Immediate Loading of 4 guided implants supporting a maxillary Overdenture using a Novaloc TiN retention system: Open ended prospective study

NCT06083506

15 Dec 2021

WVU+kc Protocol #: 1801929813
PI: Arif Salman Abdul Shakore

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Section I: Team and Research Summary

Study Team Composition

1) **Principal Investigator** –**Arif Salman Abdul Shakore**, WVU Affiliate, Assistant Professor, Contact information: 1) email address: salman.abdulshakore@hsc.wvu.edu; 2) Office phone: 304-293-7429. Delegated tasks: recruiting; consenting; data collection/analysis; procedures.

Co-Investigator(s) –

DoHeum Choi, DDS

Research Summary

Lay Summary – Complete dentures represent the traditional dental treatment for patients without teeth. However, retention and stability of this type of denture are often lacking, so dental implants are indicated in order to improve the stability of the denture, along with the satisfaction of the patient. Usually, the dental implants are inserted and then a period of 3-6 months is waited before any denture is connected to them. Recent studies have demonstrated that connecting the lower denture to the implants immediately after the implant placement, leads to an improvement in the result, with a social and psychological benefit for the patient. Therefore, the aim of this research project is to evaluate the application of the immediate connections of the implants for the upper dentures. 15-40 patients wearing an upper denture will receive 4 dental implants and the denture will be immediately connected. To simplify the surgical procedure, the implants will be placed without exposing the bone. This surgical technique is called guided surgery. Secondary objective of this research project will be the evaluation of the precision of the implant positioning, using this specific technique. The patients will be followed up for 12 months, for the implant and denture evaluation, as well as the evaluation of patient satisfaction and impact on quality of life through questionnaires.

Study Population – Total number of patients is from a minimum of 15 subjects to a maximum of 40. This research project is aimed at patients who wear a complete maxillary denture and would like to improve its stability with the use of dental implants. Patients will be recruited within WVU dental clinics. Patients identified as potential candidates will be evaluated by the PI and CO-Is. If the patient meets the requirements, the patient will be contacted by the dentist, and PI and Co-Is will be presenting the protocol. The Principal Investigator, Sub-Investigators, and Study Coordinators working closely together to identify potential study participants. If a particular patient is found to meet the inclusion criteria, the PI and or Study Coordinator are alerted so that they may determine eligibility. If eligibility is met, the patient is usually approached by their treating dentist, who may also be the PI or Co-I, and the study introduced during their routine clinic visit.

Study Design – This study will be performed at the WVU School of Dentistry. Total number of patients is from a minimum of 15-40 subjects. Each subject will receive 4 implants. Implants will be placed flapless using a guided surgical protocol and will be immediatelly loaded by means of a NOVALOC TiN retained maxillary overdenture. The patients will be followed up for 12 months, with a total of at least 8 visits (screening, surgery, 1 week, 2 weeks, 4 weeks, 3 months, 6 months, 12 months).

Study Duration – The estimate start of the study is planned to be June 2018. The enrollment of participants will be performed for 2 years, approximately until June 2020. Data collection and analysis will be concluded in June 2021.

Section II: Design

Background & Significance

Since the first application, implant-supported overdentures have been shown to be a reliable and long-term predictable treatment option for completely edentulous patients in terms of both prosthodontic and implant outcomes (Attard, et al., 2004). Besides providing retention and stability, dental implants assist in reducing the impact of tissue borne edentulous prosthesis and are considered the best option when the patient is not able to acquire new muscular patterns and cope with complete dentures (Mericske-Stern, 1994): it has been reported that implant rehabilitations slow the rate of residual ridge resorption (Adell, et al., 1981), increase the masticatory efficiency (Geertaman, et al., 1994) (Mericske-Stern, 1998) and improve the stability and retention of dentures (Jemt, et al., 1996). Moreover, compared to the conventional removable prosthesis, implant overdentures result in an improvement of the general health-related quality of life, with an evident social and psychological impact for the benefit of the patient (Heydecke, et al., 2003). In particular, according to a recent prospective study, patient satisfaction significantly increased for implant-supported maxillary dentures compared with old dentures in all seven OHIP parameters (functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, handicap), as well as for cleaning ability, general satisfaction, ability to speak, comfort, esthetics, and stability (Zembic, Wismeijer 2014).

