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

by

Anna Hsu

THESIS

Submitted in partial satisfaction of the requirements for the degree of

MASTER OF SCIENCE

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[redacted]

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

Anna Hsu DDS

Abstract

Introduction: Conventional mandibular dentures can pose a problem for severely atrophic mandibles in regards to lack of retention, stability, and support resulting in functional deficiencies in mastication and speech. In addition, patient comfort may be compromised. Mini-implants can be used in cases where standard diameter implants are impractical to provide stabilization of a dental prosthetic appliance. The purpose of this study is compare the long term clinical success and patient's quality of life between standard versus mini dental implant retained overdenture.

Materials and Methods: 35 patients were randomly assigned to two groups, the mini dental and standard implant, to retain a complete mandibular denture. The patients were followed for a period of 36 months and quality of life surveys were utilized to evaluate patient satisfaction.

Results: The results showed that there was no significant difference in long term clinical success and patient's quality of life between standard versus mini dental implants placed in the interforaminal area of the mandible over the 36 months follow up period.

Conclusions: There is no difference in the long-term implant survival rate or in the quality of life between the standard dental implants and mini-dental implants retained overdenture in the mandible.

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Section 1

Introduction:

Conventional dentures are no longer the most appropriate option for restoring the edentulous mandible and that the two-implant retained over-denture should become the first choice prosthodontic treatment. [1] The standard of care for implant-supported prostheses of edentulous mandibles is a 2-implant-retained over-denture. This over-denture is a traditional denture that uses two standard-sized implants (SDIs) placed in the front part of the lower jaw onto which the denture is easily "snapped" into place.

Oral rehabilitation using two to four implants to support mandibular overdentures has been shown to have success rates of approximately 96% with implants placed in a one- or two-stage procedure. Several authors have looked at patient satisfaction with mandibular-implant supported over-dentures. [2-6] One author Meijer et al reported that patient's with two implant supported mandibular over-dentures had a higher satisfaction scores than patients who had conventional mandibular dentures. [7]

Miniature-sized dental implants have been in use in various forms for approximately 20 years and initially used for transitional and provisional purposes, but it was observed that these implants appeared to osseointegrate. In 1997, the Sendax IMTEC mini dental implant has the US Food and Drug Administration approval for both ongoing and long-term use. [8] The advantages of these dental implants include: low cost, ease of placement, shortened surgical and healing times, and utilization in narrow jaws.

In edentulous patients, retention of dentures is a key indicator to patient satisfaction. However, ridge resorption can result in a lack of retention, especially for mandibular dentures. Such a lack of retention often leads to abnormal speech, difficulty in

mastication, and an altered or sunken facial appearance. To help alleviate such issues for patients experiencing mandibular ridge resorption, mini-dental implants (MDI) can be placed to provide optimal retention for mandibular dentures.

Purpose and Hypothesis

The purposes of this long-term clinical study are to: (i) to evaluate the long term implant survival rate of standard-sized dental implant (SDI, the current gold standard), or mini-dental implants (MDI) 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 null hypothesis of this research is that there will be no difference in long-term survival rate, clinical success, and quality of life experienced between standard dental implants and mini-dental implants placed in the interforaminal region of the anterior mandible.

Section 2

Review of Literature

Implant Overdenture Background:

Conventional mandibular dentures for patients with severely atrophic mandibles often presents with retention, phonetic, and functional complications. In addition, patients often experience discomfort due to instability of the dentures. It is widely accepted by both dentists and patients that implant supported/retained mandibular complete prostheses are a significant improvement over 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. [8]

The mandibular fixed full arch prosthesis requires an adequate number of implants of sufficient size with enough anterior- posterior spread. 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. [9-12] An alternative implant treatment option is the removable implant-retained overdenture, which has also been evaluated in a number of studies and documented in the literature by several authors. [10, 13-22]

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. [8]

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. [8]

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. [8]

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. [8]

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 (Warsaw, Indiana), ITI (Andover, Massachusetts), and Noble Biocare (Zurich, Switzerland), and Bicon (Boston, Massachusetts) 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. [23] 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" [24,25] 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. [24,25]

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. [26]

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 evaluated with standardized radiographs. [24]

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. [25]

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. [27]

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. [28]

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. [29] 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. [30] 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. [31] In a 5-year case series article, Mazor and coworkers (2004), reported on 32 mini-implants that were immediately loaded and restored. [32]

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. [33]

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. [34]

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. [35] Several authors have reported implant success when using two implants to retain a mandibular overdenture over a five year period. [36-39] 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. [36]

In a five-year longitudinal study by Mericske-Stern R and coworkers (1994), they 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. [37]

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. [38]

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. [39]

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: [35]

- 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. [41]

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. [40]

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. [41]

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. [42]

According to several authors, masticatory forces do not seem to differ between the tissue-supported implant overdenture and implant-supported overdenture when opposing a conventional maxillary denture. [43-46]

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. [43]

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. [44]

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. [45-48] 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. [49] The choice of attachments for the mandibular

overdenture include but not limited to the following parameters: patient retention, support, stability needs, jaw morphology and anatomy, and compliance to hygiene and maintenance recalls. [35]

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. [48] Overloading of the implants retaining an overdenture might be more influenced by the superstructure fit and occlusion, rather than the anchorage. [50]

Both solitary attachments and bars have advantages and disadvantages. The solitary attachment is less costly, easier to restore, [51] easier to clean, [52] and causes less gingival hyperplasia. [53] However, bars have greater retention. [54] With regards to maintenance requirements, controversy still remains whether solitary attachments or bars require more maintenance. [55-57] 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). [55-65]

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. [66]

There are several different loading modes: [67]

- 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. [68-73] 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). [69]

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. [70]

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. [72]

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. [73]

Anterior and Posterior Mandibular Bone Preservation:

When patients wear a conventional complete denture, there will be alveolar ridge height reduction over time. [35] 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. [74,75] Implants in the anterior mandible have been shown to increase positive bone remodeling. [35]

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. [76]

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. [38, 77,78]

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. [35] 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. [79]

In the Jacobs and coworkers (1992) study, three groups of patients with different prosthetic reconstructions was 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. [79]

Other researchers have found that fixed implant complete denture may regenerate posterior mandibular bone. [80] 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. [80]

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. [35]

Effect of Mandibular Implant Prosthesis on the Maxillary Arch:
Combination syndrome has been reported when a mandibular overdenture opposes a complete maxillary denture. [81-84] 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. [35]

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. [81]

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. [82]

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. [83]

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. [84]

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. [85-88] 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. [85]

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. [89] Maxillary denture relines may be needed in the range of 25% to 33% of the time over a five-year period. [90,91]

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. [89]

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. [92]

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. [93]

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, [75] 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. [94]

Edentulism can be disabling within the context of appearance, appetite, eating, general health, mood, recreation, weight, and work. [95,96] 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. [97]

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. [93]

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. [93] 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. [98] 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. [93] 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. [99]

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. [100] 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). [101]

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. [102-105]

Many authors have addressed patient satisfaction with implant overdentures. [21, 39, 53, 102, 106-121, 123, 129] Awad MA and coworkers (1998), [102] 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. [102]

In another study by Awad MA and coworkers (2000), [106] 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. [122] 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. [106]

In Boerrigter EM and coworkers (1995), [107] 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. [107]

Raghoebar GM and coworkers (2000), [108] 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. [108]

In a randomized clinical trial, Awad MA and coworkers (2003), [112] 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. [112]

In a similar randomized clinical trial, Awad MA and coworkers (2003), [113] 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. [113]

Feine and coworkers (1994), [116] 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. [116]

De Grandmont P and coworkers (1994), [117] 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. [117]

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. [123] 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. [124-128]

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. [129]

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. [129]

Patient expectations of the outcome may play an important role in their preferences. [130] 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. [129] 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. [131]

Patients with positive expectations of treatment tend to ignore adverse symptoms and focus on apparent improvements following therapy. [130] 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. [129]

Section 3

Materials and Methods

Thirty-five completely edentulous subjects were enrolled in a single-center, case controlled clinical study. 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-year period or referred from other Veteran's Administration hospitals with ill fitting mandibular denture due to severely atrophic mandibles complaining of denture stability, comfort and/or retention. Patients selected were screened by telephone interview, and subjects that were eligible and interested were appointed for a clinical and radiographic examination.

Patients were examined and enrolled based on inclusion and exclusion criteria (**Table 1**). The inclusion criteria for this study were as followed: 1) recently made maxillary and mandibular complete dentures; 2) mandibular dentures with adequate support and stability that are poorly retained; 3) maxillary dentures with adequate retention, support and stability, with at least one month experience wearing the existing denture; 4) ability to answer the questionnaires; 5) no systemic diseases which could influence the outcome of therapy; 6) good level of oral hygiene and denture care; 7) compliance with the recall and maintenance program; 8) presence of adequate bone quantity and quality to support dental implants; and 9) dental coverage at SFVADC.

Volunteers were excluded from the study if they have the following: 1) bleeding

disorders and blood dyscrasias; 2) uncontrolled diabetes; 3) history of having either oral or IV bisphosphonate treatment; 4) history of head and neck radiation; 5) history of chronic hyposalivation or Sjögrens Syndrome; 6) history of disorders affecting the structure and/or healing of the patient's bone; or 7) diminished capacity to provide consent; 8) inadequate mandibular ridge bone support for placing either MDI or SDI.

Prior to any surgical intervention, all subjects received a verbal and written description of the study, the time involved with participating in this study, including information regarding the two implant systems utilized in this project (MDI or SDI), and all risks, benefits, alternatives were discussed with patient. **Appendix 1** is the study flowchart that was given to all subjects involved in the study. The research protocol, recruitment procedures, exclusion/inclusion criteria, and the informed consent were approved by UCSF and SFVAMC Committees on Human Research. No monetary incentives were exchanged between patients, providers, or implant companies. In addition, the implant companies played no part in patient selection, study design and execution, or in data analysis.

Subjects were informed and randomly assigned via random permutations into one of two treatment regimens: (1) Two 3i full Osseotite internal hex (BIOMET Incorporated) standard diameter implants, approximately 4mm × 11.5~ 13mm (**SDI group**); or (2) Four MD (mini-dental) implants (IMTEC Company), approximately 1.8-2.2mm x 10 ~ 13mm (**MDI group)**, placed in the anterior region of the lower jaw. Locator attachments were utilized for overdenture stabilization. The overdenture treatment was provided by

modification of their adequate existing conventional mandibular denture. Prior to implant placement and denture alteration, baseline perception data for their conventional complete mandibular dentures were obtained using a visual analog scale (VAS: range from 0 to 100) **Appendix 2** [117, 132, 133]. After implant placement and healing period, the mandibular dentures were modified, and attachments were placed into the intaglio surface of the dentures to engage the implants. An adaptation period of two month was given to all subjects. Using the same VAS based questions given at baseline; data was collected at 6 months, 12 months, 24 months, 36 months and 60 months [92,106,112,113,117, 132, 133]. Details of the timeline of appointments can be found in **Appendix 3**. During the 60 months follow-up, patients returned for additional treatment with problems such as denture adjustments, relines, replacements of male/female components of the overdentures, explants and implant replacements in the event of implant failures.

Surgical Procedures

The surgical treatment was performed under local anesthesia by a periodontal resident under the supervision of an experienced periodontist as well as input from an experienced prosthodontist. Patients were anesthetized with 2% lidocaine with 1/100000 epinephrine. Local infiltration was completed on the buccal and lingual surfaces of the edentulous mandible. Some patients received bilateral lingual and inferior-alveolar block injections. After adequate anesthesia, the anterior mandible was evaluated to determine the volume of bone particularly for patients with thin, spiny ridges or large lingual undercuts. Full thickness flap elevation was required if osteoplasty was needed to increase buccal/lingual

width approximately 7mm for SDI group or 5mm for MDI group. Osteoplasty was performed with copious saline irrigation with high speed round bur to allow for sufficient bone width of at least 1.5mm on the buccal and lingual aspects of the implant. If patients did not require osteoplasty, full-thickness bilateral semilunar flaps were performed in the SDI group and four narrow-diameter, one-piece implants (MDI) were placed in the mandibular anterior area between the foramina using a flapless surgical procedure. (**Figures 19-42**)

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. [134,135] 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. Guide pins were used to check angulations and parallelism of the implants. 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. A post-operative panoramic radiograph was taken at the end of the surgical treatment.

MDI Group

For the MDI group, all patients received four Sendax IMTEC Collard Thread Design, O-Ball Prosthetic Head mini dental implants (IMTEC Corp., Ardmore, OK, USA) with a standard diameter and length of 1.8 mm and 13 mm, respectively. The surgical protocol for implant placement was performed according to previous research. [27] All clinicians followed the IMTEC instructions for implant site and implant insertion instructions. In detail, four 1.1 mm pilot holes were drilled with the MDI 1.1 mm surgical drill (single patient use only) approximately 6 mm and 12 mm from midline, bilaterally. With copious saline, the pilot drill was lightly pumped up and down until the cortical plate was penetrated, approximately one-third to one-half the threaded length of the implant. 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.

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. Post operative panoramic radiograph was taken at the end of the surgical procedure.

Postoperative Care:

All subjects received postoperative analgesia (Vicodin 5 mg/500 mg, q4-6h or Ibuprofen 600 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. 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. Patients were advised to avoid chewing on hard foods and putting pressure on the implants during healing.

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. [136] **(Figure 1-24)**

Prosthodontic Protocol

The prosthodontic treatment was performed by periodontal residents under the supervision of an experienced implant prosthodontist. The prosthodontic protocol for attachment placement and overdenture modification was performed according to previous research. [136]

MDI Retrofit

Since the MDI is a one piece implant with an o-ball attachment, the intaglio surface of the patient's denture was relieved by excavating 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 is an important step to prevent auto-polymerizing acrylic resin from curing to the implant fixture. The keeper caps (i.e., O-ring attachment housings) with the rubber elastomer (i.e., O-rings) were placed over the O-Ball until they were fully seated and could easily rotate. The denture was 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

Since the SDI is a two-piece implant with a cover screw placed at the time of surgery, the intaglio surface of the patient's denture was relieved and relined with silicone 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 is an important step to prevent auto-polymerizing acrylic resin from curing to the implant fixture. The locator caps (i.e., locator attachment housings) with the black elastomers were placed over the locator until they were fully seated and could easily rotate. The denture was 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 Analysis

The statistical data were collected to detect a difference between the four mini-dental implants and two standard dental implants groups in the following: (i) differences in the long term implant survival rate of standard-sized dental implant (SDI, the current gold standard), or mini-dental implants (MDI) 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. Difference in the long term implant survival rate between the two groups (MDI vs SDI) was compared using Kaplan-Meier methods, a non-parametric test comparing ordinal data. A Kaplan-Meier analysis allows estimation of survival of the implants over time, even when a patient may drop out or are studied for different lengths of time. A log-rank test was conducted to determine if the time to implant failure between the groups was significantly different. Statistical analysis for the quality of life between the mini-dental implants versus the standard dental implants groups were not completed due to insufficient follow up data at each time interval.

Results

Of the 35 subjects who participated in the study, four patients had failures of the implants to integrate and the implants were subsequently removed. Two patients were from the MDI group and two patients were from the SDI group. In the MDI group, one patient had the mini-implants fail at 6 months after implant placement and the other patient had the mini-implants fail at 1 month. In the SDI group, one patient had the implants fail at 5 months following placement and the other patient had the implants fail 1 month following placement.

Kaplan-Meier methods were used to compare the implant long term implant survival rate between the SDI vs. MDI group. At 60 months of observation, 90.4% (95% CI 66.8%-97.5%) of the mini-implants were still functional, compared to 83.9% (49.4%-95.7%) of the standard implants. The time to failure of the two implant groups can be found on the survival curve (**Figure 1)**. This difference was not found to be statistically significant using a log-rank test (p=0.57;**Table 2)**

The results showed that there was an average increase in patient QOL scores between MDIs and SDIs placed in the interforaminal area of the mandible 3, 6, 12, and 36 months after placement of the implant. (**Figures 2-18)**. Data for the 60 months follow up were not used due to insufficient number of patient follow up QOL scores available for analysis.

QOL variables in VAS Scale:

All QOL variables that were assessed demonstrated a general trend of an increase from baseline to 36 months. There were variations in the QOL scores over time partially due to the change in number of patients responding.

General Satisfaction:

The average QOL baseline score for the MDI group was 38.59, and 28.08 for the SDI group. There was a general increase in the mean general satisfaction scores from baseline to the 36-month evaluation with the MDI score at 91.00 and the SDI score at 76.00 (**Figure 2**). The drop in QOL scores at 3 months and 6 months in the SDI group was due to insufficient data in QOL response (**Table 3**).

Overall Function:

The average QOL baseline score for the MDI group was 34.63, and 35.66 for the SDI group (**Table 4**). There was a general increase in the mean overall function scores from baseline to the 36-month evaluation with the MDI score at 87.83 and the SDI score at 62.2 (**Figure 3**).

