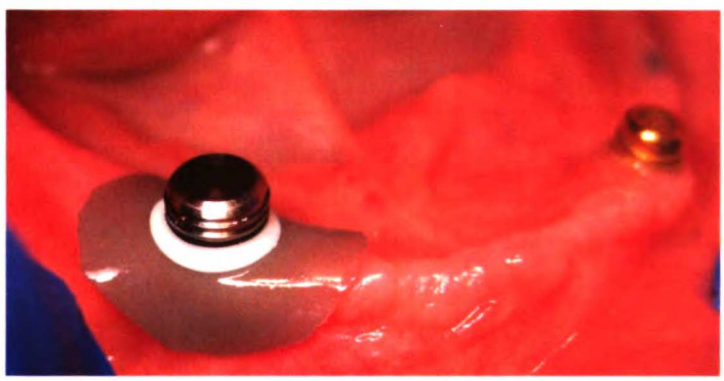
Case 4: Figure 20: Removal of adequate acrylic for housing pick-up. Lingual placement of implant #27 required removal of lingual flange in that area with placement of acrylic vent holes on lingual



Case 4: Figure 21: Completion of housing pick-up using auto-polymerizing acrylic resin



Case 5: Figure 22: Typical SDI 4 month post-op for retrofit



Case 5: Figure 23: SDI Locator with rubber dam and block-out shim

Case 5: Figure 24: Completion of Locator housing pick-up using auto-polymerizing acrylic resin

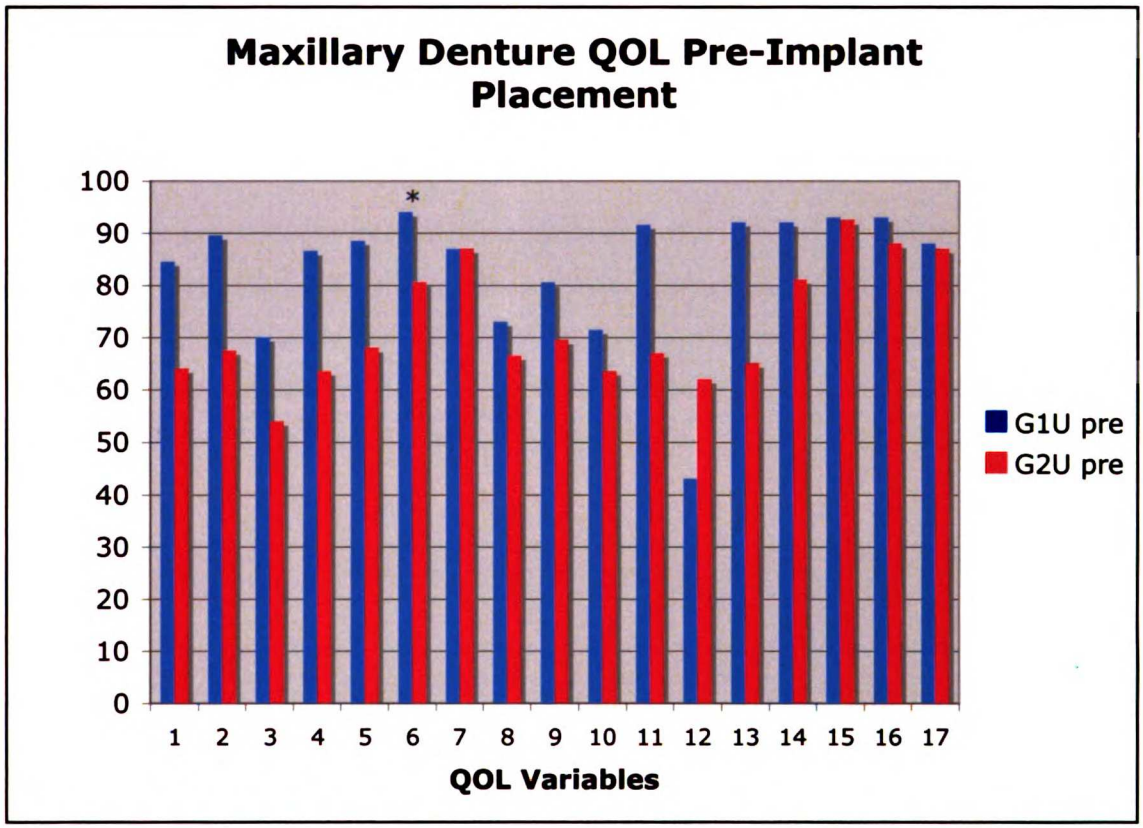


Figure 25: Median Maxillary Denture Pre-Implant QOL and VAS (1-100): G1U: Mini-Dental Implant Group Maxillary Denture. G2U: Standard-Dental Implant Group Maxillary Denture.
1. General Satisfaction, 2. Overall function, 3. Stability, 4. Retention, 5. Fit, 6. Appearance, 7. Speech ability, 8. Overall chewing ability, 9. Chewing hard foods, 10. Chewing tough foods, 11. Chewing crisp foods, 12. Chewing whole fruits, 13. Chewing fruit pieces with peels, 14. Chewing fruit with out peels, 15. Chewing soft/dry foods, 16. Chewing soft/wet foods, 17. Chewing flat vegetables. *Significant differences between the groups.

