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LOMA LINDA UNIVERSITY
Graduate School

An Evaluation of Progressively Loaded Root Form Dental Implants Placed into
Extraction Sites

by

Franco Audia

A Thesis submitted in partial satisfaction of
the requirements for the degree of
Master of Science in Oral and Maxillofacial Surgery

August 2001

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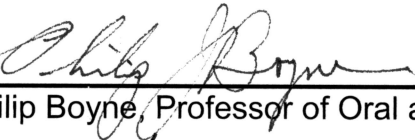
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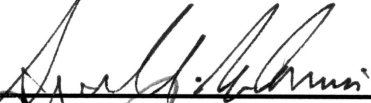


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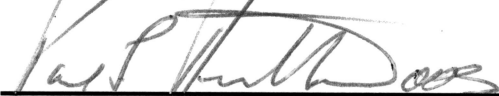
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ABSTRACT OF THESIS

An Evaluation of Progressively Loaded Root Form Dental Implants Placed into Extraction Sites

by

Franco Audia

Master of Science, Graduate Program in Oral and Maxillofacial Surgery
Loma Linda University, August 2001
Dr. Alan Herford, Chairperson

The conventional protocol for placement of endosseous root form implants requires up to twelve months of ossification of the extraction socket prior to implant placement. An alternative approach includes the immediate placement of dental implants into a prepared extraction socket following tooth removal. The purpose of this study was to compare conventionally placed non-loaded dental implants with those placed immediately into extraction sockets and progressively loaded in adult patients. A total of twenty implants were placed in eighteen patients and followed for a twelve-month period.

Clinically, no significant differences between conventional and immediately placed dental implants were observed. Radiographically, immediately placed implants had statistically significant greater bone height (measured from the implant collar to the alveolar crest) at twelve months than did conventionally placed implants at the same time interval.

This study suggests that progressively loaded dental implants placed into extraction sites is an effective alternative to conventional implant placement.

INTRODUCTION

STATEMENT OF PURPOSE

PRIMARY OBJECTIVE

To evaluate the effectiveness of progressively loaded dental root form implants placed into extraction sites, beginning at the time of surgery.

SECONDARY OBJECTIVE

To compare the effectiveness of progressively loaded dental root form implants placed into extraction sites with conventionally (two stage) loaded implants.

To evaluate the radiographic vertical bone height around progressively loaded dental root form implants placed into extraction sites at 0,4-6 and 12 months postoperatively.

To evaluate the clinical mobility of progressively loaded dental root form implants placed into extraction sites at 0,4-6 and 12 months postoperatively.

To determine the practicality of progressively loading dental root form implants placed into extraction sites.

REVIEW OF RELEVANT LITERATURE

One of the conventional surgical and prosthetic principles employed for the successful integration of dental implants has historically involved the use of a two stage surgical protocol. A minimum of 4 months of non-loaded healing for implants placed in the mandible and 6 months in the maxilla has been recommended.¹⁻³ These recommendations were based on anecdotal

observations made by clinicians who believed early implant loading resulted in a fibrous encapsulation rather than osseointegration.⁴

Recent histological and clinical studies are supporting the premise that dental implants may be functionally loaded sooner than previously recommended.⁴⁻⁶ Advances in implant materials and design have allowed for earlier integration at the implant-bone interface. This early osseointegration, combined with primary stabilization, makes immediate or progressive loading possible.⁶

Hydroxylapatite (HA) is a calcium phosphate ceramic ($\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$) which is synthesized in various forms. HA is an alloplastic material which has been shown to form a bioactive bond with bone.⁷ Implants coated with HA generate earlier direct bone apposition with the implant surface than do titanium analogues. This appears to result in earlier and possibly better integration of the implant with the bone.⁸

The immediate placement of dental implants into extraction sites has also become an accepted treatment modality to restore an edentulous region.^{9,10} The normal resorptive process which ensues following tooth removal involves resorption in an apical and palatal/lingual direction.¹⁰ This often necessitates the use of an augmentation procedure prior to placement of a dental implant. By placing an implant immediately into the extraction site the amount of post-extraction resorption is greatly reduced. The hypermetabolic state of an extraction site following removal of a tooth can be used advantageously in the development of a new bony interface around the dental implant.^{10,11} By allowing

the process of implant osseointegration and socket regeneration to occur simultaneously, the patient's treatment time may be reduced.¹⁰ Immediate placement following tooth extraction also enables the surgeon to place the implant into a natural tooth position which ultimately leads to improved aesthetics.¹⁰

The purpose of this clinical investigation is to evaluate the method of early progressive loading of dental implants placed immediately into extraction sites as compared with the conventional staged technique. A total of eighteen patients who met criteria for placement of twenty single dental implants were included in this study. Ten consecutive implants placed in eight patients who have undergone conventional two-stage treatment served as the control group. The remaining patients received immediate placement of a dental implant into an extraction site. These ten patients received dental implants, which were immediately restored with a provisional restoration. The root-form osseointegrated dental implants were of the same brand and surface type (Steri-Oss Replace HA, Yorba Linda, CA). All implants were evaluated radiographically at 0, 4-6 and 12 months postoperatively. Subjective evaluation of peri-implant bone density and an objective evaluation of vertical bone height were performed. Clinically, all implants were evaluated for peri-implant tissue quality, and implant mobility.

HYPOTHESIS TO BE TESTED

To determine if progressively loading a dental root form implant, beginning at the time of surgical placement into an extraction site, is as effective as the conventional technique.

