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Short-term Clinical Evaluation of NobelReplace® Tapered Groovy Implant

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Short-term Clinical Evaluation of the NobelReplace® Tapered Groovy Implant

by

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A Thesis submitted in partial satisfaction of
the requirement for the degree of
Master of Science in Implant Dentistry

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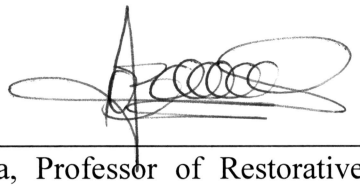
Each person whose signature appears below certifies that this thesis in his opinion is adequate, in scope and quality, as a thesis for the degree Master of Science.



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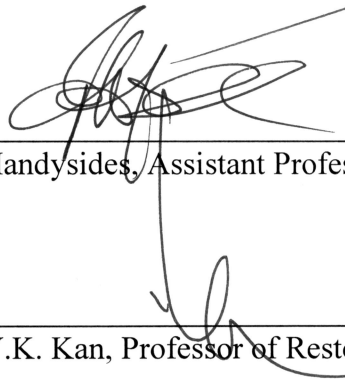

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ABBREVIATIONS

BIC	Bone-to-Implant Contact
CE	Continuing Education
CDB (also C.Dist.Bone)	Control Distal crestal Bone height
CDP (also C.Dist.Pap.)	Control Distal Papillary height
CMB (also C.Mes.Bone)	Control Mesial crestal Bone height
CMP (also C.Mes.Pap)	Control Mesial Papillary height
CP	Commercially pure
EDB (also E.Dist.Bone)	Experimental Distal crestal Bone height
EDP (also E.Dist.Pap.)	Experimental Distal Papillary height
EMB (also E.Mes.Bone)	Experimental Mesial crestal Bone height
EMP (also E.Mes.Pap)	Experimental Mesial Papillary height
FDA	Food and Drug Administration
mm	Millimeter
µm	Micrometer
NaOH	Sodium Hydroxide
Ncm^2	Newton per square centimeter
S_a	Surface area of roughness
SLA	Sandblasted and add-etched
SD	Standard Deviation
RFA	Resonance Frequency Analysis
TiO2	Titanium Oxide
TPS	Titanium Plasma-sprayed Sprue

VAS	Visual Analogue Scale
WNL	Within Normal Limits

ABSTRACT OF THE THESIS

Short-term Clinical Evaluation of the NobelReplace® Tapered Groovy Implant

by

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Master of Science, Graduate Program in Implant Dentistry
Loma Linda University, December 2008
Dr Jaime Lozada

The purpose of this clinical investigation was to make comparisons and to achieve estimates of the short-term implant success, marginal bone resorption, and soft tissue responses around the immediately loaded NobelReplace® Tapered groovy implant (with groove on a rough collar portion) as compared to an implant without a groove on the collar (Replace®Select Tapered). This was a randomized controlled and prospective investigation in which subjects were consecutively included according to strict inclusion/exclusion criteria. Single stage procedure was used with immediate function. Seventeen subjects were recruited, and were randomly divided in two groups. Each group was received the predetermined type of dental implant. Surgery was performed and implant was provisionalized at the same appointment. Final restoration delivered, and the subjects were followed for 1 year after receiving their implant insertion. Drop-outs and withdrawals, as well as possible adverse events, were carefully monitored during the entire investigation period. The change in the level of distal papillae was significantly different between two groups ($p=0.027$), in favor of Replace® Select Tapered group. Statistical analysis showed no significant difference between two groups in regards to other examined aspects.

CHAPTER ONE

INTRODUCTION

Properties of Implants

One major factor in the success and biocompatibility of an implant is its surface properties [Kim et al., 2003]. The surface quality will determine tissue reaction to dental implants, and implant surface topography may have influence on the bone response after implantation [Göransson and Wenerberg, 2005]. Surface properties can be divided into four types: 1- mechanical, 2- topographical, 3- physical, and 4- chemical. Changing one aspect may lead to changes in the others. For example, it was shown that machined implants display a lower concentration of titanium on the surface and a higher concentration of carbon than sandblasted, acid-etched, or plasma-sprayed surfaces [Morra, Asinelli, et al., 2003].

Mechanical Properties

Mechanical properties of implant surfaces relate to potential stresses in the surface that may result in increased corrosion rate and wear relating to the hardness of the material. Decreased fatigue strength of implant surfaces has been described with porous coatings [Kohn and Ducheyne, 1990].

Topographical Properties

The surface topography relates to the degree of roughness of the surface and the orientation of the surface irregularities. Surface roughness has been the main focus on

oral implants for more than a decade. The original Brånemark implant was a turned screw of minimal surface roughness, between 0.5 and 1.0 μm in S_a (surface area) value. For a long time, this implant was the gold standard, based mainly on a good clinical record [Albrektsson et al., 1988, Eckert et al., 1997]. However, by the mid-1990s, new experimental evidences surfaced, indicating that implants with a roughness of about 1.5μm (S_a) show better bone response than turned (smoother) and plasma-sprayed (rougher) implants [Wennerberg, 1996].

Interfacial bone may indicate a stronger bone response in experimental animals. This response, however, does not necessarily indicate greater clinical success. Furthermore, potential drawbacks of roughening the implant surface include greater problems with peri-implantitis and a greater risk of ionic leakage. The risk of increased peri-implantitis with rougher surfaces had some clinical support from independent investigations [Astrand et al., 2000, Becker et al., 2000], although this is related to very rough (> 2.0 μm S_a) plasma-sprayed implants. On the other hand, clinical documentation of moderately roughened surfaces, such as the Tioblast screw (Astra Tech, Waltham, MA), showed no increased incidence of peri-implantitis and, in fact, maintained bone height levels at 5 years of follow-up [Norton, 1998, Palmer et al., 2000, Gotfredsen and Karlsson, 2001, Steveling et al., 2001].

Increased risk of ionic leakage is the other potential drawback of roughened surfaces. Ionic leakage is defined as releasing metallic and non-organic ions in bodily fluids, and the greater the interface of tissue-implant contact the greater the potential for ionic leakage. The impact of ionic leakage on ossiointegration is not clear, and it seems probable that the increase in ionic leakage with slight roughening of an oral implant is

negligible. Changes in implant roughness at the micrometer level of resolution may simultaneously result in changes at the nanometer level, and it is not known whether nanometer-sized irregularities will affect the bone response. It is therefore difficult to reliably exclude the possibility that nanometer-sized surface irregularities may influence the bone response to an implant [Albrektsson and Wennerberg, 2004].

Physical Properties

Physical characteristics refer to two factors; surface energy, and charge. Surface energy is a measure of the extent to which ionic bonds are unsatisfied at the surface. A surface with a high energy has a high affinity for adsorption. An oral implant with high surface energy may, at least theoretically, show stronger osseointegration than implants with a low surface energy. Baier [1986] claims that high surface energy influences proteins to form an advantageous primary coat on the implant. The hypothesis that implants with a high surface energy result in stronger osseointegration has not been supported by in vivo studies [Carlsson et al., 1989].

Chemical Properties

Chemical properties seem to be the main focus for the future in oral implant research. The chemical composition of the surface will provoke different reactions from the surrounding media. The chemical composition of the surface often differs from that of the bulk material because of preparation methods and impurities trapped in the surface [Smith et al., 1992]. The surface layer may contain reactive bonds, and a continuous exchange of water and various ions influences the binding of proteins to the surface and the subsequent cell reactions [Smith et al., 1993].

Biomechanical Bonding

It is generally accepted that bone needs a minimum of 50 to 100 µm cavities or pores for proper in-growth. Electro-polished titanium surfaces of roughness similar to abutments (about 0.2 µm S_a) do not become adequately osseointegrated [Carlsson et al., 1988]. The strongest biomechanical bonds are seen with surfaces of a roughness of about 1.5 µm.

Titanium is considered to be bioinert. Biochemical bonding mode of implant anchorage can be defined as: "Bioactivity is the characteristic of an implant material which allows it to form a bond with living tissues" [Albrektsson and Wennerberg, 2004(1)]. Commercially pure (cp) titanium in its native form is only capable of biomechanical bonding, chemical modifications of cp titanium, such as oxidation of surface, may lead to a bioactive material. Surface oxidative modifications have consisted of sodium hydroxide and heat treatment, ion implantation with calcium, or anodizing with electrolytes containing phosphorus, sulphur, calcium, or magnesium ions. [Albrektsson and Wennerberg, 2004(1)] Such modified titanium surfaces have not yet been clinically introduced.

In order to evaluate the bioactivity of oxidized implants, Sul et al., 2002 investigated the oxidized TiUnite™ surface (Nobel Biocare, Yorba Linda, CA). This experimental study failed to indicate any bioactivity of an oxidized surface with embedded phosphorus ions, one characteristic of the TiUnite™ implant.

Clinical Application of Surface Modification

Earlier in implant dentistry history, several authors [Albrektsson et al., 1986, Albrektsson et al., 1991, Roos et al., 1997] have pointed out the lack of clinical

information about oral implants and the fact that mainly one oral implant system (the Brånemark turned screw) had been adequately documented. The situation has changed in that now a number of other implants have been adequately documented for a full 5 years [Buser et al., 1997, Arvidsson et al., 1998, Deporter et al.,1999, Deporter et al., 2001, Deporter et al., 2002, Vigolo et al., 2000, Jeffcoat et al., 2003, McGlumphy et al., 2003]. However, many well-documented oral implant systems have been replaced with the new devices. The potential benefits of new systems have not completely been examined.

Comparative Studies Between Rough and Turned-Machined Implants

A prospective, randomized controlled study comparing 184 Tioblast and 187 Brånemark turned implants has been reported after 1 year [Astrand et al., 1999] and 3 years [Engquist et al., 2002]. Originally, 68 patients were selected for the study; 2 failed to match the inclusion criteria because they needed some sort of bone augmentation procedure. By chance, 12 Tioblast and only 6 Brånemark patients were smokers. On the other hand, only 1 Tioblast but 8 Brånemark patients had bone quality 4. At 1 year, there was no significant difference between the two systems with respect to maintained bone height. Only 1 failure occurred among the Tioblast implants, compared to 8 failures for the Brånemark system. However, 5 of the latter failures occurred in 1 patient [Astrand et al., 1999]. In the 3-year report, there were 2 Tioblast and 9 Brånemark failures. Bone height loss was 1.7 mm and 2.2 mm, respectively. Success rates were 98.9% for Tioblast implants and 95.2°/o for Brånemark implants [Engquist et al., 2002].

In an attempt to compare rough vs. smooth collar portion, van Steenberghe et al., [2000] presented a 2-year comparison between 50 Tioblast and 45 turned, machined Brånemark implants in a split-mouth study in 18 patients. There were 28 maxillary and

22 mandibular Tioblast implants and 23 maxillary and 20 mandibular Brånemark implants. No difference in soft tissue indices were found between the two systems. Tioblast implants lost on average 1.48 mm of bone height, compared with 2.27 mm for the turned Brånemark screws ($p > 0.001$). No Tioblast implants but 1 Brånemark implant failed, for 2-year success rates of 100% and 97.7%, respectively [van Steenberghe et al., 2000].

Gotfredsen and Karlsson [2001] presented a prospective, comparative study of 64 turned, machined and 64 Tioblast implants followed up for a full 5 years. Ten patients with 16 implants were lost to follow-up. Bone height measurements indicated bone loss of around 0.5 mm for both surfaces. Three machined and no blasted implants failed [Gotfredsen and Karlsson, 2001].

Puchades-Roman et al., [2000] presented a comparative study of 15 Tioblast and 15 Brånemark single-tooth implants, with special focus on microbiologic and radiographic parameters. They selected 30 partially dentate patients with single implants in their maxillae (no implant in the mandible). Most of the Tioblast implants had been followed up for 6 years, whereas the majority of Brånemark implants had been followed up for fewer than 5 years. Probing depths and bone loss were greater for the Brånemark implants. No implant failures were reported [Puchades-Roman et al., 2000].