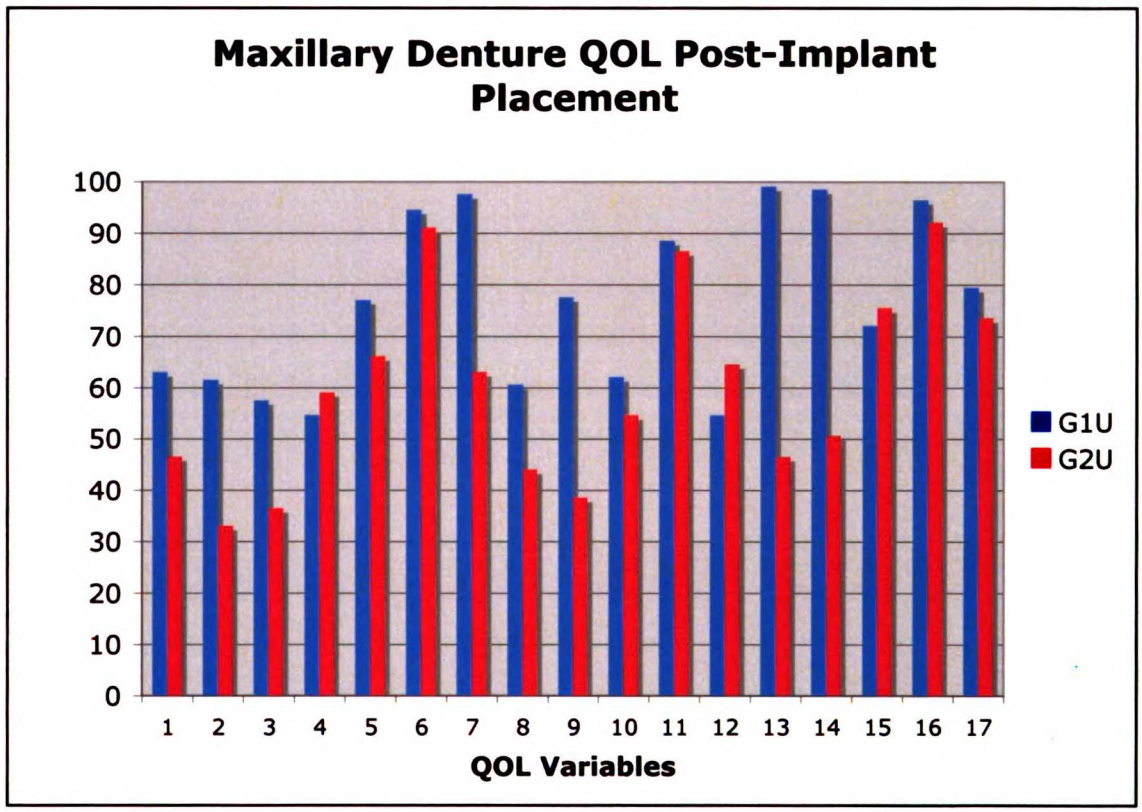


Figure 26: Median Maxillary Denture Post-Implant QOL and VAS (1-100): G1L: Mini-Dental Implant Group Maxillary Denture. G2L: Standard-Dental Implant Group Maxillary Denture.
1. General Satisfaction, 2. Overall function, 3. Stability, 4. Retention, 5. Fit, 6. Appearance, 7. Speech ability, 8. Overall chewing ability, 9. Chewing hard foods, 10. Chewing tough foods, 11. Chewing crisp foods, 12. Chewing whole fruits, 13. Chewing fruit pieces with peels, 14. Chewing fruit with out peels, 15. Chewing soft/dry foods, 16. Chewing soft/wet foods, 17. Chewing flat vegetables. *Significant differences between the groups.

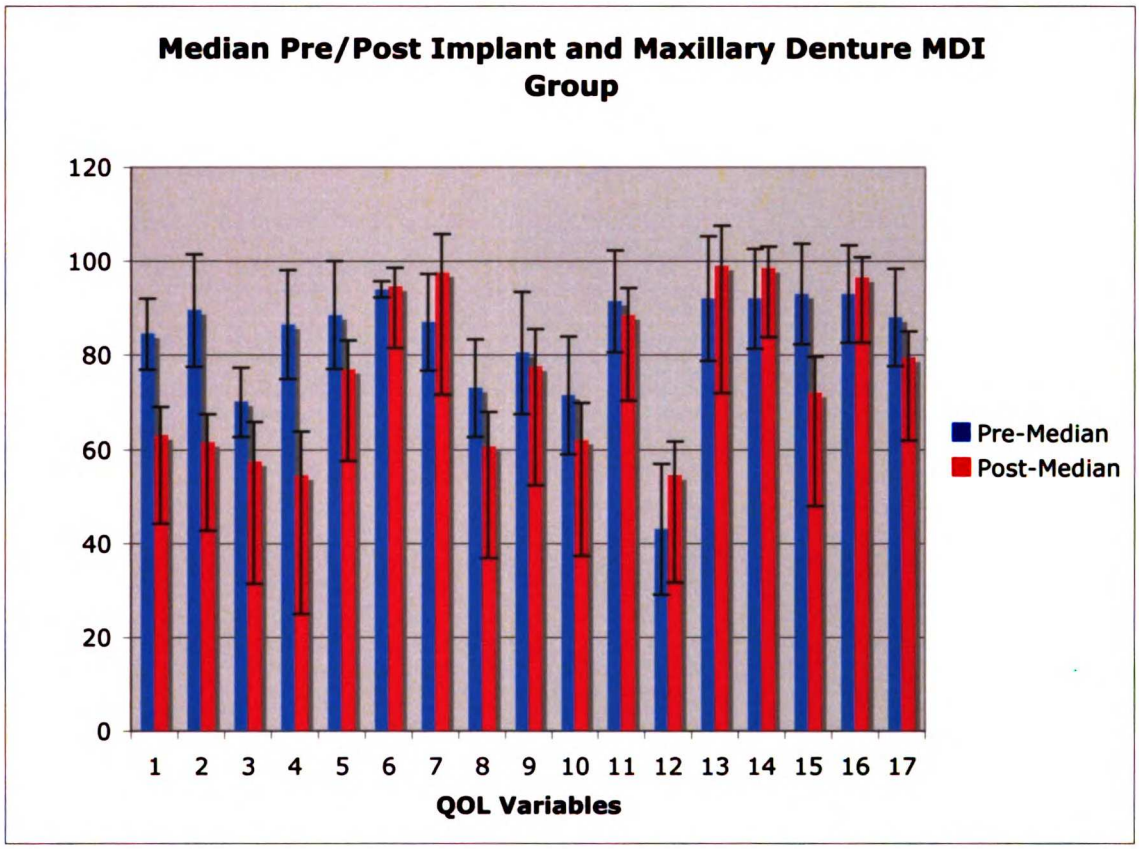


Figure 27 Group 1; Pre-Implant and 6 months Post-Implant placement Mini-Dental Implant Group VAS (1-100) QOL and Maxillary Denture QOL: Maxillary Denture Pre- and Post-Implant QOL Median and standard error. 1. General Satisfaction, 2. Overall function, 3. Stability, 4. Retention, 5. Fit, 6. Appearance, 7. Speech ability, 8. Overall chewing ability, 9. Chewing hard foods, 10. Chewing tough foods, 11. Chewing crisp foods, 12. Chewing whole fruits, 13. Chewing fruit pieces with peels, 14. Chewing fruit with out peels, 15. Chewing soft/dry foods, 16. Chewing soft/wet foods, 17. Chewing flat vegetables.

