Immediate Loading Of 4 Guided Implants Supporting A Maxillary Overdenture Using A Novaloc Retention System

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Immediate Loading Of 4 Guided Implants Supporting A Maxillary Overdenture Using A Novaloc Retention System

DoHeum Choi

A thesis submitted to the School of Dentistry at West Virginia University
In partial fulfillment of the requirements for the degree of Master of Science in Periodontics and Implant Surgery

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2022

Keywords: maxilla, dental implants, implant overdentures, immediate loading, guided surgery, flapless surgery

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ABSTRACT

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The purpose of this study was to test the treatment concept of maxillary overdenture retained by four unsplinted implants placed using a flapless guided approach and immediate loading with Novaloc® attachments. Subjects with fully edentulous maxillae received 4 BLX implants (Roxolid®, SLActive®, 3.75mm diameter, Institut Straumann AG, Basel, Switzerland) to support an immediately loaded overdenture. Implants were connected with Novaloc® attachments (Institut Straumann AG, Basel, Switzerland) immediately following surgery if insertion torque (IT) reached 20 N/cm or above. The primary outcome variable was the radiographic bone level change at 6- and 12-months following implant placement. Secondary outcome variables were peri-implant soft tissue assessment (PD, KT, BoP, PI), implant stability quotient (ISQ), and implant survival throughout the study period. Ten patients with a mean age of 61.0 years (range: 27-80, SD=14.5) were enrolled in the study and 40 implants were placed. Thirty-eight and 35 implants were available for data analysis at 6 and 12 months. Radiographic bone level change averaged $0.16 \pm 0.42$ (p=0.017) and $0.33 \pm 0.87$ mm (p=0.013) at 6 and 12 months respectively. The implant survival rate was 95.0% as two implants failed. Within the limitations of this study, results indicate that this minimally invasive treatment approach may be a suitable treatment option for the edentulous maxilla.
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1. Introduction

1.1. Definition

With the growing geriatric population, clinical management of aging dentition has been a topic of discussion, as they might present with intact dentition to be maintained, partial edentulous dentition to replace the missing teeth, or complete edentulism to replace the whole arch. Management of complete edentulism had historically been anywhere from straightforward to arduous depending on many factors, such as individual status of the alveolar ridge, finance, and so on. The complete denture was one of the simplest treatment options for these patients with complete edentulism, despite numerous limitations, including inadequate retention and quality of life with room for improvement. A plethora of treatment options came up due to the development of implant dentistry to mitigate those limitations via either removable or fixed treatment approaches.

According to the American Academy of Periodontology glossary of terms, when complete or partial dentures are supported by soft tissue and dental implants, the prosthesis is called an overdenture which can improve the support, retention, and stability of the denture. To further classify overdentures, they can be divided based on whether the denture is supported or retained by dental implants or both. When the intaglio surface of the prosthesis is not supported by soft tissue but solely by the dental implants, it is an implant-supported overdenture. On the other hand, a prosthesis is called a soft tissue-supported, implant-retained overdenture if the underlying mucosa provides support of the denture.

1.2. Benefits of overdentures

Implant overdenture therapy has been vastly documented in the literature for its many benefits to edentulous patients and long-term predictability. According to Alsaggaf et al. (2020), wearing complete dentures increased the rate of alveolar ridge resorption compared to edentulous patients without dentures. If the alveolar resorption progressed to the point where the alveolar ridge height was at the floor mouth or palate and was deficient in both height and width, rehabilitation of the edentulous jaw could become more complicated because of compromised stability and
retention of the prosthesis as well as treatment options utilizing dental implant placement. Especially in the atrophic maxilla, pneumatized maxillary sinuses could further complicate the implant placement. On the contrary, alveolar bone levels marginal to dental implants had been shown to remain stable. A 5-year prospective study by Jemt et al. (1996) showed a highly stable marginal bone level (MBL) around implants during the follow-up period.² Radiographic analysis of alveolar bone resorption was 0.8mm around the 53 implants placed in the maxilla, loaded with overdentures. Consequently, compared to conventional complete dentures without implants, overdentures were therapeutic and preventive of accelerated alveolar bone resorption.

When the chewing efficiency was assessed for implant overdentures, research by Geertman et al. (1994) showed a comparison of overdenture to conventional. This study divided patients into conventional mandibular denture and two-implant retained overdentures.³ All maxillae had been given conventional dentures. A comparison of chewing efficiency favored implant overdentures by 1.5-3.6 times. Although the result corroborated the superior masticatory efficiency of implant overdentures in relation to conventional dentures, this evidence only pertained to the mandibular overdentures supported by a heavy body of literature. While there was no strong evidence in implant literature confirming the superiority of masticatory power of overdentures in the maxilla, Boven et al. (2019) clearly stated that maxillary implant overdentures had the superior masticatory ability to conventional dentures both objectively and subjectively by the patients.⁴ Moreover, when the above patients were further classified into bar-retained versus solitary attachments for maxillary overdentures, objective masticatory abilities were not significantly different between the two groups as both groups of maxillary overdentures, proving improved chewing abilities.

Another sizable benefit of removable overdenture included increased retention of the prosthesis. As discussed earlier, the alveolar ridge resorption rate was accelerated when edentulism was treated with only conventional dentures, which could lead to poor stability and retention of removable prostheses. Jemt et al. (1996) conducted a multicenter study where nine different groups recruited patients that reported functional problems with conventional dentures of the maxilla or mandible.² After a five-year-follow-up, most patients treated with overdentures
showed increased retention and stability provided by the bar-type attachments compared to complete dentures.

This functional improvement also enhanced the quality of life associated with oral health. Sixty edentulous patients were included in the study by Heydecke, et al. (2003) and divided into a control group of thirty and an experimental group of thirty.\textsuperscript{5} Control group received maxillary and mandibular complete conventional dentures while the experimental group had mandibular overdentures supported by two implants to oppose conventional maxillary dentures. These patients provided quality of life assessment data to be compared between pre-experiment and six-month follow-up. The analysis included patient-reported outcomes on functional limitations, psychological disability, physical pain and disability. At the end of the study, a clear difference was shown with the superiority of the implant overdenture group having improved oral health status. Even though this study was well-conducted research from the McGill group after the McGill consensus, it was focused on the mandibular implant overdentures and their benefit to oral health-related quality of life.

Another recent study by Zembic, et al. (2019) had a similar study aim but in the maxilla.\textsuperscript{6} Out of 40 candidates who volunteered to participate due to their dissatisfaction with conventional maxillary prostheses, the investigators included 21 patients to receive at least two implants with either bar or ball attachments in the maxilla to retain the complete denture with or without palatal coverage based on the patients’ choice. The mean follow-up period was four years with a range of 2.4 to 4.8 years. Patient-reported outcomes were again assessed via the OHIP-20 questionnaire throughout the study period and compared to the baseline conventional denture OHIP scores. Results showed overall improvement with time, but a more positive score in quality of life was shown with the implant overdentures than with the conventional dentures. However, the improvement in patient satisfaction over the four years was insignificant.

