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UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES
POSTGRADUATE DENTAL COLLEGE
NAVAL POSTGRADUATE DENTAL SCHOOL
8955 WOOD ROAD
BETHESDA, MARYLAND 20889

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Name of Candidate: Christopher M. Tully
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6/14/21

Keith R. Merchant
PERIODONTICS DEPARTMENT, NAVAL POSTGRADUATE DENTAL SCHOOL
Committee Chairperson

6/11/21

John H. Wilson
PERIODONTICS DEPARTMENT, NAVAL POSTGRADUATE DENTAL SCHOOL
Committee Member

6/11/21

Glen M. Imamura
RESEARCH DEPARTMENT, NAVAL POSTGRADUATE DENTAL SCHOOL
Committee Member

LASER ASSISTED NEW ATTACHMENT PROCEDURE (LANAP): A 12-MONTH OUTCOMES STUDY

by

Christopher M. Tully
Lieutenant Commander, Dental Corps
United States Navy

A thesis submitted to the Faculty of the
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ABSTRACT

Laser Assisted New Attachment Procedure (LANAP): A 12-Month Outcomes Study

Christopher M. Tully, D.D.S.

Thesis directed by: Keith R. Merchant, D.D.S., M.S.
Program Director
Department Of Periodontics

Introduction: As a modern alternative to conventional therapies, the Laser Assisted New Attachment Procedure (LANAP) protocol utilizes an Nd:YAG laser to treat periodontal disease. Purported advantages of LANAP include improved access to root surfaces, more predictable hemostasis, and increased patient acceptance due to a lack of need for conventional surgical flaps and suturing. Despite widespread use of the LANAP protocol, there is limited research that reports on general treatment outcomes, post-operative pain, and rapidity of healing. **Objectives:** The primary purpose of this study is to investigate the clinical healing and resolution of periodontal disease after LANAP by comparing full-mouth clinical measurements at baseline and 12 months after treatment. Secondarily, the study will assess the patient-reported outcome measures of pain and perceived improvement in oral health. **Methods:** Thirty patients with generalized Stage II to Stage IV Periodontitis will be enrolled in the study. Qualifying subjects will have at least 4 sites per quadrant with a probing depth of ≥ 4 mm and bleeding on probing. Full-mouth clinical measurements recorded at baseline, including plaque, probing depth, clinical attachment level, recession, bleeding on probing, purulence, mobility, and furcation involvement, will be compared to measurements gathered 12 months after LANAP therapy. Additionally, after each LANAP procedure, the patient's level of post-operative

pain will be recorded via a visual analog scale (VAS)-based pain questionnaire. Lastly, at baseline, 6, and 12 months after treatment, patient's perceived improvements in their oral health status will be analyzed through an oral health impact profile (OHIP-14) questionnaire. **Results:** This human research study is pending approval by the Institutional Review Board. **Conclusion:** This study will contribute to the body of literature by providing a greater knowledge of objective and patient-reported healing outcomes following LANAP treatment.

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LIST OF ABBREVIATONS

AAP	American Academy of Periodontology
ANOVA	Analysis of Variance
ASA	American Society of Anesthesiologists
B	Buccal
BMI	Body Mass Index
BOP	Bleeding on Probing
CAC	Common Access Card
CAL	Clinical Attachment Level
CAPT	Captain
CO_2	Carbon Dioxide
DB	Distobuccal
DC	Dental Corps
DDS	Doctor of Dental Surgery
DL	Distolingual
DoD	Department of Defense
E1	Evaluation Appointment #1
E2	Evaluation Appointment #2
EDI-PI	Electronic Data Interchange Personal Identifier
Er:YAG	Erbium-doped Yttrium-Aluminum-Garnet
Er,Cr:YSGG	Erbium, Chromium-doped Yttrium-Scandium-Gallium-Garnet
FDA	Food and Drug Administration
FMX	Full Mouth X-rays
h	hour
HbA1c	Glycated Hemoglobin
HCG	Human Chorionic Gonadotropin
HIPAA	Health Insurance Portability and Accountability Act
Hz	Hertz
IL-1β	Interleukin 1 Beta
IRB	Institutional Review Board
IV	Intravenous
J	Joule
L	Lingual
L1	LANAP Therapy Appointment #1
L2	LANAP Therapy Appointment #2
LANAP	Laser-Assisted New Attachment Procedure
LCDR	Lieutenant Commander
LT	Lieutenant
MB	Mesiobuccal
ML	Mesiolingual
µs	microsecond
µm	micrometer
mg	milligram
mm	millimeter