SIGNIFICANCE OF RESEARCH

The potential benefits to patients would include avoiding a second surgical procedure to uncover the dental implant and the ability to have a temporary crown placed on the implant, which will provide improved aesthetics. This procedure may eliminate the need for preprosthetic surgical bone augmentation by preserving the alveolus. This study is expected to demonstrate whether this method will offer a better alternative for future dental patients.

MATERIALS AND METHODS

DESCRIPTION OF EXPERIMENTAL DESIGN

The study group involves patients who underwent a single stage surgical placement of a root form dental implant into an extraction site with progressive loading throughout the healing period. The conventional group involves patients who underwent placement of a root form dental implant into an edentulous site with a two-stage surgical protocol. The conventional implants were uncovered and loaded at 4 months in the mandible and 6 months in the maxilla.

TEST MATERIALS

Threaded root form tapered dental implants NobelBiocare© Steri-Oss Replace® HA (hydroxylapatite coating) (Yorba Linda, CA)

Patients who underwent placement of endosseous implants into tooth extraction sites had xenogeneic bone grafting of the tooth socket with Osteograft/N® (Ceramed, Lakewood, CO)

CONCOMITANT MEDICATIONS

The use of chlorhexidine has been shown to reduce the microbial complications associated with implant failure when used in the immediate perioperative period.¹⁷ All patients used an oral antimicrobial rinse (0.12% chlorhexidine gluconate) in the immediate perioperative period.

It has been previously shown that significantly fewer implant failures occur when preoperative antibiotics are used.¹⁸ All patients received preoperative antibiotics. Penicillin was selected as a first choice antibiotic, clindamycin was used in penicillin-allergic patients.

INCLUSION CRITERIA

The patients met the following conditions in order to be included in this study.

1. The patient was 18 years of age or older.
2. The patient had a dental prophylaxis within 6 months prior to surgery.
3. The patient was able to comply with all perioperative instructions, including exercising good oral hygiene.
4. The patient had a prosthodontic treatment plan.
5. The patient was able to provide a signed informed consent.
6. The patient presented with a Class 2 or 3 edentulous residual ridge as defined by Cawood and Howell,¹³ or a tooth deemed non-restorable by the prosthodontists.
7. The patient presented with a Type I or II bone morphologic type as defined by Lekholm and Zarb.¹⁴

Additional inclusion criteria were used for patients who underwent placement of endosseous implants into tooth extraction sites as outlined by Block and Kent:⁹

1. Traumatic loss of teeth with a small amount of bone loss.
2. Teeth lost because of gross decay without the presence of purulent exudate or cellulitis.
3. Inability to complete endodontic procedures.
4. Presence of severe periodontal bone loss without purulent exudate.
5. Adequate soft tissue health and quantity.

EXCLUSION CRITERIA

The presence of any of the following classified the patient as ineligible for participation in this study.

1. The patient had received and failed a previous dental root form implant placement surgery.
2. The patient had received a graft procedure to the implant site consisting of an alloplastic type material.
3. The patient had significant untreated periodontal disease (>AAP Type III), caries, acute or chronic inflammation of the oral cavity within two adjacent tooth positions of the study treatment area.
4. The patient used any nicotine-containing products within 3 weeks prior to surgery such as, but not limited to: smoking and chewing tobacco, nicotine patch, nicotine gum, etc.
5. The patient was an insulin dependant diabetic.
6. The patient had a history of head or neck malignancy within the past 5 years.
7. The patient was taking medications (including estrogen/progesterone therapy) or having treatments which are known to have an effect on bone turnover such as, but not limited to:
 - Calcitonin within 6 months.
 - Chronic tetracycline or tetracycline analogs, (e.g. ongoing within one month).
 - Chronic steroids, parenteral or oral (e.g. cumulative dose of 150 mg of prednisone or equivalent within 6 months).

-Bisphosphonates or fluorides, at bone therapeutic levels, for 30 days or more within 12 months.

-Vitamin D (800 IU/day) and Vitamin D metabolites at therapeutic levels for 30 days or more within 6 months.

8. The patient had a disease that affects bone metabolism, excluding idiopathic osteoporosis, such as but not limited to:

-Osteomalacia or renal osteodystrophy.

-Hyperthyroidism and hyperparathyroidism.

-Congenital connective tissue disease (e.g. Ehlers-Danlos syndrome or osteogenesis imperfecta).

-Paget's disease of the skull.

9. The patient had a history of autoimmune disease (e.g. systemic lupus erythematosus, dermatomyositis, etc.), documented multiple allergies, or an allergy to any component of the study agent.

10. The patient had been treated with an investigational therapy within 1 month before the surgical procedure or had plans to be treated with an investigational drug during the study period.

Additional exclusion criteria were used for patients who underwent placement of endosseous implants into tooth extraction sites as outlined by Block and Kent:⁹

1. Presence of purulent exudate at the time of extraction.
2. Adjacent soft tissue cellulitis and granulation tissue.
3. Lack of adequate bone apical to the extraction site.

4. Adverse location of the mandibular neurovascular bundle, maxillary sinus, or nasal cavity.
5. Anatomic configuration of remaining bone preventing ideal prosthetics.
6. Any clinical condition that prevents soft tissue manipulation.