Overall Chewing:

The average QOL baseline score for the MDI group was 31.45, and 26.75 for the SDI group (**Table 5**). There was a general increase in the mean overall chewing scores from baseline to the 36-month evaluation with the MDI score at 88 and the SDI score at 55.8 (**Figure 4**).

Speech Ability:

The average QOL baseline score for the MDI group was 51.95, and 45.45 for the SDI group (**Table 6**). There was a general increase in the mean speech ability scores from baseline to the 36-month evaluation with the MDI score at 92 and the SDI score at 63 (**Figure 5)**.

Stability:

The average QOL baseline score for the MDI group was 34.68, and 29.08 for the SDI group (**Table 7**). There was a general increase in the mean stability scores from baseline to the 36-month evaluation with the MDI score at 92.33 and the SDI score at 60.8 (**Figure 6**).

Retention:

The average QOL baseline score for the MDI group was 30.04, and 22.16 for the SDI group (**Table 8**). There was a general increase in the mean retention scores from baseline to the 36-month evaluation with the MDI score at 92.83 and the SDI score at 63.6 (**Figure 7**).

Appearance:

The average QOL baseline score for the MDI group was 68.72, and 68.25 for the SDI group (**Table 9**). There was a general increase in the mean appearance scores from baseline to the 36-month evaluation with the MDI score at 93 and the SDI score at 73.8

(**Figure 8**). At the 6 months follow up, the SDI group had a drop in QOL for average appearance from 68.25 to 58.33. The reason is because only three patients were included in the follow up and there was a large variation in QOL scores given (standard deviation=41.76).

Fit:

The average QOL baseline score for the MDI group was 47.04, and 46.16 for the SDI group (**Table 10**). There was a general increase in the mean fit scores from baseline to the 36-month evaluation with the MDI score at 88 and the SDI score at 64.6 (**Figure 9**).

Chewing Hard Food:

The average QOL baseline score for the MDI group was 25.05, and 22 for the SDI group (**Table 11**). There was a general increase in the mean chewing hard food scores from baseline to the 36-month evaluation with the MDI score at 93.8 and the SDI score at 59.750 (**Figure 10**).

Chewing Tough Food:

The average QOL baseline score for the MDI group was 30.72, and 28 for the SDI group (**Table 12**). There was a general increase in the mean chewing tough food scores from baseline to the 36-month evaluation with the MDI score at 88.4 and the SDI score at 59.25 (**Figure 11)**.

Chewing Crisp Food:

The average QOL baseline score for the MDI group was 38.09, and 35.66 for the SDI group (**Table 13**). There was a general increase in the mean chewing crisp food scores from baseline to the 36-month evaluation with the MDI score at 93.6 and the SDI score at 64.5 (**Figure 12**). In the SDI group, at the 6 and 12 months follow up, there was a decrease in average chewing crisp food QOL score to 66.5 and 67.5, respectively. However, the decrease in QOL scores are due to the limited number of respondents (only two patients) at these two time intervals, and also due to the large variation in QOL scores (standard deviation of 23.33 at 6 months and 31.81 at 12 months) given by the two respondents (**Table 13**).

Chewing Whole Fruit:

The average QOL baseline score for the MDI group was 28.86, and 20.16 for the SDI group (**Table 14**). There was a general increase in the mean chewing whole fruit scores from baseline to the 36-month evaluation with the MDI score at 93.8 and the SDI score at 55.75 (**Figure 13**). In the SDI group at 24 months, there was a large decrease in the average QOL score to 12. Only one patient was evaluated at the 24 month time interval, therefore, resulting in the large decline in average QOL score (**Table 14**).

Chewing Fruits, Peels:

The average QOL baseline score for the MDI group was 38.77, and 37.83 for the SDI group (**Table 15**). There was a general increase in the mean chewing fruits, with peels scores from baseline to the 36-month evaluation with the MDI score at 93.8 and the SDI

score at 48.75 (**Figure 14**). Similar to the chewing whole fruit QOL variable, at 24 months, the SDI group had only one respondent which accounted for the large decline in average QOL score to 13 (**Table 15**).

Chewing Fruits, No Peels:

The average QOL baseline score for the MDI group was 40.95, and 44.91 for the SDI group (**Table 16**). There was a general increase in the mean chewing fruits without peels scores from baseline to the 36-month evaluation with the MDI score at 88.8 and the SDI score at 56.25 (**Figure 15**). The decline in QOL scores from 12 to 24 months (91.75 to 47.5) in the SDI group is due to limited number of patients (two respondents) during this follow up period, along with large standard deviation of 48.79 between the two scores given (**Table 16**).

Chewing Soft, Dry:

The average QOL baseline score for the MDI group was 44.72, and 53.58 for the SDI group (**Table 17**). There was a general increase in the mean chewing soft, dry food scores from baseline to the 36-month evaluation with the MDI score at 93.8 and the SDI score at 69.5 (**Figure 16**). There was a decrease in average QOL score in the 24 months follow up period in the SDI group. Two patients came back for follow up and the standard deviation between the two QOL scores was 47.37 (**Table 17**).

Chewing Soft, Wet:

The average QOL baseline score for the MDI group was 57.59, and 62.75 for the SDI group (**Table 18**). There was a general increase in the mean chewing soft, wet food scores from baseline to the 36-month evaluation with the MDI score at 93.6 and the SDI score at 78.4 (**Figure 17**). The decline in QOL scores from 12 to 24 months (93 to 47.5) in the SDI group is due to limited number of patients (two respondents) during this follow up period, along with large standard deviation of 48.79 between the two scores given (**Table 18**).

Chewing Flat Vegetable:

The average QOL baseline score for the MDI group was 41.18, and 62.2 for the SDI group (**Table 19**). There was a general increase in the mean satisfaction chewing flat vegetable scores from baseline to the 36-month evaluation with the MDI score at 93.6 and the SDI score at 59.2 (**Figure 18**). There was a decrease in average QOL score in the 24 months follow up period in the SDI group. Two patients came back for follow up and the standard deviation between the two QOL scores was 28.99 (**Table 19**).

Discussion

Mini-dental implants can be an attractive option for patients who are not ideal candidates for conventional implant treatment. MDIs offer a solution for patients with deteriorating natural dentition to gain the added esthetics, stability, comfort and confidence that dentures provide. Mandibular over-dentures with different attachment designs supported by two to four implants have shown high implant survival rates reported in literature. The results from this longitudinal study showed that mandibular dentures supported by MDIs had high survival rates (90.4%) that were comparable to the SDI implants (83.9%). Therefore, mini-dental implants can be an acceptable solution for patients who are not ideal candidates for conventional implants or who cannot afford them. In addition, the results suggest that mini-dental implants and standard dental implants are more efficient than removable mandibular complete dentures. Furthermore, there is no difference between groups in quality of life after the implants were restored.

In the present study, implant-retained mandibular over-dentures improved the quality of life in the tested variables which is supported by the findings in many other studies. [21, 27, 44, 48, 53, 89, 99, 100, 102, 106-121, 123, 129, 132] Both MDI and SDI retained mandibular overdentures significantly improved masticatory function, which is in agreement with other studies. [43-46] In addition, Griffitts and colleagues 2005 reported on the efficacy of mini-implants to retain a mandibular implant-retained over-denture in thirty patients with four MDIs in the interforaminal mandible. The goal of the study was to examine the success of MDIs by evaluating four subjective measures of patient satisfaction: comfort, retention, chewing ability, and speaking ability from 1 to 10 where 1 is poor and 10 is excellent. Five months following surgery, self-reporting

questionnaires were sent to the patients. Patients reported the improvement of their denture retention from 1.7±0.42 to 9.6±0.37 (difference of 7.9). Comfort also improved from 2.2±0.63 to 9.4±0.45 (difference of 7.2) Chewing and speaking ability also improved, with a difference of 7.0 and 3.2, respectfully. In similar fashion, the results from my study also concurred with the subjective quality of life improvements reported by Griffits and colleagues. [27] Additional quality of life variables were measured and evaluated such as: general satisfaction, comfort, stability, aesthetics, and ease of chewing. My results support that such quality of life factors were improved in the implant-supported overdenture group. Several studies by Awad Ma and colleagues also report quality of life improvements in the aforementioned variables, after the placement of two standard diameter implants to support an overdenture. In two of Awad Ma and colleagues' studies, he compared quality of life variables between conventional denture wearers and those with two mandibular implant-supported overdentures. The demographic group of one study involved middle-aged subjects (35-65 years old), while the other demographic group involved an older population (65-75 years old). The results of both studies in different age groups concluded that the implant-aided prostheses provided a short-term significant improvement in oral health quality of life in comparison to the conventional prostheses. [112,113]

Patient preferences can also have an effect on the large range and standard deviation between the subjects VAS ratings. Each individual's preference is so complex and variable, even for patients who prefer the same treatment. [129] In addition to preferences, patient expectations of the outcome may play an important role. [130] Unrealistic expectations may cause patient disappointment with the prostheses. This may have lead

to disappointment with the treatment outcome of the mandibular 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 from the treatment, they tend to ignore adverse symptoms and focus on apparent improvements following therapy. [130]

There are several weaknesses to this study that need to be addressed. First of all, there was a small sample size to analyze. Since there was a small sample size, the statistical power and analysis is weak and needs to be interpreted with caution. The total number of patients in this study was 35 patients (22 patients in the MDI group and 13 patients in the SDI group). To have a statistical power of 0.8 for a long-term study, 30 patients are need in each group. Although the present data present is from a limited number of patients, initial conclusions can be drawn from the data. This study is important because it is the first study attempting 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 lack of a consistent follow-up by patients may have skewed some results. For instance, there was large range and standard deviation among the subjects' VAS ratings. This large variation is based on the patient's subjective expectations and preferences as well as the variable amounts of data included in each follow up. Patients were periodically recalled at 6, 12, 24, 36, and 60 months. Some would return and others would not. Therefore, the data collected in the study would be dependent on the number of patients that returned for the follow-up. For example, in the standard implant group,

during the 24 month follow up period for overall function, there were only three patients that were followed up with VAS ratings. Thus, if one patient gave a very low VAS score, the average and standard deviation of the results would have been greatly affected. Moreover, I was unable to perform statistical analyses on such a small follow up group and could only take the averages amongst those individuals. Accordingly, the 60 months follow up data was excluded in this study due to lack of data for follow ups.

Another weakness in this research is the study population. The study population consisted of only male patients, which weakened the correlation to women. In addition, patients who came to this particular study were screened by dentists in the VA system. Typically, patients were referred to this study due to the presence of a narrow mandibular ridge limiting the placement of traditional implants. Therefore, selection bias played a part even prior to the patient entering in the study. Every attempt was made for randomization but was not possible. Patients seen at the VA usually present with complex medical histories. After a thorough exam and medical consultation, if necessary; all patients in this study were medically stable to proceed with the implant placements and prostheses. Although the patients in this study had numerous and varied medical histories, their medical issues did not affect the surgical outcomes of the implant placement nor the results of this study.

Another weakness in this study was that different clinicians completed the treatment for the patients. There would be less variation between patients had the treatment been completed with only one clinician. In addition, periodontal residents performed the denture modifications including: repair, relining, adjustments, and maintenance. The limited or lack of experience by periodontal residents in performing prosthetic

adjustments may have affected patients' satisfaction in relation to their restorative prosthesis. Moreover, it might be noted that the outcome of the denture modification would have been better if a restorative dentist was more closely involved. Hence, denture fit may not have been ideal, considering periodontal residents infrequently, at best, modify dentures. Thus, the QOL scores in this study may have negatively been affected by a possible ill-fitting denture.

Future direction for this study would be to include more patients by having ideally 40-50 patients in each group. This would dramatically improve the power of the statistics and clinical study. In addition, follow-up of the patients should continue to obtain more data for long term results.

Conclusion

In this study, full mandibular dentures supported by mini-dental implants and standard diameter implants had high implant survival rates after a 60 month observation period, 90.4% and 83.9% respectively. Mini-dental implants placed in the interforaminal region of the anterior mandible performed as well as the standard diameter in both long term survival rate and in improving patient's quality of life. All patients in the study reported substantial increase in the stability and function of their respective prosthesis once the mini-implants or the standard implants were placed. With the limitations of this study, the data suggests that mini-implants can be effective devices for use in long-term denture stabilization. MDIs are a highly successful implant option for patients with poor tolerance to mandibular prosthesis. The implants are relatively affordable and overall patient satisfaction is excellent. Further studies are required to determine long-term success and predictability of this treatment modality. Such stabilization of prostheses via mini-implants may also have alternative applications. For instance, future studies can also include long term applications for mini-implant supported maxillary overdentures, partial dentures, and fixed restorations. In addition to providing permanent anchorage for maxillary and mandibular complete and partial prostheses, mini-implants can also provide temporary anchorage; hence their expanded use in orthodontics, where mini-implants are known and used as TADs (Temporary Anchorage Devices).

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Table 1

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 2

Log-rank test for equality of survivor functions

group	Events observed	Events expected
0	2	2.55
1	2	1.45
Total	4	4.00

chi2(1) = 0.33
Pr>chi2 = 0.5676

Table 3: General Satisfaction (QOL) for MDI and SDI from baseline to 36 months

	Time					
Mini Group	0	3 months	6 months	12 months	24 months	36 months
1	50	100	100		100	100
2	57	92		87	91	86
3	4	84			92	
4	13	88	88		90	
5	86		71	30	90	
6	9					
7	10			91		
8	60					
9	85	92		88		
10	38	100	100		100	
11	88	100				87
12	12	37				
13	94	86	83		83	
14	9	93			88	
15	50	29		75		
16	50	64	63			
17	35	36	80			
18	50		85			
19	26	98	100			
20	5	55	80			
21	5	10				
22	13		91			
Sum	849	1164	941	371	734	273
Average	38.59091	72.75	85.545455	74.2	91.75	91
SD	30.42658	29.914322	12.044614	25.449951	5.7755643	7.8102497
	Time					
	0	3 months	6 months	12 months	24 months	36 months
Standard Group						
1	14	57			43	38
2	26			94	90	
3	90	88				
4	5			87		
5	10	72				90
6	19					88
7	38					
8	12					
9	2					
10	11		37	62		88
11	98					
12						
13	12					
Sum	337	217	37	243	133	304
Average	28.08333	72.333333	37	81	66.5	76
SD	32.27005	15.502688		16.822604	33.234019	25.350871

Table 4: Overall Function (QOL) for MDI and SDI from baseline to 36 months

		Time					
Mini Group	Patient ID	0	3 months	6 months	12 months	24 months	36 months
1	1	50	100	100		100	100
2	3	8	40		87	87	85
3	7	3	74			88	
4	8	36	88	87		90	
5	9	86		30	30	87	
6	10	15					
7	11	10			91		
8	14	54					
9	17	99	99		88		97
10	18	13	100	100		100	75
11	19	81	98				86
12	25	12	35				
13	26	67	88	73		82	84
14	28	10	92			88	
15	29	50	55		75	91	
16	42	25	62	63	65		
17	44	15	73	82	70		
18	45	50		87	87		
19	46	52	100	100	100		
20	47	7	43	82			
21	49	5	13				
22	51	14		92			
Sum		762	1160	896	693	813	527
Average		34.63636	72.5	81.45455	77	90.33333	87.83333
SD		29.44009	28.01666	20.65122	20.77258	6.020797	9.196014
		Time					
		0	3 months	6 months	12 months	24 months	36 months
Standard Group	Patient ID						
1	2	25	36			42	36
2	5	100			85	80	
3	6	91	89				
4	12	5			87		
5	13	16	32				44
6	15	60					87
7	16	17					
8	20	12					
9	21	19					53
10	23	14		39	67		91
11	33	64		75	100		
12	34					94	
13	37	5	90	84			
Sum		428	247	198	339	216	311
Average		35.66667	61.75	66	84.75	72	62.2
SD		33.88841	32.08712		13.57387	26.90725	25.23292

Table 5: Overall Chewing Ability (QOL) for MDI and SDI from baseline to 36 months

		Time					
Mini Group	Patient ID	0	3 months	6 months	12 months	24 months	36 months
1	1	50	100	100		100	100
2	3	9	35			37	
3	7	4	80			85	
4	8	12	90	89		90	
5	9	88		33	30	87	
6	10	11					
7	11	38			92		
8	14	33					
9	17	83	98		89		95
10	18	38	100	100		100	75
11	19	58	100				86
12	25	14	17				
13	26	68	68	70		80	84
14	28	9	90			88	
15	29	50	28		75	94	
16	42	25	64	63	65		
17	44	10	16	93	54		
18	45	25		86	89		
19	46	23	95	100	100		
20	47	8	43	85			
21	49	3	8				
22	51	33		95			
Sum		692	1032	914	594	761	440
Average		31.45455	64.5	83.09091	74.25	84.55556	88
SD		25.36538	34.49831	20.56431	23.50532	19.02703	9.77241
		Time					
		0	3 months	6 months	12 months	24 months	36 months
Standard Group	Patient ID						
1	2	22	45			39	33
2	5	35			86	90	
3	6	91	93				
4	12	1			77		
5	13	11	35				42
6	15	23					87
7	16	34					
8	20	33					
9	21	14					30
10	23	10		32	63		87
11	33	30		75	73		
12	34					95	
13	37	17	64	84			
Sum		321	237	191	299	224	279
Average		26.75	59.25	63.66667	74.75	74.66667	55.8
SD		22.93122	25.51307		9.535023	30.98925	28.82187