Studies Related to the Implant Collar Portion

A series of studies [Wennerberg 1996] compared Tioblast-like surfaces to rougher and smoother surfaces. Smoother (turned) and rougher (plasma-sprayed) surfaces showed a weaker bone response than the blasted surfaces of moderate roughness [Wennerberg, 1996]. Ivanoff et al., [2001] used micro implants that were either TiO_2-blasted or turned,

machined surfaces. In that clinical study, the TiO_2-blasted screws showed much greater BIC (Bone to Implant Contact) than the turned, machined devices [Ivanoff et al., 2001].

TiUnite™ Implants

Launched around 2001, TiUnite™ implant (Nobel Biocare, Yorba Linda, CA) is probably the best-selling implant surface in the world today [Albrektsson and Wennerberg, 2004(1)]. The TiUnite™ surface is anodized by electrochemical anodic oxidation in galvanostatic mode, using undisclosed electrolyte(s). Since the implant surface contains phosphorus ions, it seems that some type of phosphoric acid has been used as an electrolyte. This probably indicates that TiUnite™ surfaces lack bioactivity [Sul et al., 2002]. The surface has a relatively thin oxide layer (a few hundred nanometers) and is minimally rough (0.5 to 1.0 μm) in the upper region, whereas the apical region displays an oxide thickness in the range of more than 10 μm and a roughness of more than 2 μm (S_a). The TiUnite™ surface is used in combination with various implant designs. Experimental documentation [Henry et al., 2000, Rompen et al., 2000, Gottlow et al., 2000, Sennerby et al., 2000], but no clinical evidence, was available at the time of its introduction on the market.

Rocci et al., [2002] performed a histologic analysis of one immediately loaded TiUnite™ implant placed in soft bone (grade 3 & 4) in the posterior mandible of a female volunteer; it was left in situ for 9 months. This single implant showed 93.3% BIC. A total of nine oxidized implants were removed from the posterior mandible in another study [Rocci et al., 2003]. Mean BIC was 84.2% ± 10.5%. Ivanoff et al., [2003] report much smaller BIC percentages for TiUnite™ microimplants in place for 3 months in the

mandible or 6 months in the maxilla. However, there was significantly greater BIC with the oxidized test implants than with turned controls [Ivanoff et al., 2003].

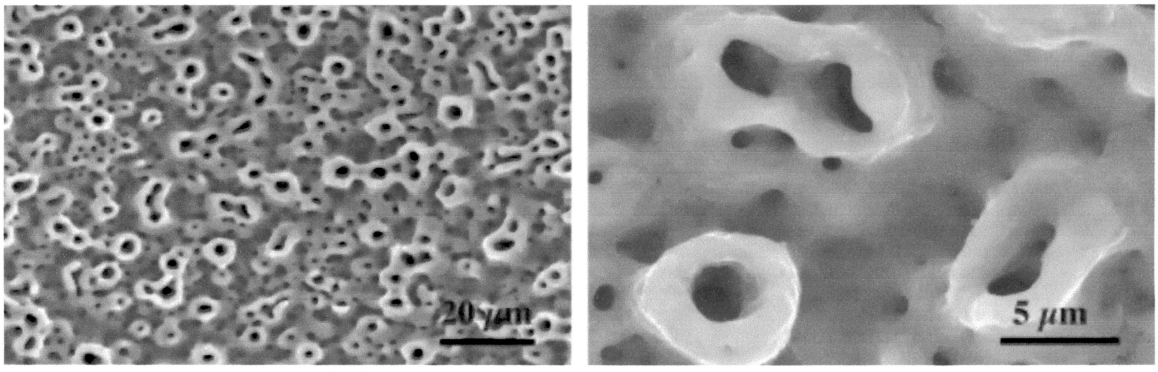


Figure 1. Scanning Electron Microscopic View of TiUnite™ Surface

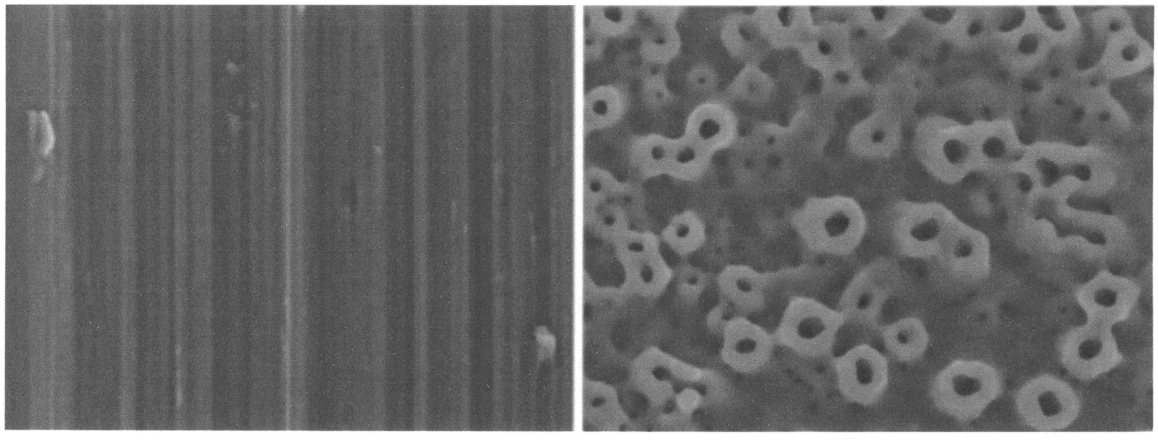


Figure 2. Scanning Electron Microscopic View of Machined Titanium and TiUnite™ Surfaces

Retrospective Studies of TiUnite™ Implants

Glauser et al., [2002] placed 16 maxillary and 11 mandibular TiUnite™ implants in bone of quality 4. Twenty five of the 27 implants were placed in the posterior region. Although bone quality was poor, bone quantity was generally good, indicated by the fact that only two maxillary implants were less than 10 mm long. No implants were placed in patients with bruxing habits. No implant was lost. There was a drop in stability during the first month after placement, but thereafter a gain in resonance frequency analysis (RFA), indicating the progression of ossiointegration, was observed. The bone loss at 1 year was 1.0 ± 0.7 mm, and the success rate was 100% [Glauser et al., [2002]. Calandrietlo et al., [2003] presented preliminary data on a multicenter study of 50 TiUnite™ implants followed for 6 months and 24 implants followed for 1 year. All implants were placed in the molar region of the posterior mandible. One inclusion criterion was at least 10 mm-long implants, and one exclusion criterion was bruxing patients. No dropouts were reported, and no implant failures were seen. Marginal bone loss was 1.0 ± 0.5 mm at 6 months and 1.3 ± 0.6 mm for the 24 implants followed up for 1 year. The cumulative survival rate at 6 months was 100% [Calandrietlo et al., 2003].

Prospective Studies of TiUnite™ Implants

Glauser et al., [2003] presented a 1-year follow-up prospective study of 38 consecutive patients who received 38 maxillary and 64 mandibular TiUnite™ implants, 88% of which were placed in the posterior region. Exclusion criteria included

parafunctional occlusal habits. Five implants were shorter than 10 mm. All the patients reported for the follow up exams. Soft bone (grade 4) was diagnosed for 27 implants. Three maxillary implants were removed from one patient because of an infection associated with guided bone regeneration treatment. Bone height measurement gave a mean bone loss of 1.2 ± 0.8 mm for these immediately loaded implants. However, 5 implants displayed more than 3 mm of bone loss. Therefore, it could be argued that the reported success rate of 97.1% should really be interpreted as a survival percentage [Glauser et al., 2003].

Vanden Bogaerde et al., [2003] presented an 18-month outcome of 111 TiUnite™ implants placed in the maxilla (n= 69) or posterior mandibles (n = 42) of 31 patients. The implants were loaded early (within 16 days of placement). Inclusion criteria were bone height adequate for a minimum 8.5 mm long implant and insertion torque before implant seating to a minimum of 40 Ncm^2. No information on how many patients were excluded because of failure to match the inclusion criteria was presented. Exclusion criteria included bruxism. Patients were consecutive and subject to informed consent to participate in the study. No patients dropped out. Bone resorption at 18 months was 0.8 mm, with standard deviation (SD) of 1.0. There was one failure, for an 18-month success rate of 99.1% [Vanden Bogaerde et al., 2003].

Comparative Studies of TiUnite™ and Turned Implants

Glauser et al., [2001] presented a comparative, but not randomized, study of immediately loaded turned, machined (n = 27) and oxidized TiUnite™ (n = 20) implants, placed in the posterior maxilla. A modified surgical technique was used to ensure primary stability for all implants. Evaluations were performed with repeated RFA

measurements until 6 months after implant placement and loading. Although identical RFA values were recorded at the time of placement, significantly higher RFA values were reported for the oxidized implants until the 6-month evaluation, when the difference was no longer significant. The study suggests that oxidized implants show less loss of stability during the healing period than turned, machined implants [Glauser et al., 2001]. Friberg and Billstrom [2002] report the preliminary results of a claimed prospective multicenter study on 584 TiUnite™ and 58 turned, machined implants. Inclusion and exclusion criteria were not presented. Only 85 implants had been followed up for 1 year. Five patients dropped out, and one had died. Failure was observed in two cases. Only 387 (not known how many of those implants were not oxidized) implants had passed the abutment connection stage. The presented cumulative survival rate of 99.7% must be interpreted with some caution. No turned implant failed [Friberg and Billstrom, 2002].

Rocci et al., [2003] performed a randomized study of 66 immediately loaded TiUnite™ and 55 turned, machined Brånemark implants. Patients were consecutively treated, with one inclusion criterion being "sufficient, primary implant stability," but no information on how many patients were excluded because of this demand was given. There were no patient dropouts. Ten TiUnite™ and 6 turned, machined implants were shorter than 10 mm. Twelve TiUnite™ implants (of which 1 failed) and 11 turned implants (of which 5 failed) were placed in grade 4 bone. The total number of failures was 3 TiUnite™ and 8 turned implants. Mean bone loss was 0.9 mm (SD 0.7, maximum 2.3 mm) for TiUnite™ and 1.0 mm (SD 0.9, maximum 3.25 mm) for turned implants.

Cumulative survival rate was 95.5% for TiUnite™ and 85.5% for turned, machined implants at 1 year of loading [Rocci et al., 2003].

Olsson et al., [2003] presented a study on 10 patients who received 61 maxillary TiUnite™ implants, all loaded between 1 and 9 days after placement. Patients were consecutively included in the study, and all were followed up for a total of 1 year. Four implants were lost in 1 patient. The mean marginal bone level was 1.3 ± 0.6 mm at 1 year, and the survival rate was 93.4% [Olsson et al., 2003].

TiUnite™ Implants and Bone Grafts

Lundgren and Brechter [2002] presented a preliminary study of 171 TiUnite™ implants placed in a two-stage procedure in conjunction with various bone augmentation procedures. Of those implants, 123 had been uncovered at the time of the report, and the mean follow-up time was 12 to 21 months. One failure was noted [Lundgren and Brechter, 2002].

In summery, the TiUnite™ surface has been shown to maintain primary implant stability and shorten the time needed for accomplishment of secondary stability when compared to the machined surface [Albrektsson et al., 2000, Glauser et al., 2001, Henry et al., 2000, Rocci et al., 2002, Rocci et al., 2003, Rompen et al., 2000, Wennerberg et al., 1995].

New TiUnite™ Line

Marginal bone remodeling is an expected biological reaction occurring around the implant, most pronounced during the first year in service, whereafter it stabilizes. To fulfill the implant success criteria proposed by Albrektsson et al., [1986] and others,

[Jemt, 1997, Lekholm and Zarb, 1985] the bone remodeling should be less than 0.2 mm annually following the implant's first year of service. Different measures have been proposed to decrease the remodeling to increase the long-term esthetic predictability. To improve the retention of the marginal bone crest by enhancing load transfer to the marginal bone, grooves have also been added to the collar of the implants. The improvement of retention is especially important in the aesthetic zone.