PROTOCOLS AND PROCEDURES

Two study centers were selected for this project; Loma Linda University School of Dentistry department of Oral and Maxillofacial surgery and Prosthodontics and the offices of R. Dean Lang DDS (Oral and Maxillofacial surgeon) and Barry K.Weber DDS (Restorative Dentist), Valencia, CA. (see letter of agreement).Appendix

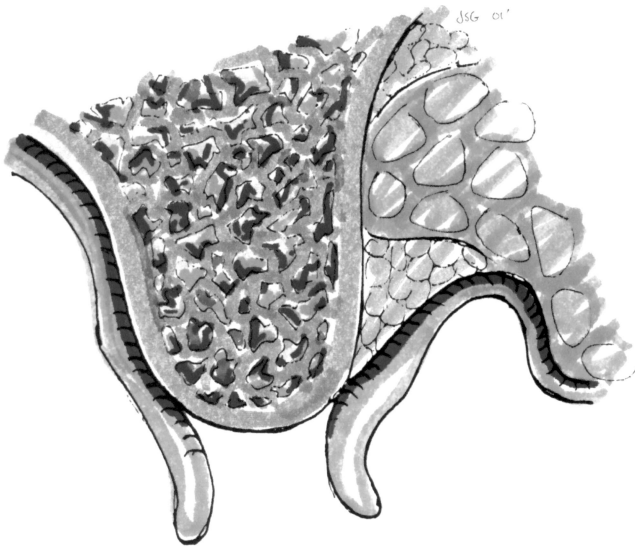
Patients who met the inclusion criteria described above underwent placement of a root form dental implant under local anesthesia or local anesthesia combined with intravenous sedation and monitoring. Clean sterile conditions were implemented for the placement of all implants. All implants were placed within the first premolar to first premolar region of maxilla or mandible.

Appendix

CONVENTIONAL IMPLANTS

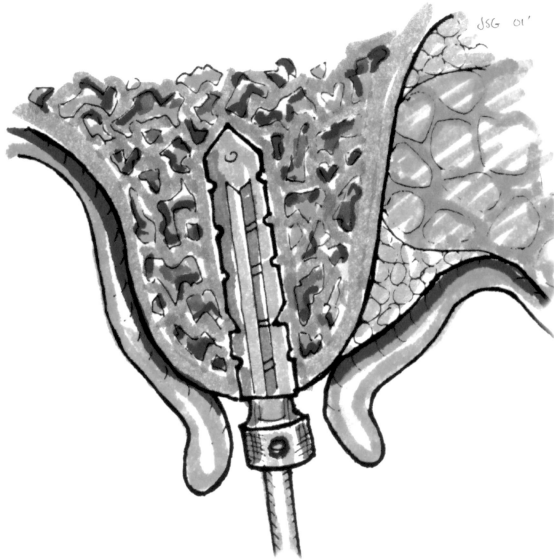
Patients performed oral rinses with 0.12% chlorhexidine gluconate solution for a minimum of 30 seconds prior to surgery. Injection of 2% lidocaine with 1:100 000 epinephrine of the surgical site was then performed. Crestal incisions were placed in the edentulous site with minimal flap reflection using a No.9 periosteal elevator. Figure 1

Figure 1 Reflection of full thickness mucoperiosteal flap



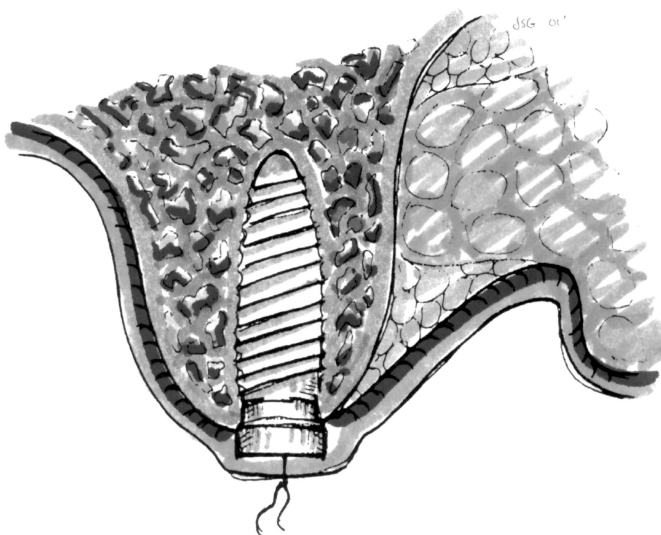
It has been demonstrated that no difference in crestal bone response is observed when a mucobuccal or crestal incision is used for implant placement.¹⁵ The implant recipient osteotomy site was then prepared per the manufacturers protocol with copious internal/external irrigation utilizing a prosthetic surgical guide. A pilot drill was used first to initiate the implant osteotomy. This was followed by a 3.0 mm round bur to allow for engagement of the cortical bone by subsequent drills. Figure 2

Figure 2 Implant osteotomy site preparation



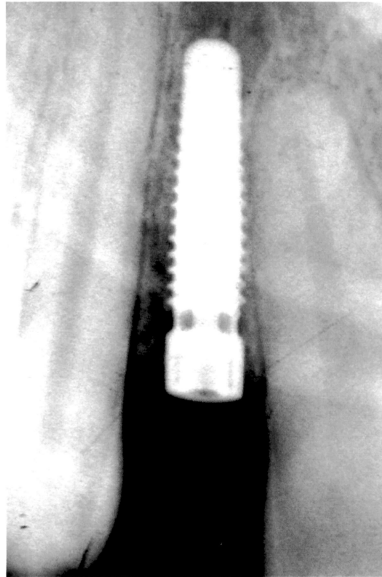
After using the counter-sinking drill, the thread-forming drill was used to finish the implant site preparation. The implants were then placed utilizing a 35 Nm torque wrench ensuring primary implant stability without overtightening. Cover screws were placed and primary closure was obtained with a 4-0 nylon suture in an interrupted fashion. Figure 3

Figure 3 Cover screw placed with primary closure



Immediate post operative periapical plain film radiographs were obtained with standardized settings for that particular region. Figure 4

Figure 4 Post operative radiograph of a conventional implant



A baseline vertical measurement was made at this time from the level of the bone crest to the collar of the implant which is used as a reference point. Measurements were conducted by this study's two surgeons. To ensure reliability, measurements were blinded and repeated at each subsequent visit. Suture removal was performed at 7 days post operatively, the implants remained covered and were allowed to heal for 4 months in the mandible and 6 months in the maxilla.