Smedberg et al. (1993) further corroborated that maxillary overdentures increased the quality of life in patients with maxillary edentulism in their short and long-term follow-ups.\textsuperscript{7} They recruited 20 patients whose maxillae were treated with implant-retained overdentures while 18 of them provided data on implant survival, peri-implant soft tissue health, and patient satisfaction in
terms of aesthetics, phonetics, and function. Among these, patient satisfaction analysis according to the visual analog scale showed a clear increase from the start of study to the two and six-year follow-up points. There could be a degree of bias, but the examiners had the same trend. Besides the patient-reported outcome, the examiner-reported outcome was also in a positive trend with an increase in VAS score from the start to the two and six years afterward in terms of aesthetics, phonetics, and comfort as part of the quality of life.

1.3. Controversy – the number of implants

Many controversies existed in implant literature regarding the treatment approaches for maxillary overdenture, relating to the number of implants, types of attachments, and loading protocols. First, the number of implants could play an important role in determining the prosthetic design. While the protocol was widely accepted as two implants for the mandibular overdentures, the maxillary treatment approach was less documented in the implant literature. Even though placing more implants would be insurance for the clinicians in unexpected situations of implant failure, placement of 6 implants would require a lot of bone volume, while many these patients might present with atrophic maxilla or pneumatized sinuses that necessitate complex grafting procedures. Even if patients had adequate bone volume, a treatment plan of six implants would cost more than that of four. Naturally, finding a feasible treatment plan with a minimum number of implants would benefit the patients financially by simply reducing the fixture cost and minimizing the cost of complex grafting procedures, which would allow clinicians to treat a larger volume of patients.

A retrospective analysis by Sanna et al. (2009) compared the implant survival rate of implants placed in the maxilla for overdentures to those for full fixed prostheses in age-matched groups. Data gathered from 44 patients wearing maxillary overdentures showed an overall high survival rate of up to 99%. This favorable survival rate came with a caveat that it was seen when there were at least four implants. With 4 to 6 implants, the implant survival rate was higher, around 99%, than when fewer than four implants were used to support the prostheses. In the latter case, the implant survival rate at 7.5 years was only 85%. Subsequently, it was made easy to believe that more implants meant higher survival of implants and prostheses.
A systematic review by Raghoebar et al. (2014) delved into how many implants are enough for maxillary overdentures. They collected studies with data on implant survival rates, prosthesis survival rates, and soft and hard tissue conditions surrounding the implants for at least one year of follow-up. Meta-analysis was done on 24 articles regarding implant and prosthetic survival rates, but the reported data could not be analyzed for hard and soft tissue conditions. Results showed higher survival rates when six or more splinted implants were placed with 98.1% and 99.5% survival rates of implants and prostheses respectively, compared to four or less splinted with 97.0% and 96.9%. Furthermore, when four or fewer implants were unsplinted, survival rates were even lower at 88.9% and 98.8%. The significance of this study was that more implants seemed to have higher predictability as well as splinting the implants. Still, the limitation of the study was that the group with the fewer number of implants did not equate to four implants but to four and less than four.

Likewise, the number of implants needed varied among different authors for maxillary overdentures, while the consensus discouraged placement of fewer than four implants. If fewer than four were considered too few, how many is enough was the ultimate question. Another study by Sadowsky et al. (2007) was a systematic review of treatment considerations in maxillary overdenture. According to this review, implant survival rate and the prosthetic survival rate of 95% or above required at least four dental implants to support the maxillary overdentures without the palatal coverage. At the same time, placing 6 implants for overdentures rather than four was recommended if an implant failed to osseointegrate. Should an implant fail, prosthetic design of the attachment apparatus or the survival of the prosthesis would be affected less with more fixtures available to attach to when compared to one of four implants failing. Still and all, the authors proposed that the minimum number of implants was four to support maxillary overdentures. At the same time, it was still unclear whether more than four implants could be justified or recommended.

While some authors might prefer six implants to support maxillary overdentures, more and more evidence started to show no statistically significant difference between four versus more than four implants in survival rate. A systematic review by Slot et al. (2010) collected data from 31 studies with at least one-year follow-up for a meta-analysis of implant survival rates with
different numbers of implants and attachment apparatus. Pooled data included over 3100 implants from close to 800 patients to be analyzed with survival rates ranging from 61% to 100% with an average of 98.2%. When these were divided into cases with six implants for maxillary overdentures, the implant survival rate was 98.2%, while it was 96.3% for four splinted implants and 95.2% for four unsplinted implants. Data from this systematic review showed that as long as there were at least four implants, survival rates were above 95% with a slight variation among attachment types.

Six years after the above systematic review, Slot et al. (2016) published another study. This randomized clinical trial aimed to compare the clinical, radiographic, and patient-reported outcomes of four and six implant-supported maxillary overdentures in 50 patients. All cases involved splinted attachments. Forty-six patients provided data after a five-year follow-up period. Only one implant failed in the overall study period, which was from the group with six implants. Radiographic crestal bone loss measured minimal, 0.5mm in either group. Patient satisfaction was comparable across the board, with no statistical difference between the two groups. With these measurements, four implants failed to show inferiority compared to six implants when they were all splinted. This might justify the placement of just four implants for a comparable outcome.

In addition, a systematic review by Di Francesco et al. (2021) gave further evidence to this puzzle. Authors analyzed studies only if they fit the strict inclusion criteria of either four or six implants, instead of grouping all studies with four or less and six or more, to give clearer dichotomous results between the number of implants. All of these overdentures had splinted bar attachments to further standardize the analysis. Analyzed data summarized as implant survival rates of 97.7% and 98.3% for four and six implants respectively while prosthesis survival rates were 97.6% and 97.9%, respectively. Compared to the other systematics reviews that were reviewed thus far, this one had less variability in its study design by standardizing the attachment method and dichotomous numbers in implants used of either four or six, showing a lack of statistical significance of implant survival rates when at least four implants were placed.
1.4. Controversy – the type of attachments: splinted versus unsplinted

Besides the number of implants, what type of attachment on these implants was another topic of controversy. As mentioned above, in numerous systematic reviews and other studies, many different combinations among the number of implants and types of attachments existed, and one strong consensus was still lacking. In Raghoebar’s systematic review (2014), the overall conclusion favored splinting of fixtures for a more favorable outcome.\(^9\) In the group with fewer implants of four or less than four, splinting resulted in a 97.0% implant survival rate while non-splinted implants had a significantly lower rate of 88.9%. Numerically speaking, it showed clear superiority of splinting. However, in this systematic review, the number of implants was not standardized among the included studies. Instead of comparing a specific number of implants used, analyzed studies had varying counts of fixtures. In other words, it was not the fairest comparison between the two groups of attachments since the number of fixtures varied within each group and between the two groups.

This difficulty in standardizing the number of implants persisted in other studies as well while attempting to compare the attachment methods. In the previously mentioned systematic review by Slot et al. (2010), the conclusion was that splinting had higher survival rates than non-splinted attachments. The splinted six or more implants were recommended over unsplinted four or fewer implants.\(^{11}\) Among the studies with four or less attachments, splinting had 96.3% implant survival while non-splinted had 95.2%. According to these data, splinting of six implants with a bar attachment was the first line of treatment. However, clinical significance in these implant survival rates was questionable since regardless of types of attachment, implant survival rates were all above 95% with minimal difference in percentage. Plus, included studies had a great variability in the numbers of fixtures used by grouping these studies into ranges of numbers.