Table 6: Speech Ability (QOL) for MDI and SDI from baseline to 36 months

		Time					
Mini Group	Patient ID	0	3 months	6 months	12 months	24 months	36 months
1	1	50	100	100		100	100
2	3	64	65		43	85	85
3	7	22	81			94	
4	8	39	90	89		90	
5	9	61		34	30	86	
6	10	13					
7	11	64			89		
8	14	47					
9	17	87	95		97		96
10	18	86	100	100		100	100
11	19	64	94				87
12	25	12	67				
13	26	94	86	96		83	84
14	28	87	94			86	
15	29	75	42		84	98	
16	42	50	86	64	65		
17	44	14	47	86	73		
18	45	75		85	87		
19	46	77	97	100	100		
20	47	8	43	70			
21	49	9	34				
22	51	45		90			
Sum		1143	1221	914	668	822	552
Average		51.95455	76.3125	83.09091	74.22222	91.33333	92
SD		28.50811	23.19977	20.16162	24.18046	6.800735	7.509993
		Time					
		0	3 months	6 months	12 months	24 months	36 months
Standard Group	Patient ID						
1	2	68	65			42	62
2	5	61			82	100	
3	6	92	90				
4	12	1			100		
5	13		72				19
6	15	23					88
7	16	61					
8	20	36					
9	21	39					55
10	23	13		88	87		91
11	33	76		53	100		
12	34					93	
13	37	30	72	70			
Sum		500	299	211	369	235	315
Average		45.45455	74.75	70.33333	92.25	78.33333	63
SD		28.27495	10.68878		9.17878	31.65965	29.1976

Table 7: Stability (QOL) for MDI and SDI from baseline to 36 months

Mini Group	Patient ID	0	3 months	6 months	12 months	24 months	36 months
1	1	40	100	100		100	100
2	3	36	40		45	84	85
3	7	5	81			87	
4	8	12	85	85		90	
5	9	60		29	30	87	
6	10	12					
7	11	12			91		
8	14	88					
9	17	90	94		88		96
10	18	38	100	100		100	100
11	19	91	90				89
12	25	7	15				
13	26	71	52	81		81	84
14	28	11	92			87	
15	29	43	23		81	97	
16	42	37	63	65	65		
17	44	5	9	72	38		
18	45	25		87	88		
19	46	28	92	100	100		
20	47	10	48	60			
21	49	20	12				
22	51	22		88			
Sum		763	996	867	626	813	554
Average		34.68182	62.25	78.81818	69.55556	90.33333	92.33333
SD		28.37401	33.86739	21.47938	25.93796	7	7.284687
		Time					
		0	3 months	6 months	12 months	24 months	36 months
Standard Group	Patient ID						
1	2	7	64			44	61
2	5	12			91	100	
3	6	95	91				
4	12	1			66		
5	13	20	39				25
6	15	21					88
7	16	11					
8	20	13					
9	21	85					40
10	23	7	71	18	31		90
11	33	71		63	100		
12	34					90	
13	37	6	55	56			
Sum		349	320	137	288	234	304
Average		29.08333	64	45.66667	72	78	60.8
SD		33.77858	19.26136		30.88689	29.86637	28.75239

Table 8: Retention (QOL) for MDI and SDI from baseline to 36 months

		Time					
Mini Group	Patient ID	0	3 months	6 months	12 months	24 months	36 months
1	1	40	100	100		100	100
2	3	57	85		71	88	87
3	7	5	84			92	
4	8	13	88	88		90	
5	9	66		38	54	88	
6	10	11					
7	11	14			92		
8	14	53					
9	17	84	97		87		98
10	18	12	100	100		100	100
11	19	37	100				88
12	25	8	14				
13	26	71	53	80		81	84
14	28	11	73			92	
15	29	41	28		84	97	
16	42	38	64	63	60		
17	44	15	7	75	73		
18	45	25		89	68		
19	46	28	91	100	100		
20	47	10	50	40			
21	49	1	12				
22	51	21		90			
Sum		661	1046	863	689	828	557
Average		30.04545	65.375	78.45455	76.55556	92	92.83333
SD		23.66528	33.90157	22.57593	15.21604	6.22495	7.27782
		Time					
		0	3 months	6 months	12 months	24 months	36 months
Standard Group	Patient ID						
1	2	9	68			43	59
2	5	15			92	100	
3	6	89	94				
4	12	1			94		
5	13	16	69				68
6	15	15					88
7	16	12					
8	20	12					
9	21	4					14
10	23	6		12	87		89
11	33	80		35	100		
12	34					90	
13	37	7	85	91			
Sum		266	316	138	373	233	318
Average		22.16667	79	46	93.25	77.66667	63.6
SD		29.54452	12.67544		5.377422	30.43572	30.58267

Table 9: Appearance (QOL) for MDI and SDI from baseline to 36 months

		Time					
Mini Group	Patient ID	0	3 months	6 months	12 months	24 months	36 months
1	1	100	100	100		100	100
2	3	91	86		83	88	89
3	7	34	81			91	
4	8	89	88	87		90	
5	9	58		53	10	88	
6	10	35					
7	11	88			90		
8	14	53					
9	17	98	95		88		98
10	18	88	100	100		100	100
11	19	98	98				87
12	25	43	94				
13	26	97	95	98		81	84
14	28	86	89			89	
15	29	86	96		90	100	
16	42	75	88	65	65		
17	44	40	37	76	22		
18	45	100		88	88		
19	46	100	98	100	100		
20	47	7	54	87			
21	49	14	14				
22	51	32		88			
Sum		1512	1313	942	636	827	558
Average		68.72727	82.0625	85.63636	70.66667	91.88889	93
SD		30.92261	25.04521	15.39658	32.48461	6.697844	7.155418
		Time					
		0	3 months	6 months	12 months	24 months	36 months
Standard Group	Patient ID						
1	2	76	69			48	60
2	5	85			84	100	
3	6	86	92				
4	12	100			100		
5	13	66	88				69
6	15	45					88
7	16	63					
8	20	36					
9	21	87					62
10	23	36		11	90		90
11	33	99		90	100		
12	34					93	
13	37	40	80	74			
Sum		819	329	175	374	241	369
Average		68.25	82.25	58.33333	93.5	80.33333	73.8
SD		24.14398	10.14479		7.895146	28.21938	14.28986

Table 10: Fit (QOL) for MDI and SDI from baseline to 36 months

		Time					
Mini Group	Patient ID	0	3 months	6 months	12 months	24 months	36 months
1	1	50					100
2	3	11	86		87	90	60
3	7	5	80			90	
4	8	39	87	87		90	
5	9	63		54	32	88	
6	10	88					
7	11	14			94		
8	14	80					
9	17	92			89		97
10	18	86					100
11	19	91					87
12	25	44	25				
13	26	70	92	74		80	84
14	28	10	85			88	
15	29	50	14		86		
16	42	50	88	65	60		
17	44	7	72	80	42		
18	45	75		87	87		
19	46	52	95				
20	47	31	50	85			
21	49	6	13				
22	51	21		91			
Sum		1035	787	623	577	526	528
Average		47.04545	65.58333	77.875	72.125	87.66667	88
SD		30.61042	31.45403	12.78881	24.09171	3.88158	15.29706
		Time					
		0	3 months	6 months	12 months	24 months	36 months
Standard Group	Patient ID						
1	2	50	76			44	45
2	5	88			89		
3	6	90	91				
4	12	26			95		
5	13	12	67				63
6	15	15					88
7	16	66					
8	20	14					
9	21	10					39
10	23	64		18			88
11	33	90		70			
12	34					94	
13	37	29	60	85			
Sum		554	294	173	184	138	323
Average		46.16667	73.5	57.66667	92	69	64.6
SD		32.33583	13.37909		4.242641	35.35534	23.11493

Table 11: Chewing Hard Food (QOL) for MDI and SDI from baseline to 36 months

		Time					
Mini Group	Patient ID	0	3 months	6 months	12 months	24 months	36 months
1	1	30	100	100		100	100
2	3	15	65			87	
3	7	1	81			93	
4	8	12	88	87		90	
5	9	63		32	18	57	
6	10	11					
7	11	14			91		
8	14	75					
9	17	97	96		89		97
10	18	12	100	100		100	100
11	19	37	91				88
12	25	7	15				
13	26	65	94	74		78	84
14	28	11	84			89	
15	29	9	24		73	82	
16	42	10		66	65		
17	44	3	8	83	44		
18	45	25		88	89		
19	46	28	95	100	100		
20	47	7	48	75			
21	49	5	11				
22	51	14					
Sum		551	1000	805	569	776	469
Average		25.04545	66.66667	80.5	71.125	86.22222	93.8
SD		26.33751	35.42329	20.76455	27.94606	13.16983	7.362065
		Time					
		0	3 months	6 months	12 months	24 months	36 months
Standard Group	Patient ID						
1	2	8	76			43	45
2	5	7			60		
3	6	88	91				
4	12	1			77		
5	13	20	72				
6	15	22					88
7	16	34					
8	20	12					
9	21	8					17
10	23	11		38	62		89
11	33	50		50	96		
12	34					92	
13	37	3	70	68			
Sum		264	309	156	295	135	239
Average		22	77.25	52	73.75	67.5	59.75
SD		25.09618	9.5		16.66083	34.64823	35.11291

Table 12: Chewing Tough Food (QOL) for MDI and SDI from baseline to 36 months

		Time					
Mini Group	Patient ID	0	3 months	6 months	12 months	24 months	36 months
1	1	30	100	100		100	100
2	3	15	41			87	
3	7	5	82			90	
4	8	62	88	87		90	
5	9	62		54	53	60	
6	10	12					
7	11	12			92		
8	14	74					
9	17	95	98		90		97
10	18	12	100	100		100	75
11	19	37	87				86
12	25	6	20				
13	26	61	93	74		80	84
14	28	9	88			89	
15	29	25	17		75	89	
16	42	12	64	66	65		
17	44	2	11	80	74		
18	45	50		86	87		
19	46	54	97	100	100		
20	47	4	48	68			
21	49	6	9				
22	51	31					
Sum		676	1043	815	636	785	442
Average		30.72727	65.1875	81.5	79.5	87.22222	88.4
SD		27.08748	35.04705	16.03642	15.61135	11.94548	10.16366
		Time					
		0	3 months	6 months	12 months	24 months	36 months
Standard Group	Patient ID						
1	2	5	77			44	44
2	5	9				80	
3	6	88	90				
4	12	1			96		
5	13	16	70				
6	15	22					86
7	16	62					
8	20	11					
9	21	38					17
10	23	11		38	62		90
11	33	70		50	96		
12	34					84	
13	37	3	72	82			
Sum		336	309	170	254	208	237
Average		28	77.25	56.66667	84.66667	69.33333	59.25
SD		29.57579	8.995369		19.62991	22.03028	35.01785

Table 13: Chewing Crisp Food (QOL) for MDI and SDI from baseline to 36 months

		Time					
Mini Group	Patient ID	0	3 months	6 months	12 months	24 months	36 months
1	1	50	100	100		100	100
2	3	10	66			91	
3	7	10	83			95	
4	8	77	88	87		90	
5	9	62		52	53	35	
6	10	16					
7	11	12			94		
8	14	54					
9	17	97	96		92		97
10	18	87	100	100		100	100
11	19	71	93				87
12	25	7	22				
13	26	97	93	74		82	84
14	28	10	86			89	
15	29	25	12		75	95	
16	42	25	61	65	65		
17	44	3	13	85	74		
18	45	25		88	83		
19	46	54	95	100	100		
20	47	5	49	74			
21	49	8	15				
22	51	33		87			
Sum		838	1072	912	636	777	468
Average		38.09091	67	82.90909	79.5	86.33333	93.6
SD		31.94029	33.90575	15.41074	15.86551	20.0624	7.569676
		Time					
		0	3 months	6 months	12 months	24 months	36 months
Standard Group	Patient ID						
1	2	7	75			45	42
2	5	11			87		
3	6	89	89				
4	12	37			100		
5	13	18	87				
6	15	23					88
7	16	63					
8	20	39					
9	21	37					33
10	23	12			62		95
11	33	71		50	95		
12	34					90	
13	37	21		83			
Sum		428	84	133	344	135	258
Average		35.66667	83.66667	66.5	86	67.5	64.5
SD		26.16845	7.571878		16.87207	31.81981	31.52248

Table 14: Chewing Whole Fruit (QOL) for MDI and SDI from baseline to 36 months

		Time					
Mini Group	Patient ID	0	3 months	6 months	12 months	24 months	36 months
1	1	40	100	100		100	100
2	3	10	61			84	
3	7	0	79			81	
4	8	11	61	60		90	
5	9	61		38	7	58	
6	10	9					
7	11	11			92		
8	14	63					
9	17	96	84		92		97
10	18	11	50	50		0	100
11	19	6	68				88
12	25	7	21				
13	26	71	80	73		80	84
14	28	11	86			86	
15	29	25	17		52	83	
16	42	25		62	62		
17	44	4	7	82	53		
18	45	25		87	87		
19	46	30	95	100	100		
20	47	10	42	70			
21	49	5	15				
22	51	16		94			
Sum		547	866	816	545	662	469
Average		24.86364	57.73333	74.18182	68.125	73.55556	93.8
SD		25.69843	31.00108	20.52714	31.11012	29.7326	7.362065
		Time					
		0	3 months	6 months	12 months	24 months	36 months
Standard Group	Patient ID						
1	2	8	75			12	11
2	5	10					
3	6	89	88				
4	12	1			93		
5	13	21	62				
6	15	24					87
7	16	60					
8	20	7					
9	21	3					35
10	23	14		70	67		90
11	33	2		50	95		
12	34						
13	37	3	38	87			
Sum		242	263	207	255	12	223
Average		20.16667	65.75	69	85	12	55.75
SD		27.11871	21.32878		15.6205		39.08431

Table 15: Chewing Fruits, Peels (QOL) for MDI and SDI from baseline to 36 months

		Time					
Mini Group	Patient ID	0	3 months	6 months	12 months	24 months	36 months
1	1	50	100	90		100	100
2	3	9	60			91	
3	7	0	83			91	
4	8	13	63	62		90	
5	9	65		54	28	63	
6	10	9					
7	11	14			92		
8	14	52					
9	17	99	100		91		97
10	18	87	100	100		0	100
11	19	72	100				88
12	25	6	17				
13	26	71	78	73		77	84
14	28	86	86			89	
15	29	50	19		76	88	
16	42	41		64			
17	44	4	3	90	54		
18	45	25		86	87		
19	46	65	93	100	100		
20	47	10	45	70			
21	49	7	12				
22	51	18		95			
Sum		853	959	884	528	689	469
Average		38.77273	63.93333	80.36364	75.42857	76.55556	93.8
SD		31.94479	35.95924	16.32344	25.70251	30.57414	7.362065
		Time					
		0	3 months	6 months	12 months	24 months	36 months
Standard Group	Patient ID						
1	2	25	76			13	12
2	5	11			86		
3	6	93	87				
4	12	1			89		
5	13	21	62				
6	15	79					86
7	16	70					
8	20	39					
9	21	39					57
10	23	36		8	39		40
11	33	25		47	95		
12	34						
13	37	15	71	72			
Sum		454	296	127	309	13	195
Average		37.83333	74	42.33333	77.25	13	48.75
SD		28.58745	10.42433		25.77305		30.99866

Table 16: Chewing Fruits, No Peels (QOL) for MDI and SDI from baseline to 36 months

		Time					
Mini Group	Patient ID	0	3 months	6 months	12 months	24 months	36 months
1	1	50	100	100		100	100
2	3	12	63			88	
3	7	30	82			91	
4	8	62	88	87		90	
5	9	58		54	28	61	
6	10	10					
7	11	38		95	93		
8	14	53					
9	17	97	98		91		97
10	18	88	100	100		100	75
11	19	72	100				88
12	25	6	19				
13	26	70	81	73		80	84
14	28	35	84			90	
15	29	57	15		75	96	
16	42	25		62			
17	44	4	86	93	68		
18	45	25		88	90		
19	46	73	94	100	100		
20	47	8	45	75			
21	49	10	33				
22	51	18		98			
Sum		901	1088	1025	545	796	444
Average		40.95455	72.53333	85.41667	77.85714	88.44444	88.8
SD		28.48137	30.08765	15.81977	24.59965	12.04275	10.08464
		Time					
		0	3 months	6 months	12 months	24 months	36 months
Standard Group	Patient ID						
1	2	26	78			13	12
2	5	41			86		
3	6	100	94				
4	12	1			98		
5	13	21	39				
6	15	80					89
7	16	57					
8	20	13					
9	21	61					34
10	23	35		58	88		90
11	33	76		45	95		
12	34					82	
13	37	28	71	86			
Sum		539	282	189	367	95	225
Average		44.91667	70.5	63	91.75	47.5	56.25
SD		30.01956	23.10123		5.678908	48.79037	39.43243