Initial animal studies and preliminary data from histological studies on humans, have shown that placement of a groove at the center of the flank of the implant thread further stimulates bone formation along the TiUnite™ surface [Hall et al., (manuscript in preparation), Miranda-Burgos P, et al., (manuscript in preparation 1), Miranda-Burgos et al., (manuscript in preparation 2), Miranda-Burgos et al., (manuscript in preparation 3)]. This new implant line (Groovy) features a groove along the full length of the intra-osseous portion of the implant. Research results have shown that bone formation was more rapid within and along the groove, resulting in 30% higher removal torque [Hall et al., 2005]. The groove also resulted in faster osseointegration.

Purpose

The purpose of this clinical investigation was to compare three outcome factors from placement of either immediately loaded NobelReplace® Tapered groovy implants versus the implant (Replace® Select Tapered system) with the same surface topography with machined collar portion without a groove: 1-short-term (1 year) implant success, 2-marginal bone resorption, and 3-soft tissue response.

The null hypothesis was that the NobelReplace® Tapered Groovy implant design is superior to Replace® Select Tapered implant design in regard to hard and soft tissue

response, and the difference is statistically significant. The alternate hypothesis was that difference between Group A and Group B was not statistically significant.

CHAPTER TWO

MATERIALS AND METHODS

Design of the Clinical Investigation

Success and Failure Criteria

This investigation was a part multi-center study, designed and financed in part by Nobel Bicare USA, Yorba Linda, CA. The design of investigation was prospective, randomized, and controlled, in which subjects were consecutively included according to strict inclusion criteria. NobelReplace® Tapered Groovy implants (group A) were compared to Replace® Select Tapered implants (group B). Single stage procedures were done with immediate function. Seventeen subjects were recruited and randomly divided into two groups. Each group received the predetermined type of dental implant. The subjects were followed for 1 year after receiving their implants (recalls at 3, 6, 12 months), and possible drop-outs and withdrawals, as well as possible adverse events, were carefully monitored during the entire investigation period.

The success criteria used in this investigation were a modification of the success criteria suggested by van Steenberghe [1997], and were as follows:

A "successful implant" is an implant that

1. does not cause allergic, toxic, or gross infectious reactions either locally or systematically.
2. offers anchorage to a functional prosthesis.

3. does not show any signs of fracture or bending.
4. does not show any mobility when individually tested by tapping or rocking with a hand instrument.
5. does not show any signs of radiolucency on an intra-oral radiograph using a paralleling technique strictly perpendicular to the implant-bone interface.

A "surviving implant" is one that remains in the jaw and is stable, and the subject's treatment is functionally successful even though all the individual success criteria are not fulfilled.

A "successful prosthesis" is a prosthetic reconstruction that is stable and in good function.

Failure criteria were as follows:

A "failed implant" is an implant that:

1. has been removed,
2. has fractured beyond repair, or
3. cannot be classified as a successful or surviving implant.

Participants

Healthy subjects in need of implant retained prosthetics, to replace teeth from the right maxillary second premolar to the left maxillary second premolar, were accepted. Subjects were at least 18 years old at the time of initial exam, and not older than 65. Seventeen subjects qualified for the study. All subjects scheduled for implant-supported restorations were asked to participate in the investigation in a consecutive order, provided they fulfill the criteria as stated below. Nine subjects received the Nobel Replace Tapered Groovy implant (group A) and 8 subjects constituted the group B and received the

Replace Select Tapered implant. The subjects were assigned to being either groups in random order.

Eligibility

All the subjects were patients of the Loma Linda School of Dentistry and they had previously been determined to be acceptable candidate for root-form implants.

Inclusion Criteria

1. Edentulous sites, from the right maxillary second premolar to the left maxillary second premolar.
2. The subjects had an adequate osseous architecture to receive an implant with a diameter of at least 3.5 mm and a sufficient amount of bone for placing implants with a length of at least 10 mm.
3. The subjects as well as the implant site(s) fulfilled the criteria for immediate functional loading.
4. The implant site(s) were free from any pathosis, infection, and extraction remnants.

Exclusion Criteria

Subjects were not included in the investigation if they had any of the following:

1. Alcohol or drug abuse as noted in patient records or in patient history.
2. Health conditions that do not permit the surgical procedure.
3. Reason to believe that the treatment might have a negative effect on the subject's total health, as noted in patient records or in patient history.
4. The subject was not able to give her/his informed consent to participate.

5. The need of bone augmentation before implant installation to obtain a prosthetically correct implantation transversally.
6. Any disorders in the planned implant area such as previous tumors, chronic bone disease, or previous irradiation
7. Resorption of residual ridge, devoid of three-dimensional bony architecture in interproximal peak.
8. Bruxism and/or other parafunctional occlusal habits.
9. On-going infections, endodontic or periodontal problems in teeth adjacent to the implant.
10. Implant bridges connected to a natural tooth or teeth.

Components

The implants used were either Nobel Replace® Tapered Groovy or Replace Select Tapered. The Nobel Replace® Tapered Groovy implant has a groove on the thread and the collar with TiUnite™ surface characteristics all the way up to the platform. It is available in diameters of 3.5, 4.3, and 5 mm with lengths of 10, 13, and 16 mm. The Replace Select Tapered has a TiUnite™ surface ending at the collar, and is available in diameters of 3.5, 4.3, and 5 mm with lengths of 10,13, and 16 mm.

Study implants, cover screws and healing abutments were obtained from Nobel Biocare USA, Department of Clinical Research Yorba Linda, CA. These components were provided free, leading to reduced fee for the patients. Abutments were custom-made. All implants had authority clearance (ie FDA approval, CE-marking etc.). Approval of the Institutional Review Board of the Loma Linda University, Loma Linda, CA, was also obtained (OSR#56023).

Sequence of Treatment

All subjects scheduled for implant-supported restorations were asked to participate in the investigation in a consecutive order, provided they fulfill the inclusion criteria. The sequence of treatment was;

Subject inclusion > implant placement, temporary abutment connection, loading > 3 months recall, starting the prosthetic procedures > 6 months recall > 1 year recall.

Pre-treatment Examination

Patient data, medical history and pretreatment examination were recorded for each patient according to the case record form.

Implant insertion

Pre- and postoperative procedures were performed according to the routines of the Department of Implant Dentistry at Loma Linda University. The clinical procedures were performed by one investigator (MP), and according to the Nobel Replace Tapered Groovy or the Replace Select Tapered Implant placement manual. One-stage procedures with immediate loading were done. Implants needed to be clinically stable as judged by the operator and were functionally loaded after implant installation on the day of surgery. Temporary abutments were connected and patients received a custom-made provisional crown. The provisional restorations were placed out of occlusion, or with a contact limited to light contact in central occlusion. The bone level was at the level of platform on the vertically positioned implant. Accordingly, the length of the collar (having grooves) was below the alveolar bone crest. Patients were provided with home-care

maintenance instructions and scheduled for post-operative check-ups on an individual basis.

Follow-ups

Follow-up assessments were performed at 3 months, 6 months and 1year counted from the day of loading (i.e. implant insertion). The 3 month and 1 year follow-ups were considered routine follow-up intervals; the 6-month follow up was for the study purpose. At each visit a clinical evaluation was made, two periapical radiographs were exposed using customized jigs which were built at the day of surgery. Digital photographs were also taken.

A sample of forms used for clinical registration can be found in Appendix 1.

Adverse Events

An adverse event is defined as any undesirable clinical occurrence in a subject whether it is considered to be device-related or not. If the adverse event was regarded as device-related it was stated as an adverse device effect.

An adverse event or adverse device effect could be serious/severe or non-serious/non-severe. If, as a result of an adverse event during a clinical investigation, a subject had to be hospitalized, or their hospitalization was unduly prolonged because of potential disability or danger to life because an intervention had been necessitated or the event was terminal, the adverse event or adverse effect was regarded as serious.

If applicable, according to ISO 14155-1, the clinical investigator would informe the concerned Institutional Review Board /Ethics committee and the competent authority

of any serious adverse device effect. All adverse events, serious or non-serious, were carefully recorded on the appropriate form.

Radiographic Examination

Regular intra-oral radiographs from the pre-treatment examination, implant insertion, 3 months recall, prosthesis insertion, 6 month and 1 year follow-up visits were taken for evaluation. These radiographs were taken perpendicularly with a long-cone parallel technique and showed the implant/abutment connections, and at least 2 mm on each side of the implant. Double film was always used. Radiographs were marked with date and patient number. All the measurements were taken from the bone to implant point of contact to the platform of implant.

Subject Withdrawals

If any subject withdrew before implant insertion no action was taken except that the subject was replaced with another subject. The reason was clearly stated on the first case record form.

If any subject withdrew after implant insertion, the reason was clearly stated and all relevant case record forms completed. These subjects would be included in the final analysis of the investigation.

Evaluation

Clinical Evaluation

The height of each papillae on the mesial and distal aspects of the edentulous site was measured before placement of root-form implants and at 1 year recall exam on dental

casts. The measurements were calibrated using the Mesial-Distal and Incisal-Gingival dimension of adjacent tooth, measured on the dental casts.

Radiographic Evaluation

All the radiographs were digitized using a negatoscope and a digital SLR camera under controlled conditions. The height of the mesial and distal crestal bone level was measured from the implant platform, at the 1 year follow up exam. Image J software was used for this purpose, and this measurement was then calibrated using the dimension of implant platform.

Statistical Evaluation

A comparison of the treatments between the group B (Replace Select Tapered) and the group A (Nobel Replace Tapered Groovy) was performed, by using the non-parametric procedure, Wilcoxon-Mann-Whitney rank-sum test. This statistical analysis was used for presentation of results.

CHAPTER THREE

RESULTS

Characteristics of the Participants

Fifteen patients (10 female and 5 male) were recruited for this study using strict inclusion/exclusion criteria. The mean age was 42.5 years (19 to 69 years). Nineteen edentulous spaces qualified to receive dental implants. All the patients were screened by the primary investigator to confirm their eligibility. Summery of the demographic information is presented in Table 1.

Patient #6 did not return for treatment. One of the patients (#14) had received bone graft on the edentulous site. This procedure was done more than six months prior to the time of the surgery, after excision of a cyst. All the surgical procedures were performed by a single operator (MP). Flapless approach was used for all cases according to the established protocol.

Three patients (#11, 14, & 15) were disqualified since the initial stability was not adequate, and the implant could not be temporarily restored during the surgical phase of treatment. These patients received a customized healing abutment instead of provisional prosthetic, or the implant was covered with cover screw and soft tissue. Essix temporary prosthetic were constructed for patients #14 and 15, (teeth #6 to 11).

One patient (#7) later dropped out due to change in prosthetic treatment plan. All the patients, regardless of the degree of stability at the time of placement, received the appropriate prosthetic treatment according the established guidelines. Figures 1 to 10 present the sequence of treatment in one of the patients.