MMP-8	Matrix Metalloproteinase 8
NAVMED	Navy Medicine
Nd:YAG	Neodymium doped Yttrium-Aluminum-Garnet
nm	nanometer
NSAID	Non-steroidal Anti-inflammatory Drug
OA	Osteoarthritis
OHIP	Oral Health Impact Profile
P1	Post-op Appointment #1
P2	Post-op Appointment #2
P3	Post-op Appointment #3
P4	Post-op Appointment #4
P5	Post-op Appointment #5
P6	Post-op Appointment #6
P7	Post-op Appointment #7
P8	Post-op Appointment #8
PD	Probing Depth
PDL	Periodontal Ligament
PHI	Protected Health Information
PI	Plaque Index
RA	Rheumatoid Arthritis
RCT	Randomized Controlled Trial
SRP	Scaling and Root Planing
SSN	Social Security Number
tbsp	tablespoon
TNF-α	Tumor Necrosis Factor alpha
US	United States
VAS	Visual Analog Scale
WRNMMC	Walter Reed National Military Medical Center

CHAPTER 1: Introduction

BACKGROUND

Periodontitis is a common disease of the oral cavity caused by the accumulation of pathogenic bacterial plaque in a susceptible host. Based on data from the National Health and Nutrition Examination Survey from 2009-2014, the estimated prevalence of periodontitis in the United States adult population was 42%, with 7.8% having severe periodontitis.[1] The effects of periodontitis on the oral cavity include inflammation of the periodontal tissues and loss of the supporting structures to the teeth, including the apical migration of the junctional epithelium with subsequent pathologic pocketing, clinical attachment loss, and loss of alveolar bone. The ultimate effect of the loss of this supporting attachment on the tooth is tooth loss. The most common treatment for periodontitis is the removal of the pathogenic bacterial plaque from the root surface through mechanical means, such as scaling and root planing. The gold standard treatment of scaling and root planning involves the removal of bacterial plaque, calculus, and endotoxin from root surfaces in an effort to reduce pathologic periodontal pockets and gain new attachment to the root surface. Yet, there are common anatomic variations that limit the success of scaling and root planing. Accessing areas with deep pockets, furcations, grooves, and/or root concavities is challenging with conventional mechanical instrumentation. For example, the efficacy of scaling and root planing drops dramatically in periodontal pockets deeper than 3.73 mm, and the mechanical instruments used to perform this debridement reach no farther than 5.7 to 8.3 mm.[2] Thus, alternative or adjunctive treatments that do not rely on a purely mechanical means of removal, such as systemic antibiotics, locally-delivered antimicrobials, and/or laser therapy, have been proposed in order to overcome the limitations of scaling and root planing.

LASER PHYSICS

The first working laser was created by Theodore Maiman in 1960.[3] Maiman's laser was a solid-state pink ruby laser and was successfully fired on May 16, 1960. He subsequently documented the invention and described the science and technology behind the laser. Since that time, many other lasers have been developed and laser technology has rapidly expanded to include many applications in the medical field. The LASER acronym stands for Light Amplification by Stimulated Emission of Radiation. Light is a form of electromagnetic radiation that can behave as both a wave and a particle, with the basic unit of light being the photon. Laser light is different from ordinary light in that it is monochromatic, coherent, and collimated.[4] The laser light's wavelength and amplitude define the characteristics of the wave of photons emitted from the laser. Quantum theory was first theorized by Max Planck in 1900 and applied to the atomic structure by Niels Bohr. In this theory, it was proposed that when the electrons of an atom absorb a quantum, they are excited to a temporarily higher energy state. From this higher energy state, the electron will subsequently relax to its preferred lower resting energy state and release the quantum in a process called spontaneous emission. In 1916, Albert Einstein theorized that if an additional photon with the same energy level was to travel in the field of the excited atom, an additional quantum could be released, resulting in a coherent wave of two photons, a phenomenon he termed stimulated emission. If this process of stimulated emission was to continue, additional atoms would be energized to the higher energy state and identical photons of the same wavelength would be released. The total population of energized atoms could become greater than the non-energized atoms, a term called population inversion. To maintain this state, a constant energy supply is necessary to maintain this excitation. One common mechanism to achieve this in laser