Nowadays, in edentulous mandibles, two-implant overdentures represent the minimum standard, since they provide excellent long-term success and survival, including patient satisfaction and improved oral functions (Carlsson, 2014). However, on implant-supported maxillary overdentures, consensus or a treatment concept is lacking. Maxillary overdentures can be considered a favorable treatment in cases of insufficient bone volume and complaints about retention and stability of the full denture (Visser, et al., 2009). Based on survival rate studies, 4 endosseous implants are regarded the minimum number needed to support a maxillary overdenture (Rodriguez, et al., 2000) (Jivraj , et al., 2006) (Sadowsky, 2007), with a high implant and prosthetic survival rate (> 95% per year) (Raghoebar, et al., 2014), with either a bar or a ball attachment (Slot, et al., 2010). Regarding the prosthetic components, unsplinted anchorage require less space, are usually easier to clean and more economical, as well as less technique sensitive (Watson, et al., 2001). Moreover, according to recent literature systematic reviews, it seems that there is no significant difference in mean bone loss and success rate between ball or bar-retained overdentures (Trakas, et al., 2006) (Sadowsky, 2007) .

The original Bränemark protocol dictated that the initial phase of implant osseointegration should be at least 4-6 months before any prosthetic restoration is placed (Bränemark, 1983). However, technological advancements have resulted in modern dental implant protocols that provide the possibility to immediately load implants, with the advantage of reducing the length of treatment time and satisfying patient demands (Chung, 2011). In addition, this protocol avoids the recourse of a removable prosthetic whose placement may interfere with healing (Collaert, et al., 2008). In numerous clinical trials, immediate loading has been shown to have excellent survivability and now is deemed a reliable treatment option for edentulism in the mandible, with an overall survival rate greater than 98% (Chiapasco, 2004), both for fixed or removable full restorations. The reported success in immediate loading in the mandible has encouraged the application of a similar treatment in the maxilla. Compared to the mandible, the main factor which has been considered to jeopardize the success for maxillary overdentures is related mainly to poorer bone density (Nordin, et al., 2007). Lekholm and Zarb described maxillary bone as more trabecular and softer in nature (type 3 or type 4), whereas mandibular bone is more cancellous and denser (type 1 or type 2) (Lekholm, et al., 1985). This anatomic difference results in lower primary stability and, in case of immediate loading, may expose the implants to the risk of excessive micromotions (Trisi, et al., 2009) (Javed, et al., 2013): if the implant undergoes micromovements exceeding 150 µm, new bone formation will be prevented and a non-calcified, collagenous poorly vascularized scar tissue will characterize the interface (Brunski, et al., 1979) (Szmukler-Moncler, et al., 2000).

Consequently, these factors advice the use of moderately rough surfaced implants (Sa =1.0-2.0 µm), which lead to higher bone-to-implant contact and higher removal torque values compared to conventional machined surfaces

(Albrektsson, et al., 2004) (Buser, et al., 1998). In addition, these surfaces have been demonstrated to maximize the osteoconductivity of the device (Sul, et al., 2005), allowing an accelerated healing process of the alveolar tissue (Abrahamsson, et al., 2003), due to a mechanism known as de novo bone formation (Davies, 1998) (Berglundh, et al., 2003). For these reasons, moderately rough surfaces find a clinical application in immediate loading protocols and particularly where bone density and quantity are inadequate to achieve the initial stability of implants (Fung, et al., 2011).

According to the recent scientific evidence, provided an optimal primary stability, immediate loading has not been shown to compromise osseointegration in the mandible nor in the maxilla (Olsson, et al., 2003) (Romanos, 2009) (Francetti, et al., 2012) (Vervaeke, et al., 2013). Moreover, some authors confirmed that immediate loading can achieve similar success rates as those observed with early or delayed loading approaches (Chiapasco, 2004) (Chen, et al., 2004) (Avila, et al., 2007) (Ostman, et al., 2008). Experiments that were conducted on animals have been shown that immediate loading can produce greater levels of osseointegration and in some cases a more favorable bone architecture with which to resist functional stress (Neugebauer, et al., 2006) (Romanos, et al., 2003). A recent RCT comparing immediate- and delayed-loading implants supporting a mandibular overdenture reported a statistically significant reduction in marginal bone loss around immediate-loading implants at 12 months, compared to the delayed implants, with no difference in frequency of maintenance visits and prosthetic complications between the groups (Schincaglia, et al., 2016). To the best of our knowledge, no studies have been published about immediate-loaded maxillary overdentures.