Table 17: Chewing Soft, Dry (QOL) for MDI and SDI from baseline to 36 months

		Time					
Mini Group	Patient ID	0	3 months	6 months	12 months	24 months	36 months
1	1	50	100	100		100	100
2	3	15	69			89	
3	7	34	94		99	95	
4	8	66	86	85	93	90	
5	9	61		55	30	86	
6	10	38					
7	11	40			91		
8	14	53					
9	17	98	99		91		97
10	18	89	100	100		100	100
11	19	87	80				88
12	25	4	18				
13	26	72	83	81		80	84
14	28	9	88			88	
15	29	62	25		75	95	
16	42	50	60	65	63		
17	44	4	33	85	80		
18	45	25		89	85		
19	46	68	97	100	100		
20	47	6	47	84			
21	49	30	32				
22	51	23		97			
Sum		984	1111	941	807	823	469
Average		44.72727	69.4375	85.54545	80.7	91.44444	93.8
SD		28.65922	29.39607	14.65854	21.09792	6.635343	7.362065
		Time					
		0	3 months	6 months	12 months	24 months	36 months
Standard Group	Patient ID						
1	2	41	75			15	37
2	5	36			93		
3	6	88	90				
4	12	20			95		
5	13	36	89				44
6	15	81					87
7	16	62					
8	20	63					
9	21	91					71
10	23	10		38	66		88
11	33	71		45	95		90
12	34					82	
13	37	44	72	87			
Sum		643	326	170	349	97	417
Average		53.58333	81.5	56.66667	87.25	48.5	69.5
SD		26.44878	9.327379		14.198	47.37615	23.56905

Table 18: Chewing Soft, Wet (QOL) for MDI and SDI from baseline to 36 months

		Time					
Mini Group	Patient ID	0	3 months	6 months	12 months	24 months	36 months
1	1	50	100	100		100	100
2	3	14	67			88	
3	7	72	92			93	
4	8	86	86	85		90	
5	9	62		56	55	88	
6	10	37					
7	11	90			92		
8	14	72					
9	17	99	95		89		97
10	18	87	100	100		100	100
11	19	96	100				87
12	25	5	18				
13	26	74	95	95		80	84
14	28	60	86			89	
15	29	75	30		93	97	
16	42	75	62	65	63		
17	44	18	65	98	90		
18	45	50		85	85		
19	46	72	96	100	100		
20	47	10	48	85			
21	49	33	32				
22	51	30		96			
Sum		1267	1172	965	667	825	468
Average		57.59091	73.25	87.72727	83.375	91.66667	93.6
SD		29.14603	28.02737	14.91369	15.77464	6.538348	7.569676
		Time					
		0	3 months	6 months	12 months	24 months	36 months
Standard Group	Patient ID						
1	2	50	71			13	68
2	5	66			93		
3	6	87	90				
4	12	67			99		
5	13	21	90				62
6	15	81					88
7	16	59					
8	20	65					
9	21	87					83
10	23	40		83	86		91
11	33	75		50	94		
12	34					82	
13	37	55	80	89			
Sum		753	331	222	372	95	392
Average		62.75	82.75	74	93	47.5	78.4
SD		19.51747	9.142392		5.354126	48.79037	12.7397

Table 19: Chewing Flat Vegetable (QOL) for MDI and SDI from baseline to 36 months

		Time					
Mini Group	Patient ID	0	3 months	6 months	12 months	24 months	36 months
1	1	50	100	100		100	100
2	3	17	62			85	
3	7	9	80			97	
4	8	88	88	87		90	
5	9	65		31	53	88	
6	10	10					
7	11	88			92		
8	14	54					
9	17	66	99		62		97
10	18	89	100	100		100	100
11	19	37	72				87
12	25	5	19				
13	26	73	80	79		80	84
14	28	53	88			88	
15	29	50	15		81	85	
16	42	3		64	65		
17	44	2	35	92	77		
18	45	25		87	91		
19	46	73	90	100	100		
20	47	10	49	83			
21	49	9	18				
22	51	30		96			
Sum		906	995	919	621	813	468
Average		41.18182	66.33333	83.54545	77.625	90.33333	93.6
SD		30.58577	31.34068	20.55901	16.5092	7.123903	7.569676
		Time					
		0	3 months	6 months	12 months	24 months	36 months
Standard Group	Patient ID						
1	2	25	76			12	41
2	5	11			64		
3	6	93	91				
4	12	1			84		
5	13	21	75				44
6	15	81					87
7	16	14					
8	20	12					
9	21	63					34
10	23	12		58	36		90
11	33	75		50	95		
12	34					53	
13	37	7	68	70			
Sum		415	310	178	279	65	296
Average		34.58333	77.5	59.33333	69.75	32.5	59.2
SD		33.26603	9.678154		25.90206	28.99138	27.01296

Figure 1:

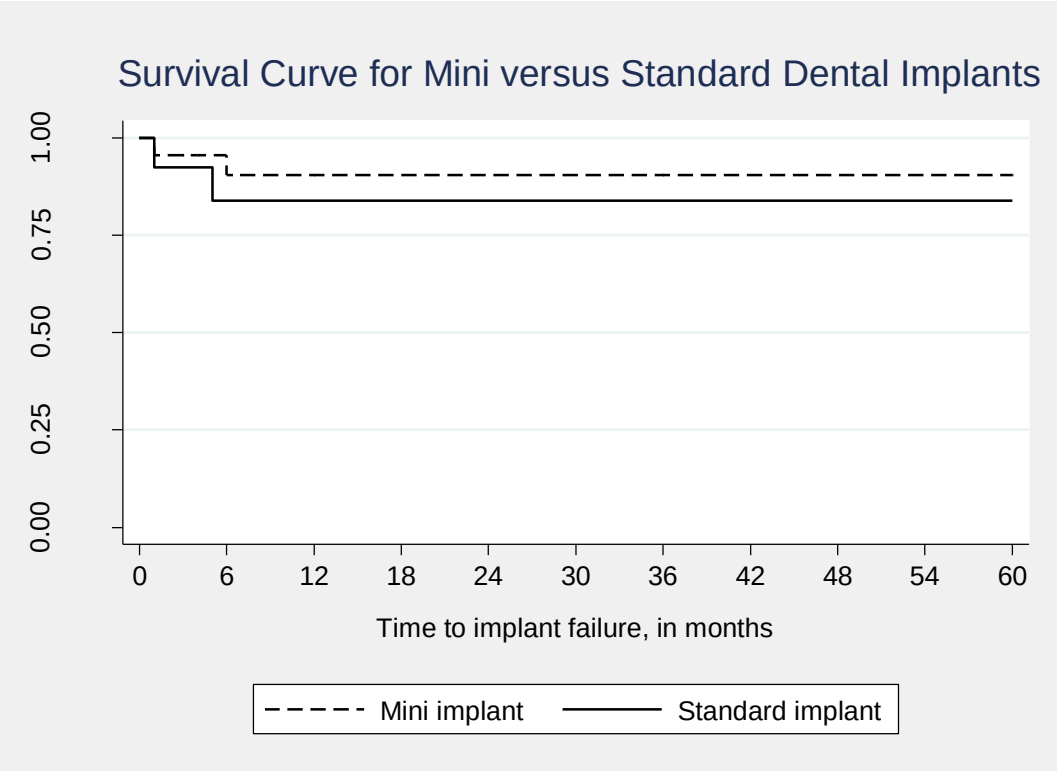
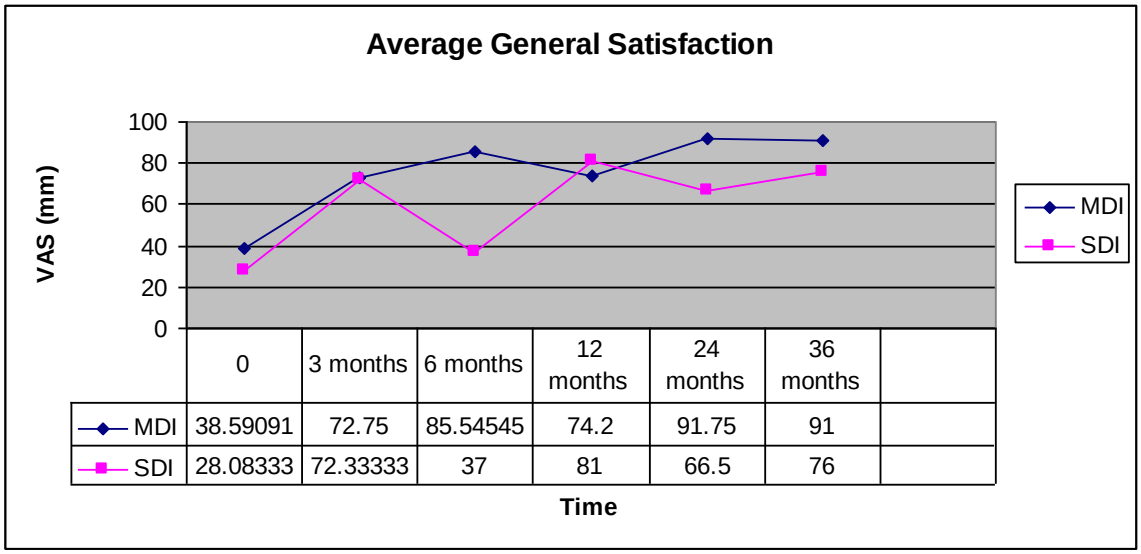
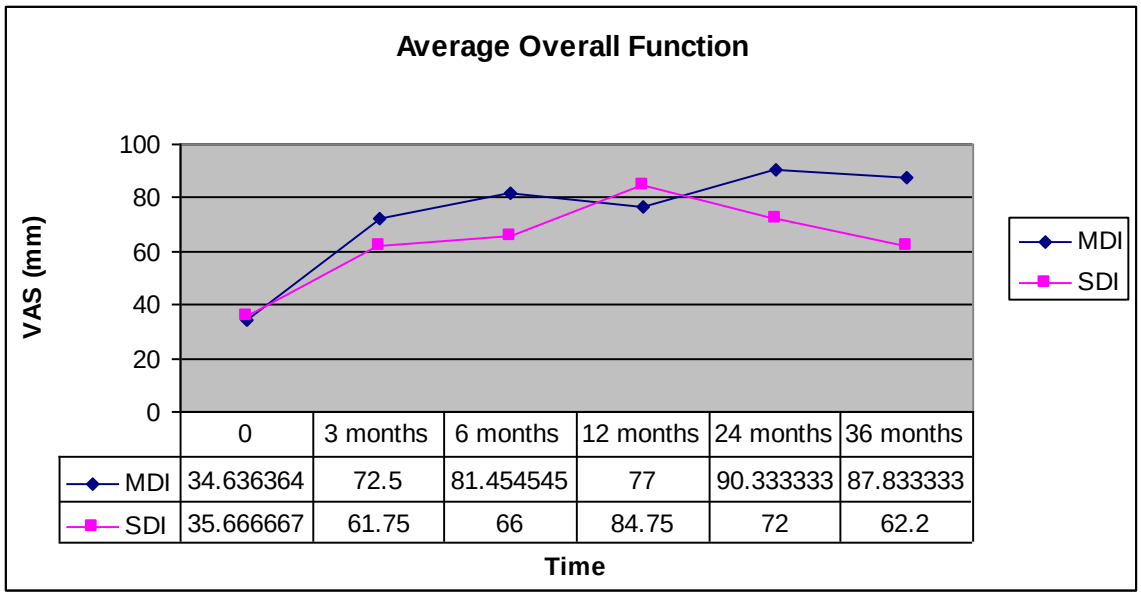

Survival Curve for Mini versus Standard Dental Implants
1.00
0.75
0.50
0.25
0.00
0
6
12
18
24
30
36
42
48
54
60
Time to implant failure, in months
Mini implant
Standard implant

Figure 2: Average General Satisfaction (QOL) of MDI and SDI from Baseline to 36 months



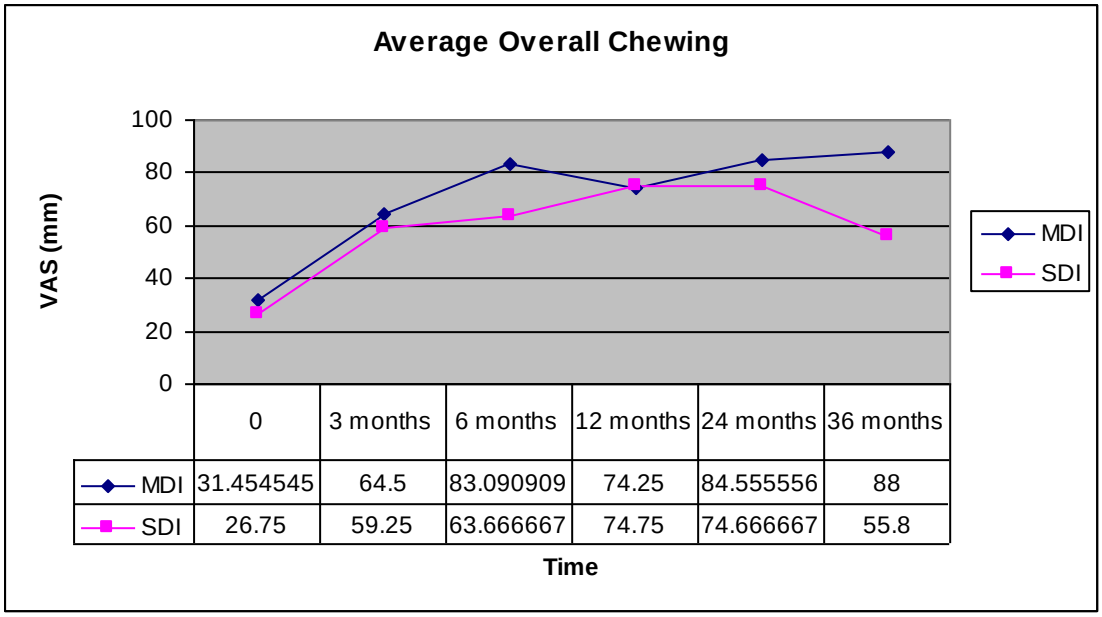
	0	3 months	6 months	12 months	24 months	36 months
MDI	38.59091	72.75	85.54545	74.2	91.75	91
SDI	28.08333	72.33333	37	81	66.5	76

Figure 3: Average Overall Function (QOL) of MDI and SDI from Baseline to 36 months



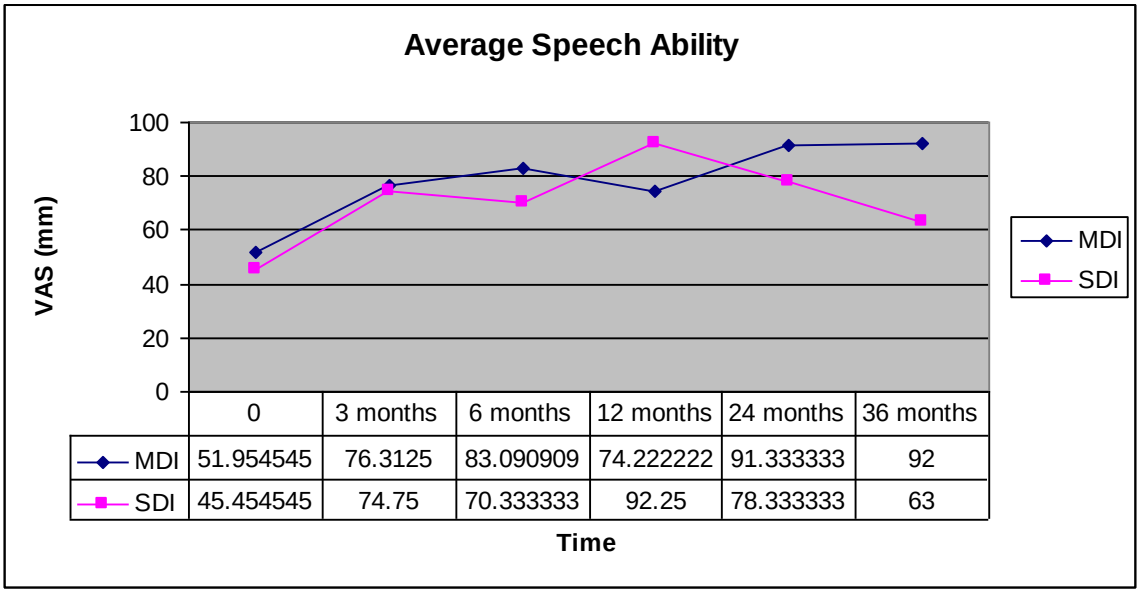
	0	3 months	6 months	12 months	24 months	36 months
MDI	34.636364	72.5	81.454545	77	90.333333	87.833333
SDI	35.666667	61.75	66	84.75	72	62.2