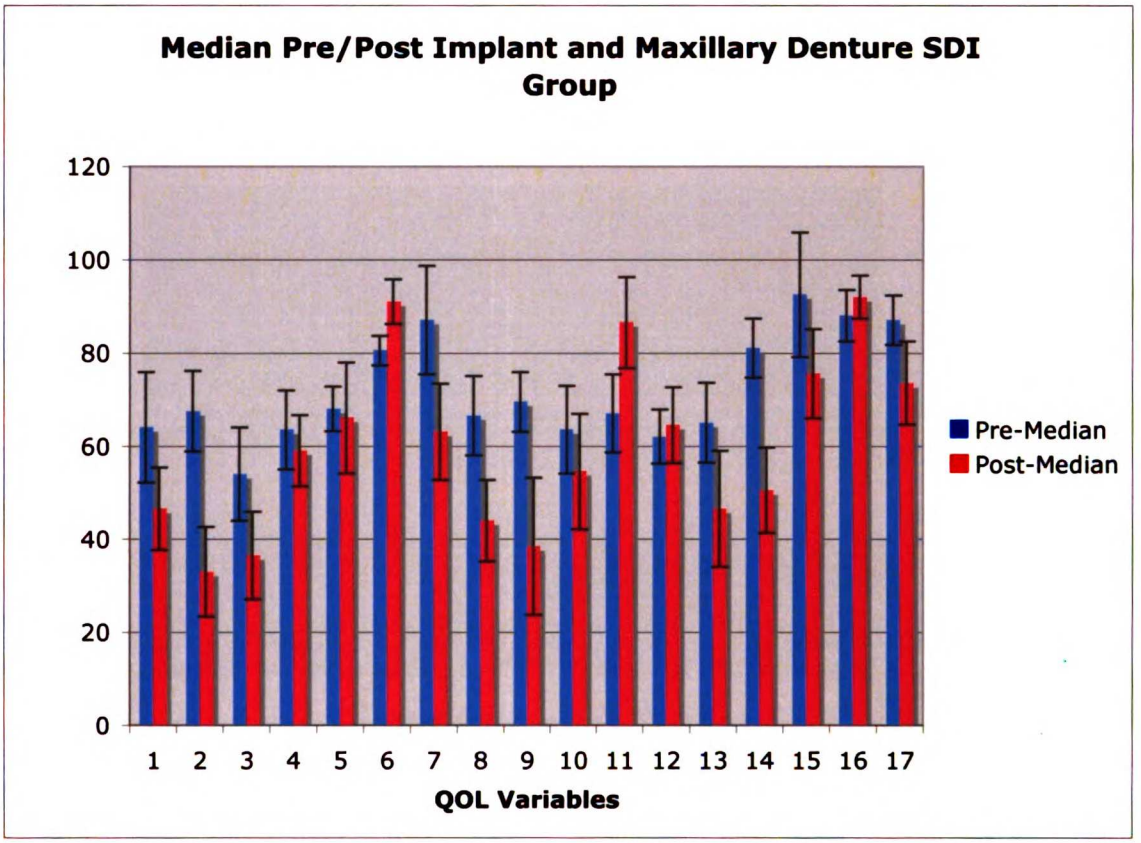


Figure 28. Group 2; Pre-Implant and 6 months Post-Implant placement Standard-Dental Implant Group VAS (1-100) QOL and Maxillary Denture QOL: Maxillary Denture Pre- and Post-Implant QOL Median and standard error. 1. General Satisfaction, 2. Overall function, 3. Stability, 4. Retention, 5. Fit, 6. Appearance, 7. Speech ability, 8. Overall chewing ability, 9. Chewing hard foods, 10. Chewing tough foods, 11. Chewing crisp foods, 12. Chewing whole fruits, 13. Chewing fruit pieces with peels, 14. Chewing fruit with out peels, 15. Chewing soft/dry foods, 16. Chewing soft/wet foods, 17. Chewing flat vegetables.

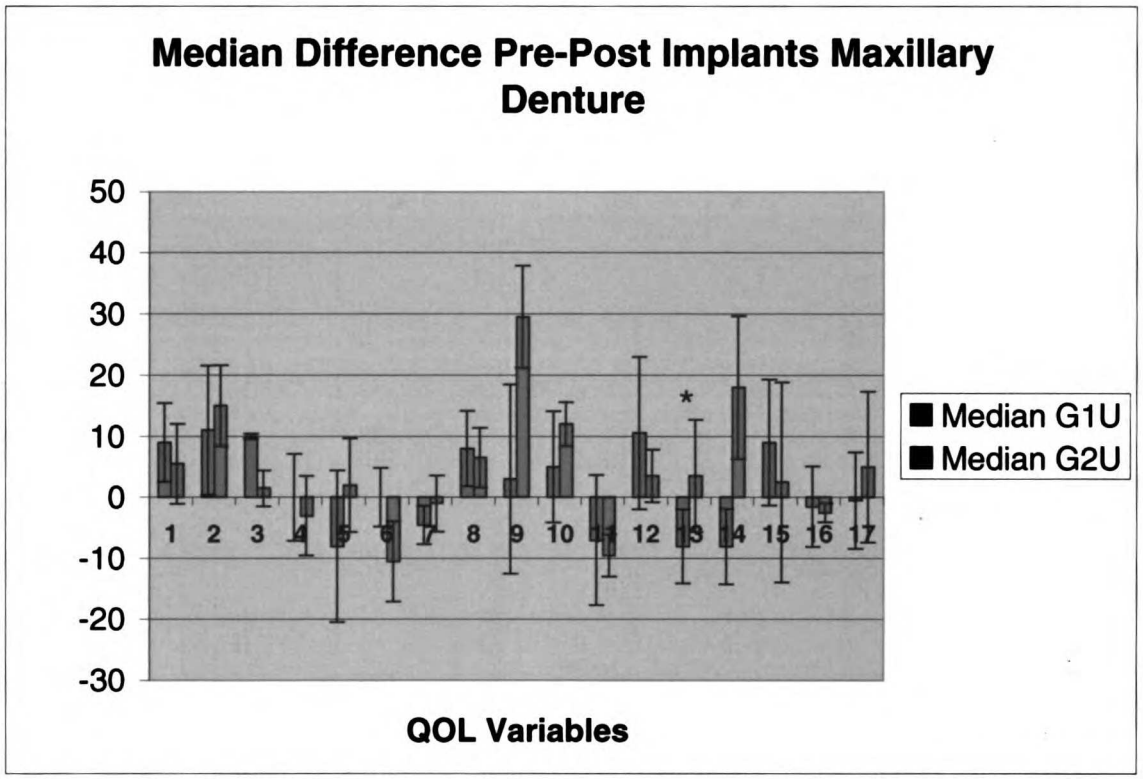


Figure 29. Difference Pre-Implant and 6 months Post-Implant placement between G1U (Mini-Dental Implant Group) and G2U (Standard-Dental Implant Group) VAS rating (1-100) and Maxillary Denture QOL: Maxillary Denture Pre- and Post-Implant QOL Median and standard error. 1. General Satisfaction, 2. Overall function, 3. Stability, 4. Retention, 5. Fit, 6. Appearance, 7. Speech ability, 8. Overall chewing ability, 9. Chewing hard foods, 10. Chewing tough foods, 11. Chewing crisp foods, 12. Chewing whole fruits, 13. Chewing fruit pieces with peels, 14. Chewing fruit with out peels, 15. Chewing soft/dry foods, 16. Chewing soft/wet foods, 17. Chewing flat vegetables. *Significant differences between the groups.