technology is amplification, achieved through the reflection of the photons back and forth in an active medium.[4] The subsequent monochromatic, coherent, and collimated beam of light emitted by the laser is a form of electromagnetic radiation described by the electromagnetic spectrum. This spectrum can be described by the wavelength of the specific energy and ranges from gamma rays at one end to radio waves at the other end of the electromagnetic spectrum. Gamma rays have very small wavelengths (10^{-10} meters) and radio waves have very large wavelengths (thousands of meters). The dividing line between ionizing and non-ionizing radiation is at the junction of ultraviolet and visible light on the electromagnetic spectrum (approximately 390 nm). This distinction is important because ionizing radiation is generally considered harmful to human tissues in that it can produce charged atoms that have a mutagenic effect, whereas non-ionizing radiation is not considered harmful. All currently available lasers for dental therapy are of the non-ionizing type.[4]

Dental lasers have similar components that are shared between different laser types. These shared features include an optical cavity, active medium, reflective mirror and partially transmissive mirror or medium, excitation source to activate a medium, cooling system, and focusing lenses. The laser types are commonly named according to their active medium, which is the core of the optical cavity that contains chemical elements, materials, or compounds. The active medium can either be a gaseous media, a solid rod of garnet crystal grown with combinations of other elements, or a solid-state semiconductor wafer made with multiple layers of metals.[4]

Lasers also have a variety of operation or emission modes. The most common emission modes include continuous wave, gated/superpulsed, and free-running pulsed

modes. The continuous wave mode is the delivery of a continuous and constant energy source. Gated or superpulsed modes are varieties of the continuous mode in that there is an electronic control or mechanical gate that helps to minimize the length of time the laser energy is being delivered to help minimize any undesirable thermal effects of continuous wave modes. Finally, the free-running pulsed mode operates through true pulses produced by a flashlamp that also minimizes any undesirable effects of continuous wave modes.[4]

When encountering matter, laser light interacts with it through a variety of mechanisms. Laser light can be transmitted, scattered, reflected, or absorbed when it reaches a specific type of matter. Transmission is the general movement of the electromagnetic radiation through a material. Scatter is witnessed when the material that the electromagnetic radiation passes through causes the radiation to deviate from a straight trajectory to one or more alternate paths. Reflection is seen when the electromagnetic radiation is returned by a surface, without change in wavelength and with no effect on the material. Absorption occurs when matter takes up the photon's energy and transfers the electromagnetic energy to internal atomic structure. Absorption is also the mechanism that produces the primary therapeutic effect of the laser energy. Absorptive potential depends on the wavelength and frequency of the light and the nature of the atoms in the target object. When such characteristics are complementary, light will be absorbed. In contrast, light will be transmitted, scattered, or reflected when a less than complementary relationship exists between the light and the object. The concept of selective absorption of laser energy by different tissues explains why each type of laser displays a unique clinical effect in dental structures. In summary, the performance of a

laser depends on its degree of absorption, which is influenced largely by the specific tissue components (such as water, proteins, and/or pigments) and their degree of interaction with a laser's pre-determined wavelength.[5]

In tissue, particularly dental tissues, the main determinant of the laser's performance is its absorption coefficient in water. Lasers can be broadly categorized by penetration potential through their interaction with water. Superficially absorbed lasers (e.g., CO_2 and Erbium lasers) are highly absorbed in water found in the outermost layers of the tissues, and thus do not readily energize deeper structures. Deeply penetrating lasers, such as the Nd:YAG laser, are minimally absorbed in water and more capable of penetrating beyond the superficial structures.