About a decade following the systematic review by Slot et al. (2010), another systematic review by Di Francesco et al. (2019) delved into the differences between bar and ball attachments via a clear study design.\(^{11,13}\) Authors collected studies only if the maxillary overdentures had four implants. Of these cases with four implants, prostheses were attached by either bar or ball, allowing the authors to clearly and solely determine the effect of two different attachment systems. At the same time, other factors like the number of fixtures were matched. The
resulting data failed to find any statistically significant differences between the two groups as long as they were attached to four implants as implant survival rates compared to 97.7% and 98.9% for splinted and unsplinted, respectively. Prosthetic survival rates were 96.8% and 98.4% for splinted and unsplinted, respectively. The overall conclusion was that when maxillary overdentures had four implants, the attachment system or prosthetic design did not significantly influence on implant and prosthetic survival rates or patient satisfaction. Corroborated by the abundance of evidence, unsplinted attachments grew popular especially with other clinical benefits of less restorative space requirement, less technique sensitive use, and ease in hygiene maintenance.

1.5. Controversy – loading protocols and immediate loading

One aspect of implant dentistry was different protocols for when the fixtures were loaded with the full-arch prostheses. Original Branemark protocol included submerged healing of all dental implants for 3-4 months for mandible and 5-6 months for maxilla as stated by Adell et al. (1981). In their case report, implant survival rates (N=895 fixtures) ranged from 81-88% in the maxilla and 91-97% for the mandible after 15 years of follow-up. Although the survival rates were higher in the mandible, overall implant therapy loaded with a conventional protocol was a totally viable fixed treatment option for edentulous jaws. However, development in implant dentistry pushed the envelope on all fronts.

After years of development in implant dentistry, clinicians strived to shorten the duration of implant therapy by loading the implants earlier and earlier. At first, the original Branemark protocol involved the healing of submerged implants for 3-4 months in the mandible and 4-6 months in the maxilla. This conventional loading protocol supported long-term evidence of high implant survival rates to prove as the gold standard method (Adell et al. 1981). Meanwhile, the downfall of this conventional approach involved a lengthy treatment period, the need for secondary surgery to expose the submerged implants, and a period of treatment with a removable prosthesis if the final prosthesis was planned to be fixed in nature, not to mention longer chair time from the clinicians’ stand point (Chung et al. 2011).
One of the first investigations was the Branemark implants that were loaded immediately by Schnitman et al. (1997) and followed up for ten years. In this clinical trial, ten patients were included to receive 63 implants in the mandible, with 28 of them being immediately loaded while 35 were submerged for 3-month healing. Ten-year implant survival rates were compared and showed a drastic difference favoring conventional loading. Immediately loaded implants had a survival rate of 84.7% at ten years, while the conventional group showed 100% survival. This study evidently discouraged clinicians from loading the fixtures immediately at placement.

Despite quite dismal comparison between the two loading protocols, various technological and surgical advancements in implant dentistry rendered immediate loading more and more predictable, which included improvements in micro and macro designs of implant surfaces. Albrektsson et al. (2004) introduced the topographic classification as smooth, moderately rough, and rough surfaces. This surface area roughness, denoted as Sa, pertained to the superficial microscopic resolution and its irregularities in micrometers. Smooth machined surface Branemark implants were considered the gold standard until the 1990’s when stronger bone response was found during the healing of rougher surfaces. However, appropriate middle ground had to be found because prevalence of peri-implantitis increased with rough surfaces with Sa values above 2.0 μm, such as plasma-sprayed surfaces. On the other hand, peri-implantitis was not seen more often when the surfaces were not smoother than 1.0 μm and not rougher than 2.0 μm. This window was then known as moderately rough surfaces and is applied to most implants these days.

A model study performed on dog was published by Berglundh et al. (2003) in efforts to provide a scientific justification for this phenomenon of a moderately rough surface. Standard Straumann implants with SLA surface were used in this study with its unique thread design that created experimental wound chambers in between the thread pitch, measuring 0.40 mm deep. This secluded space within the wound chamber was able to show the histologic activities occurring on the implant surface distant from the native bone surface. During the healing of these implants, the new bone formation did not only occur on the native bone surface of the osteotomy with which the pitch was in contact but also directly on the SLA surface. New bone on the SLA surface was far from the native bone but immediately contacted the implant surface,
known as contact osteogenesis. With this heightened bone response on a moderately roughened surface, authors suggested that when the primary stability of implants decreases during osseointegration, this de novo bone formation provides a great deal of secondary stability in wound healing.

Upon introduction of this concept, further scientific evidence was reported to compare de novo formation between smooth and moderately rough surfaces. A study by Abrahamsson et al. (2004) utilized the same implant design as the previous study by Berglundh et al. (2004), but these implants had two different groups of surface smoothness: one with a smooth surface like Branemark implants and another with moderately rough SLA surface.\textsuperscript{18,19} Same wound chambers provided histologic investigation of bone healing around these implant surfaces. The difference was significant in the two groups where the SLA group showed higher osteoblastic activity with more woven bone formation at earlier time points. This led the authors to consider more prominent osseointegration on the SLA than the turned surface, which provided more bone-to-implant contact allowing for earlier functional loading of the implants.

This was further corroborated by clinical manifestation in the comparative study by Buser et al. (1998) in their pig model.\textsuperscript{20} Two groups of implants were tested: machined Osseotite and moderately rough SLA. During the healing phase of 12 weeks, removal torque values were recorded for these two groups of implants at 4-, 8-, and 12-week points. The differences observed were quite dramatic. The smooth surface group had 62.5 Ncm, 87.6 Ncm, and 95.7 Ncm at the 4, 8, and 12 week measurements respectively while moderately rough group recorded 109.6 Ncm, 196.7 Ncm, and 186.8 Ncm at the three time points. Overall, removal torque values were around 75% to 125% higher in the moderately rough surface implants than in the smooth during the three-month healing period. Consistently higher level of osseointegration was likewise shown in the modified implant surface, which encouraged clinicians to load the implants earlier and earlier despite the above mentioned historically discouraging evidence of immediate loading by Schnitman.

With these improvements in implant technology, studies after studies came publishing data on immediate loading. Literature on maxillary immediate loading was heavily reviewed at this time
to be more pertinent to the study being done. Firstly, Grunder et al. (2001) reported a case series of five patients who received 31 implants in edentulous maxillae that were immediately loaded with provisional restorations. In this study, the cumulative implant survival rate was 87.5%, similar to the implant survival rate in conventional loading by Adell’s report of 81% in the maxilla group. Secondly, a case series by Olsson et al. (2003) involved ten patients receiving 61 maxillary dental implants loaded immediately, resulting in the implant survival rate of 93%, which was higher than the previous report even with a larger number of patients. Thirdly, a study by Bergkvist et al. (2005) had an even larger patient pool of 28 patients and 168 implants, averaging six implants per maxilla. In this study, 98% implant survival rate was reported, but the marginal bone loss averaged 1.6mm despite the short follow-up period of 8 months.

Besides numerous case series, a recent randomized controlled trial by Schincaglia et al. (2016) compared the marginal bone level between immediately loaded implants and delayed. A total of 30 patients received mandibular overdentures supported by two non-splinted implants divided into 15 patients in the test group and 15 in control. The cumulative survival rate was higher in the immediately loaded group, but this difference did not reach a statistical significance. When the radiographic bone level change was compared between the two groups, the immediate loading group consistently showed a lesser degree of marginal bone remodeling than delayed loading. These findings were further confirmed with a subsequent study with longer follow-up period of 60 months by Salman et al. (2019).