A second radiograph was obtained when the implant was uncovered and a healing abutment was placed. Although direct measurements of bone height can be made at the time of implant insertion and uncover, subsequent direct measurements can cause tissue trauma¹⁶ and thus, direct measurements were

avoided. Implant mobility was also assessed at this time by tapping on the implant with the blunt end of a dental instrument. Clinically detectable mobility is a parameter of low sensitivity and high specificity.¹⁹ With a clinical mobility index, there are two possible evaluations: mobility or no mobility.²⁰ Peri-implant gingival tissue health was also assessed at this time. Evaluations were made of erythema and edema as none/mild/moderate/severe, per the gingival index of Silness and Loe.²¹

These patients were then restored with a permanent prosthetic and returned for a radiograph at 12 months postoperatively. These radiographs were measured with the same reference points, then implant mobility and tissue health were reassessed as previously described. Information was collected on a data collection sheet for each of the three intervals. Appendix 1

PLACEMENT OF IMPLANTS INTO EXTRACTION SITES

Patients performed oral rinses with a 0.12% chlorhexidine gluconate solution for a minimum of 30 seconds prior to surgery. Injection of 2% lidocaine with 1:100 000 epinephrine of the surgical site was then performed. Sulcular incisions were made around the necks of teeth to be extracted utilizing a beaver shaped scalpel blade. Atraumatic extraction was carried out with sectioning if necessary to avoid loss of labial or buccal cortical bone. Figures 5,6

Figure 5 Non restorable tooth to be extracted

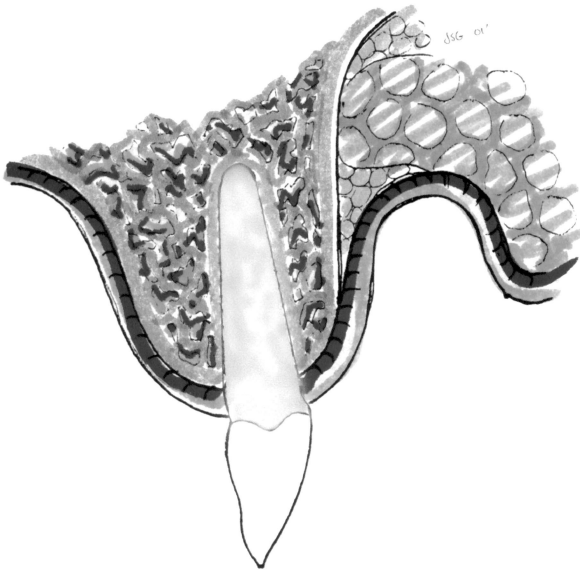
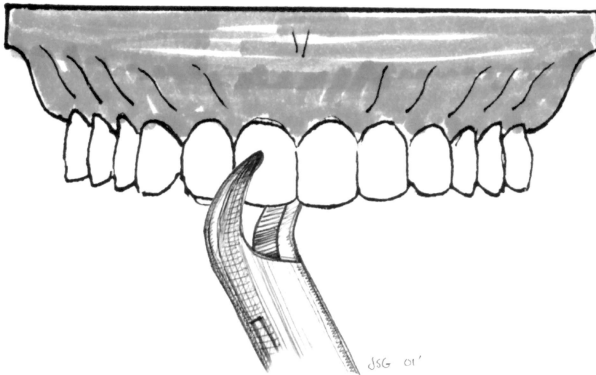


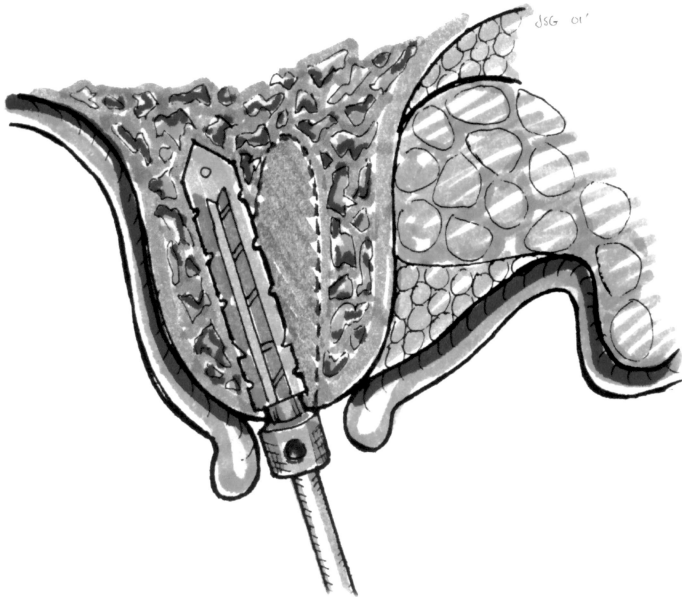
Figure 6 Atraumatic extraction of tooth



The sockets were then curettaged to remove any soft tissue remnants. The implant recipient osteotomy site was then prepared per the manufacturers protocol with copious internal/external irrigation utilizing a prosthetic surgical guide. A pilot drill was used to initiate the implant osteotomy within the extraction site. This was followed by a 3.0 mm round bur to allow for engagement of the medullary bone by subsequent drills. The drill is angulated slightly palatal on