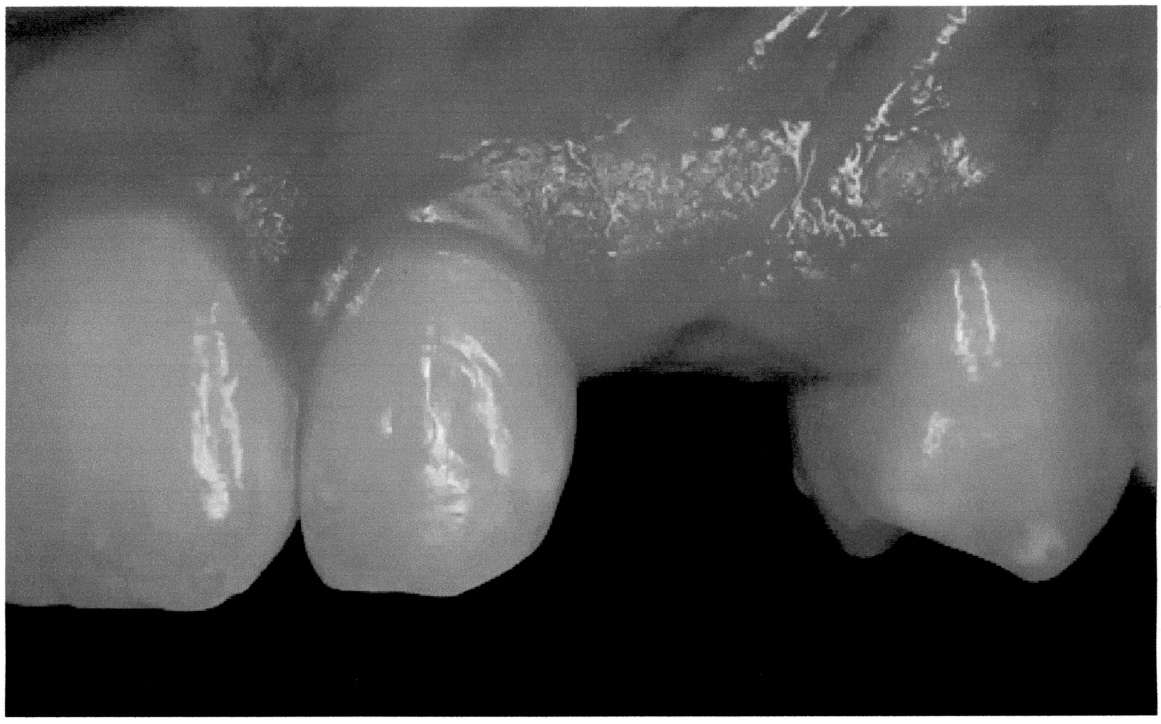


Figure 3. Preoperative View

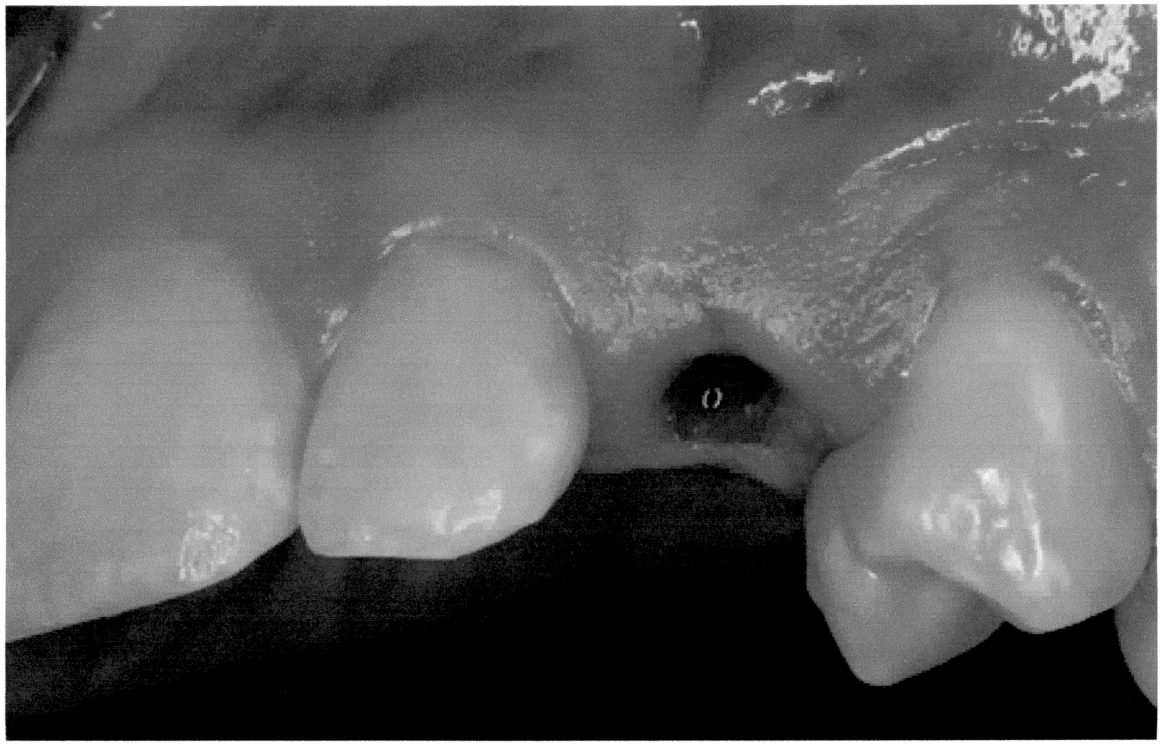


Figure 4. Osteotomy

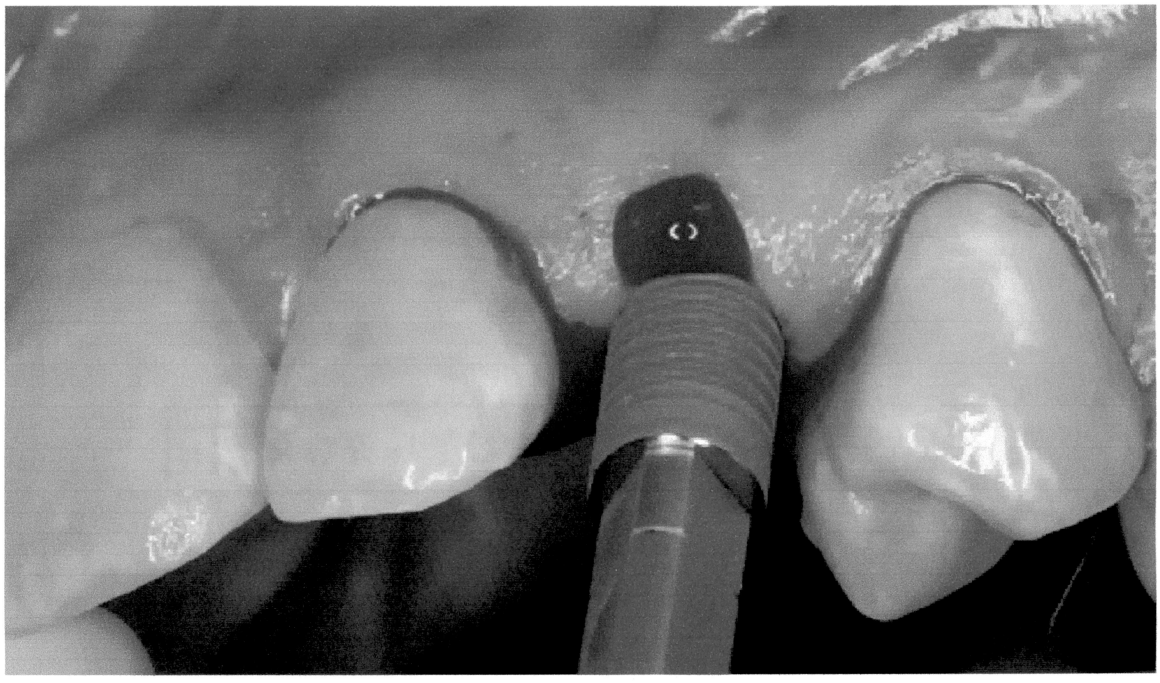


Figure 5. Implant Insertion

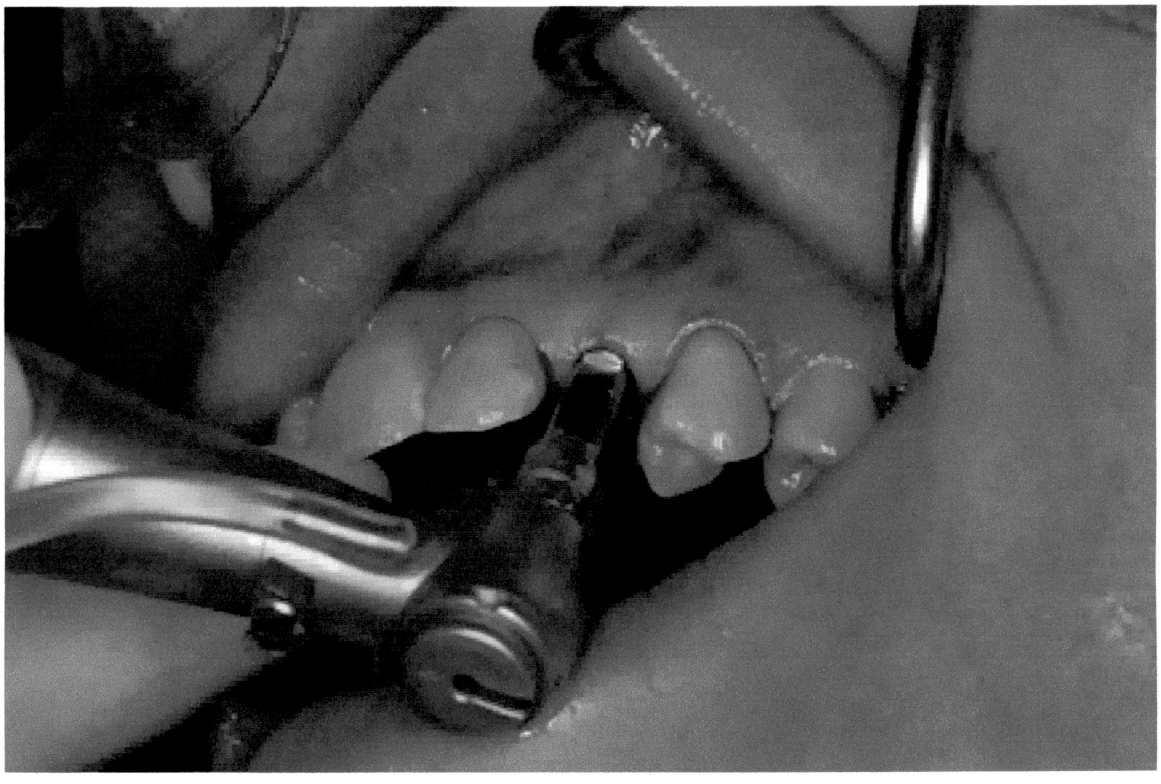


Figure 6. Insertion

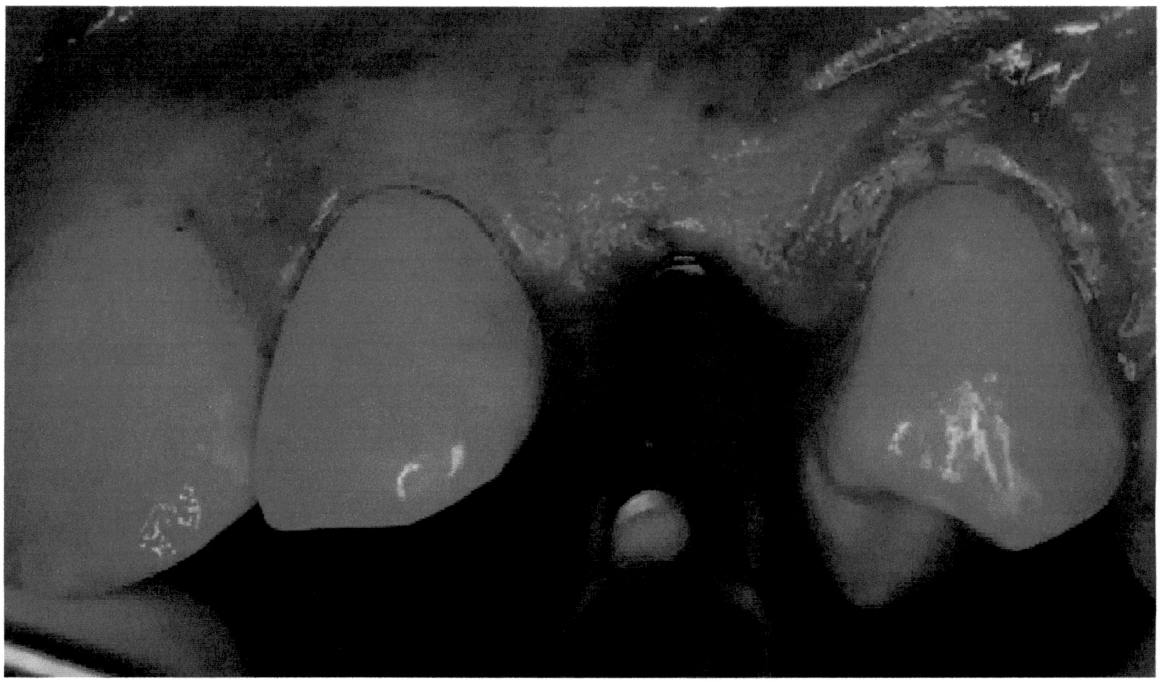


Figure 7. Torquing

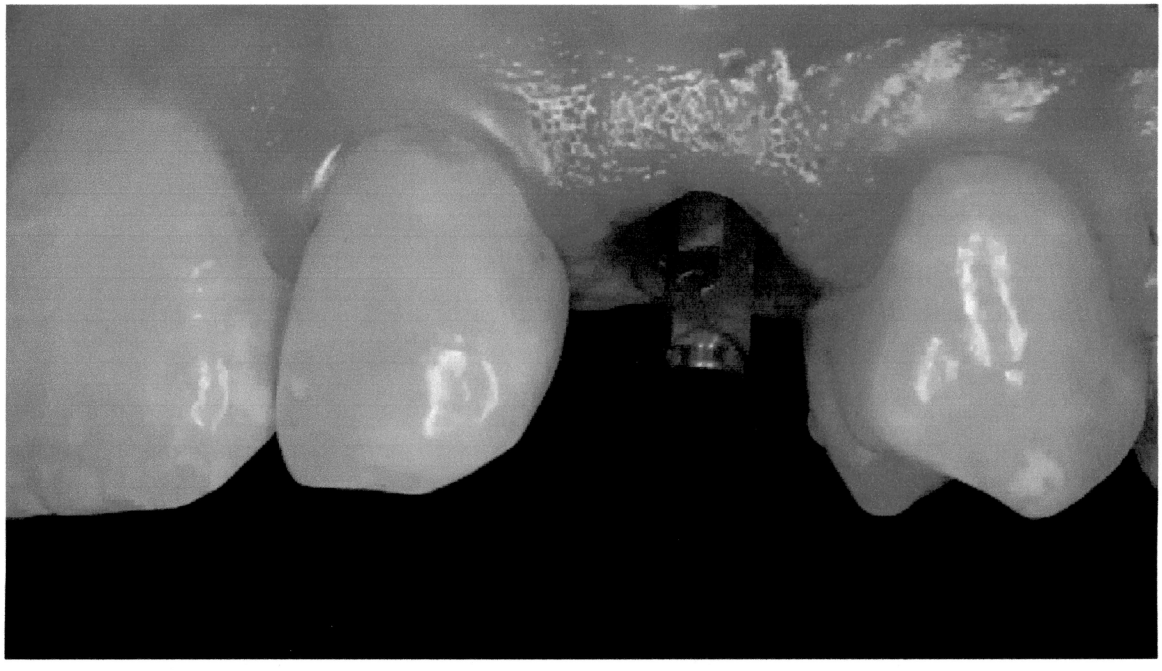