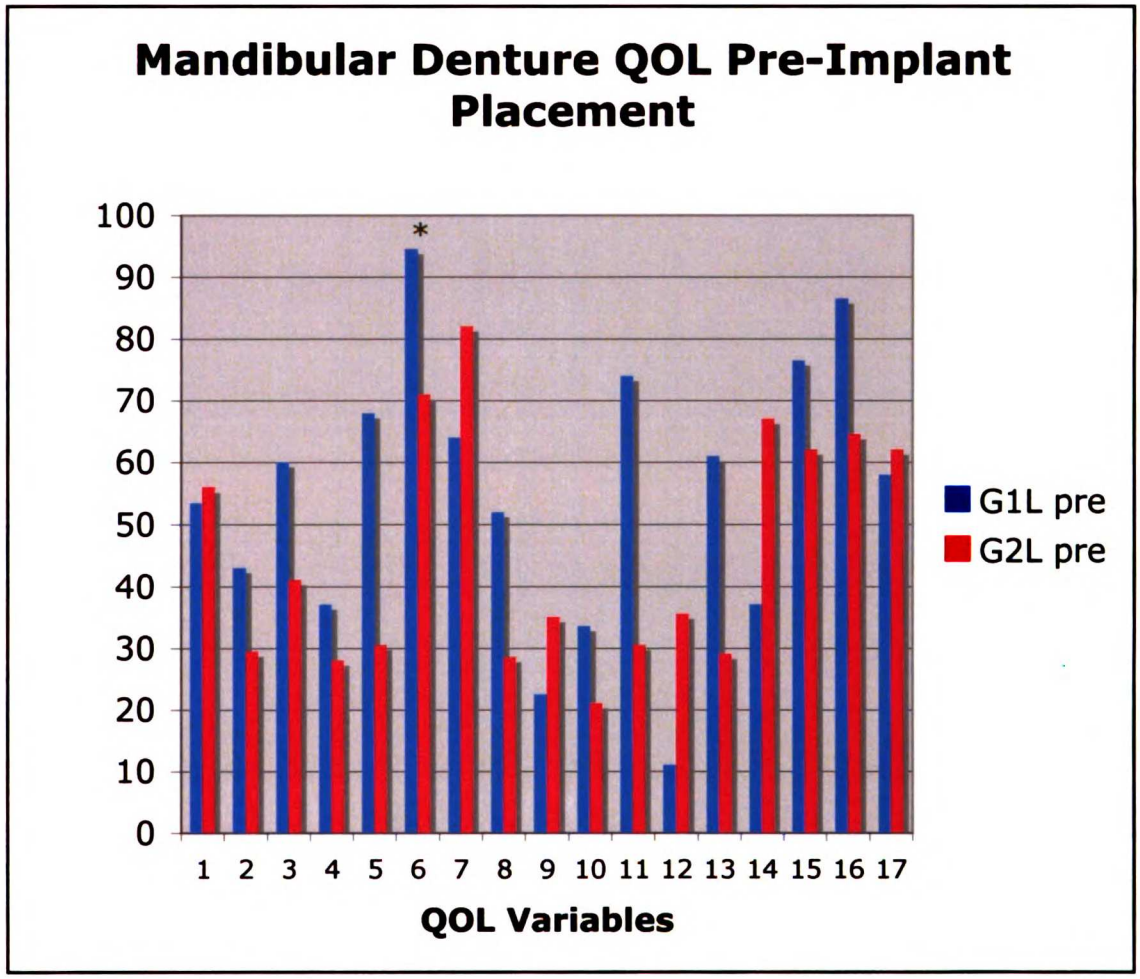


Figure 30: Median Mandibular Denture Pre-Implant QOL and VAS (1-100): G1L: Mini-Dental Implant Group Maxillary Denture. G2L: Standard-Dental Implant Group Maxillary Denture. 1. General Satisfaction, 2. Overall function, 3. Stability, 4. Retention, 5. Fit, 6. Appearance, 7. Speech ability, 8. Overall chewing ability, 9. Chewing hard foods, 10. Chewing tough foods, 11. Chewing crisp foods, 12. Chewing whole fruits, 13. Chewing fruit pieces with peels, 14. Chewing fruit with out peels, 15. Chewing soft/dry foods, 16. Chewing soft/wet foods, 17. Chewing flat vegetables. *Significant differences between the groups.