The degree of tissue response to laser energy is also dependent on absorption. After absorption, the electromagnetic energy is converted into internal energy stored by the atoms that absorb the electromagnetic energy. This internal, low-level laser energy storage initially affects the tissue through non-thermal, bio-stimulatory effects. These interactions are theorized to promote a positive influence on biological processes such as cell proliferation and differentiation, reduction of inflammation, pain relief, and wound healing.[5] As the energy absorbed by the tissue rises, the high-level laser energy transitions from non-thermal interactions to temperature-dependent photo-thermal effects. The consequences of increased temperature include hyperthermia at >37 °C, inactivation of non-sporulating bacteria at >50 °C, coagulation and protein denaturation at >60 °C, tissue welding at 70-80 °C, vaporization at 100 °C, and carbonization at >200 °C.[4]

ND:YAG AND LANAP

In 1961, Snitzer published the prototype of the Nd:YAG laser, which was further developed by Geusic in 1964.[3] Several manufacturers of the Nd:YAG laser gained FDA 510(k) clearance for use in dental surgery. All of the available Nd:YAG dental lasers have indications for incising, excising, and coagulating oral soft tissue, and several have gained clearance for use in non-surgical pocket therapy.[5] However, only one manufacturer (Millennium Dental Technologies) and one specific laser (PerioLase MVP-7) has produced evidence of human histologic periodontal regeneration with the Nd:YAG laser when used with a prescribed treatment protocol.[6,7] The specific non-surgical pocket therapy protocol that led to this aforementioned regeneration was developed by Gregg and McCarthy in 1990. They termed the therapy LANAP (Laser Assisted New Attachment Procedure) and formulated a set of specific criteria for the protocol that received FDA clearance in 2004. Several subsequent studies by Yukna[7], McAllister[8], Nevins[9], and Harris[10] have reported positive effects after treatment with the LANAP protocol. In addition, studies by Yukna in 2007 and by Nevins in 2012 showed evidence of human histologic regeneration following LANAP therapy.[6,7] These were instrumental in paving the way for the PerioLase MVP-7 to gain approval by the FDA in 2016 as the only device in medicine and dentistry that mediates true regeneration.[11]

The Nd:YAG laser's medium is a crystal of ytrrium, aluminum, and garnet doped with neodymium. It has a characteristic wavelength of 1,064 nm and is classified as a deeply-penetrating type of laser. The specific penetration depth ranges from 0.5 to 4.0 mm, but varies as a function of optical scattering, minimal absorption and reflection, and the mode of delivery.[3] The tissue ablation mechanisms of the superficially absorbed lasers are almost purely due to the photo-thermal mechanism of absorption. However,

deeply penetrating lasers, such as the Nd:YAG, have a different primary mode of ablation that involves secondary thermal effects that lead to coagulation and vaporization of the contacted tissues.[5] Following superficial ablation with the Nd:YAG laser, thermal changes can occur in the surrounding tissues, but due to the inherent depth of penetration, a relatively thick coagulation layer and subsequently strong hemostasis is observed following Nd:YAG laser use.[5] While the ability to energize the tissues beyond the superficial layer can be beneficial, the impact of the laser energy on root cementum and dentin, periosteum, and bone has unknown consequences. Specifically within the scope of non-surgical pocket therapy, the inappropriate use of the Nd:YAG laser has shown the potential for thermal damage to the tooth root, resulting in carbonization, melting, and/or resolidification. However, the Nd:YAG is safe and effective when used in accordance with established safety guidelines.[5] Other generally positive effects of the Nd:YAG laser include bactericidal effects through preferential absorption in pigments found in pathogenic bacterial species such as *Porphyromonas gingivalis*, a member of the black-pigmented bacteria family. In addition, lasers have been shown to inactivate toxic non-cellular bacterial substances such as lipopolysaccharide, a potent initiator of the inflammatory host response.[5] Lastly, a characteristic of the Nd:YAG laser that is shared with other lasers is the potential for biostimulation, and due to its deeply penetrating nature, the theoretical biostimulatory effects are greater than other laser types.[4]