Figure 8. Immediate Temporary Abutment

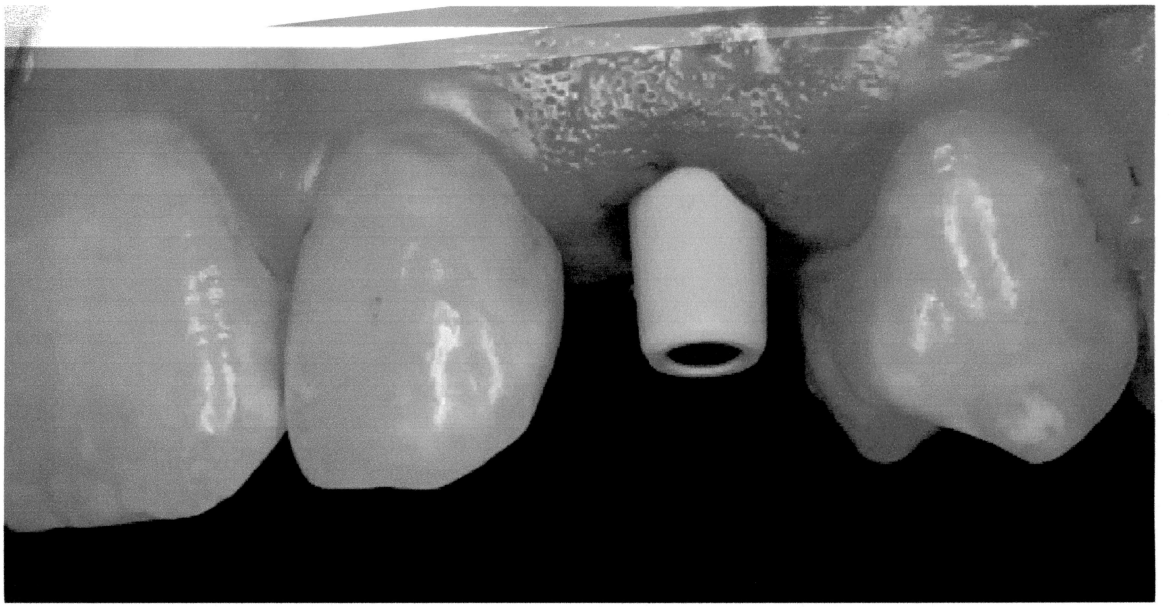


Figure 9. Plastic Coping

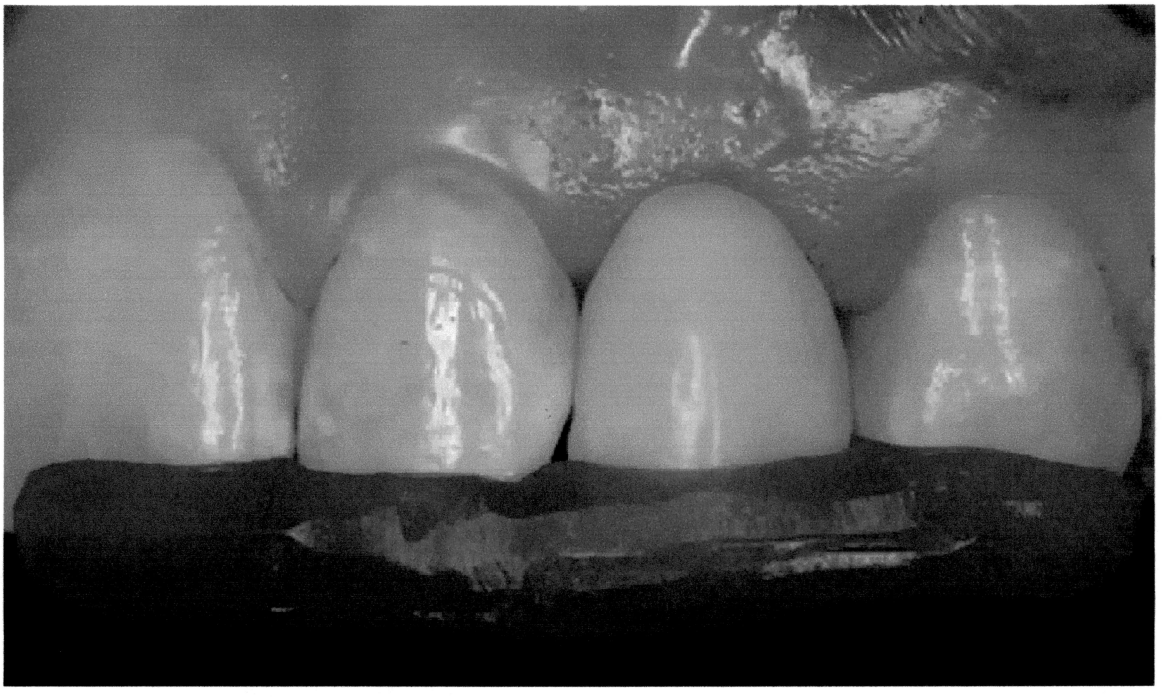


Figure 10. Customized Jig and Temporary Crown

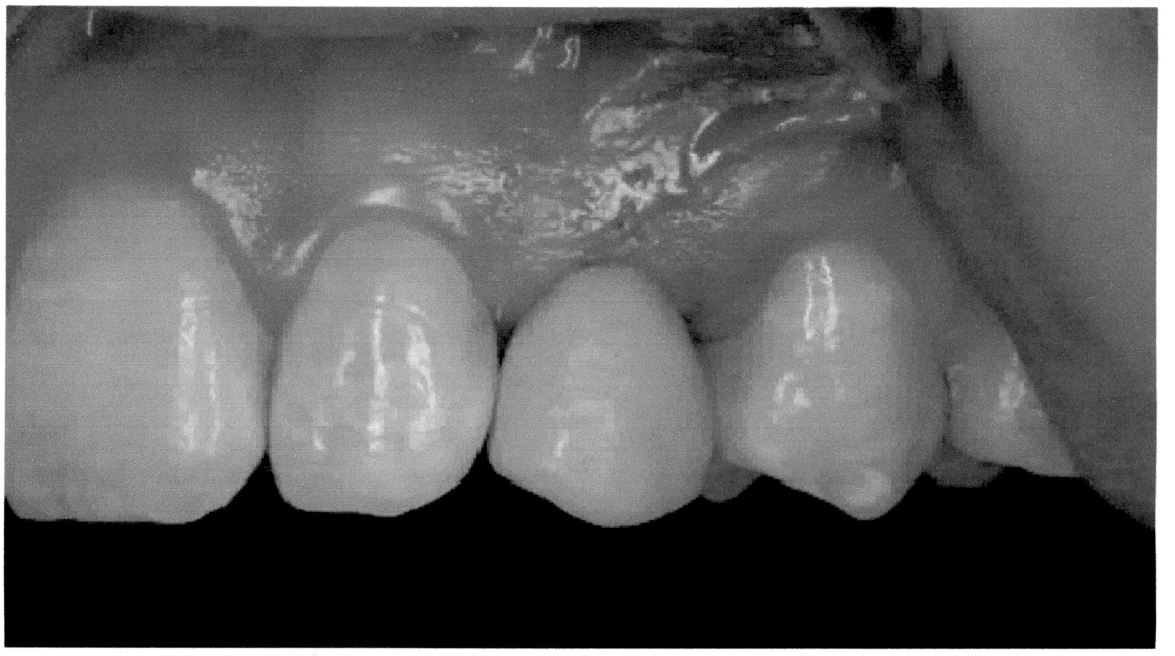


Figure 11. Temporary Crown Cementation

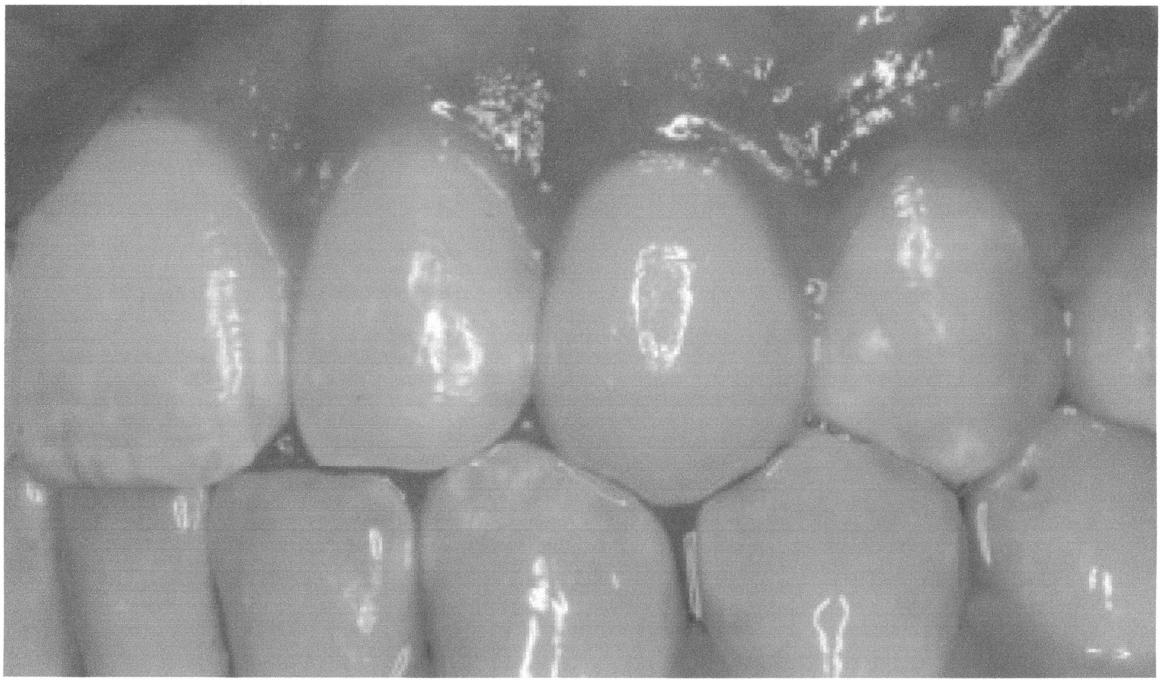


Figure 12. Final Restoration (1 Year Recall)