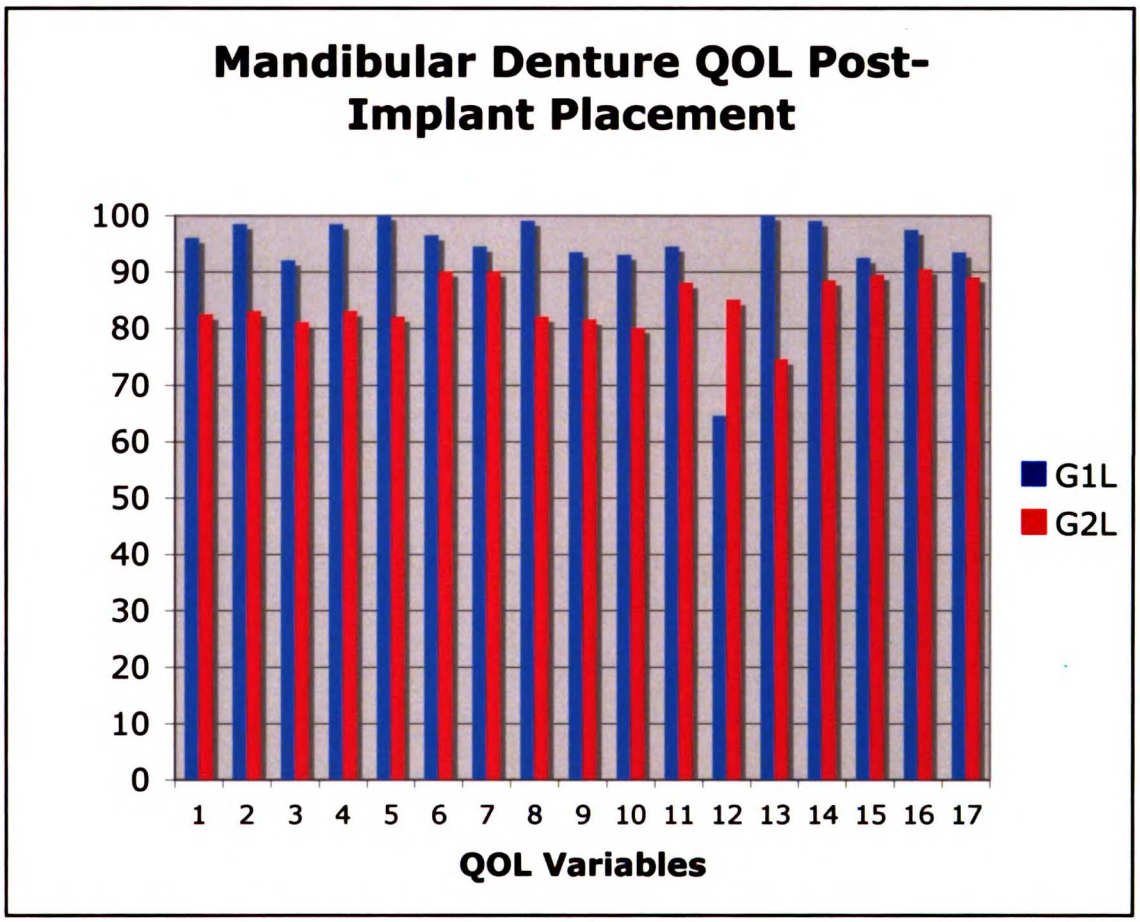


Figure 31: Median Mandibular Denture Post-Implant QOL and VAS (1-100): G1L: Mini-Dental Implant Group Maxillary Denture. G2L: Standard-Dental Implant Group Maxillary Denture. 1. General Satisfaction, 2. Overall function, 3. Stability, 4. Retention, 5. Fit, 6. Appearance, 7. Speech ability, 8. Overall chewing ability, 9. Chewing hard foods, 10. Chewing tough foods, 11. Chewing crisp foods, 12. Chewing whole fruits, 13. Chewing fruit pieces with peels, 14. Chewing fruit with out peels, 15. Chewing soft/dry foods, 16. Chewing soft/wet foods, 17. Chewing flat vegetables. *Significant differences between the groups.

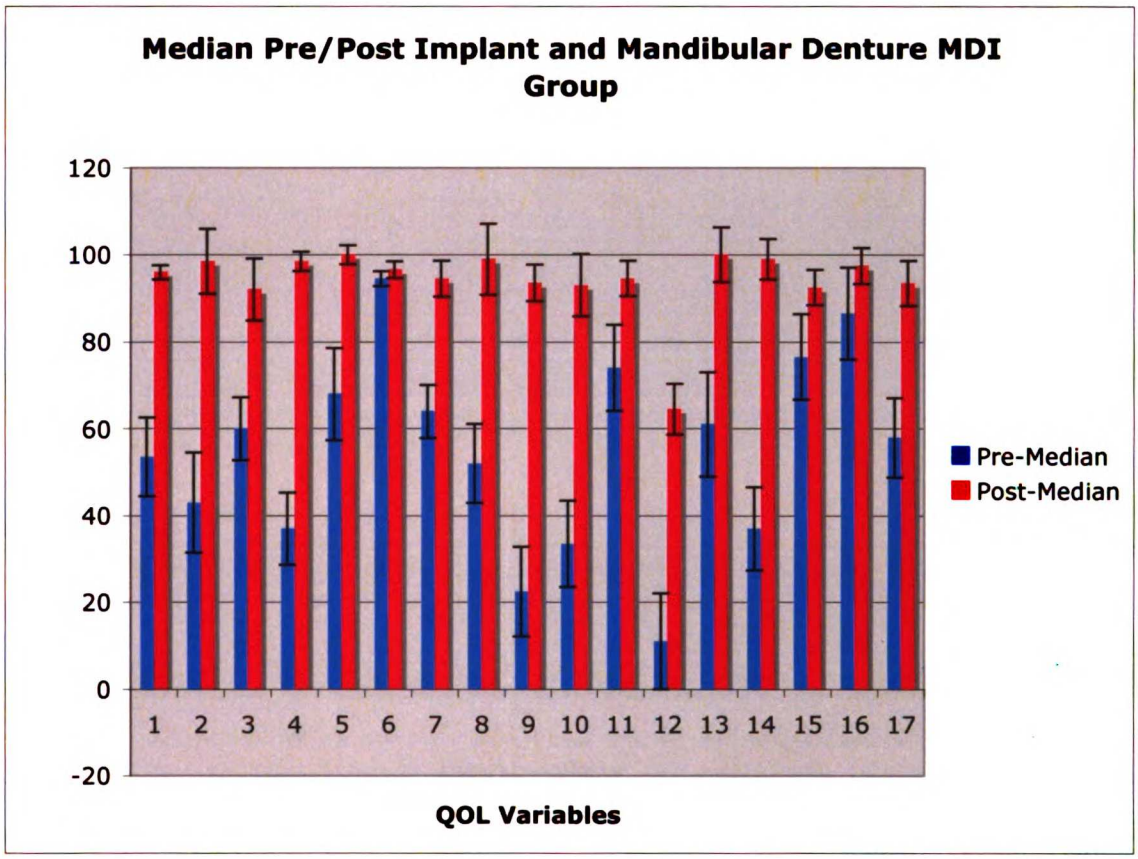


Figure 32. Group 1; Mandibular Denture Pre- and Post-Implant QOL Median and standard error: Pre-Implant and 6 months Post-Implant placement Mini-Dental Implant Group VAS (1-100) QOL and Mandibular Denture QOL. 1. General Satisfaction, 2. Overall function, 3. Stability, 4. Retention, 5. Fit, 6. Appearance, 7. Speech ability, 8. Overall chewing ability, 9. Chewing hard foods, 10. Chewing tough foods, 11. Chewing crisp foods, 12. Chewing whole fruits, 13. Chewing fruit pieces with peels, 14. Chewing fruit with out peels, 15. Chewing soft/dry foods, 16. Chewing soft/wet foods, 17. Chewing flat vegetables.