Furthermore, a systematic review by Xu et al. (2014) collected randomized controlled trials to compare immediate loading versus early loading. When this study was published, the definition of immediate loading was when the implants were loaded with the prosthesis within 72 hours of surgical placement while early loading had a window from 6 weeks to 2 months of healing time prior to prosthesis connection. Although the collected data had variabilities and limitations since for example, they involved both mandibles and maxillae, implant success rate ranged from 96.5% to 100% whether immediately or early loaded, supporting the safety of immediate load.
Afterwards, multiple systematic reviews followed to show the clinical efficacy of immediate loading. One by Pigozzo et al. (2018) compared the implant survival between immediate and early loading protocols. Even though their aim was not to compare immediate loading to conventional loading, the data provided on the immediately loaded implants were valuable to this literature review. This study did not only find insignificant differences between the two protocols but also found that immediate loading had a fairly high implant survival rate of 97.3%. A more relevant systematic review by Chen et al. (2019) compared immediate loading to early and conventional. Data pooled 39 randomized clinical trials involving 3746 implants in 1785 patients between test and control groups quite evenly split in number. Overall analysis showed a statistically significant decrease in implant survival rate in the immediate group while no difference was seen in marginal bone level between the two groups. This systematic review had an appreciable conclusion on implant survival rate, but the caveat was that prosthesis was not standardized. In other words, some studies had a single implant while only one study had full-arch prostheses.

1.6. Guided surgery

Another huge part of advancement in implant dentistry was guided surgical technique as opposed to manual surgery. Many kinds of surgical guidance exist nowadays ranging from static guides that can be either lab-made or stereolithographic from 3D imaging to dynamic guides assisted by computer imaging. Use of guided surgery was claimed to increase precision but decrease patient morbidity and surgical time. Subsequently, accuracy and safety of guided surgery were exhaustively tested in literature. Among many, a review by Van Assche et al. (2012) collected 19 studies on accuracy of stereolithographic guided implant surgery. Meta-regression analysis showed 0.99mm deviation ranging from 0 to 6.5mm at the entry point while 1.24mm ranging from 0 to 6.9mm at the apex of implants with angular deviation of 3.8 degrees. In addition, systematic review by Laleman et al. (2016) assessed the safety of these mucosa supported stereolithographic guides. Analysis included 36 articles reporting the rates and descriptions of complications. There was no harm or injuries to the neurovascular bundles especially in the mandible when surgical guides were used to place the implants compared to conventional methods. Combined results thus far suggested that the use of stereolithographic static guides was accurate and safe for predictable implant placement.
1.7. Proof of principle

Recently, a proof of principle was published by Agusto et al. (2021), reporting a treatment method of the edentulous maxilla by implant retained overdenture. This treatment plan included placement of four Straumann BLX implants with four Novaloc attachments that are unsplinted and loaded immediately after being placed via stereolithographic guides. As this approach was a valid treatment of maxillary edentulism, this investigation was therefore undertaken to test this principle in a bigger population.

1.8. Study purpose and hypothesis

The primary aim of this study was a radiographic examination of MBL change around the implants immediately loaded with Novaloc attachments at 6 and 12 months by standardized radiographs. Secondary aims include implant survival rate, soft tissue profile of peri-implant mucosa, and implant stability. The null hypothesis is there is no difference in the clinical and radiographic parameters during the 12 month follow-up period. This prospective clinical trial hopes to shed further light on the previously discussed controversies that exist in maxillary implant-supported overdenture treatment in terms of the number of implants, type of attachments, loading protocol, and guided surgery.
2. Material and Methods

2.1. Patient recruitment

The Institutional Review Board of West Virginia University approved this prospective study (IRB # 1801929813). Edentulous maxilla received four unsplinted implants placed via flapless surgery through a stereolithographic guide, immediately loaded with an overdenture, and followed up for 12 months. Patients were recruited in West Virginia University School of Dentistry clinics, private practice referrals, and through word of mouth. Written advertisements approved by the IRB were also used. The target population was 15-20 male and female adult patients of at least 21 years of age with no ethnic or racial restrictions for equitable selection. However, the vulnerable population was selected and excluded on the basis of pregnant women, children, prisoners, WVU faculty, staff, students, and cognitively impaired individuals.

2.2. Inclusion and exclusion criteria

Patients were screened with the following inclusion and exclusion criteria:

- **Inclusion criteria**
  - Complete maxillary edentulism of at least four months after extraction
  - An adequate maxillary complete denture
  - Panoramic radiograph available
  - Adequate bone volume in premaxilla and posterior maxilla at least at the second premolar position to house a 3.75 mm diameter implant of minimum 10mm length without grafting
  - An implant placed with insertion torque of at least 20 N/cm

- **Exclusion criteria (systemic)**
  - Conditions requiring chronic routine prophylactic use of antibiotics
  - Conditions requiring prolonged use of steroids
  - History of leukocyte dysfunction and deficiencies
  - Bleeding disorders
○ History of neoplastic disease requiring the use of radiation or chemotherapy
○ Metabolic bone disorders
○ Uncontrolled endocrine disorder
○ Use of any investigational drug or device within 30 days prior to implant surgery
○ Smoking more than ten cigarettes per day
○ Alcoholism or drug abuse
○ Patient infected with HIV
○ Condition or circumstances, in the opinion of the investigator, which would prevent completion of study participation or interfere with the analysis of study results, such as history of non-compliance or unreliability.

• Exclusion criteria (local)
  ○ Local inflammation including untreated periodontitis
  ○ Mucosal diseases such as erosive lichen planus
  ○ History of local irradiation therapy
  ○ Osseous lesion
  ○ Severe bruxism and clenching habits
  ○ Active infection with suppuration or fistula tract
  ○ Persistent intraoral infection
  ○ Lack of primary stability <20 N/cm resulting in patient withdrawn from the study
  ○ Inadequate oral hygiene or unmotivated home care
  ○ Need for bone augmentation
  ○ Inadequate bone volume for implant insertion as measured on the pre-treatment CBCT analysis

2.3. Clinical and radiographic examination

Screened patients were enrolled for further clinical and radiographic examination. Clinically, patients’ medical history and intraoral examination were acquired. Medical history was
thoroughly taken to make sure patients did not have any systemic conditions that meet the exclusion criteria. Intraoral examination involved checking the stability of existing complete dentures. If the prosthesis presented with mediolateral or anteroposterior rocking movements when seated, a new properly fitting denture was to be fabricated by an investigator from the graduate prosthodontics department prior to further involvement in the study. Maxillary alveolar ridge was also examined to visually check for clinical ridge width.

These findings were combined with radiographic analysis from the orthopantomogram at first for sufficient bone height in the anterior maxilla. If the patient showed a radiographic appearance of adequate bone height, CBCT was taken for accurate measurement of required bone volume. This CBCT was taken in a dual scan fashion where two scans were acquired: one with the patient wearing the maxillary complete denture containing fiduciary markers and another with just the complete denture containing fiduciary markers but no patient. These two scans were merged so that a 3D relationship could be formed radiographically between the denture and the patient’s anatomy. Once this merge was successfully completed, implant planning software, coDiagnostix, was used to check for implant position without any need for hard tissue grafting. Implants were Straumann BLX with SLActive surface, uniform in diameter of 3.75mm while the length was at least 10mm at the second premolar position posteriorly and had no restriction in the two anterior implants. According to the planned positions of implants, a stereolithographic surgical guide was designed on the same software and printed in-house.