Data Screening

The surgeries were performed during the period of 9/19/06-11/7/06. No serious complication was noted during the period of recovery after surgery, or during periodic recall examinations.

The average time elapsed from the time of implant insertion to prosthetic delivery was 6 months. All the subjects reported on the assigned appointments for periodic exams. One year follow-up exams were performed from 10/08/07 till 12/3/07. No implant was lost during the course of the investigation, resulting in a success rate of 100% for both systems. Radiographs, casts, and intra-oral images were evaluated according to established protocols. Table 2 demonstrates a summery of the collected data. The compiled average of crestal bone loss in the mesial and distal aspect of both experimental groups was 1.33 mm for group A and 1.21 mm for group B. The compiled average gain for mesial papillary height in both groups was 0.71 mm. For distal papillae the compiled average gain was 0.54 mm. Figures 11 to 14 demonstrate he methods of measurements. Measurements obtained for groups B and A are reported separately in Tables 3 and 4, respectively. The average crestal bone loss in the mesial aspect was 1.1 mm for ReplaceSelect Tapered TiU group, and 1.55 mm for NobelReplace tapered Groovy group. The average crestal bone loss in the distal aspect implants was 0.98 mm and 1.43 mm for ReplaceSelect Tapered TiU group and NobelReplace tapered Groovy group, respectively. The average gain in the mesial papillae height was 1.1 mm for ReplaceSelect Tapered TiU group, and 0.3 mm for NobelReplace tapered Groovy group. The average gain in distal papillae height of the implants was 1.2 mm and -0.2 mm for ReplaceSelect Tapered TiU group and NobelReplace tapered Groovy group, respectively.

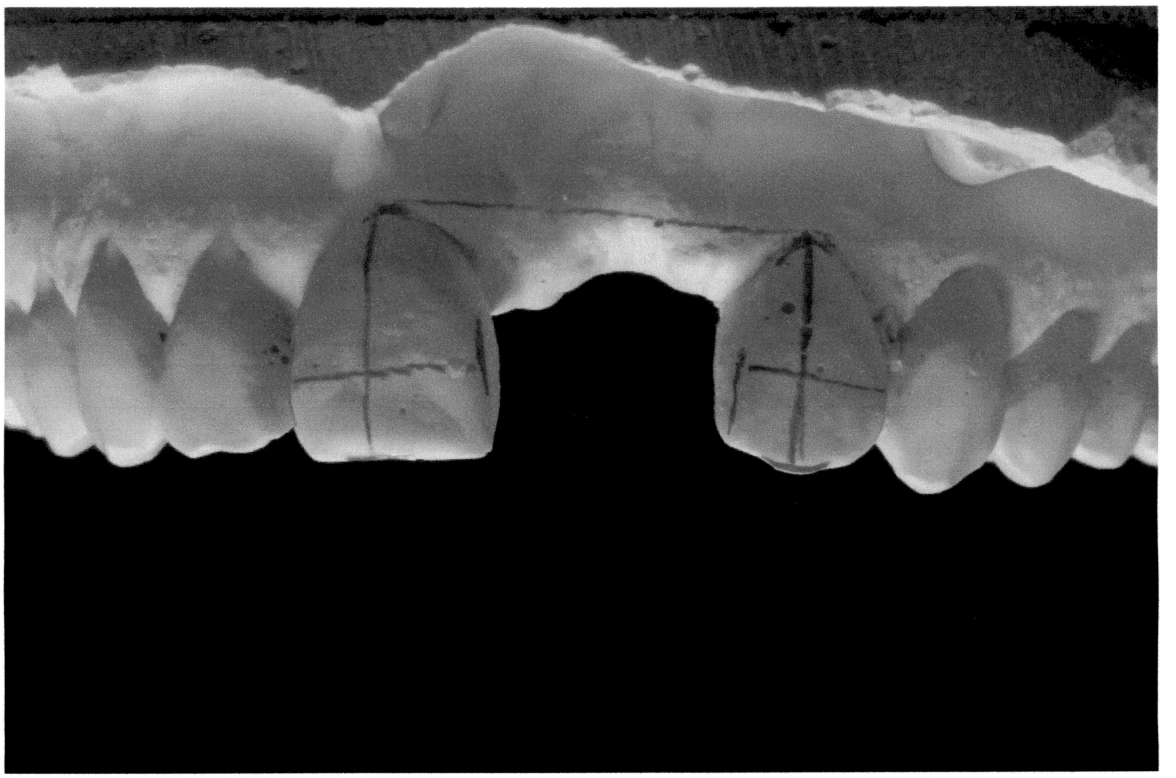


Figure 13. Preparing Cast for Measurement

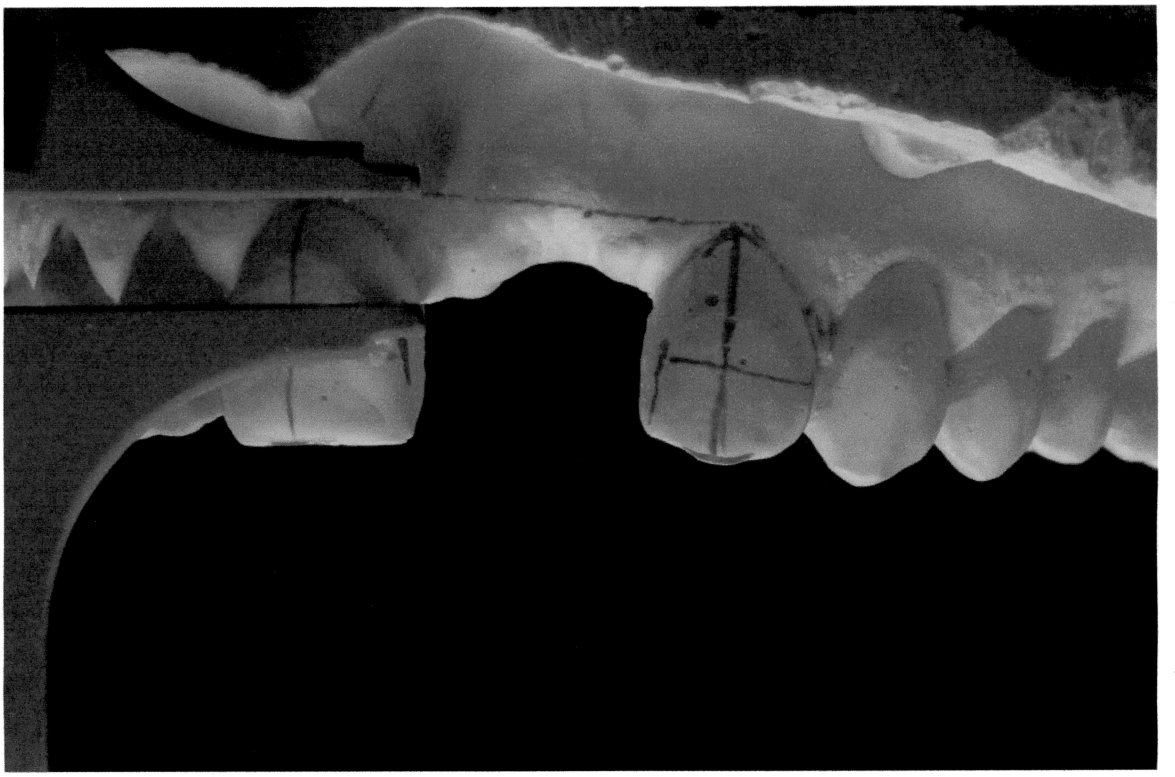


Figure 14. Papillary Height Measurement

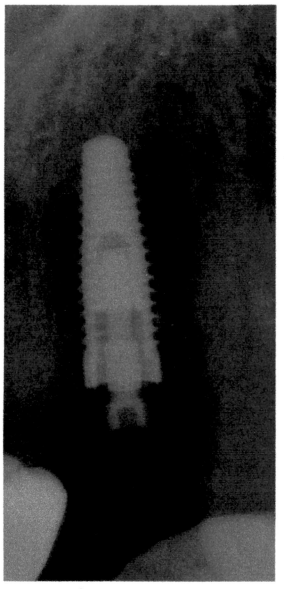


Figure 15. Post-operative Radiograph

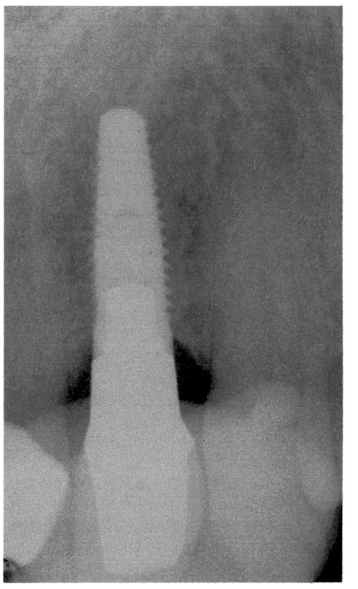


Figure 16. 1 Year Recall Radiograph

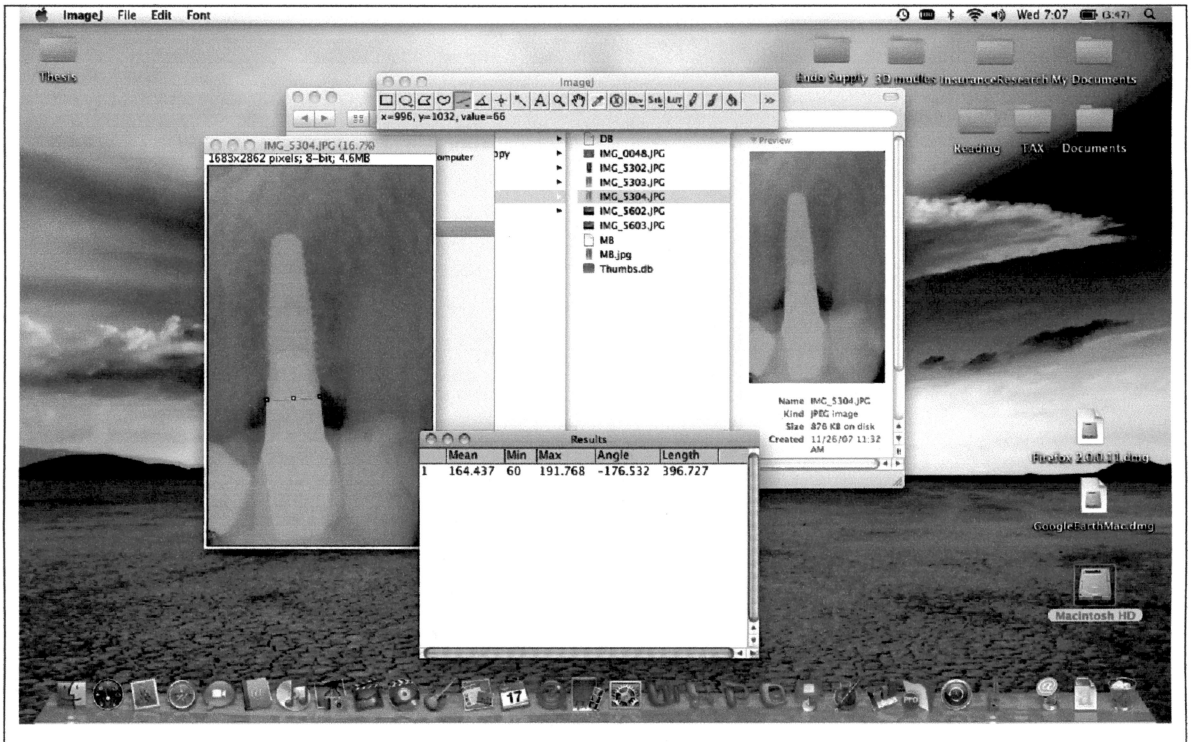


Figure 17. Image J Software

Collected data were then processed using appropriate statistical methods. The statistical analysis performed using Mann-Whitney U-test, at the significance level of α=0.05. Descriptive statistics could be found in Tables 5 and 6. The results are presented under "Analytical Results" heading.