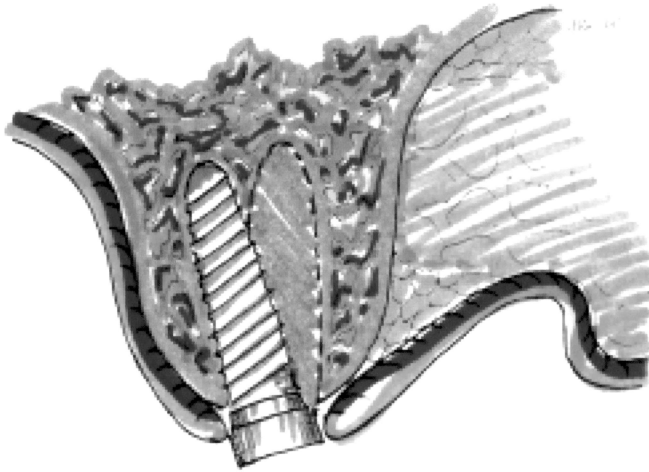
maxillary and lingual on mandibular teeth to enable primary stability of the implant. Figure 7

Figure 7 Implant osteotomy site prepared



After using the counter-sinking drill, the thread-forming drill was used to finish the implant site preparation . Xenogeneic bone grafting of the tooth socket with Osteograf/N® (Ceramed, Lakewood,CO) was used to fill any defects where there was not direct implant/bone apposition. The implants were then placed utilizing a 35 Nm torque wrench ensuring primary implant stability without overtightening. Figure 8

Figure 8 Placement of implant into site



Indexing of the implant was carried out prior to surgery on a study model by the prosthodontist utilizing the same surgical guide used in the surgery. This was then sent to a dental laboratory for fabrication of a provisional restoration.

Figure 9 Stone cast of patients dentition

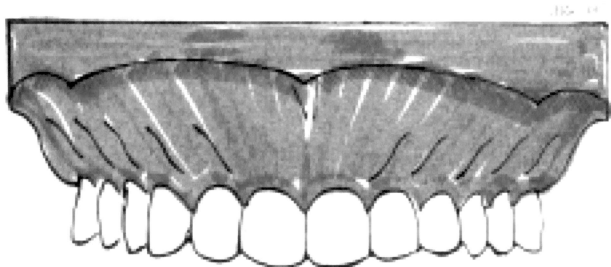


Figure 10 Proposed implant site prepared in stone cast

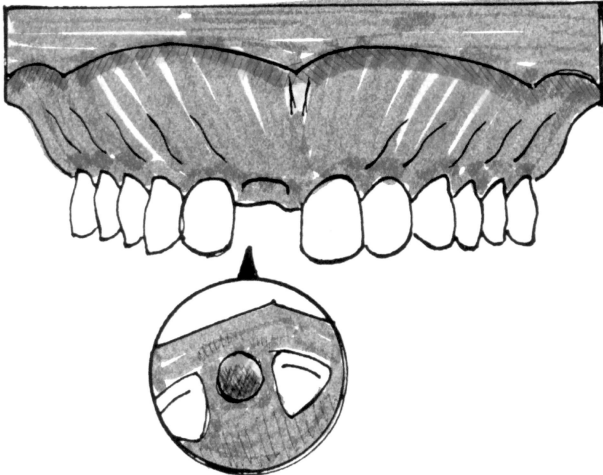


Figure 11 Implant analogue inserted into desired position with fabrication of surgical guide