2.4. Surgical procedure

The day of the surgery began with a single loading dose of prophylactic antibiotics one hour prior to the surgical procedure. The routine regimen was 2 g of amoxicillin per os, but 600 mg clindamycin or other class of antibiotic was administered for patients allergic to the penicillin class of drugs. 0.12% chlorhexidine solution was used to rinse intraorally for one minute as well as to scrub the perioral site to finish surgical preparation. Fabricated surgical guide and opposing dentition were brought to occlusion in stable intercusplation for accurate and reproducible interocclusal relationship. After acquisition of the bite record, local anesthesia was administered by depositing as distant as possible from the vestibule to ensure that the mucosa-supported guide could seat intimately on undisturbed mucosa. Surgical guide was fixated in at least three
different points while using the interocclusal record for maximum stability and accuracy. Once the guide was fixated, four implant sites received tissue punch to allow flapless implant placement with no incisions nor flap elevation. Osteotomy was prepared following the drilling sequence provided by the manufacturer manual and using the specific keys and burs as directed by the coDiagnostix surgical protocol. Implants were placed through the guide, again, as planned in the surgical protocol for the depth control.

Besides the implant length and diameter, the maximum insertion torque required to place the most coronal thread was recorded at the time of placement as measured by the Straumann implant motor as <20, 20, 30, 40, 50, and >50 N/cm. If this primary stability did not reach 20 N/cm, the patient was then withdrawn from the study but treated according to the standard of care outside this research. Prior to attachment of Novaloc, implant stability quotient (ISQ) was measured by attaching the Osstell SmartPeg only with hand torque and using Osstell Beacon. Then, finally, Novaloc attachments were installed as planned on coDiagnostix for immediate loading with overdentures, whose process was executed by prosthodontic investigators on the team. When the attachments were successfully connected, baseline periapical radiographs were taken with the standardized acrylic stents that have the Novaloc housing embedded for complete seating of Novaloc and perpendicular angulation of the implant platform to be shown on the radiographs.

2.5. Post-operative care

Each patient was given verbal instructions on post-operative care. Patients were to avoid disconnecting the denture by taking it out of their mouth for the first seven post-operative days and to stay on a soft diet for the first two weeks. Instead, they were instructed to use 0.12% chlorhexidine mouth rinse twice daily for two weeks: once in the morning for one minute and another time in the evening for one minute. For analgesic, 400mg ibuprofen every four hours was given if needed.

2.6. Follow-up protocol and data acquisition

Patients were brought back for follow-up visits at 1, 2, 4, 12 weeks, 6 and 12 months post-operative time points. At each visit, denture was checked for any needs in occlusal adjustment as
well as for stability and retention. Standardized periapical films were taken by the paralleling technique to assess the RBLC at 6 and 12 months compared to the baseline. Acquired radiographs were analyzed by calibrated investigators on software MiPACS; calibrated measurement was taken from the implant platform to the most coronal evidence of marginal bone level at the mesial and distal sites. The bone level was defined as the distance from the implant platform to the most coronal radiopaque mineralized tissue attachment to the implant thread. If the bone level was more coronal than the implant platform, it was recorded as zero, but for example, RBL 1 mm apical to the platform was recorded as -1 mm. Radiographic change of bone level recorded at 6 and 12 months was then compared to the baseline. Other clinical parameters were all recorded including implant drop-out, buccal/facial keratinized mucosa (KM) width and thickness, plaque index, probing depth, and bleeding on probing on four sites per implant (vestibular, mesial, palatal, and distal) by UNC-15 periodontal probe at 1-, 3-, 6-, and 12-month visits. KM width was measured in millimeters from the mucosal margin immediately vestibular to the implant attachment to the mucogingival junction. Vestibular KM thickness was measured at the mucosal margin. Plaque index was recorded as dichotomous presence or absence of soft, white debris accumulated directly on the abutment surface from the four different perspectives for each implant. Probing depth measurement was calibrated between the examiners and recorded in millimeters. Upon measuring the probing depths, if there was a red point or line around the implant, that was consistent with bleeding on probing and recorded as either present or absent. ISQ was taken at each follow-up visit starting at three months to give adequate time for osseointegration in a similar way described during the intraoperative measurement. OHIP-14 was acquired at baseline, 2 week, 3, 6, and 12 months for patient-reported outcome. At any point during the follow-up period of 12 months, any complication or adverse event related or unrelated to the study was also recorded, and implant failure was recorded if an implant presented with pain, mobility, and/or radiographic bone loss >70% of implant length.

2.7. Statistical Analysis

Variables not normally distributed were compared using the Wilcoxon signed-rank test for intra-group analysis. Data relative to patient demographics, prosthetic complications, and implant
failure rates were considered nominal and presented with descriptive statistics. All our statistical analyses were performed using statistical software, SPSS. The chosen sample size was considered adequate to provide enough power to deliver significant results. The level of significance was set at 5% for all statistical tests.
3. Results

3.1. Demographics

Out of twenty-nine patients screened, 25 were eligible for the study. There were 11 drop-outs due to various factors like low insertion torque at the time of placement, patient deviation from research protocol, inability to contact, and change in patient’s treatment preference. Among the included 14 patients, 10 and 9 subjects finished the 6- and 12-month follow-up. The age of the participants ranged from 27 to 80 with an average of 61.0 ± 14.5. Two of the ten patients were well-controlled diabetics with the HbA1c reported by the lab to be below 7. One smoker participant reported smoking less than ten cigarettes per day at the time of enrollment. Out of 10 patients, nine were male and one female.

![Flow-chart of current status](image1)

3.2. Implants placed

A total of 40 implants were placed with varying lengths: 19 of them were 10 mm, 19 were 12 mm, and 2 of them were 14 mm. All 40 implants were immediately loaded since their primary stability had adequate insertion torque of 20 N/cm or above. Their existing maxillary conventional dentures were successfully converted to implant overdentures by the prosthodontics investigator on the same day of surgery upon attachment connection. Two implants had failed between 1- and 3-month follow-ups. Hence, thirty-eight and 35 implants were available at 6- and
12-month respectively to provide clinical, radiographic, and patient-reported data. The overall cumulative implant survival rate was 95.0%.

Table 1. Number of implants included from each major time point

<table>
<thead>
<tr>
<th>Time</th>
<th>Baseline</th>
<th>6 months</th>
<th>12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implants (n)</td>
<td>40</td>
<td>38</td>
<td>35</td>
</tr>
</tbody>
</table>

Figure 2. Clinical series from (a) baseline, (b) stereolithographic guide, (c) immediate post-operative, (d) attachment connection and loading (denture not shown), (e) 6 month-visit, (f) 12 month-visit

3.3. Primary outcome - RBLC

The primary outcome was radiographic bone level change (RBLC) from baseline to 6 and 12 months. RBLC distribution was tabulated to show that most of them were less than 0.5 mm with some outliers. In the first six months, 86.8% of 38 implants showed RBLC of 0 mm or less than 0.5 mm, while three implants accounting for 7.9% presented with 0.5 mm to 1.0 mm RBLC. Two implants showed higher RBLC with one each in the next two brackets. At 12-months follow-up, 77.1% of 35 implants remained in the first bracket of less than 0.5 mm RBLC. 8.6%
of them were in the 0.5 mm to 1.0 mm RBLC bracket, and another 8.6% in the 1.0 mm to 1.5 mm bracket. One implant (2.9%) was again in the 1.5 mm to 2.0 mm group, while one implant was an outlier with 4.45 mm RBLC.