Figure 4: Average Overall Chewing Ability (QOL) of MDI and SDI from Baseline to 36 Months



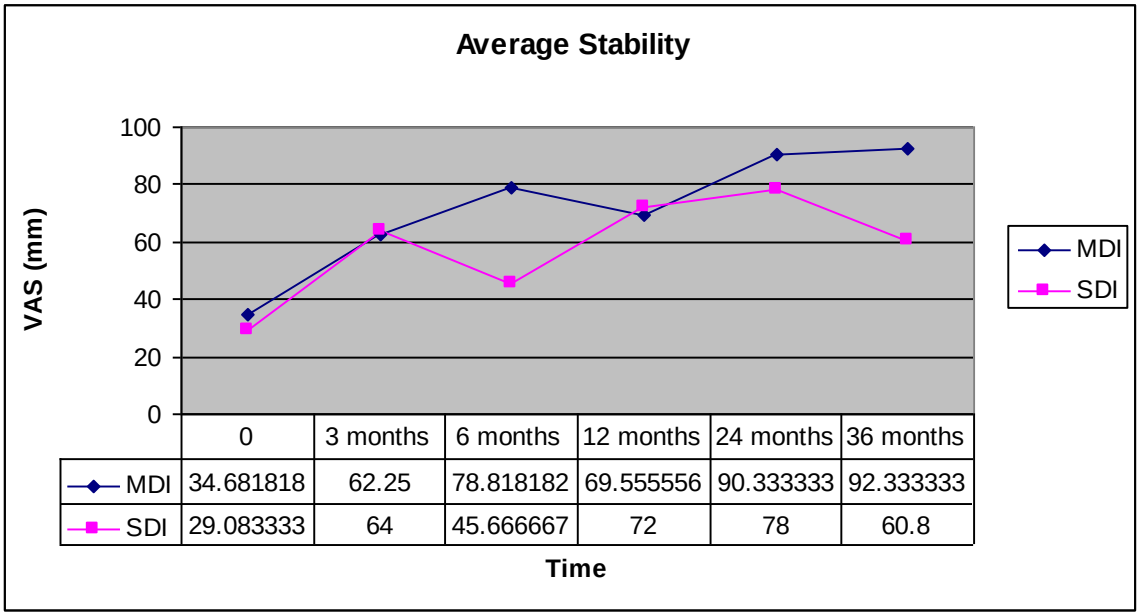
	0	3 months	6 months	12 months	24 months	36 months
MDI	31.454545	64.5	83.090909	74.25	84.555556	88
SDI	26.75	59.25	63.666667	74.75	74.666667	55.8

Figure 5: Average Speech Ability (QOL) of MDI and SDI from Baseline to 36 months



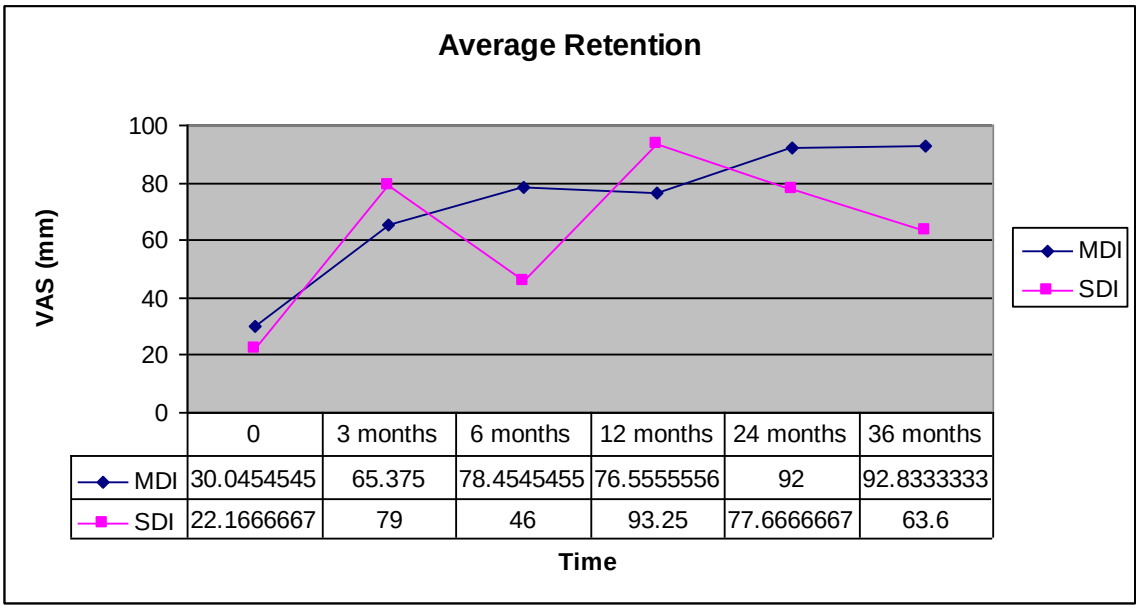
	0	3 months	6 months	12 months	24 months	36 months
MDI	51.954545	76.3125	83.090909	74.222222	91.333333	92
SDI	45.454545	74.75	70.333333	92.25	78.333333	63

Figure 6: Average Stability (QOL) of MDI and SDI from Baseline to 36 months



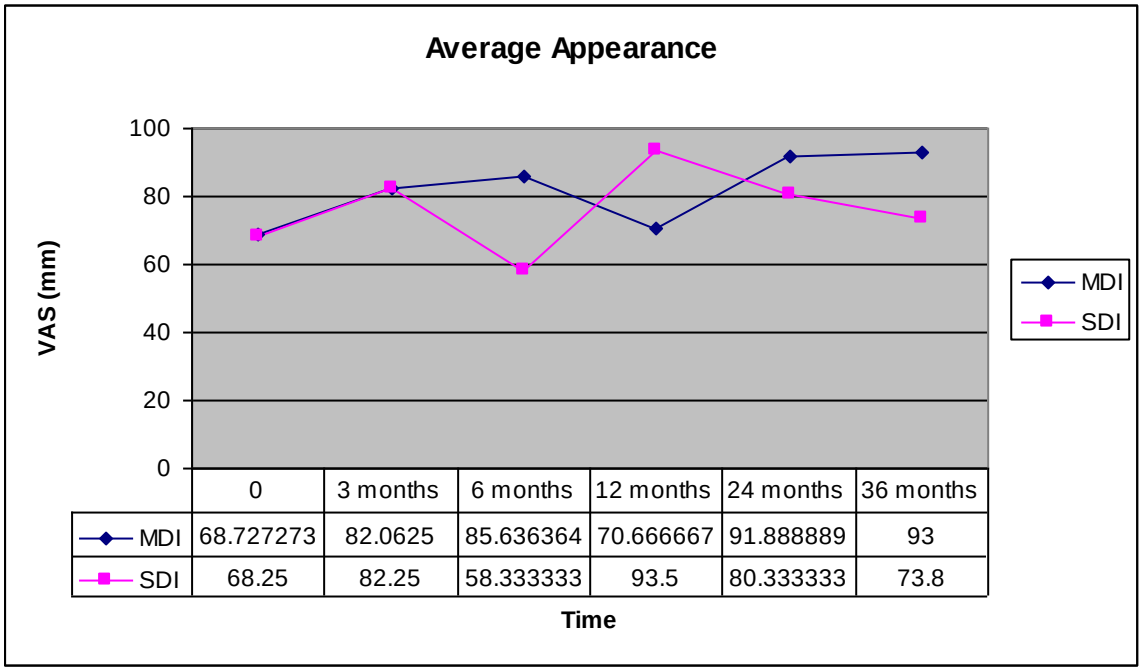
	0	3 months	6 months	12 months	24 months	36 months
MDI	34.681818	62.25	78.818182	69.555556	90.333333	92.333333
SDI	29.083333	64	45.666667	72	78	60.8

Figure 7: Average Retention (QOL) of MDI and SDI from Baseline to 36 months



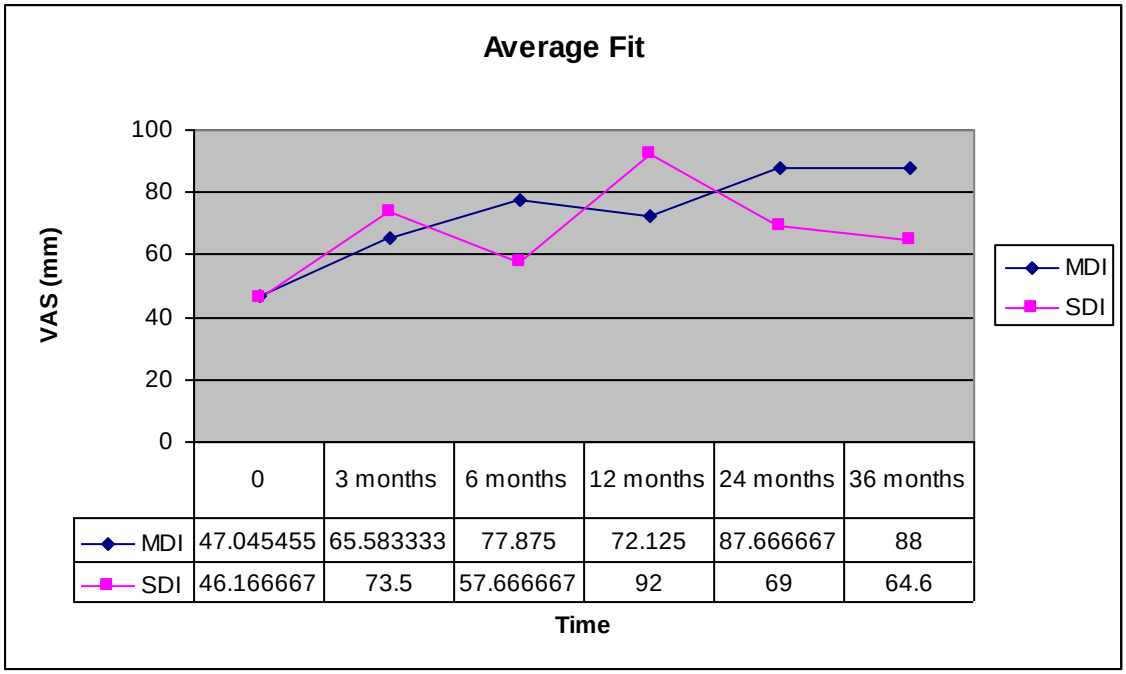
	0	3 months	6 months	12 months	24 months	36 months
MDI	30.0454545	65.375	78.4545455	76.5555556	92	92.8333333
SDI	22.1666667	79	46	93.25	77.6666667	63.6

Figure 8: Average Appearance (QOL) of MDI and SDI from Baseline to 36 months



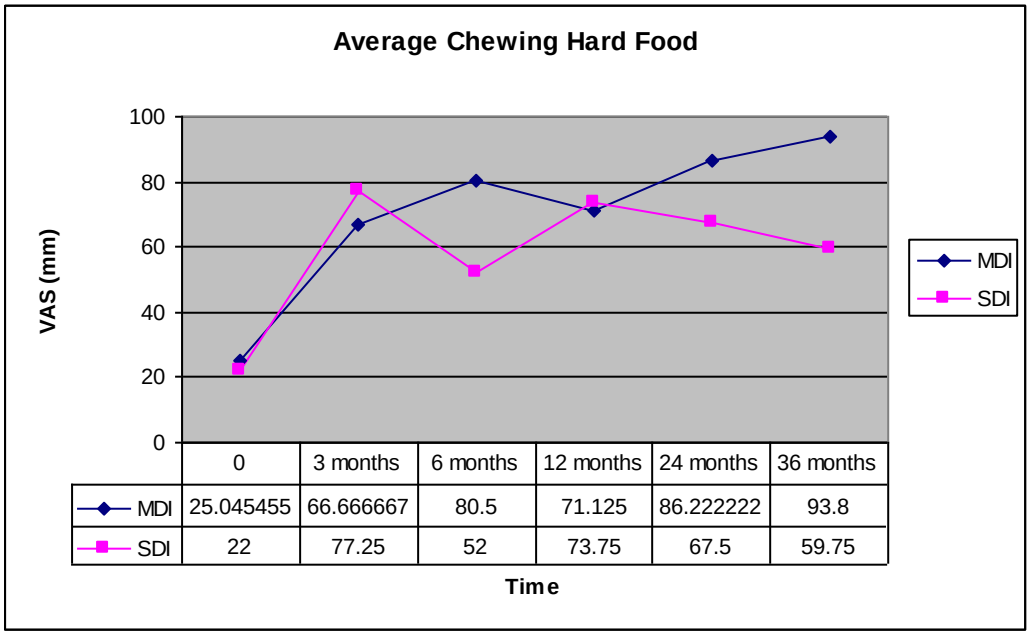
	0	3 months	6 months	12 months	24 months	36 months
MDI	68.727273	82.0625	85.636364	70.666667	91.888889	93
SDI	68.25	82.25	58.333333	93.5	80.333333	73.8

Figure 9: Average Fit (QOL) of MDI and SDI from Baseline to 36 months



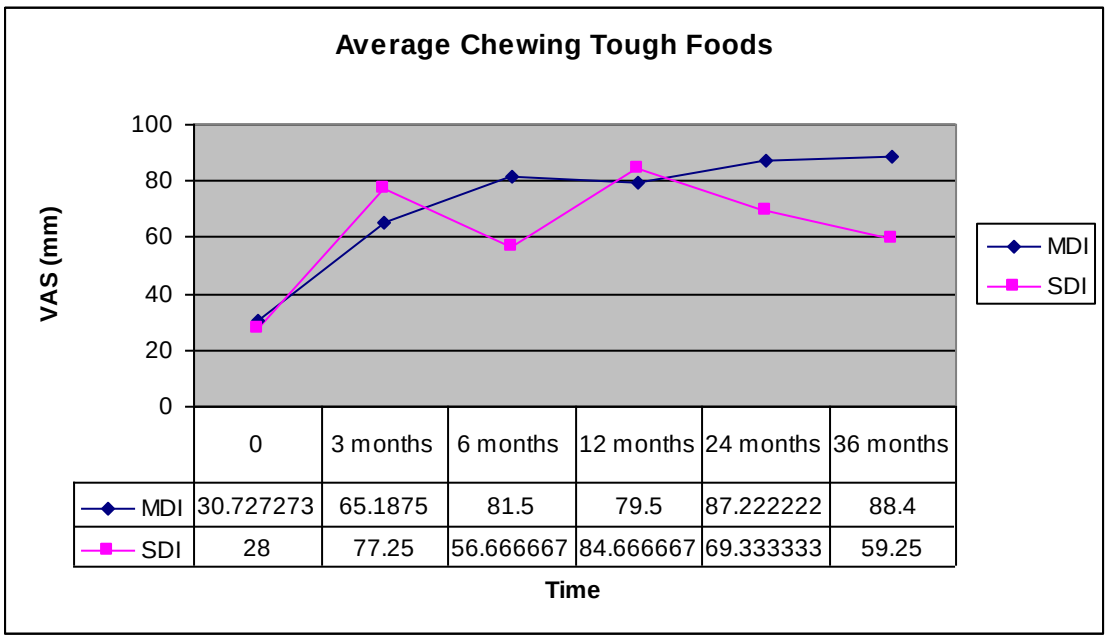
	0	3 months	6 months	12 months	24 months	36 months
MDI	47.045455	65.583333	77.875	72.125	87.666667	88
SDI	46.166667	73.5	57.666667	92	69	64.6

Figure 10: Average Chewing Hard Food (QOL) of MDI and SDI from Baseline to 36 months



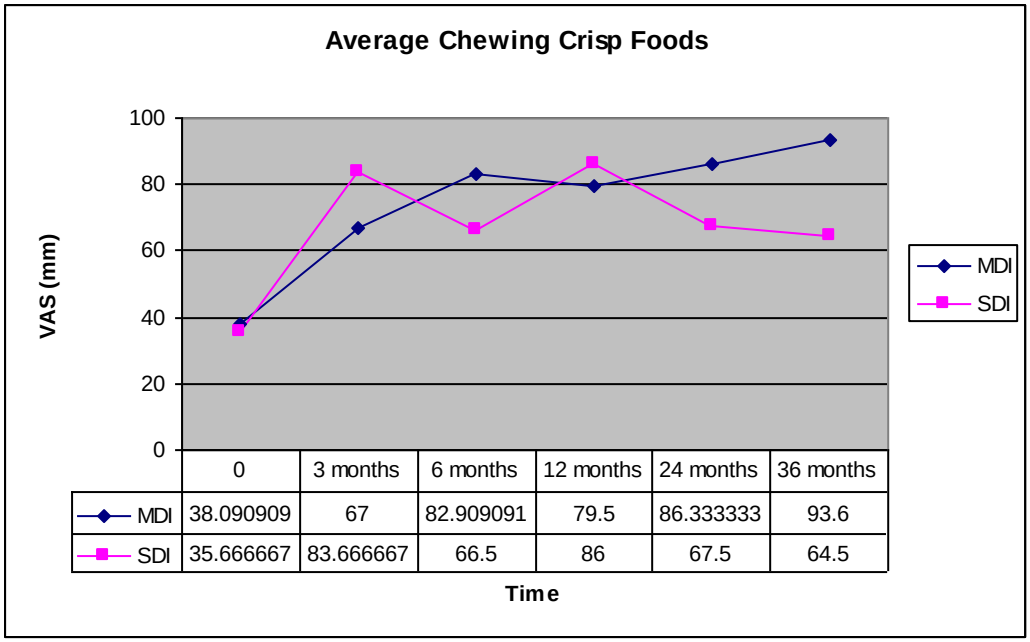
	0	3 months	6 months	12 months	24 months	36 months
MDI	25.045455	66.666667	80.5	71.125	86.222222	93.8
SDI	22	77.25	52	73.75	67.5	59.75