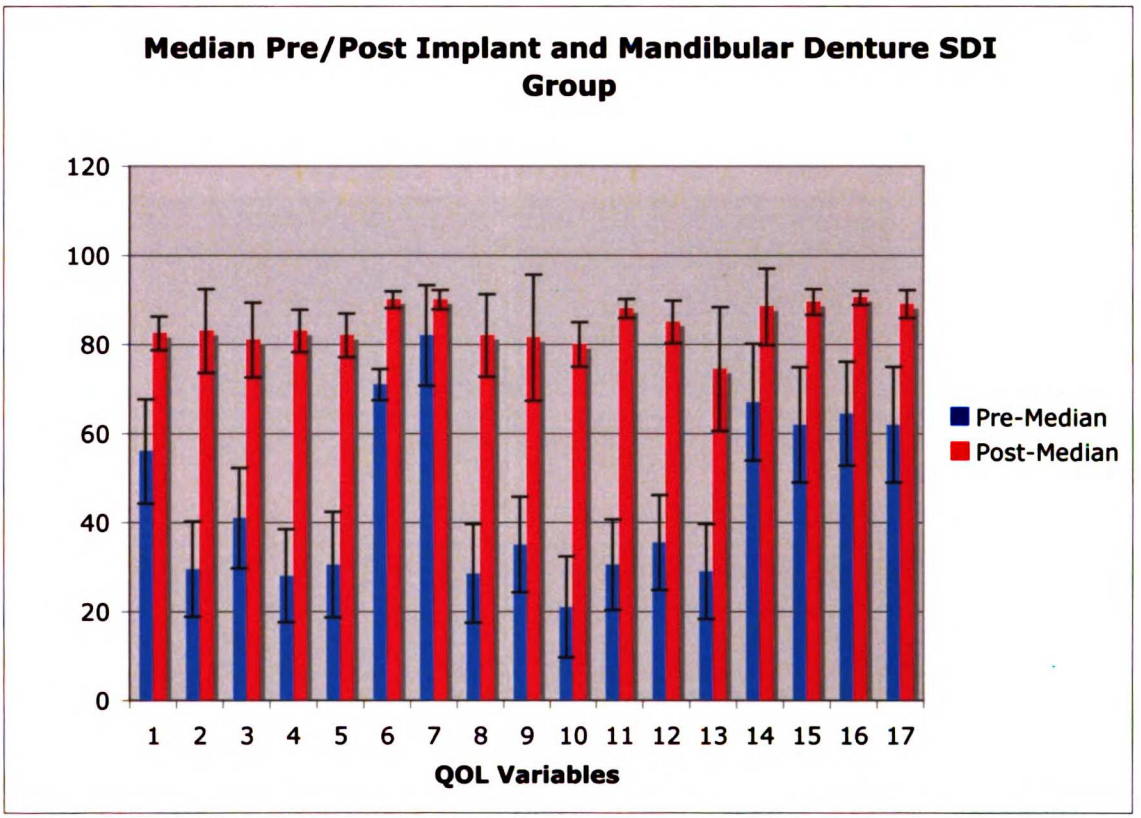


Figure 33. Group 2; Mandibular Denture Pre- and Post-Implant QOL Median and standard error: Pre-Implant and 6 months Post-Implant placement Standard-Dental Implant Group VAS (1-100) QOL and Mandibular Denture QOL. 1. General Satisfaction, 2. Overall function, 3. Stability, 4. Retention, 5. Fit, 6. Appearance, 7. Speech ability, 8. Overall chewing ability, 9. Chewing hard foods, 10. Chewing tough foods, 11. Chewing crisp foods, 12. Chewing whole fruits, 13. Chewing fruit pieces with peels, 14. Chewing fruit with out peels, 15. Chewing soft/dry foods, 16. Chewing soft/wet foods, 17. Chewing flat vegetables.