Lasers have several advantages in treating periodontal disease over traditional non-surgical and surgical treatments. These include easier ablation of soft tissues, increased coagulation and hemostasis, tissue surface sterilization due to bactericidal effects, improved access and visibility, a lack of need for suturing, and increased patient

acceptance.[12] In non-surgical laser pocket therapy, there are some suggested advantages that are not consistently supported throughout the literature, including decreased post-operative pain and tooth hypersensitivity, decreased recession, and improved healing.[11] Additionally, when used with the LANAP protocol, the Nd:YAG laser has a remarkable predilection for regeneration that can be attributed to the laser energy being selectively absorbed by diseased tissues and pigmented bacteria, and by the thermal fibrin clot that secures the contents of the pocket entrance and restricts movement of the epithelium apically.[11]

Despite widespread use of the Nd:YAG laser, clinical studies documenting the positive benefits over conventional therapy have been limited, and this scarcity of evidence has been reflected in the conclusions of historical publications and consensus statements. In 2006, the AAP commissioned a review by Cobb who reported that there was insufficient evidence to declare any particular laser therapy superior to conventional modes of treatment.[12] In 2009, Slot performed a systematic review evaluating the effect of a pulsed Nd:YAG laser as a monotherapy or as an adjunctive periodontal pocket treatment for chronic periodontitis patients, and concluded that there was no evidence to support the superiority of the Nd:YAG laser.[3] In 2011, the AAP released a statement on the efficacy of lasers in the non-surgical treatment of inflammatory periodontal disease, concluding that any adjunctive method of curettage has little benefit over SRP alone, and that lasers were unpredictable in their ability to reduce subgingival bacterial loads beyond SRP alone.[13] In an effort to bolster the limited clinical evidence in the body of literature, Qadri published three RCT's that showed an adjunctive benefit of the Nd:YAG laser in reducing probing depth, periodontal inflammatory indices, and markers over SRP

alone.[14-16] Additionally, Gómez compared adjunctive Nd:YAG laser therapy + SRP to SRP alone and found no differences in clinical or microbial parameters, but did find that levels of inflammatory biomarkers (IL-1β and TNF-α) were significantly lower in the laser therapy group at 4 and 8 weeks after treatment.[17] Eltas (2012) investigated the 9-month post-operative differences between SRP + Nd:YAG laser and SRP alone, finding that the SRP + Nd:YAG laser group had significantly greater reduction of GI, PD, and attachment loss. In addition, the levels of IL-1β and MMP-8 were lower in the adjunctive laser group.[18] In a 9-month prospective case series that included 8 subjects treated with LANAP, Nevins reported an overall PD reduction in 73% of sites (average of 4.62 mm to 3.14 mm) and CAL gain in 58% of sites (average of 5.58 mm to 4.66 mm). When sites with initial probing depths of ≥ 5 mm were compared, probing depth reduction was noted in 88% of sites (6.50 mm to 3.92 mm) and CAL gain was seen in 74% of sites (average of 7.42 mm to 5.78 mm).[9] Due to the increase in published evidence supporting adjunctive laser treatment, the AAP released a best evidence consensus statement that updated their position on laser therapy.[19] They concluded that adjunctive laser therapy might provide a modest additional benefit of less than 1 mm in PD and CAL measurements compared to SRP alone. In addition, they highlighted that evidence suggested superior results in deeper pockets of ≥ 7 mm when adjunctive Er:YAG or Nd:YAG therapy was employed.