Figure 11: Average Chewing Tough Food (QOL) of MDI and SDI from Baseline to 36 months



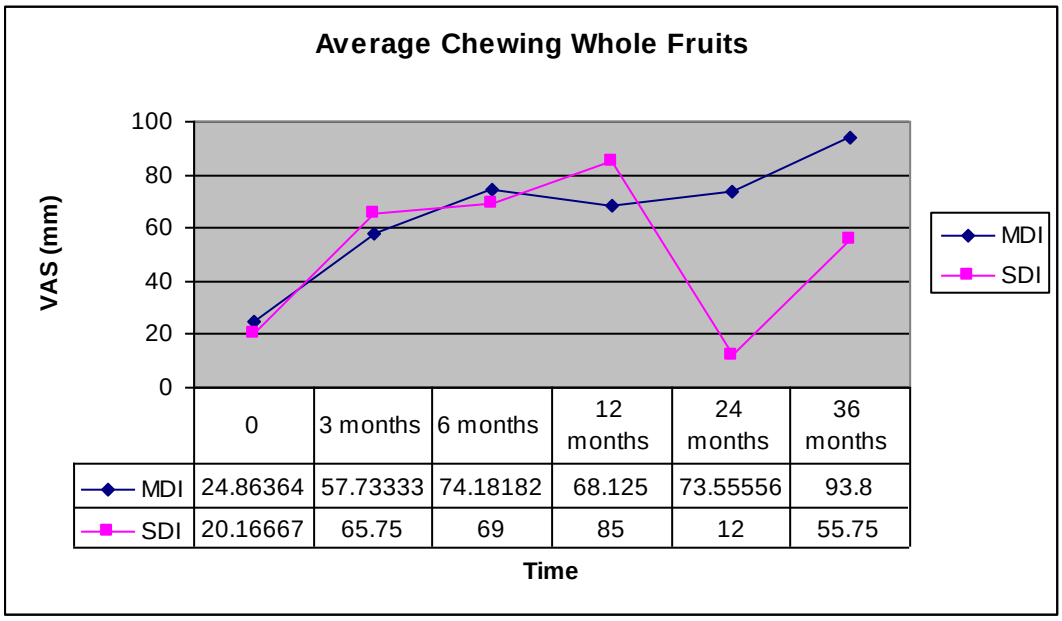
	0	3 months	6 months	12 months	24 months	36 months
MDI	30.727273	65.1875	81.5	79.5	87.222222	88.4
SDI	28	77.25	56.666667	84.666667	69.333333	59.25

Figure 12: Average Crisp Food (QOL) of MDI and SDI from Baseline to 36 months



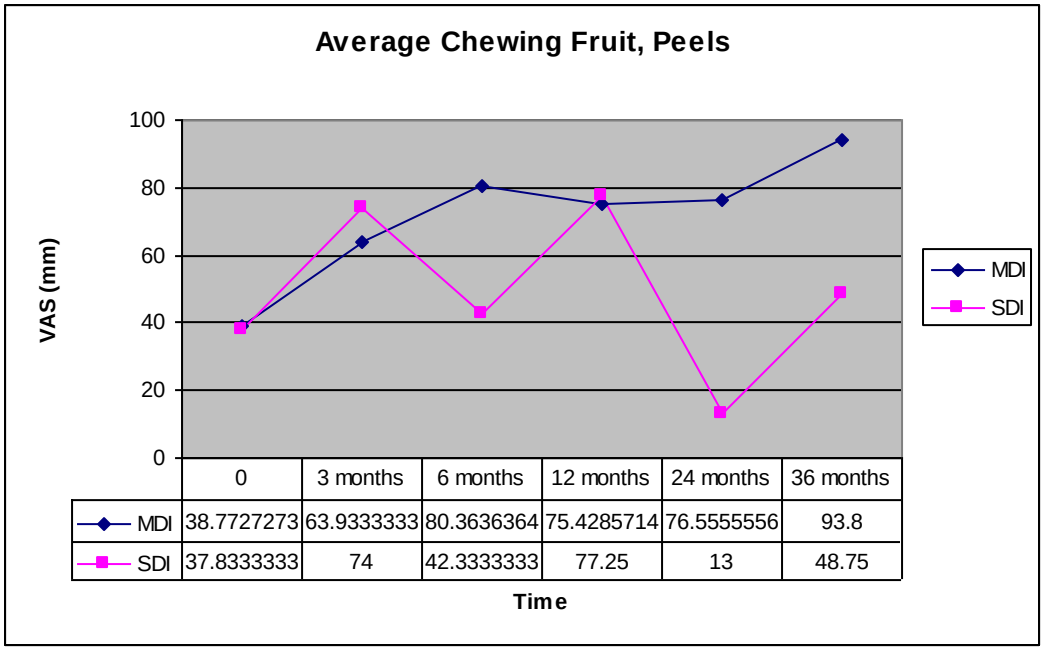
	0	3 months	6 months	12 months	24 months	36 months
MDI	38.090909	67	82.909091	79.5	86.333333	93.6
SDI	35.666667	83.666667	66.5	86	67.5	64.5

Figure 13: Average Chewing Whole Fruit (QOL) of MDI and SDI from Baseline to 36 months



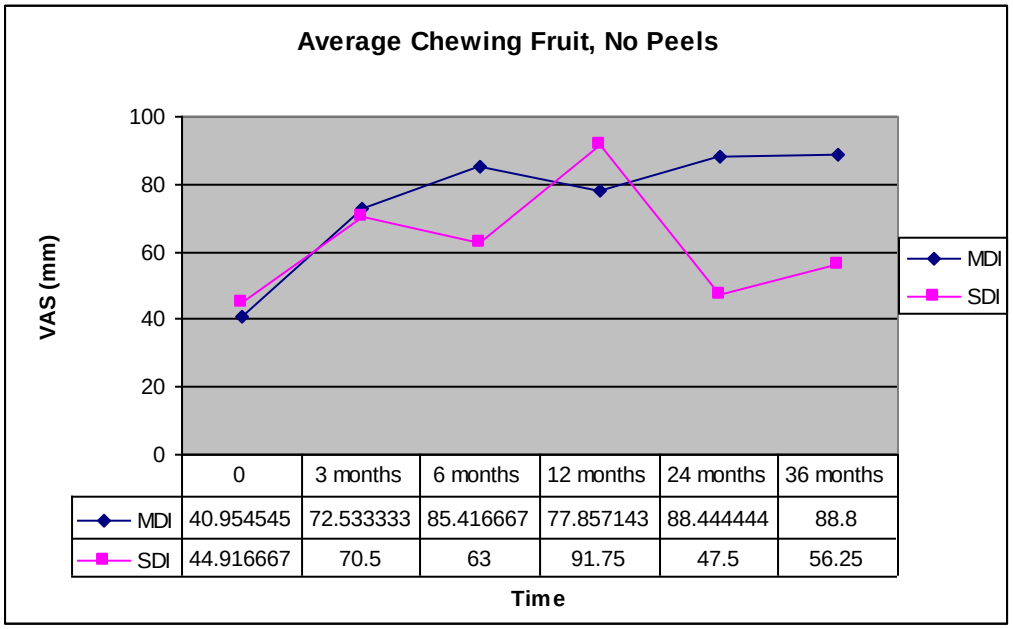
	0	3 months	6 months	12 months	24 months	36 months
MDI	24.86364	57.73333	74.18182	68.125	73.55556	93.8
SDI	20.16667	65.75	69	85	12	55.75

Figure 14: Average Chewing Fruits, Peels (QOL) of MDI and SDI from Baseline to 36 months



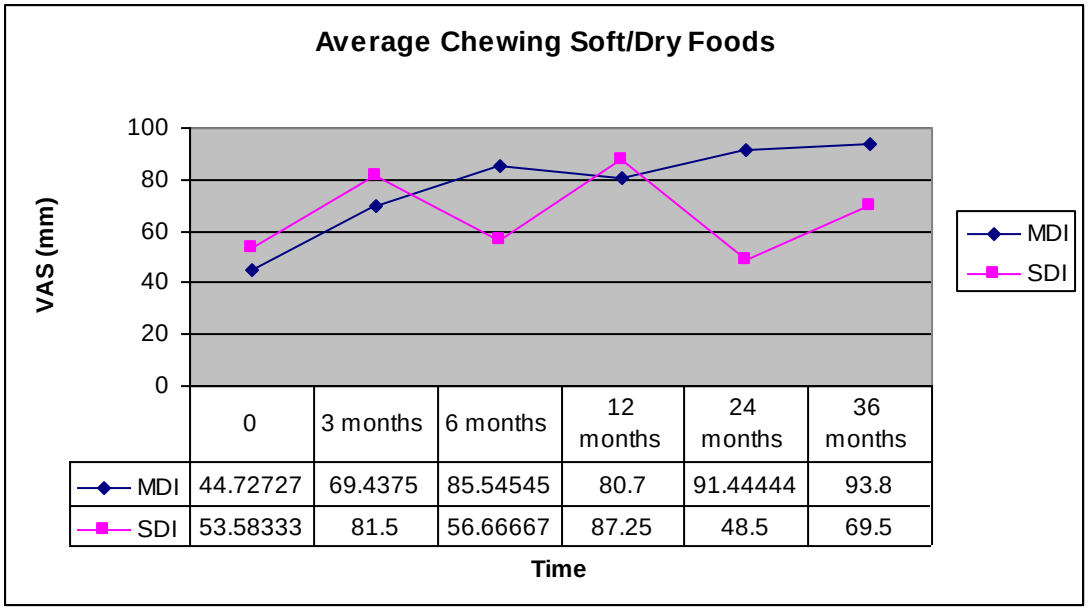
	0	3 months	6 months	12 months	24 months	36 months
MDI	38.7727273	63.9333333	80.3636364	75.4285714	76.5555556	93.8
SDI	37.8333333	74	42.3333333	77.25	13	48.75

Figure 15: Average Chewing Fruits, No Peels (QOL) of MDI and SDI from Baseline to 36 months



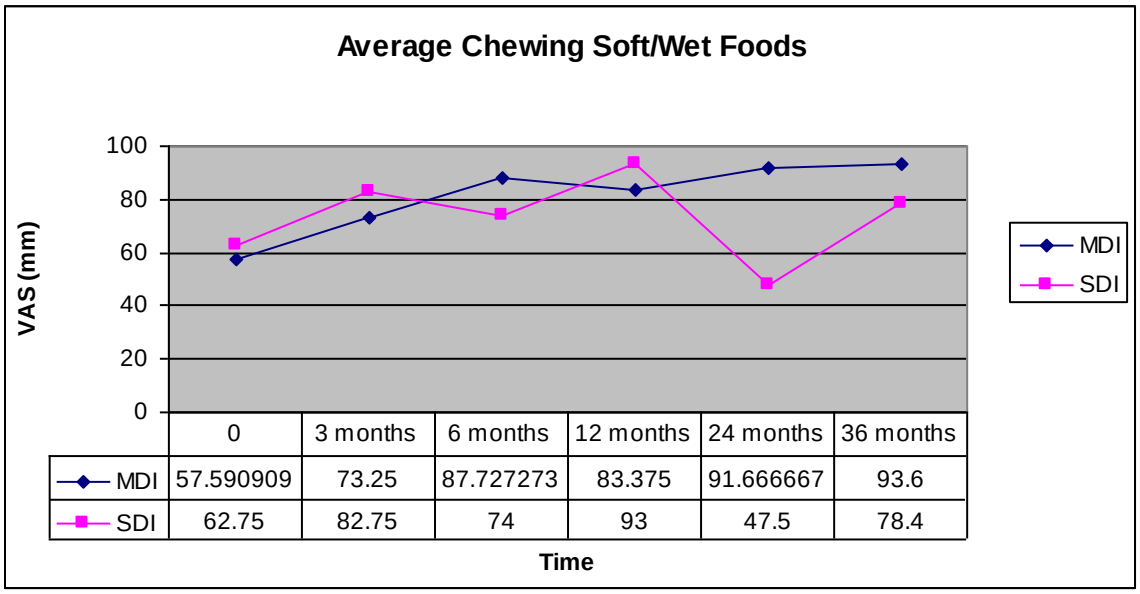
	0	3 months	6 months	12 months	24 months	36 months
MDI	40.954545	72.533333	85.416667	77.857143	88.444444	88.8
SDI	44.916667	70.5	63	91.75	47.5	56.25

Figure 16: Average Chewing Soft, Dry (QOL) of MDI and SDI from Baseline to 36 months



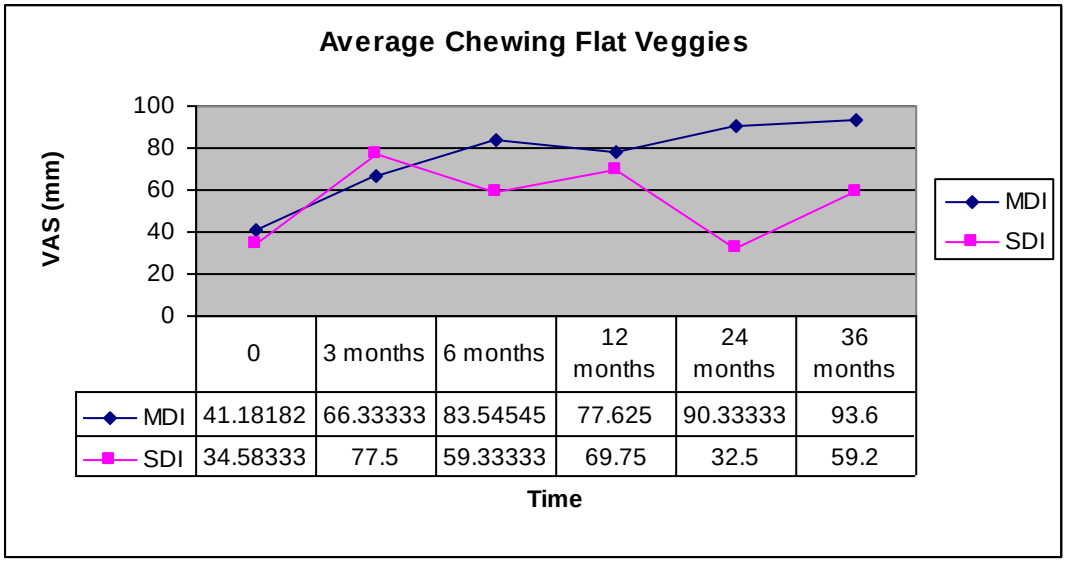
	0	3 months	6 months	12 months	24 months	36 months
MDI	44.72727	69.4375	85.54545	80.7	91.44444	93.8
SDI	53.58333	81.5	56.66667	87.25	48.5	69.5

Figure 17: Average Chewing Soft, Wet (QOL) of MDI and SDI from Baseline to 36 months



	0	3 months	6 months	12 months	24 months	36 months
MDI	57.590909	73.25	87.727273	83.375	91.666667	93.6
SDI	62.75	82.75	74	93	47.5	78.4

Figure 18: Average Chewing Flat Vegetable (QOL) of MDI and SDI from Baseline to 36 months



	0	3 months	6 months	12 months	24 months	36 months
MDI	41.18182	66.33333	83.54545	77.625	90.33333	93.6
SDI	34.58333	77.5	59.33333	69.75	32.5	59.2

Figure 19: Typical pre-surgical case randomized to MDI, which requires full thickness flap