Another interesting aspect of immediate loading of implants regards the patient-related outcomes: previous studies in the immediate loading of two dental implants mandibular overdentures showed a substantial improvement in patients' satisfaction and quality of life (Sara, Nikolai e Lesle 2009) (Emami, et al. 2016). The same results would reasonably be expected for immediate-loaded maxillary overdenture.

In order to avoid or limit the need of bone augmentation, reduced diameter implants have been introduced. Narrow implants have been used for different applications, such as limited tooth-to-tooth spacing (Reddy, et al., 2008) (Cordaro, et al., 2006), partially edentulous patients (Barter, et al., 2012) (Romeo, et al., 2006), edentulous mandibles (Flanagan, 2011) and recently also edentulous maxillae (Veltri, et al., 2008) (Hallman, 2001). In particular, a recent study (Cannizzaro, et al., 2007) evaluated the use of reduced diameter implants made of Ti-Zr alloy supporting maxillary overdentures retained with locator abutments: after 12 to 16 months of follow-up, no implants were lost, only one implant showed bone resorption greater than 1.5 mm, with an overall success rate of 97.5% and a survival rate of 100%. In that study, Ti-Zr implants were used, in order to compensate the potential drawback of the reduced diameter titanium implants, that is a lower mechanical strength, with the related risk of fracture, especially at the implant-abutment interface.

During the last decades, particular attention has been focused on the computer–guided and –navigated surgery, with the development of different strategies to transfer the digitally planned implant positions to the patient (Van Assche N, 2012). This methodology has been shown to have numerous advantages: high precision in the implant placement, maximization of bone anchorage to the implant, reduction of surgical time and reduction of patient morbidity (Vercruyssen, et al. 2014). For this reason, nowadays computer-guided surgery is a validated and reliable option for implant placement.

Considered the insufficiency of clinical documentation for immediate loading protocols in maxilla, the aim of this study is to assess the clinical and radiographic performance of Roxolid™ 3.75 mm implants 12 months post-loading supporting a maxillary overdenture, using a flapless guided surgery and an immediate loading protocol.

Objectives

Purpose – The purpose of the study is to evaluate the radiographic, clinical and patient-related outcomes of implant-

retained immediately-loaded maxillary complete dentures..

Null Hypothesis
No difference in the radiographic and clinical parameters between baseline, 6 and 12 months post-operative intervals.

Primary Objective – The primary objective of this study is to evaluate radiographically at 6 and 12 months post-loading the performance of the Roxolid™ BLX 3.75 mm implants placed using a flapless guided surgery and immediately loaded with a maxillary overdenture. The outcome will be evaluated using peri-implant, radiographic bone level changes from baseline to 6 and 12 months post implant placement.

Secondary Objective(s) – The secondary objectives include evaluation of:

- Condition of the peri-implant mucosa (pocket depth and bleeding on probing).
- Implant stability quotient (ISQ) at baseline and 12 months
- Implant survival at 6 months and 1 year
- The nature and the frequency of surgical and prosthetic complications
- Patient-centred outcomes (OHIP 14)
- Accuracy of the implant placement (additional CBCT is required)

Study Design & Methodology

General overview
This study will be performed at the WVU School of Dentistry. Total number of patients is from a minimum of 15/20 subjects. Each subject will receive 4 implants. Implants will be placed flapless using a guided surgical protocol and will be immediatelly loaded by means of a locator retained maxillary overdenture. The study is an Investigator Initiated Project: Straumann accepted to partly sponsor the study, providing some financial support and materials (implants and abutments). Also, study participants will receive $100 as reimbursement for travel expenses for each of the 3 months, 6 months and 12 months recall visits, (visit 6,7,and 8 as per visit schema) for a total of $300 .

Pre-treatment procedures
An initial evaluation will be conducted to determine whether a patient meets the study inclusion criteria. This evaluation will include medical history, clinical examination and radiographic examination (OPT). A pre-operative prosthetic evaluation of the existing prostheses will be made to establish their quality and the need for a new set of complete dentures before the implant placement. The maxillary denture will be used as radiographic guide for the pre-treatment CBCT assessment. The tridimensional image obtained with the CBCT will be used for the surgical planning of the implant positioning by means of a dedicated implant planning software (coDiagnostix, Dental Wings Gbmh, Chemniz Germany)) and a stereo-lithographic surgical guide will obtained.