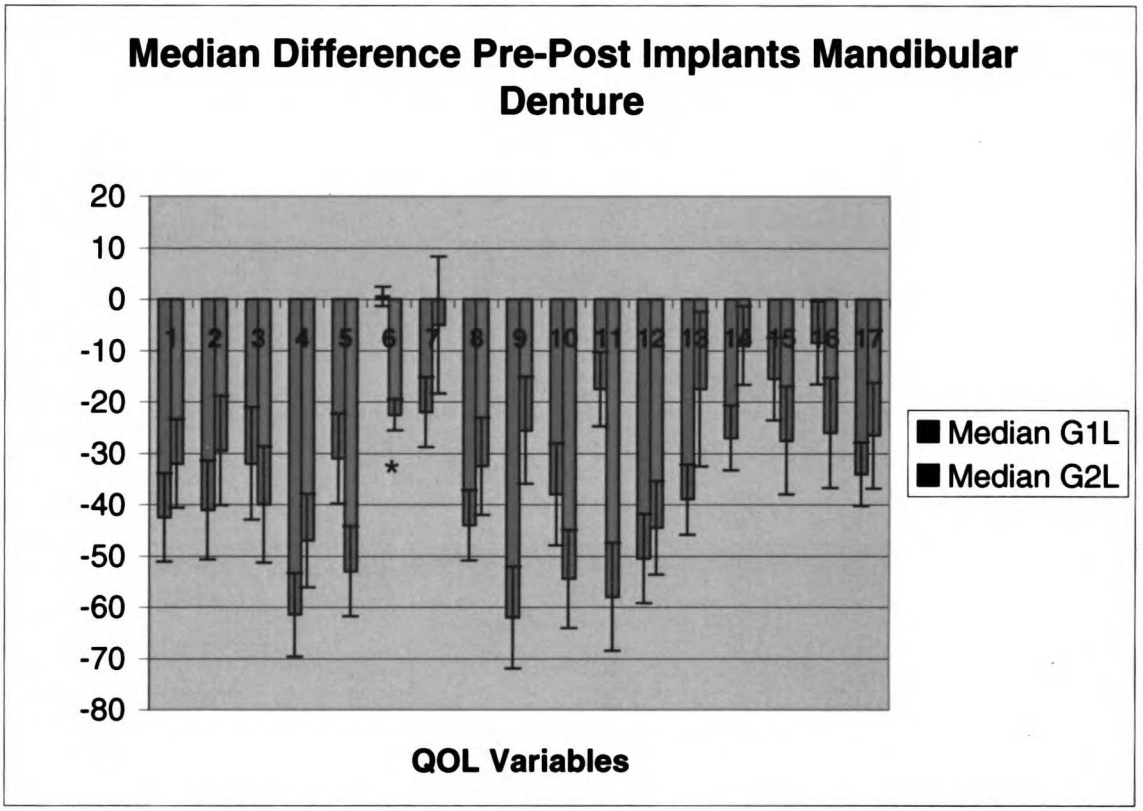
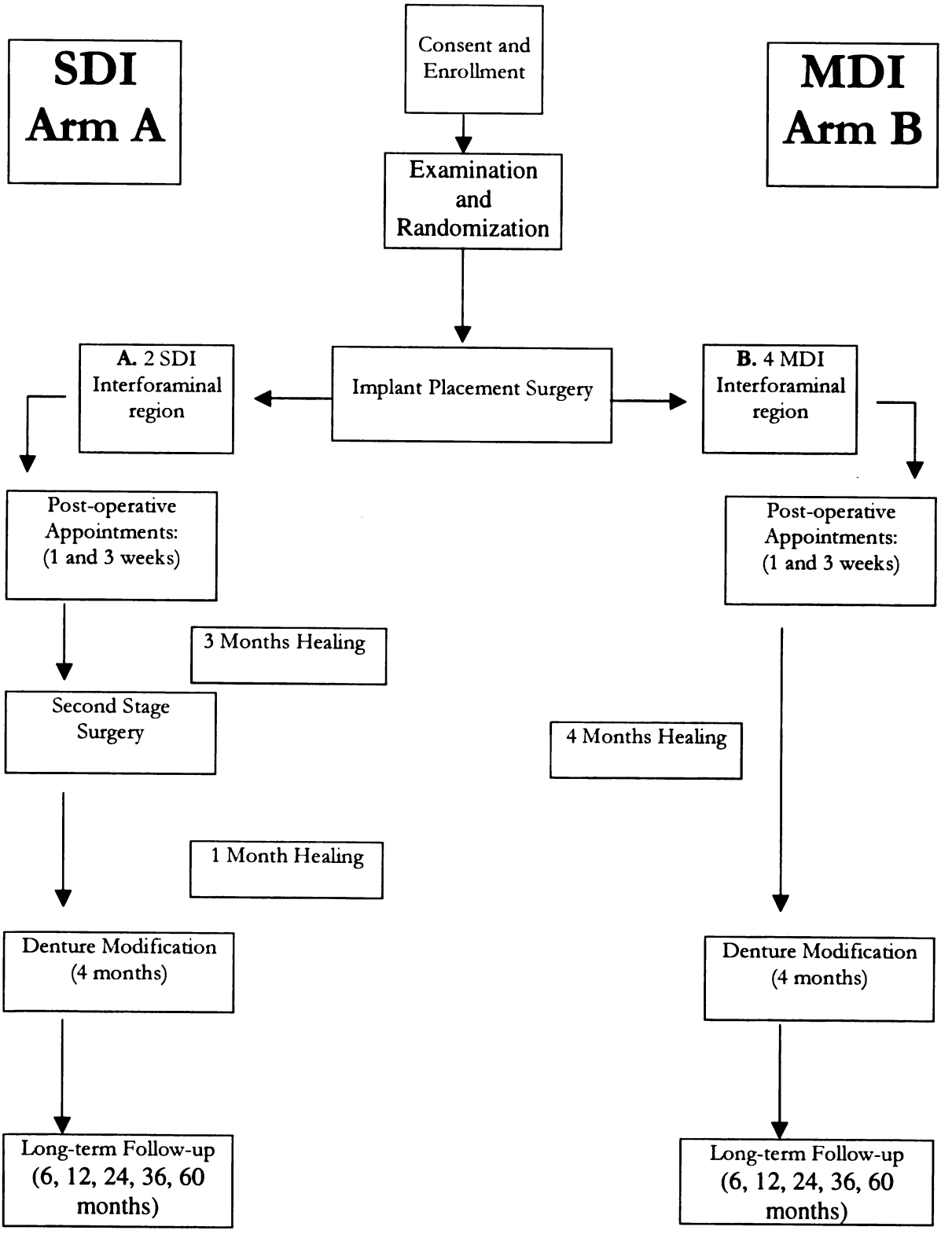


Figure 34. Difference Pre-Implant and 6 months Post-Implant placement between G1L (Mini-Dental Implant Group) and G2L (Standard-Dental Implant Group) VAS rating (1-100) and Mandibular Denture QOL: Mandibular Denture Pre- and Post-Implant QOL Median and standard deviation. 1. General Satisfaction, 2. Overall function, 3. Stability, 4. Retention, 5. Fit, 6. Appearance, 7. Speech ability, 8. Overall chewing ability, 9. Chewing hard foods, 10. Chewing tough foods, 11. Chewing crisp foods, 12. Chewing whole fruits, 13. Chewing fruit pieces with peels, 14. Chewing fruit with out peels, 15. Chewing soft/dry foods, 16. Chewing soft/wet foods, 17. Chewing flat vegetables. *Significant differences between the groups.

Appendix 1: Appointment Flow Chart



Appendix 2:

VAS Clinical Evaluations:

Please indicate how much in each category is present at this visit:

1. General satisfaction:

In general, are you satisfied with your lower denture?

Not at all **Completely**
Satisfied _____ **satisfied**

In general, are you satisfied with your upper denture?

Not at all **Completely**
Satisfied _____ **satisfied**

2. Overall function:

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

Not at all **Completely**
Satisfied _____ **satisfied**

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

Not at all **Completely**
Satisfied _____ **satisfied**

3. Overall chewing ability:

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

Not at all **Completely**
Satisfied _____ **satisfied**

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

Not at all **Completely**
Satisfied _____ **satisfied**

4. Speech ability:

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

Not at all **Completely**
Satisfied _____ **satisfied**

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

Not at all **Completely**
Satisfied _____ **satisfied**

5. Stability (rocking side to side):

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

Not at all **Completely**
Satisfied _____ **satisfied**

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

Not at all **Completely**
Satisfied _____ **satisfied**

6. Retention (dislodging):

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

Not at all **Completely**
Satisfied _____ **satisfied**

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

Not at all **Completely**
Satisfied _____ **satisfied**

7. Appearance:

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

Not at all **Completely**
Satisfied _____ **satisfied**

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

Not at all **Completely**
Satisfied _____ **satisfied**

8. Fit (comfort):

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

Not at all **Completely**
Satisfied _____ **satisfied**

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

Not at all **Completely**
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 **Completely**
Satisfied _____ **satisfied**

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

Not at all **Completely**
Satisfied _____ **satisfied**

10. Chewing tough foods (examples: beef):

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

Not at all **Completely**
Satisfied _____ **satisfied**

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

Not at all **Completely**
Satisfied _____ **satisfied**

11. Chewing crisp foods (examples: chips):

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

Not at all **Completely**
Satisfied _____ **satisfied**

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

Not at all **Completely**
Satisfied _____ **satisfied**

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

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

Not at all **Completely**
Satisfied _____ **satisfied**

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

Not at all **Completely**
Satisfied _____ **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 **Completely**
Satisfied _____ **satisfied**

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

Not at all **Completely**
Satisfied _____ **satisfied**

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

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

Not at all **Completely**
Satisfied _____ **satisfied**

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

Not at all **Completely**
Satisfied _____ **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 **Completely**
Satisfied _____ **satisfied**