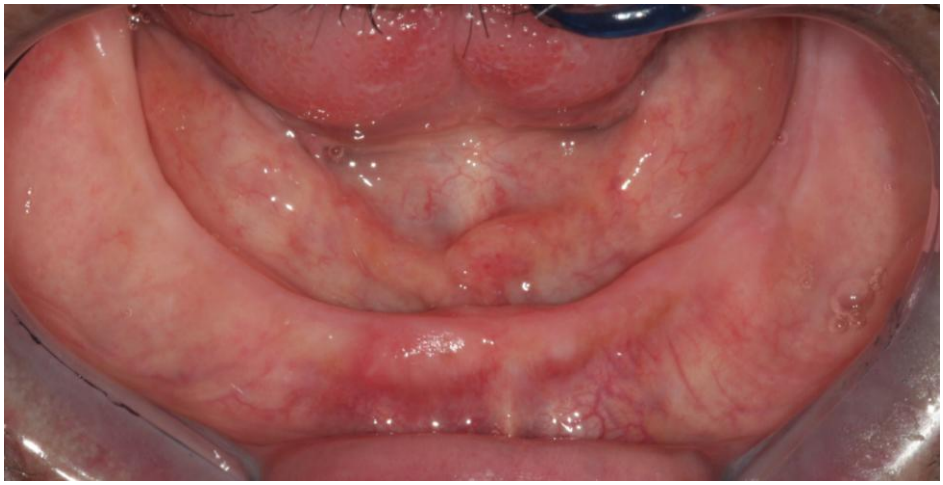


Figure 20: Pre-surgical panoramic radiograph

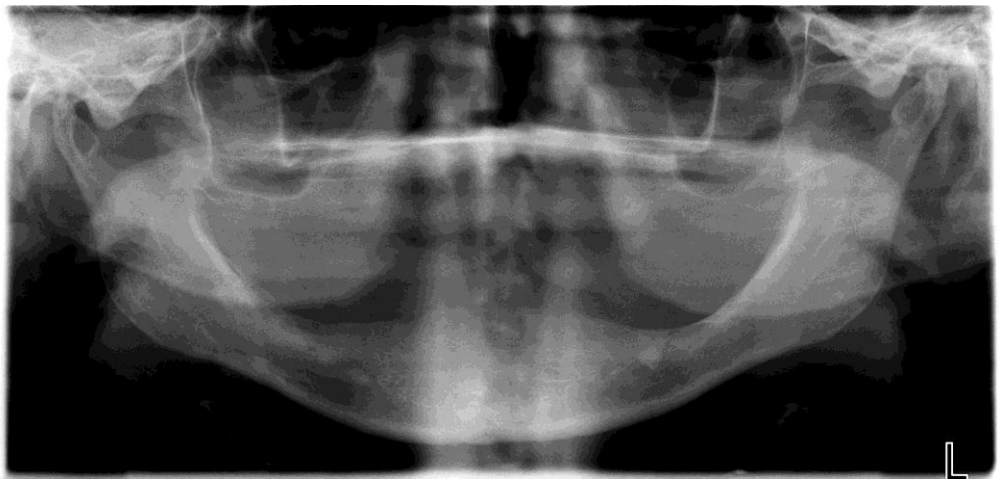


Figure 21: Full thickness flap reveals the need for osteoplasty to increase buccal-lingual width to approximate 5mm

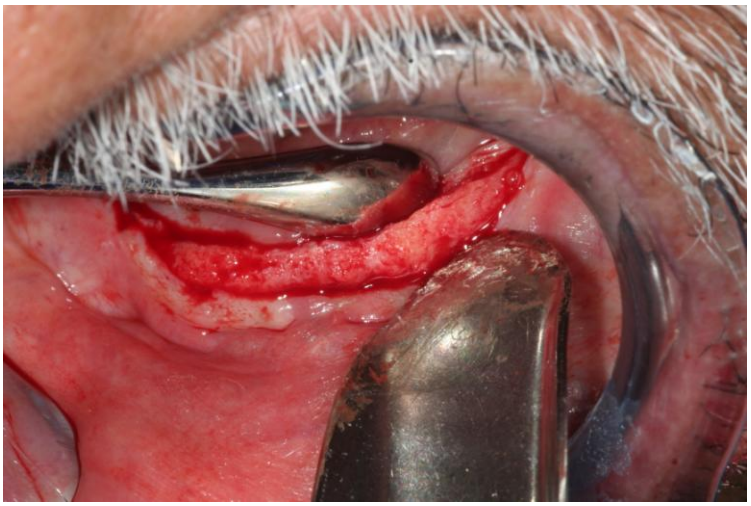


Figure 22: Completion of osteoplasty and osteotomy for MDI (1.8x13mm) at sites #22, #24, #25, and #27.

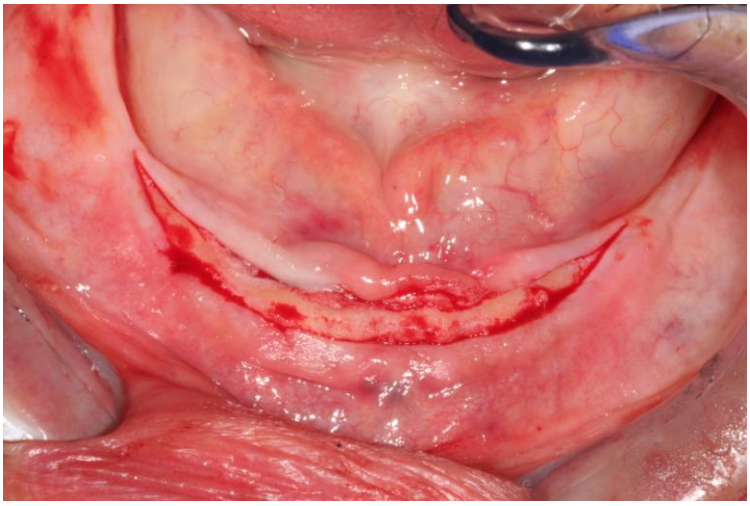


Figure 23: Completion of MDI (1.8x13mm) #22, #24, #25, and #27

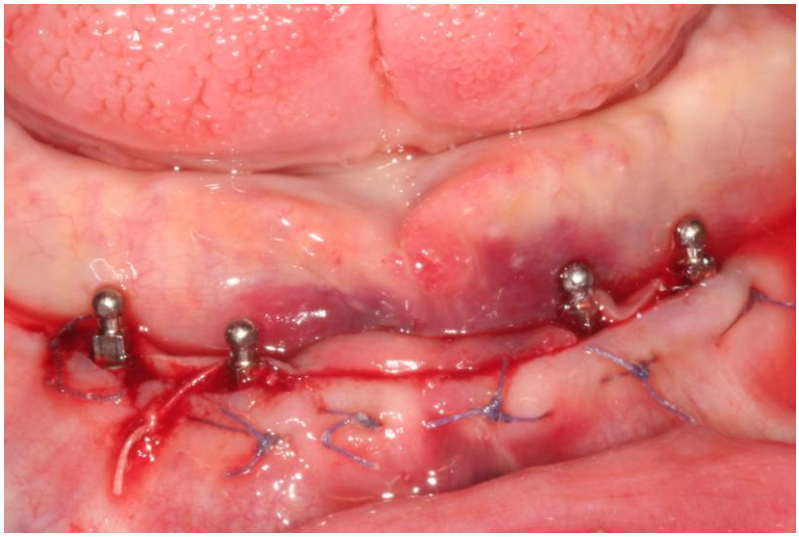


Figure 24: Post-surgical panoramic radiograph

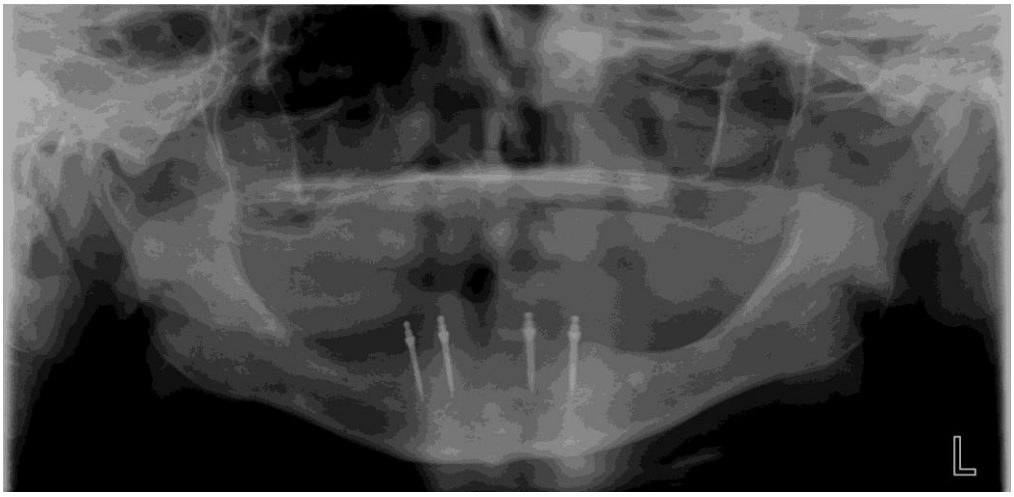


Figure 25: 1 week post-op

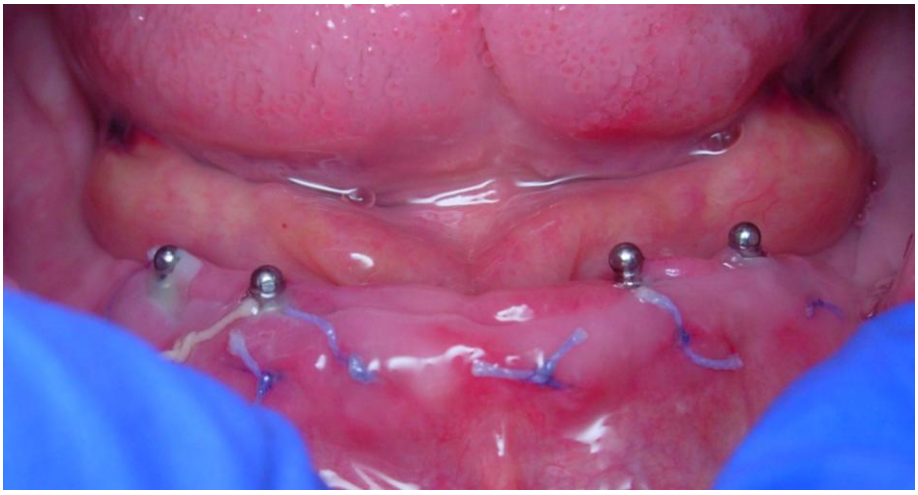


Figure 26: 3 weeks post-op

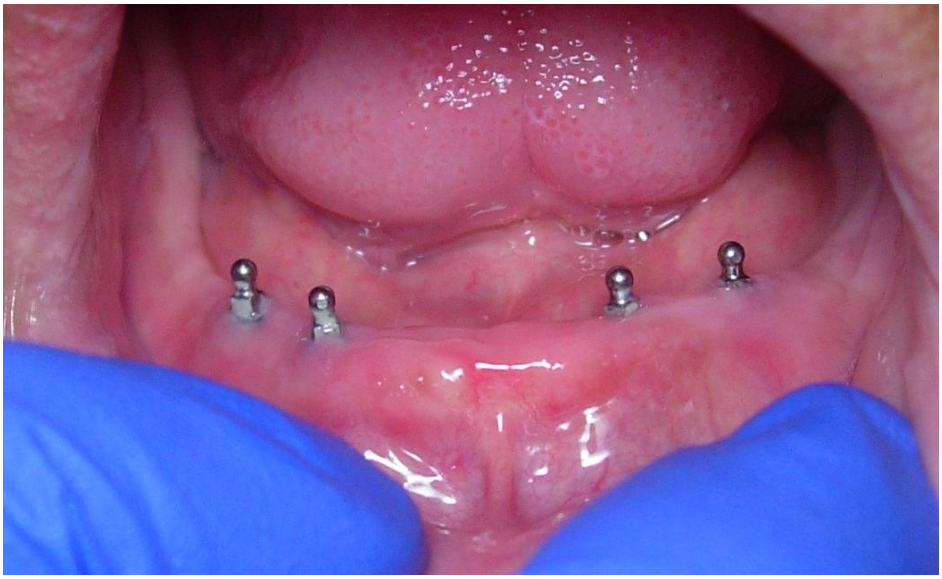


Figure 27: Typical pre-surgical case randomized to SDI, which requires full thickness flap

Figure 28: Implants at sites #22 and #27 with cover screws in place

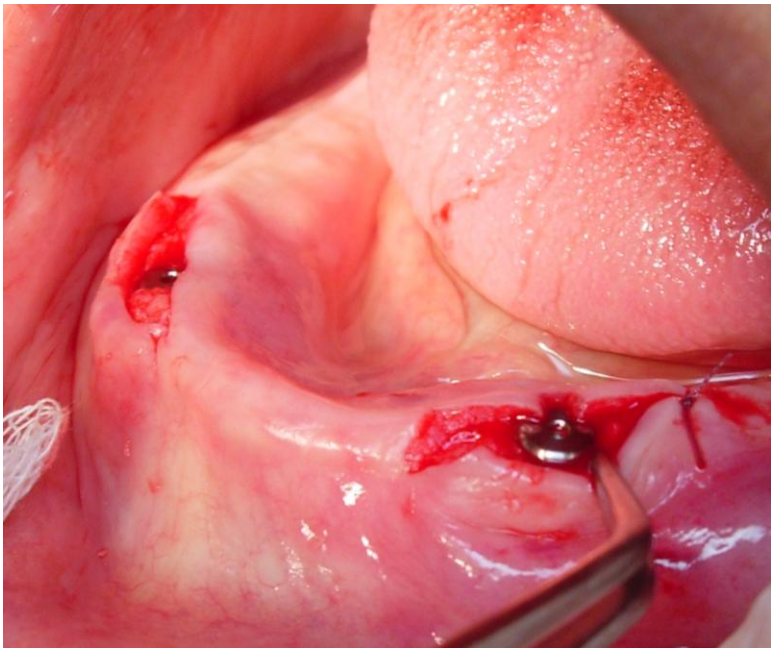


Figure 29: 3 months post-surgical panoramic radiograph

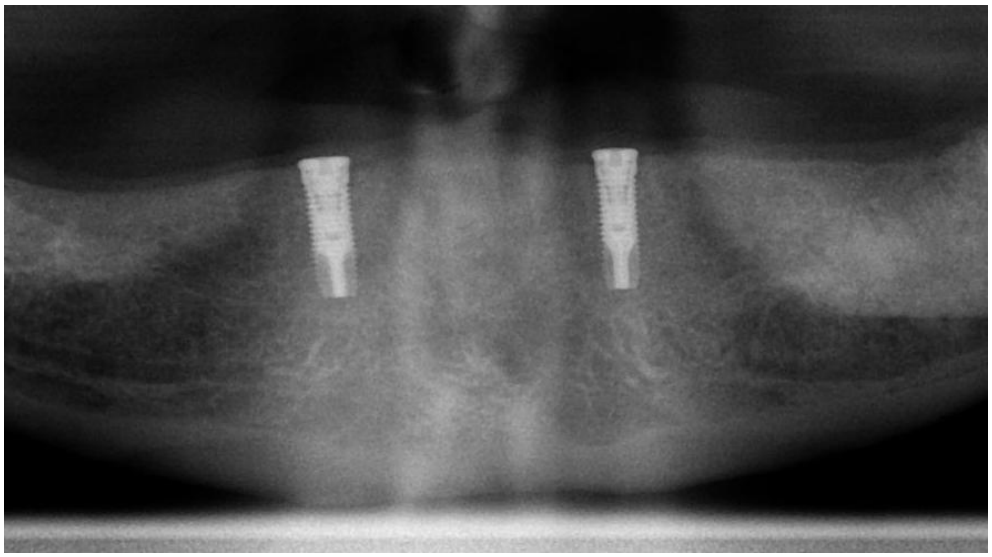


Figure 30: 4 months post-op

Figure 31: Post-retrofit panoramic radiograph with locator abutments

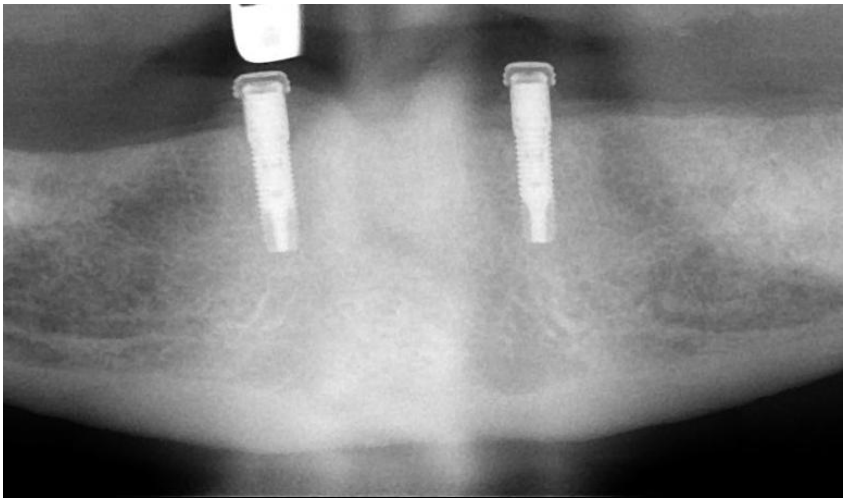


Figure 32: Additional auto-polymerizing acrylic resin needed to increase the height of acrylic in the area of #23 and #26