Surgical procedures
The implants will be inserted under local anesthesia, following consumption of prophylactic antibiotic medications consisting of 2 grams of amoxicillin 1 hour before the surgical procedure. If the patient is allergic to penicillin or penicillin derivatives, clindamycin or other classes of antibiotics will be administered according to ADA guidelines. The implant placement will be performed using the stereo-lithographic surgical guide with a flapless approach, that is no crestal incision and flap elevation is needed. The osteotomy site will be prepared following the drilling sequence provided by the manufacturer surgical manual. The implant will be placed and the maximum value of insertion torque (peak of insertion torque, IT) will be measured during the seating of the most coronal implant threads by means of the surgical unit (W&H, Burmoos, Austria) and recorded as 20, 30, 40, 50 N/cm IT category. In case of IT lower than 20 N/cm the implant will not be immediately loaded; the patient will be excluded from the study and the implant treatment will be completed following the standard delayed protocol. Novaloc TiN abutments will be secured on the implant at 10 N/cm torque.

Prosthetic procedures

The denture will be immediately connected to the implants. The Novaloc TiN cap attachments will be picked up intra-orally using cold curing resin. To avoid contact of the resin with the surgical wound, a circular portion of a sterile rubber dam sheet will be adapted on the cap attachment once placed on the Locator abutment during the pickup procedure. Occlusion is then checked and adjusted if necessary as well as the adaptation on the residual ridges and the patient dismissed. As post-surgical instructions, the patients will be asked not to brush the operated areas and to rinse instead with 0,12% chlorhexidine solution twice a day for 1 minute for 14 days. Pain control is provided with 400 mg ibuprofen, as needed. Soft diet is recommended for 2 weeks. The patients will be instructed not to remove the prosthesis for one week.

Follow-up visits

Patients will be recalled at 1, 2, 4, 12 weeks and 6 months and 12 months after surgery. At the post-operative visit occlusion will be checked, as well as stability and retention of the prostheses and the need for any prosthetic maintenance. Periapical radiographs will be taken at baseline and 6 and 12 months visit by paralleling technique using a Rinn® (Dentsply Rinn, Elgin, Illinois, USA) film holder. The film holder will be indexed on the Locator attachment so that the film position could be reproduced for the follow up radiographs. All patient complaints or any complications resulting from a change in health status from baseline or any implant related complications such as pain, parasthesia or peri-implant infection will be recorded as an adverse event in the CRF and will be monitored until the condition is resolved. OHIP-14 questionnaire will be administered at baseline, at 2 weeks' post-surgery and at 3 months, 6 months and 1 year.

Outcome variables

The following clinical parameters will be considered for treatment evaluation:

Independent Variables

- Patient age
- Patient gender
- Implant length
- Implant position
- Implant insertion torque

Dependent Variables:

- Implant failure/success
- Radiographic bone level change
- Prosthetic complications
- Patient-centered outcomes
- PD
- BoP
- PI (O'Leary 1974)
- KT
- (ISQ analysis)

<u>Implant Failure/Success</u>

The success criteria for the implants will be 1) no radiolucency around the implant, 2) no mobility, 3) no suppuration, pain or ongoing pathologic process. Implant that will not fulfil the success criteria will be considered as failed. The failed implants will be removed and replaced with another implant after 8 weeks of healing of the implant site. The replaced implant will be loaded after 3 months of healing.

<u>Radiographic bone level</u>

Radiographic bone level (RBL) change will be measured on standardized periapical radiographs. A masked examiner will make the bone height measurements. The distance between the implant platform and the most coronal level of the

bone deemed to be in contact with the implant surface will be evaluated. Mesial and distal bone height measurements will be averaged for each implant. The measurements of the bone level at implant placement will be considered as baseline. The RBL change will be calculated in comparison with the baseline value.

Prosthetic complications
The number and nature of prosthetic complications will be recorded as well as the number and nature of any unplanned visit for each group.

Patient-centered outcomes
Patient centered outcomes will be recorded through the Oral Health Impact Profile (OHIP-14), which is a 14-items questionnaire designed to measure self-reported functional limitation, discomfort and disability attributed to oral conditions (Slade 1997). The OHIP-14 has been shown to be reliable (Slade 1997); sensitive to changes (Locker, Jokovic e Clarke 2004) and it has adequate cross-cultural consistency (Allison, et al. 1999).

Accuracy of the guided system
The Software will compare the actual position of the implants with the pre-surgical planned placement. Difference in angulation and depth will be recorded. A second CBCT will be performed immediately after the surgical placement of the implants.

Target Population & Recruitment Methods

The study population consists of 15-40 patients (15 minimum, 40 maximum), male or female ≥ 21 years of age, requiring 4 implants supported maxillary overdenture. The enrollment of patients will be open to a diverse racial and ethnical backgrounds in order to ensure equitable selection.