Focusing on the possibility of regeneration in humans following non-surgical laser therapy, Yukna (2007) and Nevins (2012) published the only two studies that report regeneration with the Nd:YAG laser and the LANAP protocol.[6,7] Yukna treated pairs of single-rooted teeth in a split-mouth study of six subjects exhibiting moderate to severe

periodontitis.[6] The test group received SRP + Nd:YAG laser energy to the inner pocket wall of all teeth, followed by an additional application of the laser to seal the pocket. After 3 months of healing, the laser treated sites revealed new cementum and connective tissue attachment while the control sites frequently exhibited a long junctional epithelium without signs of new attachment or regeneration.[6] In 2012, Nevins also published a case series of eight subjects in which he performed LANAP therapy with the Nd:YAG laser, and was able to show histologic evidence of periodontal regeneration with new cementum, PDL, and alveolar bone in 50% of the treated sites.[7] Although limited, such results show the promising nature of LANAP treatment in the field of periodontics.

While there have been several reports of Nd:YAG laser therapy showing beneficial effects in the treatment of periodontitis, few studies have evaluated patients treated with the full LANAP protocol. Therefore, the primary purpose of this study is to investigate the magnitude of periodontal disease resolution after full LANAP therapy by reporting changes in plaque scores, gingival bleeding on probing, gingival purulence, probing depth, gingival recession, tooth mobility, fremitus, furcation involvement, and clinical attachment level. Secondary purposes are to evaluate the subjects' self-reported outcome measures of pain and improvement in oral health via the visual analog scale (VAS) and the Oral Health Impact Profile-14 (OHIP-14), respectively.

CHAPTER 2: Materials and Methods

This Walter Reed National Military Medical Center (WRNMMC) study is currently under review by the Institutional Review Board (IRB). Pending approval, the following study design will be utilized by the Periodontics Department at the Naval Postgraduate Dental School.

STUDY DESIGN

This 12-month outcomes study will evaluate the clinical healing and self-reported outcome measures of post-operative pain and perceived improvement in oral health status after treatment with the LANAP protocol. The study population will consist of 30 male or female military healthcare beneficiaries, 18 years or older, who present with generalized stage II-IV periodontitis with the following inclusion criteria:

Inclusion Criteria:

- ≥ 18 years old with ASA Physical Status Classification of 1-3
- Generalized stage II-IV periodontitis (grade A, B, or C)
- At least 4 sites per quadrant with PD ≥ 4 mm with BOP
- At least 5 teeth per quadrant
- Ability to complete full-mouth LANAP therapy within one month
- Ability to complete all follow-up visits spanning a minimum of 1 year

Exclusion Criteria:

- Currently pregnant and/or lactating
- History of periodontal surgery within 12 months or SRP within 3 months
- Presence of any number of dental implants

- Presence of any acute periodontal infections (e.g., periodontal abscess, necrotizing gingivitis, necrotizing stomatitis, perio-endo lesions, acute herpetic gingivostomatitis) at time of enrollment
- History of systemic steroid use within 3 months of proposed enrollment
- History of systemic antibiotic use within 3 months of proposed enrollment
- Allergy to any mandatory post-operative medications

STUDY TIMELINE

- **First Visit (E1):** Initial evaluation, periodontal charting, and full-mouth x-rays (FMX). Treatment plan presentation and enrollment of patient in study (can be concurrent with E1). Patient completes baseline OHIP-14 form in person.
- **Second Visit (L1) Day 0**: LANAP surgery – first half-mouth. Patient given 1st VAS questionnaire to take home.
- **Third Visit (P1) Day 7-14 following L1**: Post-operative visit for first half-mouth and occlusal adjustment first side. 1st VAS questionnaire collected.
- **Fourth Visit (L2) Day 7-28 following L1**: LANAP surgery – second half-mouth (can be concurrent with P1). Patient given 2nd VAS questionnaire to take home.
- **Fifth Visit (P2) Day 7-14 following L2**: Post-operative visit for second half-mouth and occlusal adjustment second side. 2nd VAS questionnaire collected.
- **Sixth Visit (P3) 1 month following L2**: Full-mouth polish, occlusal adjustment, and impressions for occlusal guard.
- **Seventh Visit (P4) 2 months following L2**: Full-mouth polish, occlusal adjustment, and occlusal guard delivery.