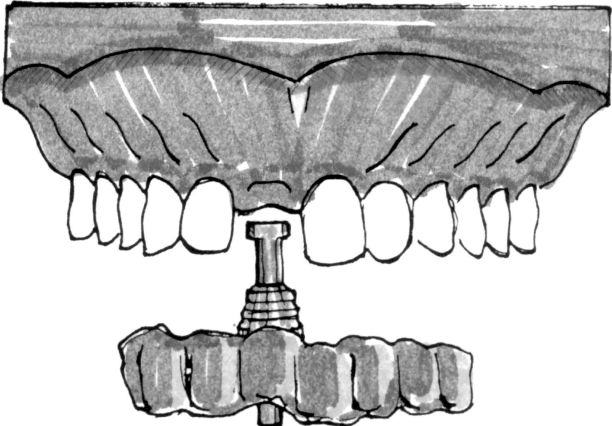


Figure 12 Implant analogue secured into desired position

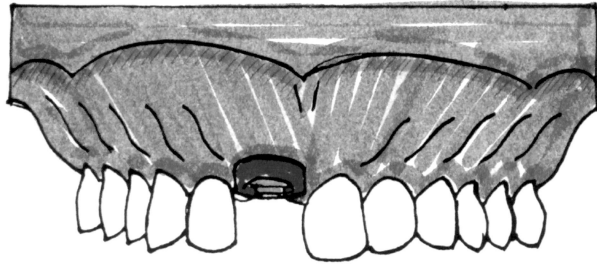


Figure 13 Prosthetic abutment is customized

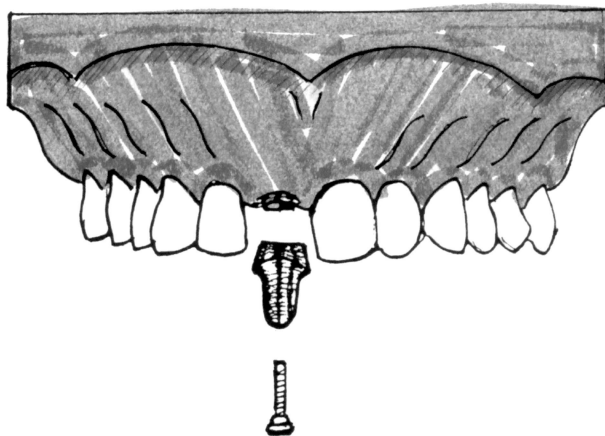
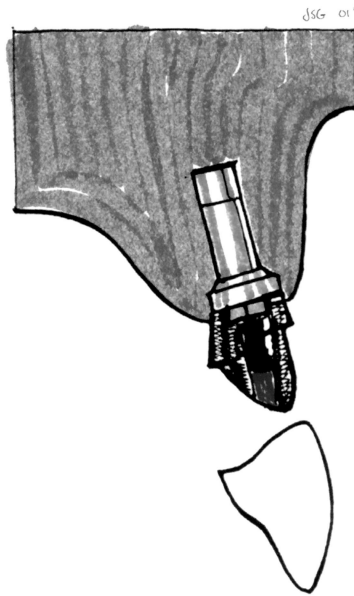
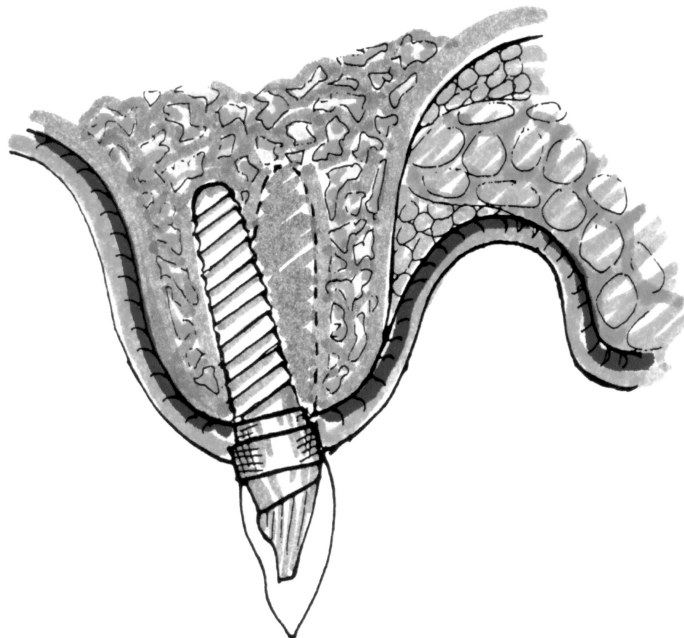


Figure 14 Provisional restoration is fabricated



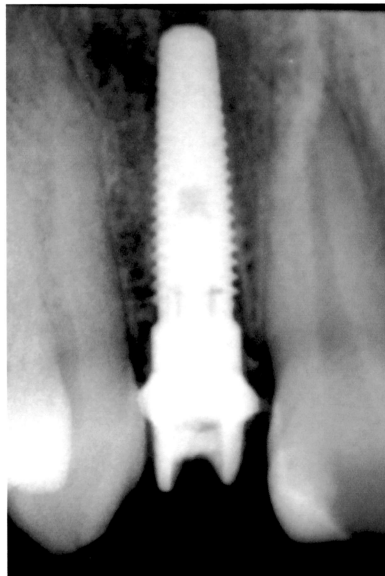
The provisional restoration was then available for immediate placement and adjusted out of centric and excursive/protrusive occlusion. Figure 15

Figure 15 Provisional restoration is seated at completion of surgery



Immediate post operative periapical plain film radiographs were obtained with standardized settings for that particular region. Figure16

Figure 16 Post operative radiograph of progressively loaded implant



A baseline vertical measurement was made at this time from the level of the bone crest to the collar of the implant which was used as a reference point. Progressive loading was achieved by instructing patients on a strict puréed diet for 6 weeks. Patients were then advanced to a soft mechanical diet for the next 6 weeks and then advanced to a regular diet.

At 4-6 months a second radiograph was obtained and evaluation of the implant was performed. Although direct measurements of bone height can be made at the time of implant insertion, subsequent direct measurements can cause tissue trauma¹⁶ and thus, direct measurements were avoided. Implant mobility was also assessed at his time by light tapping on the implant with the blunt end of a dental instrument. Clinically detectable mobility is a parameter of

low sensitivity and high specificity.¹⁹ With a clinical mobility index, there are only two possible evaluations: mobility or no mobility.²⁰ Peri-implant gingival tissue health was also assessed at this time. Evaluations were made of erythema and edema as none/mild/moderate/severe, per the gingival index of Silness and Loe.²¹ The progressive loading was now completed by placing a permanent restoration in occlusion.

These patients returned for a radiograph at 12 months postoperatively. These radiographs were measured with the same reference points, then implant mobility and tissue health were reassessed as previously described. Information was collected on a data collection sheet for each of the three intervals.

Appendix 2

STATISTICAL METHODS AND TESTS

The primary statistical techniques used were the Mann-Whitney U and binomial tests.

Three response variables were identified, which included:

1. Implant mobility, which was a yes or no response.
2. Radiographic measurements, which were made via computer measurements directly from the radiographic plain films obtained throughout the study period. Measurements were in millimeters.
3. Tissue health, which was noted and applied to an index with a scale from 0-3.