Inclusion Criteria – Inclusion criteria include:

- Males and females must be at least ≥ 21 years of age
- Fully edentulous maxilla
- The implant site has to be healed for at least 4 months after extraction
- Wearing complete dentures deemed adequate
- Orthopantomogram available (OPT)
- Adequate amount of bone at least at the 2nd premolar position to house a 3.75 x 10 mm implant
- No bone grafting required
- Implant IT ≥ 20 N/cm

Exclusion Criteria – These are both systemic and local exclusion criteria:
Systemic exclusion criteria

- Conditions requiring chronic routine prophylactic use of antibiotics
- Conditions requiring prolonged use of steroids
- History of leukocyte dysfunction and deficiencies
- Bleeding disorders
- History of neoplastic disease requiring use of radiation or chemotherapy
- Metabolic bone disorders
- Uncontrolled endocrine disorder
- Use of any investigational drug or device within the 30-day period prior to implant surgery
- Smoking more than 10 cigarettes a day
- Alcoholism or drug abuse
- Patient infected with HIV

- Condition or circumstances, in the opinion of the investigator, which would prevent completion of study participation or interfere with analysis of study results, such as history of non-compliance, unreliability.

Local exclusion criteria

- Local inflammation including untreated periodontitis
- Mucosal disease such as erosive lichen planus
- History of local irradiation therapy
- Osseous lesion
- Severe bruxism and clenching habits
- Active infection with suppuration or fistula track
- Persistent intraoral infection
- Lack of primary stability <20Ncm. In this instance, the patient must be withdrawn and treated according to the standard protocol.
- Inadequate oral hygiene or unmotivated home care.
- Bone grafting
- Inadequate bone volume for implants insertion as measured on the per-treatment CBCT.

Vulnerable Populations – Since implant therapy is regarded as an elective treatment, no vulnerable populations (children, cognitively impaired individuals, pregnant women and fetuses, prisoners, WVU/UHA/WVUH employees, or WVU students) will be included in the study populations.

Recruitment – Patients will be recruited within WVU Dental Clinics: patients identified as potential candidates will be evaluated by PI and Co-I, in order to verify the possibility to participate in the study. If the patient meets the requirements, PI and Co-I, fully trained according to Human Research Criteria, will be presenting the protocol and consenting the patient. The types of advertisement methods will include flyer and bulletin board. The ads will be placed at: Dental Clinics, Reception areas, Common areas in the Health Science Center. Advertisements clearly state that research is being conducted, the department/agency conducting the research – along with the PI/Co-I contact information, time commitment to the participant, inclusion/exclusion criteria, that participation is voluntary, and that WVU IRB approval is on file.

Risk & Benefit

Risk – The risks for the participants are represented by the possible complications from the surgical procedure, which may include: implant failure, pain; postoperative discomfort; swelling; restricted mouth opening that may last for several days; bleeding; infection requiring additional treatment; stretching of the corners of the mouth resulting in cracking and/or bruising; change in the occlusion (bite); jaw joint pain; fracture of the jaw; injury to nerve branches; numbness or tingling of the lip, gums, cheek that may last for several months.

Benefit – The advantages of implant rehabilitations for the patients include: improved stability and retention of denture; increased masticatory efficiency; slower rate of bone ridge resorption. In particular, according to a recent prospective study, patient satisfaction significantly increased for implant-supported maxillary dentures compared with old dentures in all seven OHIP parameters (functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, handicap), as well as for cleaning ability, general satisfaction, ability to speak, comfort, esthetics, and stability (Zembic, Wismeijer 2014). The single patient may not receive any direct benefit from this study. The knowledge gained from this study may eventually benefit others.

Statistical Analysis Plan

Primary outcome variables will test for normal distribution and two-way Paired t test or Student t-test will be used to compare the means. Descriptive statistics will be used to describe patient population. Non-parametric inferential

statics will be used for ordinal/non-parametric data set. The chosen sample size will provide enough power to deliver significant results.

Data Safety Monitoring – Any information that is obtained as a result of this research will be kept as confidential as legally possible. The research records and test results may be subpoenaed by court order or may be inspected by the study sponsor or federal regulatory authorities without your additional consent. In any publications that result from this research, neither name nor any information from which the patients might be identified will be published without their consent.

Safety Monitoring & Unanticipated Event Reporting

The safety of participants will be monitored during the study by the PI and Co-Is. All the Co-Is will report to the PI. At each visit, the presence of adverse events and unanticipated events will be evaluated and promptly reported to the PI and to the IRB.