A Box-Whisker plot (Table 7) was used to summarize and present the collected data. This graph provides a visual presentation of location, variability, and outlier of the data. Except for the crestal bone loss on mesial aspect of implants, Group B (ReplaceSelect Tapered TiU) showed less diversity and more concentration in regard to collected data compared to Group A (NobelReplace tapered Groovy). This fact might indicate a more predictable tissue response in Group B. Other obvious presentation of this plot was that collected data for Group B had more favorable average (Q_2 line) in any examined aspect.

Analytical Results

Using the Mann-Whitney U-test at the significance level of $\alpha = 0.05$, the results showed that:

1. Group B Mesial Papillae (BMP) vs. Group A Mesial Papillae (AMP):

There was no statistically significant difference between BMP and AMP at the significance level of $\alpha = 0.05$, with $p = 0.180$.

2. Group B Distal Papillae (BDP) vs. Group A Distal Papillae (ADP):

The recorded reading for BDP is statistically significantly larger than ADP, at the significance level of $\alpha = 0.05$, with $p = 0.030$.

3. Group B Mesial Bone Height (BMB) vs. Group B Mesial Bone Height (AMB):

There was no statistically significant difference between BMP and AMP at the significance level of $\alpha = 0.05$ ($p = 0.310$)

4. Group B Distal Bone Height (BDB) vs. Group A Distal Bone Height (ADB): There was no statistically significant difference between BDB and ADB at the significance level of $\alpha = 0.05$ ($p = 0.485$)

Data analysis was done based on the multi-center study protocol designed by Nobel Biocare USA, Yorba Linda, CA.

Table 1: General information

Patient	Sex	Age	Tooth #	Implant size	Implant type
1	M	60	8	4.3x13	NG†
2	M	69	10	4.3x13	G‡
3	M	35	9	4.3x13	G
4	F	19	11	4.3x13	G
5	M	29	13	4.3x10	NG
6*	F	38	8	None	None
7*	F	51	5	4.3x13	G
8	F	62	5	4.3x10	NG
9	F	48	10	3.5x13	G
10	F	20	6	3.5x13	G
10	F	20	11	3.5x13	NG
11	F	23	4	3.5x13	G
11*	F	23	13	3.5x13	NG
12	F	34	8	4.3x10	NG
13	F	63	10	4.3x10	NG
14*	M	53	7	3.5x13	G
14*	M	53	8	4.3x13	NG
15*	F	34	8	3.5x13	G
15*	F	34	10	3.5x13	NG

*Subjects were excluded
†NG stands for "ReplaceSelect Tapered TiU "
‡G stands for "NobelReplace tapered Groovy"

Table 2: 1 year recall data

Patient	Mesial papilla height gain/loss	Distal papilla height gain/loss	Mesial bone gain/loss	Distal bone gain/loss
1	0.77	0.0	-3.0	-1.5
2	-0.1	0.3	-1.0	-1.0
3	-0.2	-0.8	-2.3	-2.6
4	1.0	-0.8	0.0	0.0
5	1.6	2.6	0.0	-1.0
8	0.9	1.1	-1.0	-1.2
9	2.0	0.9	-2.0	-2.2
10	0.3	-0.1	-2.1	-1.0
10	-1.2	0.3	-2.0	-1.8
11	1.0	NE	0.0	0.0
12	1.5	1.1	-0.8	-1.2
13	0.9	1.3	-1.8	-1.0

Table 3: Measurements of ReplaceSelect Tapered TiU group (gain +/ loss -) in mm

Patient	Mesial Papillae	Distal Papillae	Mesial Bone	Distal Bone
1	+0.77	0.0	-3.0	-1.5
5	+1.6	+2.6	0.0	-1.0
8	+0.9	+1.1	-1.0	-1.2
12	+1.0	Non existant	0.0	0.0
13	+1.5	+1.1	-0.8	-1.2
14	+0.9	+1.3	-1.8	-1.0

Table 4: Measurements of NobelReplace tapered Groovy group (gain +/ loss-) in mm

Patient	Mesial Papillae	Distal Papillae	Mesial Bone	Distal Bone
2	-0.1	+0.3	-1.0	-1.0
3	-0.2	-0.8	-2.3	-2.6
4	+1.0	-0.8	0.0	0.0
9	+2	+0.9	-2.0	-2.2
10	+0.3	-0.1	-2.1	-1.0
11	-1.2	+0.3	-2.0	-1.8

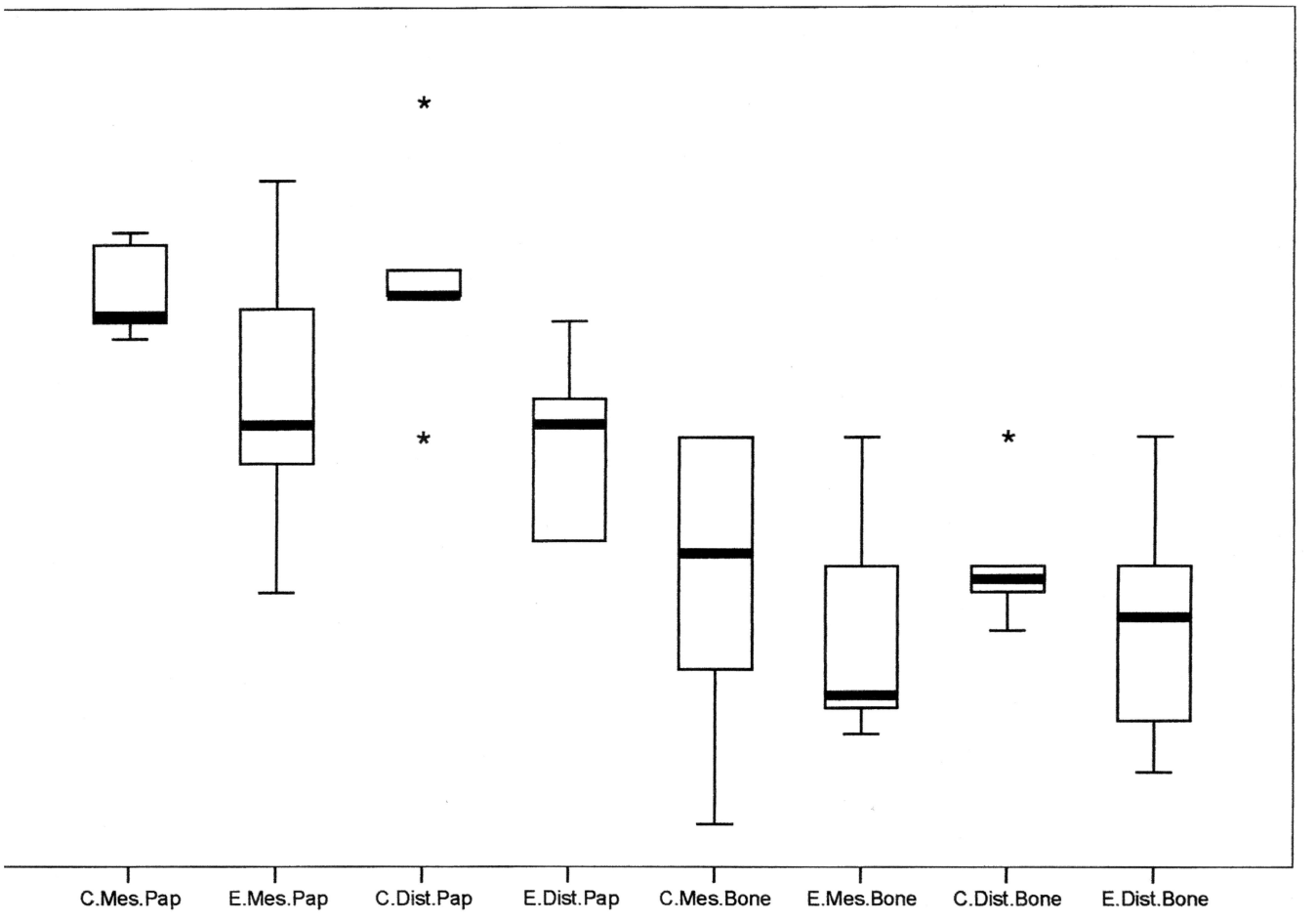
Table 5: Statistic result relevant to papillary height

	B.Mes.Pap	A.Mes.Pap	B.Dist.Pap	A.Dist.Pap
N	6	6	5	6
Mean	1.1117	.3000	1.2200	-.0333
Median	.9500	.1000	1.1000	.1000
Std. Deviation	.34874	1.09909	.92574	.67429
Coefficient of Variation	31.36%	366.36%	75.88%	-202.48%

Table 6: Statistic results relevant to crestal bone height

	B.Mes.Bone	A.Mes.Bone	B.Dist.Bone	A.Dist.Bone
N	6	6	6	6
Mean	-1.1000	-1.5667	-.9833	-1.4333
Median	-.9000	-2.0000	-1.1000	-1.4000
Std. Deviation	1.15065	.89144	.51543	.95009
Coefficient of Variation	-104.60%	-56.89%	-52.41%	-66.28%

Table 7: Box – Whisker plot



CHAPTER FOUR

CONCLUSION

The short-term outcome of implant treatment in the maxilla has been extensively investigated [Naert et al., 2002(1), Naert et al., 2002(2), Kan et al., 2003, Lorenzoni et al., 2003(1), Lorenzoni et al., 2003(2)]. The present study differs in many respects from previous reports. Only one operator (MP) placed all the implants, comparing two implant systems from one company with distinct structural and topographical differences. A very rigid inclusion/exclusion set of criteria was used in contrast to that used in most of the reports. Probably the most significant difference was that the present study was a prospective one, in contrast to the retrospective nature of many previous investigations.

Outcome Analysis

Biological outcomes of implant-supported restorations in the treatment of partial edentulism were investigated in a longitudinal clinical evaluation [Naert et al., 2002(1)]. A total of 1,956 Brånemark System implants were placed in 660 patients between 1982 and 1998. The results indicated cumulative survival rates of 91.4% for all implants and 95.8% for all restorations over a period of 16 years [Naert et al., 2002(1)]. Neither jaw site nor implant position (anterior/posterior) had any significant effect on the outcomes. The radiographic analysis of the same clinical material, assessing marginal bone height maintenance, confirmed the excellent prognosis of the currently used implants to support restorations in the treatment of partial edentulism [Naert et al., 2002(2)]. More

specifically, no statistically significant differences in bone level change were noted for either anterior or posterior sites or for single-tooth implant restorations or connected implants. The same pattern of crestal bone resorption was observed for implants placed in the anterior maxilla, compared to those replacing maxillary premolars.