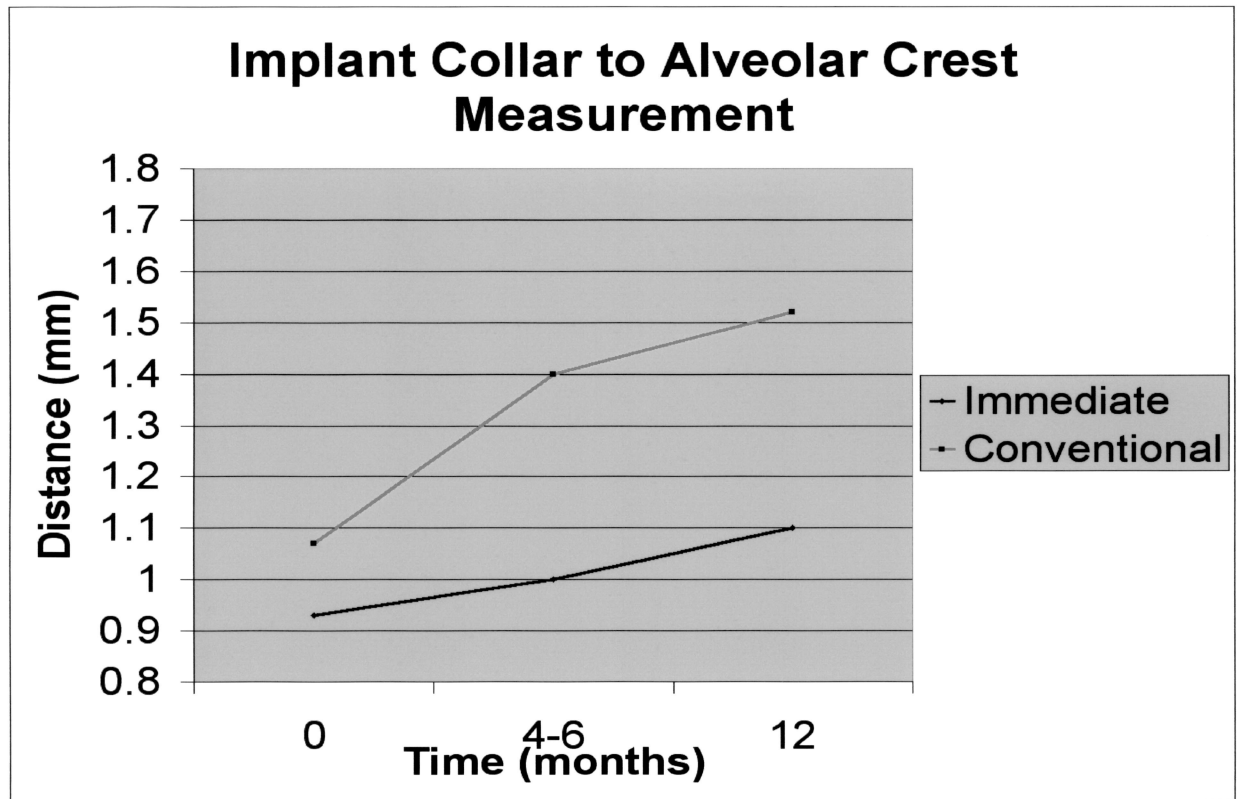
Examples of the forms used to gather the study data is outlined in Appendix.1-2.

RESULTS

A total of twenty implants were placed in eighteen patients, all achieved implant stability at time of placement. One of the ten conventionally placed implants failed to osseointegrate, which was observed at the six-month uncovering. All of the implants placed immediately into extraction sites osseointegrated. Evaluation of implant mobility using a binomial test with an alpha level of .05 revealed no significant difference between immediate and conventional implants at time of placement ($p=1.0$), 4-6 months ($p= 0.661$) or time 12 months ($p= 1.0$).

Radiographic assessment of bone height was recorded in millimeters at time 0, 4-6 and 12 months, using a Mann-Whitney U-test with an alpha level of .05. Radiographic comparison of bone height in conventional versus immediate implants was not statistically significant at time of placement ($p= 0.684$), or at time 4-6 months ($p= 0.094$). Comparison at 12 months revealed immediately placed implants had a statistically significant lower measurements from the implant collar to the alveolar bone crest than did conventional implants ($p= 0.017$).

Figure 17 Implant collar to alveolar crest measurement linear graph



All information recorded on data collection sheets for conventional implants placed during the study period is displayed in Table 1.

Table 1: Conventional implant data recordings

CIS	CBH t0	CTH t0	CCM t4-6	CBH t4-6	CTH t4-6	CCM t12	CBH t12	CTH t12
1	1	0	0	2	0	0	1.2	0
1	1.2	0	0	1.25	0	0	1.5	0
1	1.8	0	0	1.75	0	0	2	0
1	1.9	0	0	1.9	0	0	2	0
1	0.5	0	0	1	0	0	1.25	0
1	0.5	0	0	1.05	0	0	1.2	0
1	1.15	0	1	NI	1	NA	NA	NA
1	1.45	0	0	1.5	0	0	1.8	0
1	1.2	0	0	1.25	0	0	1.45	0
1	0	0	0	0.9	0	0	1.3	0

C= conventional implant, IS= implant stability, BH= vertical bone height measurement, CM= clinical mobility, TH= tissue health, t= time in months
 NI= no integration, NA= patient not available

All information recorded on data collection sheets for progressively loaded implants placed during the study period is displayed in Table 2.