Table 2. Distribution of RBLC

<table>
<thead>
<tr>
<th>RBLC (mm)</th>
<th>&lt;0.5</th>
<th>0.5-1.0</th>
<th>&gt;1-1.5</th>
<th>&gt;1.5-2.0</th>
<th>&gt;2.0</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline - 6 months (%)</td>
<td>33 (86.8)</td>
<td>3 (7.9)</td>
<td>1 (2.6)</td>
<td>1 (2.6)</td>
<td>0</td>
<td>38</td>
</tr>
<tr>
<td>Baseline - 12 months (%)</td>
<td>27 (77.1)</td>
<td>3 (8.6)</td>
<td>3 (8.6)</td>
<td>1 (2.9)</td>
<td>1 (2.9)</td>
<td>35</td>
</tr>
</tbody>
</table>

Figure 3. Example series of standardized periapical films exposed at (a) the time of placement (baseline), (b) 6 months, and (c) 12 months.
When the above results were further analyzed, RBLC averaged 0.16 ± 0.42 (n=38; range=0-1.7 mm) and 0.33 ± 0.87 mm (n=35; range: 0-4.45 mm) at 6 and 12 months respectively. Between 6 and 12 months, there was 0.15 ± 0.65 of RBLC which was also statistically significant (p=0.008). The RBLC was statistically significant from baseline to 6 and 12 months.

Table 3. RBLC at different time points.

<table>
<thead>
<tr>
<th>RBLC (n)</th>
<th>Range (mm)</th>
<th>Mean ± SD (mm)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline – 6 months</td>
<td>0 – 1.70</td>
<td>0.16 ± 0.42</td>
<td>0.017</td>
</tr>
<tr>
<td>6 – 12 months</td>
<td>0 – 3.45</td>
<td>0.15 ± 0.65</td>
<td>0.008</td>
</tr>
<tr>
<td>Baseline –12 months</td>
<td>0 – 4.45</td>
<td>0.33 ± 0.87</td>
<td>0.013</td>
</tr>
</tbody>
</table>
3.4. Secondary outcomes – IT, ISQ, and soft tissue parameters

Insertion torque and ISQ were also measured at the time of implant placement, while ISQ was repeated at 6- and 12-month visits. All 40 implants provided quantized IT at the increments of 10 N/cm, and their distribution was tabulated. More than half of the implants belonged to 50 N/cm or above groups (60.0%). ISQ had a range from 56 to 81 from the overall study period with the mean±SD of 72.1 ± 5.4, 73.9 ± 4.9, and 74.5 ±4.7 at baseline, 6 and 12 months, respectively.

Table 4. Distribution of IT represented as implant number and percentage.

<table>
<thead>
<tr>
<th>Maximum IT (N/cm)</th>
<th>20</th>
<th>30</th>
<th>40</th>
<th>50</th>
<th>&gt;50</th>
<th>Total (n, %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of implants (%)</td>
<td>5 (12.5)</td>
<td>5 (12.5)</td>
<td>6 (15)</td>
<td>9 (22.5)</td>
<td>15 (37.5)</td>
<td>40 (100)</td>
</tr>
</tbody>
</table>
Figure 6. Histogram of insertion torque. A total number of implants were 40 available for analysis.

Table 5. ISQ averages turned out to have consistency without statistically significant fluctuations

<table>
<thead>
<tr>
<th>ISQ</th>
<th>Range</th>
<th>Mean ± SD</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>56 – 79</td>
<td>72.1 ± 5.4</td>
<td>N/A</td>
</tr>
<tr>
<td>6 months</td>
<td>58 – 80</td>
<td>73.9 ± 4.9</td>
<td>0.575</td>
</tr>
<tr>
<td>12 months</td>
<td>61- 80</td>
<td>74.5 ± 4.7</td>
<td>0.466</td>
</tr>
</tbody>
</table>
Soft tissue characteristics were recorded starting 1-month visit after adequate period of soft tissue healing, regarded as the baseline. This should be distinguished from the baseline of the RBLC measurement which started at the time of surgery instead of 1-month visit in soft tissue parameters. Recorded criteria included keratinized mucosa (KM) width and thickness, plaque index, probing depths, and bleeding on probing. First of all, KM thickness was above 1 mm in all sites. Differing widths of KM over the 12 months did not reach any statistical significance with the mean ranging from 3.7 mm to 4.1 mm.

Table 6. Average and standard deviation of the width of keratinized mucosa with no statistical significance

<table>
<thead>
<tr>
<th>KM width</th>
<th>Mean ± SD (mm)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>3.9 ± 1.4</td>
<td>N/A</td>
</tr>
<tr>
<td>6 months</td>
<td>3.7 ± 1.1</td>
<td>0.115</td>
</tr>
<tr>
<td>12 months</td>
<td>3.8 ± 1.3</td>
<td>0.072</td>
</tr>
</tbody>
</table>
The plaque index was averaged for each implant from each follow-up visit, ranging from 2.9% to 20.5%. At baseline, the plaque score was the highest at 20.5 ± 28.7%. The plaque score was 11.5 ± 18.9% at six months, which did not show a statistical significance (p=0.073, Wilcoxon signed-rank test). When the baseline plaque score was compared to 12-month plaque score of 2.9 ± 8.0%, the difference showed a strong statistical significance (p<0.001, Wilcoxon signed-rank test).

Table 7. Mean plaque score over time evidently showed statistical significance at 12-month follow-up even though 6 month follow-up data almost reached statistical significance.

<table>
<thead>
<tr>
<th>Plaque Score</th>
<th>Mean ± SD (%)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>20.5 ± 28.7</td>
<td>N/A</td>
</tr>
<tr>
<td>6 months</td>
<td>11.5 ± 18.9</td>
<td>0.073</td>
</tr>
<tr>
<td>12 months</td>
<td>2.9 ± 8.0</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
Probing depth measurements were averaged on the implant level from each follow-up visit starting at one month. Mean probing depth ranged from 2.73 mm to 2.86 mm throughout the study period and stayed quite consistent among the implants when measured at four sites per implant. Differences and fluctuation during these visits were not statistically significant, as shown in the table below.

Table 8. Mean probing depths failed to show much change over time.

<table>
<thead>
<tr>
<th>Probing Depth</th>
<th>Mean ± SD (mm)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>2.86 ± 1.07</td>
<td>N/A</td>
</tr>
<tr>
<td>6 months</td>
<td>2.73 ± 0.92</td>
<td>0.165</td>
</tr>
<tr>
<td>12 months</td>
<td>2.79 ± 0.86</td>
<td>0.573</td>
</tr>
</tbody>
</table>
Bleeding on probing was also averaged on implant level for analysis over the study period of 12 months. At baseline, it was $31.3 \pm 28.1\%$ and was reduced to $27.6 \pm 28.9\%$ at six months and was not statistically significant ($p=0.450$, Wilcoxon signed-rank test). At 12 months the bleeding score of $20.7 \pm 25.4\%$ was statistically significant compared to the baseline at one month ($p=0.024$, Wilcoxon signed-rank test).