Figure 33: Typical MDI, which does not require full thickness flap

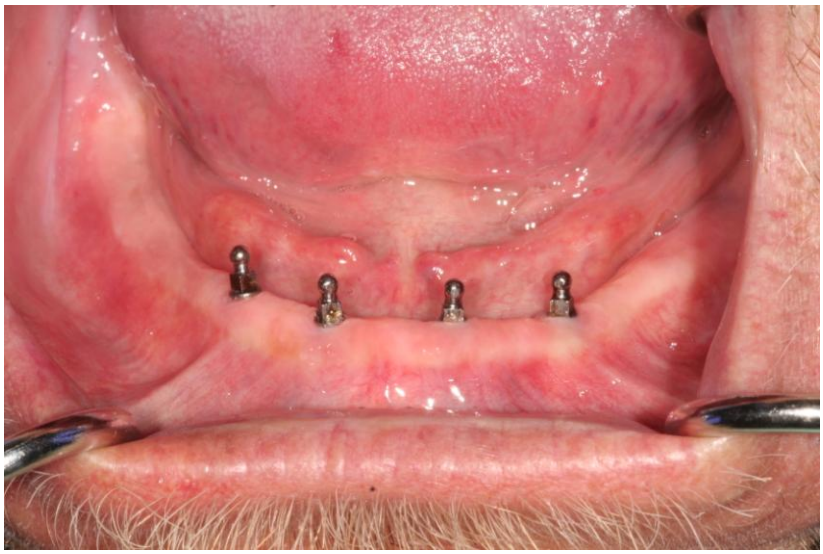


Figure 34: 4 months post-op

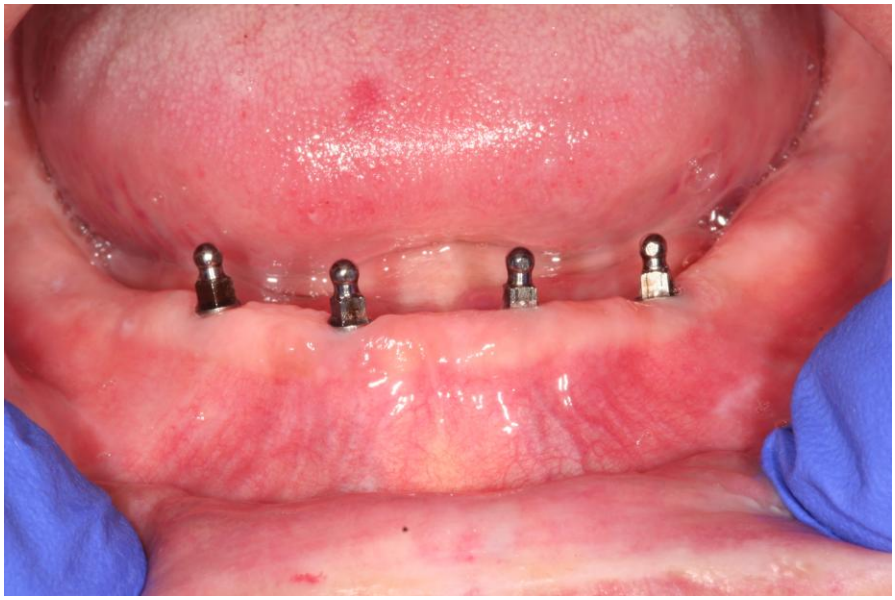


Figure 35: Adequate width of acrylic

Figure 36: 4 months post-op for retrofit

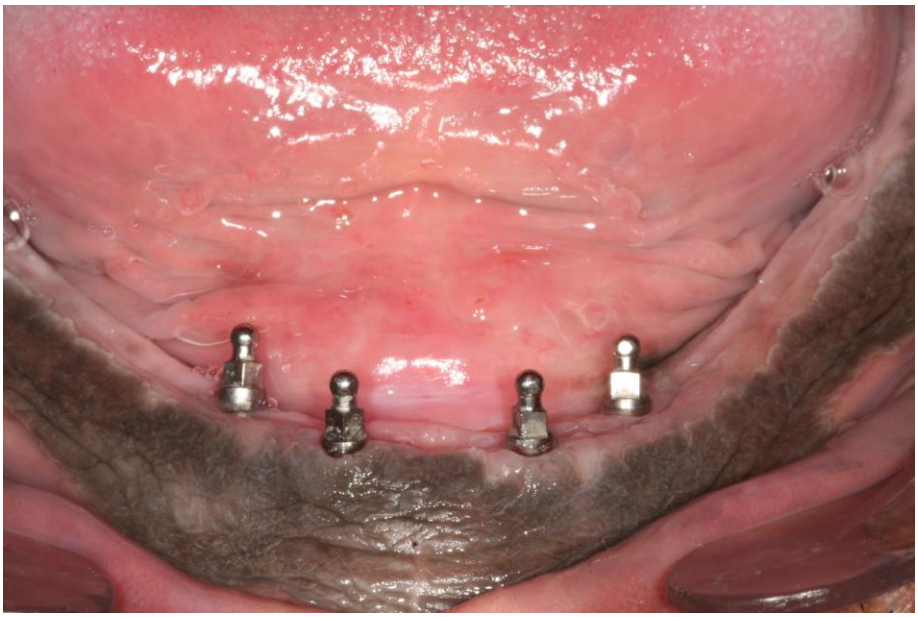


Figure 37: Placement of housing over block-out shims

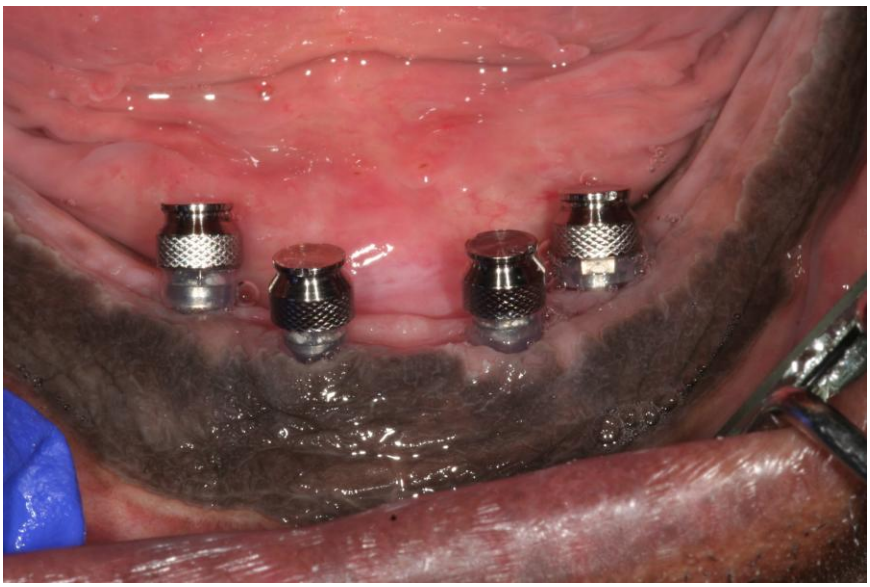


Figure 38: Removal of adequate acrylic for housing pick-up. Lingual placement of implant #27 required removal of lingual flange in that area with placement of acrylic vent holes on the lingual

Figure 39: Completion of housing pick-up using auto-polymerizing acrylic resin

Figure 40: Typical SDI 4 months post-op for retrofit

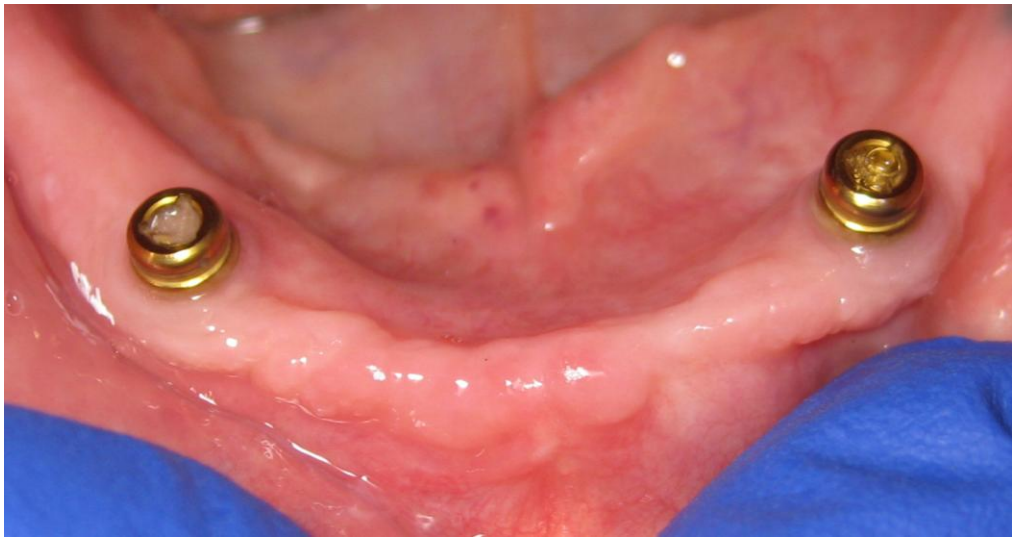


Figure 41: SDI Locator with rubber dam and block-out shims

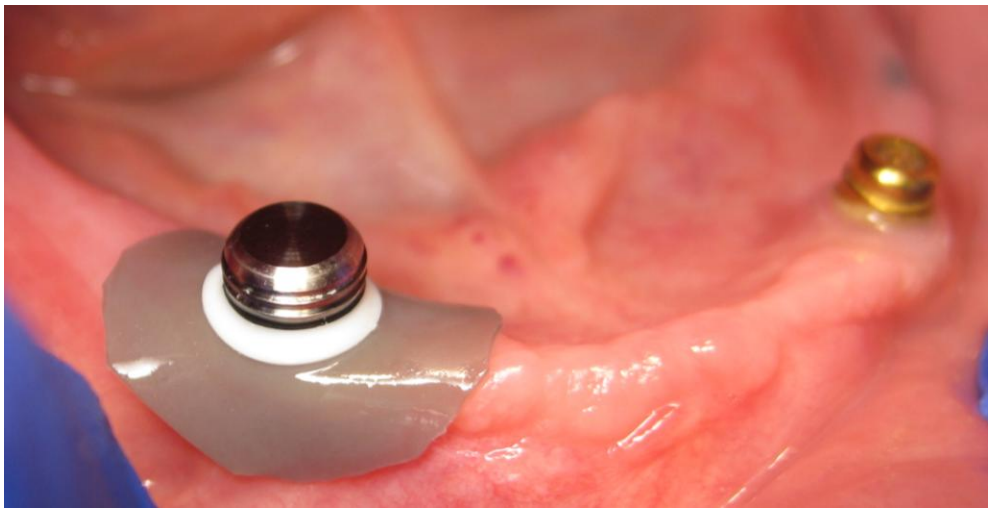
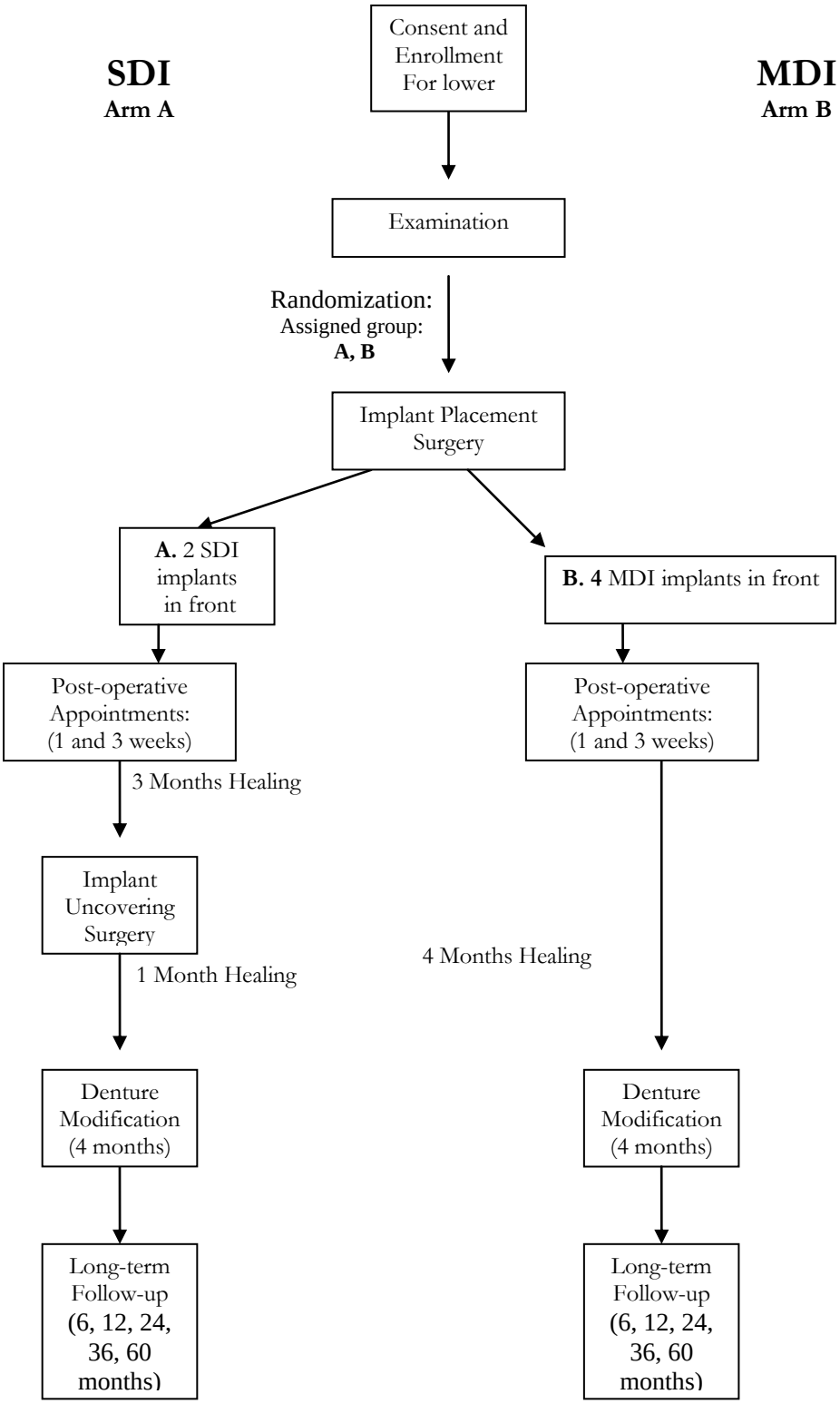


Figure 42: Completion of locator housing pick-up using auto-polymerizing acrylic resin

Appendix A: Flow Chart of study



Appendix B: VAS Clinical Evaluations

1. General satisfaction:

In general, are you satisfied with your lower denture?

Not at all Satisfied					**Totally Satisfied**

In general, are you satisfied with your upper denture?

Not at all Satisfied					**Totally Satisfied**

2. Overall function:

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

Not at all Satisfied					**Totally Satisfied**

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

Not at all Satisfied					**Totally Satisfied**

3. Overall chewing ability:

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

Not at all Satisfied					**Totally Satisfied**

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

Not at all Satisfied					**Totally Satisfied**

4. Speech ability:

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

Not at all Satisfied					**Totally Satisfied**

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

Not at all Satisfied					**Totally Satisfied**

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

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

Not at all Satisfied					**Totally Satisfied**

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

Not at all Satisfied					**Totally Satisfied**

6. Retention (dislodging):

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

Not at all Satisfied					**Totally Satisfied**

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

Not at all Satisfied					**Totally Satisfied**

7. Appearance:

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

Not at all Satisfied					**Totally Satisfied**

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

Not at all Satisfied					**Totally Satisfied**

8. Fit (comfort):

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

Not at all Satisfied					**Totally Satisfied**

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

Not at all Satisfied					**Totally Satisfied**

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

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

Not at all Satisfied					**Totally Satisfied**

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

Not at all Satisfied					**Totally Satisfied**

10. Chewing tough foods (examples: beef):

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

Not at all Satisfied					**Totally Satisfied**

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

Not at all Satisfied					**Totally Satisfied**

11. Chewing crisp foods (examples: chips):

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

Not at all Satisfied					**Totally Satisfied**

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

Not at all Satisfied					**Totally Satisfied**

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

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

Not at all Satisfied					**Totally Satisfied**

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

Not at all Satisfied					**Totally Satisfied**

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

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

Not at all Satisfied					**Totally Satisfied**

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

Not at all Satisfied					**Totally Satisfied**

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

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

Not at all Satisfied					**Totally Satisfied**

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

Not at all Satisfied					**Totally Satisfied**

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

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

Not at all Satisfied					**Totally Satisfied**

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

Not at all Satisfied					**Totally Satisfied**

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

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

Not at all Satisfied					**Totally Satisfied**

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

Not at all Satisfied					**Totally Satisfied**

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

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

Not at all Satisfied					**Totally Satisfied**

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

Not at all Satisfied					**Totally Satisfied**

Appendix C: Outline of Subjects Appointments:

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 or CT scan**
- **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 Sendax 1.8-2.2X10-13 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

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