- **Eighth Visit (P5) 3 months following L2**: Periodontal maintenance and occlusal adjustment.
- **Ninth Visit (P6) 6 months following L2**: Periodontal maintenance and occlusal adjustment. Patient completes 6-month OHIP-14 form in person.
- **10th Visit (P7) 9 months following L2**: Periodontal maintenance and occlusal adjustment.
- **11th Visit (P8 + E2) 12 months following L2**: Periodontal re-evaluation, charting, FMX **(E2)**. Periodontal maintenance and occlusal adjustment **(P8)**. Patient completes 12-month OHIP-14 form in person.

  * All evaluation visits (E1 and E2), LANAP procedure visits (L1 and L2), and post-operative visits (P1-8) will be performed by a periodontist or periodontal resident who is either a fully trained LANAP clinician or is being directly (in the treatment room) supervised by a fully trained LANAP clinician.

STUDY METHODOLOGY AND PROCEDURES

1st Periodontal Evaluation/Charting (E1)

1. Vitals/History/Subjective Assessment: The patient will be seated in the operatory and have vitals taken (blood pressure, pulse, and/or temperature as applicable). The patient's medical history, surgical history, family history, social history, current medications, and allergies will be reviewed to ensure no contraindications exist. The patient's level of pain (0/10 scale) and chief complaint will be recorded.

2. Radiographs: An updated FMX must be available to include a panoramic x-ray taken within the last three years, a complete set of vertical bitewings taken within the last six months, and a complete set of periapical films taken within the last six months. If any of the radiographs are not available, they will be captured prior to the full-mouth periodontal exam. To minimize angulation and/or positioning errors, all radiographs will be captured with the aid of XCP-DS® devices for holding the digital sensor and XCP-ORA® arms and rings for ideal positioning and alignment.
3. Full-mouth Periodontal Exam: An extraoral and intraoral exam will be performed. Plaque control will be assessed with the aid of an erythrosine disclosing agent, and the plaque score will be subsequently recorded on the *Plaque Control Record* (NAVMED 6600/1). A full-mouth periodontal exam including probing depth, clinical attachment level, bleeding on probing, presence of purulence, and recession at six sites per tooth will be recorded with the aid of a UNC-15 probe. Tooth mobility (Miller Classification), fremitus (presence/absence), and furcation involvement (Glickman Classification) will be assessed and recorded. The examination will be performed by a periodontist or periodontal resident and recorded on the *Perio Charting Form* (NAVMED 6600/2).

Treatment Plan Presentation and Patient Enrollment

1. Treatment Plan Presentation: The patient will be seated in the operatory and/or conference room. Findings from the periodontal evaluation will be explained and all periodontal diagnoses and prognoses will be reviewed with the patient. The

patient's treatment options, including possible LANAP therapy, will be presented. If the patient elects to proceed with LANAP treatment and meets the inclusion criteria for the study, the option for participation in the study will be discussed.

2. Enrollment: The patient will be informed of the research study protocol and sign the required consent forms prior to the start of treatment *(Research Consent and HIPAA Form).*
3. OHIP-14 (Baseline) Form: The patient will fill out the *OHIP-14 Form* in the waiting room prior to dismissal and the form will be filed in the research log.

LANAP Surgery Procedure (L1) – Day 0

1. Informed Consent/Surgical Timeout: The patient will be seated in the operatory and have pre-operative vitals taken. The patient's medical history, surgical history, family history, social history, current medications, and allergies will be reviewed to ensure no contraindications exist to the planned anesthesia and/or procedure. Informed consent for the procedure and/or sedation will be obtained from the patient with a discussion of risks, benefits, and potential complications of the procedure, both verbally and in writing. The universal protocol checklist will be completed, including a pre-procedural patient and treatment verification, and a surgical time out. The consent and universal protocol will be recorded on the *LANAP Procedure Consent Form.*
2. Pre-medication: The patient will swish with a 0.12% chlorhexidine gluconate (Peridex) oral rinse for 30 seconds. The patient will pre-medicate with one tablet

of 800 mg oral ibuprofen as long as no contraindications exist to the use of NSAID's.