Study Duration & Timeline

	Visit 1 Screening and pre-surgical planning	Visit 2 Implant Placement	Visit 3 1 week FU	Visit 4 2 weeks FU	Visit 5 4 weeks FU	Visit 6 3 months FU	Visit 7 6 months FU	Visit 8 12 months FU
Visit Window			IP + 1w	IP + 2w	IP + 4w	IP + 12w (± 7d)	IP + 24w (± 7d)	IP + 12m (± 1m)
Informed consent	✗							
Subject demographics	✗							
Medical/Surgical history	✗							
Inclusion/Exclusion criteria	✗							
Oral examination	✗							
Denture assessment	✗							
CBCT	✗	✗						
Radiographic examination (PA)		✗					✗	✗
Prosthesis connection		✗						
Implant data IT, length		✗						
Condition of periimplant					✗	✗	✗	✗
Soft tissue condition: KG		✗			✗	✗	✗	✗
Plaque	✗	✗			✗	✗	✗	✗
AE/ADE		✗	✗	✗	✗	✗	✗	✗
Implant stability (ISQ)		✗				✗	✗	✗
OHIP14	✗			✗		✗	✗	✗
Clinical photography	✗	✗	✗	✗	✗	✗	✗	✗

Section III: Informed Consent Process

Protected Health Information (PHI)

The patients' PHI will include:

1. **Names**
2. **All geographical information** – this includes street address, city, county, precinct, ZIP code, and their equivalent geocodes.
3. **All elements of dates**– this includes dates directly related to an individual, including birth date, admission date, discharge date, date of death.
4. **Phone and Fax number(s)**
5. **Electronic mail (E-mail) addresses**

Informed Consent Process

The informed consent will be given to the patient first screening visit. The patient will be given the opportunity to ask questions about the research and to receive answers about areas the patient does not understand. The patient will be asked to read the informed consent document carefully and, if necessary, to discuss about the research with family members, primary care physicians or friends before making a decision.

Confidentiality & Privacy

Confidentiality – All data collected will be kept for a minimum of 3 years after the conclusion of the research project. Physical copies of data collected will be locked in a drawer or file cabinet, within a locked room or office. Digital data will be on a password protected database. All participant identifiers will be stored separately from the data collected.

Privacy – The following procedures will be used to protect the confidentiality of the data. The study staff (principal investigator, research coordinator, co-investigators etc.) will keep all study records (including any codes to your data) locked in a secure location in a file cabinet in the office of the principal investigator. Research records will be labeled with a code. The code will be a sequential 3-digit number that reflects how many people have enrolled in the study. A master key that links personal data and codes will be maintained in an electronic file and stored in a password protected computer accessible only by the PI and research personnel. The Informed Consent Form and HIPAA Authorization form will be stored in separate folders away from research data. All electronic files (e.g., database, spreadsheet, etc.) containing identifiable information will be password protected. Any computer hosting such files will also have password protection to prevent access by un-authorized users. Data that will be shared with the authorities of Straumann will be de-identified to help protect your identity. Information regarding your implant treatment, health information such as laboratory test results and dental X-rays are also kept in a dental record which will be stored at the University in a locked cabinet with restricted access. We will do our best to protect the confidentiality of the information we gather from you but we cannot guarantee 100% confidentiality. You should know that the sponsor, Straumann, the Department of Health and Human Services, the Food and Drug Administration, the Health Center's Institutional Review Board and the Human Subjects Protection Office may inspect records. They may inspect records to ensure that the study is being done correctly. Also, if during the course of this study we learn of child, elder, or spousal abuse or of communicable diseases, we are required to report it to State officials.

Section IV: Other Considerations

Conflict of Interest

The PI or Co-I(s) certify that they have no affiliations with or involvement in any organization or entity with any financial interest or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials related to this research project.

Financial Considerations

The study is partly sponsored by STRAUMANN USA, LLC 60 Minuteman Road, Andover, MA 01810. The sponsor will provide specific materials for the study (implants and abutments) and will be paying for the reimbursement of patients' travel expenses (at visit 6, 7 and 8, up to $100 for each).

Publications, Presentations, & References

The results of the research may be presented to meetings, conferences and/or scientific journals interested in publishing data related to this topic, in particular the following scientific journals: Clinical oral implant research, The International Journal of Oral and Maxillofacial Implants, Journal of Clinical Periodontology.

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