**Table 9. Bleeding score over the study period reached statistical significance at the end of the study.**

<table>
<thead>
<tr>
<th>BOP</th>
<th>Mean ± SD (%)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>$31.3 \pm 28.1$</td>
<td>N/A</td>
</tr>
<tr>
<td>6 months</td>
<td>$27.6 \pm 28.9$</td>
<td>0.450</td>
</tr>
<tr>
<td>12 months</td>
<td>$20.7 \pm 25.4$</td>
<td>0.024</td>
</tr>
</tbody>
</table>
Figure 11. Mean bleeding score throughout the 12-month study reached statistical significance at 12 months with consistently reducing trend.
4. Discussion

Patients were screened with case selection protocol. Maxillary edentulism was treated with implant overdentures. Each maxilla received four dental implants via stereolithographic guide without raising any mucoperiosteal flap. If primary stability was 20 N/cm or above, it was immediately loaded upon connection to an unsplinted attachment. Patients were to leave the dentures in the mouth for one week without taking them out and were prescribed chlorhexidine mouth rinse to be used twice a day and appropriate analgesic like ibuprofen 400 mg as a primary choice. Clinical, radiographic, and patient-reported parameters were recorded at following visits for up to 12 months. The primary outcome variable was radiographic bone level change (RBLC), while the secondary outcome included soft tissue response (KM, PI, PD, and BOP), implant parameters (ISQ, length, position, insertion torque, survival rate and et cetera), and patient demographics and satisfaction.

Ten patients were analyzed in the report. There was a low proportion of female patients (10%). It was not that there was less female recruitment, but most of them had low insertion torque and were excluded from the study. This was likely an expected outcome especially in the maxillary posterior sextants presenting with lower quantity and quality of bone, which is consistent with the reporting of Huynh-ba et al. (2008).\textsuperscript{32} Otherwise, the study population included only one smoker and two diabetics, which accounted for quite a small portion. Diabetes has been associated with increased complication rates of implant therapy according to Fiorellini and Nevins (2000).\textsuperscript{33} A mechanism of action involves microvascular angiopathy during the healing phase of osseointegration due to impaired collagen turnover in the presence of advanced glycemic end-products. Poor healing capacity of diabetic patients was the reason behind the HbA1c cutoff of 7%, which was more conservative than some of the implant literature recommendations. Oates et al. (2009) showed a clinical study where diabetic individuals with HbA1c up to 8% had successfully healed implants if they were allowed four months of healing.\textsuperscript{34} Tawil et al. (2008) further narrowed the range of glycemic control to 7.2% so that there was no statistical significance compared to the control group.\textsuperscript{35}
On the other side of the systemic or environmental condition included smoking. It was also restricted to less than 10 cigarettes per day to minimize the detrimental effects of smoking on dental implants. A systematic review by Chrzanovic et al. (2015) showed a strong risk ratio of 2.23 where smokers had a more than two-fold increase in implant failure rate than non-smokers. These findings were consistent throughout the literature; Strietzel et al. (2007) also showed patient-related odds ratio of 2.64 to have implant failures for smokers compared to non-smokers. Presumably, their involvement was not considered to have a strong influence on the outcome especially since the smoker was not a heavy smoker, and diabetics were well-controlled with HbA1c <7%.

A total of 10 patients and 40 implants were available for data analysis. Of the 40 dental implants in the study, two implant failures took place at 3-month follow-up. These failed implants were removed, allowed healing for 8 weeks, and replaced with another implant loaded after three months of submerged healing. The first implant failure was in a 71-year-old-male with no history of smoking or diabetes. This implant in the #4 area was 14 mm long and placed with 40 N/cm and ISQ of 70. At the baseline, it presented with a plaque score of 75%, no bleeding, probing depths of 2 mm all around, 3 mm of KM, and no bone loss. The second implant failure was in a 27-year-old-female patient with again no contributory medical history; however, patient revealed the use of CPAP machine to help sleep at night due to obstructive sleep apnea. The seating of CPAP machine supposedly caused dislodging of the prosthesis, which could have caused a great deal of micromotion to the implants in hostile directions. This implant was in position #4 again and had 10 mm length. At the baseline, implant had no bone loss and was placed with 20 N/cm and ISQ of 65. Soft tissue characteristics at baseline were no plaque but 50% bleeding score, 3 mm to 4 mm of probing depths, and 4 mm of KM.

The primary outcome of RBLC showed progressive marginal bone remodeling in the 12-month-long study period where 0.16 mm bone loss occurred on average in the first six months while another six months brought about an average of 0.33 mm bone loss compared to the baseline. On an individual implant basis, most of the bone level changes were less than 1 mm, including 94.7% and 85.7% respectively at 6- and 12-month follow-ups. An outlier evidently existed and was the single smoker that was included in the study. This participant had two and three
implants at 6 and 12 months presenting with RBLC of at least one standard deviation away from the mean values. On the other hand, both well-controlled diabetic patients were well within one standard deviation from the mean.

The presented data were compared to comparable results from a different study where implants were immediately loaded with mandibular overdentures retained by two dental implants. \(^{24}\) RBLC in this mandibular study was 0.25 mm at 12 months post-operative compared to this maxillary investigation as 0.33 mm at 12-month follow-up. Both studies reported two implants as failed, but the sample size differed as 40 in the maxilla versus 32 in the mandible. The resulting cumulative survival rate compared 95% to 94%. At the patient level, none of the ten maxillary patients had a prosthetic failure where the implant overdenture was no longer a viable treatment option despite two implant failures. On the other hand, in the mandibular study, 1 out of 16 patients had two implant failures, which rendered the patient to return to wearing just a conventional denture.

On a larger scale, Esposito et al. (2007) presented a vast amount of data collecting 45 randomized controlled trials comparing the outcomes of different loading protocols, including immediate, early, and delayed.\(^{38}\) Some of the criteria to measure the treatment outcome were hard and soft tissue stability and implant survival. When the radiographic bone level was analyzed for immediately loaded implants, they included single and multiple implants to support either removable or fixed prostheses of a wide variety. Regardless, radiographic bone level change turned out to favor immediate loading with the mean difference of -0.10 mm. Furthermore, at the end of the review, conclusion was that there was insufficient evidence to show any clinically significant degree of difference in loading protocols, supporting the validity of immediate loading.