Table 2: Progressively loaded implant data recordings

XIS	XBH t0	XTH t0	XCM t4-6	XBH t4-6	XTH t4-6	XCM t12	XBH t12	XTH t12
1	1.8	0	0	1.3	0	0	1.35	0
1	0.5	0	0	0.8	0	0	0.9	0
1	2.2	0	0	1.9	0	0	1.2	0
1	0	0	0	0	0	0	0.4	0
1	1.1	0	0	1	0	0	1.2	0
1	0	0	0	0.7	0	0	1.51	0
1	0	0	0	1	0	0	0.9	0
1	2	0	NA	NA	NA	0	1	0
1	1.7	0	0	1.4	0	0	1.35	0
1	0	0	0	0.9	0	0	1.15	0

X= Experimental progressively loaded implant, IS= implant stability, BH= vertical bone height measurement, CM= clinical mobility, TH= tissue health, t= time in months, NA= patient not available

CONCLUSIONS

This twelve-month study suggests that progressive loading of a root form dental implant placed into an extraction site beginning at the time of surgery, is an effective alternative to conventional implant placement. The implant sites evaluated were in the first premolar to first premolar region of the maxilla or mandible.

The radiographic vertical bone height around progressively loaded dental implants placed into extraction sites versus that around conventional implants was not statistically significant from time 0 to 6 months. Progressively loaded implants placed into extraction sites did have a statistically significant lower measurement from implant collar to alveolar crestal bone at 12 months than did conventionally placed implants. This lower measurement indicates that there was statistically more bone loss occurring around the dental implants in the conventional group as compared to the progressively loaded group.

No difference in clinical implant mobility was observed between progressively loaded dental implants placed into extraction sites versus conventional implants during the 12-month evaluation.

Although placement of dental implants into fresh extraction sites followed by progressive loading is more demanding surgically and prosthodontically than conventional implant placement, however, it does provide significant advantages to the patient. Extraction site preservation is observed by maintaining more bone around the implant than the alternative technique. Total treatment time is

reduced by forgoing a post extraction healing phase and the potential for bone augmentation procedures. Improved aesthetics are achieved by papilla preservation and maintaining natural tooth-alveolar contours. Continued long term follow up and an increased sample size will enable us to conclusively prove the usefulness of this procedure.

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APPENDIX

Appendix 1

Data Collection Sheet (conventional)

Implant Placement

Immediate implant stability achieved Y/N

Radiographic vertical bone height measurement (mm) =

Tissue health	Score
Normal gingiva	0
Mild inflammation, slight change in color, slight edema.	1
Moderate inflammation, redness, edema and glazing	2
Severe inflammation, marked redness and edema, ulcerations	3

Uncovery (4 months mandibular implants, 6 months maxillary implants)

Clinical mobility Y/N

Radiographic vertical bone height measurement (mm) =

Tissue health	Score
Normal gingiva	0
Mild inflammation, slight change in color, slight edema.	1
Moderate inflammation, redness, edema and glazing	2
Severe inflammation, marked redness and edema, ulcerations	3

Post operative month 12

Clinical mobility Y/N

Radiographic vertical bone height measurement (mm) =

Tissue health	Score
Normal gingiva	0
Mild inflammation, slight change in color, slight edema.	1
Moderate inflammation, redness, edema and glazing	2
Severe inflammation, marked redness and edema, ulcerations	3

Appendix 2

Data Collection Sheet (progressive loading)

Implant Placement

Immediate implant stability achieved Y/N

Radiographic vertical bone height measurement (mm) =

Tissue health	Score
Normal gingiva	0
Mild inflammation, slight change in color, slight edema.	1
Moderate inflammation, redness, edema and glazing	2
Severe inflammation, marked redness and edema, ulcerations	3

Follow up (4 months mandibular implants, 6 months maxillary implants)

Clinical mobility Y/N

Radiographic vertical bone height measurement (mm) =

Tissue health	Score
Normal gingiva	0
Mild inflammation, slight change in color, slight edema.	1
Moderate inflammation, redness, edema and glazing	2
Severe inflammation, marked redness and edema, ulcerations	3

Post operative month 12

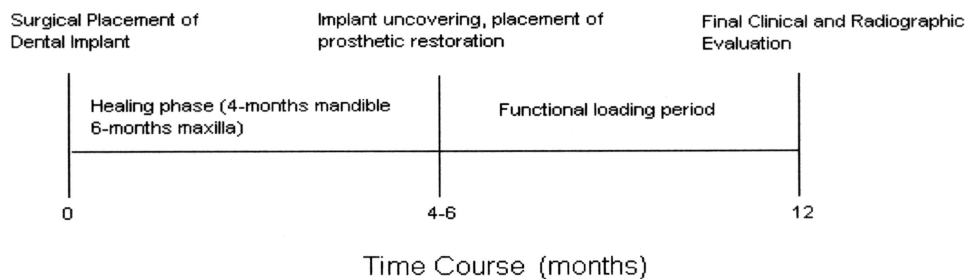
Clinical mobility Y/N

Radiographic vertical bone height measurement (mm) =

Tissue health	Score
Normal gingiva	0
Mild inflammation, slight change in color, slight edema.	1
Moderate inflammation, redness, edema and glazing	2
Severe inflammation, marked redness and edema, ulcerations	3

Appendix 3.

Patients Clinical Course (Conventional)



Appendix 4.

Patients Clinical Course (Progressive Loading)