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

Not at all **Completely**
Satisfied _____ **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 **Completely**
Satisfied _____ **satisfied**

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

Not at all **Completely**
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 **Completely**
Satisfied _____ **satisfied**

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

Not at all **Completely**
Satisfied _____ **satisfied**

Appendix 3:

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**
    - Alcohol and smoking history
    - Chronic analgesics
    - Medications
    - Diabetes
- **Head and Neck Exam:**
    - Head and neck examination including visual inspection and manual palpation of muscles for tenderness, swellings, ulcerations, lesions, or lymphadenopathy.
    - Inspection of the mouth will include visual inspection and manual palpation of the buccal mucosa, gingiva, palate, floor of mouth and tongue for tenderness, swellings, ulcerations, lesions, lymphadenopathy, erythroplakias or leukoplakias .
- **Panographic radiograph**
- **Existing Denture, Patient, and Anatomical Evaluation**
    - Number of previous dentures
    - Age of current dentures
    - Stability, retention, and support of current dentures: (0-3: 0=poor, 1=fair, 2=good, 3=excellent)
    - Occlusion: adequate, inadequate, or adjustable

- Acrylic thickness: adequate or inadequate
- House Classification: Philosophical, exacting, indifferent, hysterical
- Posterior ridge anatomy: flat, round, or spiny
- Keratinized gingiva: adequate or inadequate
- Vestibular depth: adequate or inadequate
- Facial and lingual frena: adequate or inadequate
- New or functional reline of maxillary or mandibular denture determined.
    - If new denture(s) needed, subject sent to general dentist for care
    - If functional reline(s) needed, two-three appointments for functional reline by study investigator(s)

- **Final Inclusion and Exclusion Criteria determined**
- **Questionnaires:**
    - Pain anticipation on VAS scale
    - Quality of life, before implant placement regarding your satisfaction with your lower and upper denture.
- **Randomization**:
    - Random number generator (Microsoft Excel) places subject in Group A or B.

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

- **Questionnaire:**
    - Pain immediate post-op on VAS scale

- **Surgical Forms and Summary completed:**
    - Amount and type of local anesthesia: buccal, lingual, and crestal locals only
    - Sedation
    - Type of bone quality and quantity
    - Type, size, and location of implants
    - Amount of stability
    - Type of incisions, if needed
    - Degree of soft tissue closure
    - Type and number of sutures, if needed
    - Surgical complications
    - Amount and type of analgesics prescribed, if needed
    - Amount and type of antibiotics, if needed
    - Amount, duration, and frequency of chlorhexidine
- **Panographic radiograph**
- **Denture modification**
    - **Group 1 and 2:** 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**

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

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

- **Surgical Forms and Summary completed:**
    - Amount and type of local anesthesia: buccal, lingual, and crestal locals only

- Type of incisions, if needed
- Type and number of sutures, if needed
- Implant torque test to 35Ncm
    - Implant(s) not integrated, implant removal
    - If implant failure additional implant(s) placed depending on patient's desires
- Size of healing abutment
- Amount and type of analgesics prescribed, if needed
- Amount and type of antibiotics, if needed
- 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
  - Gingival index
  - Bleeding index

- **Implant prophylaxis**

<u>Additional appointments</u>:

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

Appendix 4:

Implant Procedure Information

Chronic Use of Analgesics: no____ yes_____

Dental procedure _____

Local Anesthesia: no____ yes_____

If yes, please list: drug name_____
amount_____

Sedation: no____ yes_____

If yes, please list: oral_____ IV_____ Conscious_____
drug name_____
dose/duration_____

Analgesics prescribed: no____ yes_____

If yes, please list them: drug name_____
dose/duration_____

drug name_____
dose/duration_____

Questionnaire on Day of Procedure & 24h After

Mark the line at the point that corresponds to the following:

I. On the Day of Dental Procedure:

a) Anticipation

How much pain do you think you might have today?

No pain_____**worst pain that I will ever have experienced**

b) Immediately After the Dental Procedure:

How much pain are you experiencing now?

No pain_____**worst pain that I have ever experienced**

c) 24 hours After the Dental Procedure:

How much pain are you experiencing now?

___ No pain
___ Mild Pain
___ Moderate Pain
___ Severe Pain
___ Worst pain that I have ever experienced

Questionnaire at First Follow-up Visit

a) How much pain are you experiencing now?

No pain_____**worst pain that I have ever experienced**

b) How much pain have you experienced, on average, since the dental procedure was done?

No pain_____**worst pain that I have ever experienced**

c) If you had pain since the procedure was done, how well was it controlled by the medications and/or instructions given to you by your dentist or dental hygienist?

Not Controlled_____**Well Controlled**

Please circle the response that applies:

1. Did you need to take all your pain medication? **Yes** **No**

   For how many days did you take medications 1 2 3 4 5 6 7

   If **No**, how much did you take? **Less than Half** **Half** **More than Half**

2. Did you take anything else for pain relief? **Yes** **No**

   If **Yes**, what did you take?

_____

3. Did you have any side effects to the pain medication? **Yes** **No**

   If **Yes**, please describe _____

Questionnaire at Second Follow-up Visit

a) How much pain are you experiencing now?

No pain_____**worst pain that I have ever experienced**

b) How much pain have you experienced, on average, since the dental procedure was done?

No pain_____**worst pain that I have ever experienced**

c) If you had pain since the procedure was done, how well was it controlled by the medications and/or instructions given to you by your dentist or dental hygienist?

Not Controlled_____**Well Controlled**

Please circle the response that applies:

1. Did you need to take all your pain medication? **Yes** **No**

   For how many days did you take medications 1 2 3 4 5 6 7

   If **No**, how much did you take? **Less than Half** **Half** **More than Half**

2. Did you take anything else for pain relief? **Yes** **No**

   If **Yes**, what did you take?

_____

3. Did you have any side effects to the pain medication? **Yes** **No**

   If **Yes**, please describe _____

At First Follow-Up Visit

Clinical Evaluations:

1. Swelling - Please indicate how much swelling is present at this visit:

No Swelling_____**Extensive**

2. Wound Healing:

Poorly_____**Very Well**

3. Other complications, if yes please describe: _____

_____

_____

4. How well do you feel the analgesic medication prescribed and/or instructions given to the patient controlled their pain

Not at all_____**Extremely**

At Second Follow-Up Visit

Clinical Evaluations:

1. Swelling - Please indicate how much swelling is present at this visit:

No Swelling_____**Extensive**

2. Wound Healing:

Poorly_____**Very Well**

3. Other complications, if yes please describe: _____

_____

_____

4. How well do you feel the analgesic medication prescribed and/or instructions given to the patient controlled their pain

Not at all_____**Extremely**