Insertion torque had a wide range from 20 N/cm to above 50 N/cm from the data above. This subject of insertion torque remains controversial, especially when immediate loading is considered. On one end of the spectrum, higher insertion torque was permitted as Khayat et al. (2013) showed no statistically or clinically significant difference in implants that were placed with either low insertion torque or IT as high as 176 N/cm, and this lack of difference was
sustained after loading, also.\textsuperscript{39} This was reasoned as higher insertion torque was correlated to higher primary stability, which plays a crucial role in immediate loading. However, on the other end of the spectrum pointed to the detrimental influence of high insertion torque, as it meant higher pressure of implant onto the peri-implant bone during osseointegration phase, shown by Bashutski et al. (2009).\textsuperscript{40} According to this study, higher insertion torque led to higher degree of pressure necrosis around the marginal bone, decreasing the hard tissue stability around the implants. Amidst the lack of consensus, the systematic review by Esposito et al. (2007) recommended a generic range of high insertion torque, at least 35 N/cm, as a prerequisite for immediate or early loading.\textsuperscript{38}

There were only three implants that did not reach adequate IT and rendered two patients excluded from the study. Study participant #5 was a female who was neither a smoker nor a diabetic, but two posterior implants had 15 N/cm while the other two anteriorly had 30 N/cm. The other participant #9 was a male subject with no underlying condition besides the fact that his age of 70 was slightly above the median age of 67.5. In this participant, one implant in the #4 position had inadequate primary stability, while the other three implants were either 50 N/cm or above. Otherwise, more than half of the implants were 50 N/cm or above, while 87.5\% were at 30 N/cm or above to be safely loaded immediately.

ISQ was successfully measured at the time of placement and 3, 6, and 12 months except for one patient who failed a follow-up visit at three months. The overall range was widespread from 56 to 81 with the average of 73.3 ± 5.9. Four different timepoints measuring the ISQ failed to show any statistically significant differences but stayed more consistent throughout the study period, and the two failed implants had ISQ values of 65 and 70, which are within the acceptable to be loaded. Even the systematic review by Esposito et al. (2007) failed to show a straightforward guideline for ISQ due to high heterogeneity in the randomized clinical trials.\textsuperscript{38} Another systematic review by Monje et al. (2019) was set out to study the significance of ISQ in terms of immediate loading protocol.\textsuperscript{41} It showed no statistically significant relationship between primary stability measured by ISQ and marginal bone loss or implant survival rate. At this point in time, a strong consensus seemed lacking in terms of ISQ and its relationship to predictability in
immediately loaded implants, even though higher ISQ was correlated with higher insertion torque.

Soft tissue parameters were acquired with ease at each follow-up visit. KM thickness was always more than 1 mm. Pre-operative consideration should include KM management, such as full-thickness flap elevation via incisions or flapless surgical protocol by utilizing tissue punch. The amount of pre-operative KM present could dictate which route a surgeon can take because the residual width and thickness of KM might be limited when tissue punch is used. In this study, follow-up averages ranged from 3.7 mm to 4.1 mm during the one-year follow-up and remained quite consistent without significant change. In one specific individual, participant #11, implant #10 had started with 1 mm, measured 0 mm at three months, but ended with 2mm at the end.

The width of KM has been correlated to the implant stability. Schrott et al. (2009) divided implant sites of fixed full-arch prostheses in the mandible into those with KM less than 2 mm and those with 2 mm or greater. In the group with less KM, there were tendencies to have higher bleeding and plaque scores on the lingual aspect and have higher mucosal recession on the buccal aspect. This was also seen in a larger review by Wennstrom and Derks as they collected studies that divided the width of KM with the 2 mm threshold. Similar result was found correlating the inadequate KM to increased soft tissue clinical parameters of bleeding, plaque, and recession. This was partially attributed to poorer ability of patients to brush these areas according to Souza et al. (2016) when there was less than 2mm of KM.

Probing depths ranged from 2.73 mm to 2.86 mm between the visit averages and showed a similar trend as KM, with measurements being in a small window of range during the follow-ups. For the most part, fluctuation on the site level was also minimal. In participant #19, the vestibular aspect of implant #4 presented at 1 month with 10 mm probing but no mobility or excessive radiographic bone loss. However, at subsequent visits, implant probing depth was normalized to 2-3 mm and bleeding frequency of 2 out of 4 times in one year of examination. Another occasion to be noted was in participant #1 who was the single smoker in the study. After a year of participating in the study without complete tobacco cessation, implant #4 at its
palatal aspect presented with 7 mm probing depth with bleeding frequency of 0 out of 4 times probed. This low bleeding frequency in palatal aspect of the maxilla might be attributable to current smoking status.

While KM and PD were dependent variables that stayed rather consistent during the follow-ups, the remaining parameters showed interesting trends. First, the plaque index started out at 20.5 ± 28.7% at the baseline that was reduced to 11.5 ± 18.9% without reaching statistical significance (p=0.073). This score was further drastically reduced to 2.9 ± 8.0% at the end of the study (p<0.001). Second, bleeding score showed a similar trend where it went from 31.3 ± 28.1% to 27.6 ± 28.9% between 1 and 6 months. This was not a statistically significant change (p=0.450), even though it was a reduction. This score was eventually decreased to 20.7 ± 25.4% at the 12-month follow-up. This final drop in the score was statistically significant compared to the baseline (p=0.024).

According to the 2017 classification of periodontal and peri-implant diseases and conditions, 38 implants were classified into implant health, peri-implant mucositis, and peri-implantitis according to the clinical and radiographic parameters at the end of the 12-month follow-up, including RBL, PD, and BoP among others. To be more specific, an implant presenting with no BoP or RBLC of 2mm was classified as peri-implant health. Signs of soft tissue inflammation denoted by any bleeding on probing was categorized as peri-implant mucositis in the absence of progressive bone loss. Lastly, radiographic bone loss of 2mm from the baseline level would render the implant peri-implantitis. Seventeen of them were categorized into health, 20 peri-implant mucositis, and one peri-implantitis, which accounted for 44.7%, 52.6%, and 2.6%, respectively.

The above data were compared to some contemporary reports. Study by Derks and Tomasi (2015) reported that on average, peri-implant mucositis was seen in 43% while peri-implantitis 22%.\textsuperscript{43} Categorization of implants in this investigation showed lower prevalence of both peri-implant mucositis and peri-implantitis than the above reporting. In other studies, findings took a wide range of values in soft and hard tissue analyses. According to Smedberg et al. (1993), RBLC of implants supporting maxillary overdentures was 0.71 mm at 18.8 months post-loading.
which would place the average below the peri-implantitis threshold. In another study by Mericske-Stern et al. (1993), bone level analysis by orthopantomogram revealed angular defects prevalence of 22%, although these sites did not show any significant association with other indices of plaque index, bleeding score, probing depth, or loss of attachment. Sanna et al. (2009) reported 23.7% of bleeding score from pockets surrounding the implants of overdentures. Likewise, these values ranged widely even among the overdenture studies, but the overall prevalence fell into the systematic review by Derks and Tomasi (2015) where peri-implant mucositis ranged anywhere from 19% to 65%, while peri-implantitis from 1% to 47%.  

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5. **Conclusion**

Within the limitations of this study, maxillary edentulism could be predictably treated with implant retained, soft-tissue supported overdenture with four narrow-diameter dental implants placed via guided surgery and loaded immediately with unsplinted attachments. Marginal bone level change and implant survival rates were consistent with other contemporary studies whose topics related to maxillary implants, overdentures, and immediate loading. The other soft tissue parameters, or peri-implant conditions, were also unaffected by the tested proof of principle.
6. **Future Studies**

Future studies should be designed to further test the efficacy of this treatment modality by randomized controlled clinical trial. It would be desirable to have a control group of conventional or delayed loading of maxillary overdenture with four unsplinted implants, while the experimental group continues to test this proof of concept with four unsplinted implants that are immediately loaded with maxillary overdentures. To further strengthen the RCT, multicenter fashion could also test the center-related outcome.
7. References