Kan and colleagues [Kan et al., 2003] evaluated the feasibility of immediate placement and provisionalization of maxillary anterior single-tooth implants in a prospective 1-year study. Thirty-five patients each with one implant site were included in this study. At 12 months, all implants remained osseointegrated. The mean marginal bone loss was 0.26 ± 0.40 mm in mesial aspect and 0.22 ± 0.28 mm in distal aspect, and the mesial and distal papilla level changes from pretreatment to 12 months were 0.55 ± 0.53 mm and 0.39 ± 0.40 mm, respectively. The results of this study suggest that favorable implant success rates, peri-implant tissue responses, and esthetic outcomes can be achieved with immediately placed and provisionalized maxillary anterior single-tooth implants.

Data collected from patients who were treated with anterior maxillary single-tooth implants according to an immediate loading protocol were published by Lorenzoni and associates [Lorenzoni et al., 2003(1)]. This prospective 1-year study comprised 9 patients who had received 12 Frialit-2 implants. At the 1-year follow-up, all implants were considered successful, revealing a mean coronal bone level change at 6 and 12 months of 0.45 mm and 0.75 mm, respectively. The authors emphasized that successful immediate loading protocols required careful and strict patient selection aimed at achieving the best primary stability and avoiding any excessive functional and nonfunctional loading.

The same group [Loernzoni et al., 2003(2)] also published a comparison of immediately loaded implants (n = 14) and non-loaded implants (n = 28). No implant failures were observed up to the prosthetic restoration 6 months post-placement. The mean bone level changes at prosthetic seating were 0.9 mm resorption for the loaded implants and 0.33 mm for non-loaded implants. This difference was statistically significant.

Clinical survival rate of the implants, and the success of the restorations of the current study were 100% after period of 1 year.

Effects of Implant Design, and Surface Characteristics

In a randomized, prospective 5-year trial, Gotfredsen and Karlsson [2001] evaluated whether there was a difference between machined and TiO2-blasted implants (Astra Tech, Waltham, MA) regarding survival rate and marginal bone loss. Forty-eight implants were placed in the maxilla and 85 were placed in the mandible. Fixed partial dentures were fabricated and each supported by at least one machined and one TiO2-blasted implant. No significant difference in marginal bone loss between the 2 surface groups was found during the 5-year observation period. The cumulative implant survival rates were 100% for the TiO2-blasted implants and 95.1 % for the machined implants.

Khang and coworkers [2001] published results from a randomized controlled trial involving 97 patients that compared dual acid-etched and machined-surface implants in various bone qualities. Of the 432 implants (247 dual acid-etched, 185 machined-surface), 36 implants failed (12 dual acid-etched and 24 machined-surface). The authors concluded that the difference in success rates was most likely attributable to the acid-

etched surface characteristics. The greatest performance difference was observed in the conditions of "poor quality" or "soft" bone, where the 3-year post-loading cumulative success rates were 96.8% (dual acid-etched) and 84.8% (machined-surface).

The clinical effectiveness of implants with either a sandblasted and add-etched (SLA) or a TPS surface was compared by Roccuzzo et al., [2001] in a controlled clinical trial involving 68 SLA and 68 TPS sites (ITI/Straumann). One year after implant surgery, clinical and radiographic measurements were carried out. No significant differences were found with respect to the presence of plaque, bleeding on probing, mean pocket depth, or mean marginal bone loss. It was concluded that SLA implants were suitable for early loading at 6 weeks.

The survival rate of the experimental groups in current study was 100% for each group, and there was no significant difference in the amount of crestal bone resorption on either mesial or distal aspect. These findings correspond with the findings of the above-mentioned studies.

Soft Tissue Stability and Contour Around Anterior Implant Restorations

One common observation in the present study was that the quality and adaptation of temporary crowns as well as permanent crowns, had a major effect on the amount of bone loss, but not much on the papillary height.

Chang and colleagues [1999(1)] carried out a comparative evaluation of crown and soft tissue dimensions between implant-supported single-tooth replacements and the contralateral natural teeth, involving 20 patients with an implant in the esthetic zone of the maxilla and a minimal follow-up of 6 months. The results showed that, in comparison with the natural control tooth, the implant crown was longer, had a smaller

facial-lingual width, was bordered by a thicker facial mucosa, had a lower height of the distal papilla, showed a higher frequency of mucositis and bleeding on probing, and had greater probing depth. With regard to the papillae adjacent to the implant crown, the longitudinal evaluation revealed an improved proximal soft tissue fill.

Jemt [1999] published results from a randomized clinical trial comprising 55 patients with 63 single implants, which aimed to restore the gingival contour by means of provisional resin crowns. The data indicated that the use of provisional crowns may restore soft tissue contours faster than healing abutments alone, but the papillae adjacent to single implant restorations presented similar volume in both groups after 2 years in function. The author focused on the need for more scientific data to evaluate different clinical procedures for optimizing esthetic results in implant dentistry.

The stability of the mucosal topography around 10 anterior maxillary single-tooth implants and adjacent teeth was evaluated by Grunder [2000]. The one year results revealed that soft tissue shrinkage on the facial aspect of the implant crowns was 0.6 mm on average. The soft tissue volume in the papillae area, however, increased on average by 0.375 mm, and none of the involved papillae lost volume. In the present study a similar result was observed. Implant crowns helped to maintain, or even enhance the papillary height.

The effect of intracrevicular restoration margins on peri-implant health around esthetic implants was studied by Giannopoulou and coworkers [2003]. They examined 45 systemically healthy patients with 61 maxillary anterior implants. Clinical, microbiologic, and biochemical parameters were recorded at baseline and again after 3 years. The only statistically significant differences between baseline and follow-up examination

concerned probing pocket depth and DLM (distance between implant shoulder and mucosal margin) measurements, which increased slightly. Based on an observation period of up to 9 years (mean 6.8 years at the time of the follow-up examination), it was concluded that in patients with appropriate oral hygiene, the intracrevicular position of the restoration margin does not appear to adversely affect peri-implant health and tissue stability.

Evaluation of Patient Satisfaction

Visual analogue scale (VAS) scoring of the patients' satisfaction with the appearance of their implant crowns showed a median value of 96%, with a range from 70% to 100% [Chang et al., 1999(1)]. Thus the observed differences between implant crowns and natural teeth may be of minor importance for most patients' subjective appreciation of the esthetic outcome of anterior implant therapy. These findings were confirmed by the same group of authors in a study assessing esthetic outcomes of implant-supported single tooth replacements by the patient and by prosthodontists. [Chang et al., 1999(2)] In fact, parameters considered by professionals to be of significance for the esthetic result of the restorative treatment may not be of decisive importance for the patient's satisfaction. 97.5% satisfaction was obtained at the final stage of current study.

A quality-of life (QOL) assessment was carried out recently in patients with implant-supported and resin-bonded fixed prostheses for bounded edentulous spaces. [Sonoyama, Kuboki et al., 2002] The patients were requested to answer a self-administered QOL questionnaire with 2 major subscales: oral condition-related and general condition-related QOL scores. The authors concluded that multidimensional QOL

levels of patients with an implant-supported fixed prosthesis did not exceed those of patients with a resin-bonded fixed prosthesis in a short follow-up period.

Another retrospective study focused on patient opinion and professionally assessed quality of single-tooth restorations of Brånemark System implants. [Vermylen et al., 2003] Seventy-eight consecutively treated patients received a questionnaire covering esthetics, phonetics, and overall satisfaction. In general, the 48 patients who returned the questionnaire were very positive about these parameters. The additionally performed professional rating after a clinical and radiographic examination revealed that the objective quality-was perfect in 17 cases and acceptable in 25 cases, while 1 crown needed major modification to prevent future complications.

Levi and associates [2003] assessed patients' self-reported satisfaction with maxillary anterior dental implant treatment. Seventy-eight of 123 eligible subjects responded to the mailed, self-administered, structured questionnaire. In this limited investigation, satisfaction with implant position, restoration shape, overall appearance, effect on speech, and chewing capacity was critical for patients' overall acceptance of the dental implant treatment. All the patients participating in this study stated that they would rather receive dental implants in case they have a missing tooth.

Influence of Surgical Techniques

In a 10-year retrospective clinical analysis evaluating the effect of so-called flapless surgery on implant survival and involving 770 implants placed in 359 patients, Campelo and Camara [2002] reported a cumulative success rate that varied from 74% for implants placed in 1990 to 100% in 2000. Considering short-term follow up period for the second group (2 years vs. 10 years for first group), this result should be reported with

caution. The authors stressed the advantages of their approach and considered flapless implant surgery as a predictable procedure, provided patients are selected appropriately and proper surgical technique is meticulously followed. This is a non-factor in our study since one operator placed all the implants, and all the surgeries were performed within a short period of time.

The short term outcome in the present experiment was studied in the esthetic zone. Based on the existing data Belser and coworkers [Belser et al., 2004] concluded that the use of dental implants in the esthetic zone shows the similar survival and success rate to those reported for other segments of jaws.

In conclusion, with single-tooth replacement in esthetic zone without tissue deficiencies, predictable treatment outcomes, including esthetics, can be achieved because of tissue support provided by adjacent teeth. Under the circumstances of the present study, there was no significant differences between the studied surfaces in regard to maintaining the height of crestal bone. Group B (ReplaceSelect Tapered) maintained the height of the distal papillae better that Group A (NobelReplace Tapered groovy implant). No significant difference was observed in the height of mesial papillae between two groups. The above mentioned information supports the alternate hypothesis.

Modification of success and failure criteria for this study might result in different conclusion. The focus of van Streenberghe [1997] criteria for implant success, is clinical survival. Using more strict criteria for success/failure along with strict inclusion/exclusion criteria, seems logical.

It is of great importance to continuously follow the clinical documentation of oral implants. Only properly recorded clinical evidence can tell the true value of an implant

surface [Albrektsson and Wennerberg 2004, Gross et al., 2002]. That is why the future direction for this study could be long-term follow-up of the current subjects and/or recruiting more subjects in such study.

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APPENDIX

CLINICAL REGISTRATIONS FORM

	Pre-treatment	**Implant insertion**	**3 months follow up**	**6 months follow up**	**1 year follow up**	**Permanent prosthetic delivery**
Medical history	X					
Radiographic examinations	X	X	X	X	X	X
Clinical photographs	X	X	X	X	X	X
Flap design		X				
Implant diameter & length		X				
Type of implant site		X				
Planned Implant position		X				
Bone quality & quantity		X				
Implant stability		X		X	X	X
Papilla size		X	X	X	X	X
Status of peri-implant mucosa		X	X	X	X	X
Plaque		X	X	X	X	X

Medical history:	According to case record form.
Radiographic examinations:	For details, please see page 8 .
Clinical photographs:	1:1 right angle view of surgical site with, if applicable, adjacent teeth in picture. The photographs are to be kept at the clinic. Use 35 mm slides film or digital images.
Flap design:	The used flap design is described as: **0** = No flap, if the insertion is made in an extraction site without any incisions. **1** = Flap with/without the use of releasing incisions. **2** = If the incision is made by the use of a punch
Implant diameter & length:	Diameter and length noted in the case record form.
Type of implant site:	Is recorded as: **H** = Healed site, i.e. healed mucosa or **I** = Immediate implant placement.
Bone quality & quantity:	According to case record form.
Implant stability:	According to case record form
Bone grafting:	Bone grafting due to deficient sites is noted as **yes**, with stated material, or **no**.
Soft tissue grafting:	Soft tissue grafting is noted as **yes** or **no**.