3. Sedation (if applicable): If the anesthetic plan includes minimal sedation (anxiolysis) with oral medication, minimal sedation with nitrous oxide, or moderate sedation/analgesia (conscious sedation) and the patient is a female, the patient will be administered an hCG test. If the pregnancy test is positive, the patient will be informed of the result and the procedure will be cancelled. If the pregnancy test is negative, the planned anesthesia and procedure may proceed as scheduled. Utilization of sedation for all genders will be based upon the unique needs of each individual patient.
4. Local Anesthesia: The area to be treated will be anesthetized with a suitable local anesthetic by infiltration (not in papillary tissues) and/or block anesthesia.
5. Bone Sounding: After sufficient analgesia, baseline bone sounding measurements from the free gingival margin to the crest of the alveolar bone will be recorded for six sites per tooth (MB, B, DB, ML, L, and DL) and recorded on the *LANAP Bone Sounding and Energy Delivery Form*. Once bone sounding measurements are completed, the total energy dose safety range will be calculated and recorded on the *LANAP Bone Sounding and Energy Delivery Form*. The method for calculating the safe range of energy delivery is based on the bone sounding measurements collected, and is described in the comprehensive training program that is required for all LANAP clinicians.
6. Fiber Cleavage and PerioLase Nd:YAG Laser Settings: The proper settings of the laser include the following parameters: 100-650 μs pulse duration, 4.00 Watts of

power, and a 20 Hz repetition rate. In order to assure consistent energy delivery throughout treatment, the 360 μm-diameter laser fiber is cleaved at the onset of treatment and again after treatment of approximately three teeth. Verification of the power output is completed after each cleaving event and before beginning therapy. A properly cleaved fiber is vital for proper transmission of the laser energy through the distal end of the fiber. The method for fiber cleavage is described in the comprehensive training program that is required for all LANAP clinicians. A successful cleave of the fiber will result in the appearance of a uniformly round shape of red light that represents the aiming beam for guidance during active laser treatment.

7. First Pass - PerioLase Nd:YAG Laser: Using an appropriately cleaved laser fiber oriented parallel to the long axis of the tooth, a gingival trough in the most superficial gingival tissue is created with the goal of removing the internal epithelial pocket lining and any bacterial plaque or pathologic proteins in a "crown-down" approach. After trough creation, the accumulated proteins on the tip of the laser fiber create the "hot-tip effect", allowing continued excision into deeper areas of the pocket to the maximum accessible depth. This process will continue until all teeth have been circumferentially treated. It is important to note that adjacent areas of the same interproximal papilla should not be successively energized in order to allow full dissipation of laser energy. The energy parameters used during the first pass of the Nd:YAG are recorded on the *LANAP Bone Sounding and Energy Delivery Form.*

8. SRP and Blunt Dissection: The teeth will be thoroughly scaled and root planed with piezo-ultrasonic instrumentation and hand curettes. The root preparation will be performed from the coronal aspect of the teeth to the level of crestal bone until the roots are smooth and without visual or tactile evidence of calculus. The pockets will be irrigated well with sterile saline. After mechanical root preparation is complete, the crestal bone at the tooth surface interface will be scraped until bleeding is noted from the crestal bone.
9. Fiber Cleavage and PerioLase Nd:YAG Laser Settings Adjustment: The proper settings adjustment for the laser include the following parameters: 650 µs pulse duration, 4.00 Watts of power, and a 20 Hz repetition rate. As previously described, verify the power output of the laser fiber after cleaving and before beginning therapy.
10. Second Pass PerioLase Nd:YAG Laser: Using an appropriately cleaved laser fiber oriented parallel to the long axis of the tooth, a second pass with the laser is initiated in a "crown-up" approach from the apical extent of the bony defect to the gingival margin. At the end of the second pass, there should be visible evidence of a satisfactory clot present in all treated teeth. The energy parameters used during the second pass of the Nd:YAG are recorded on the *LANAP Bone Sounding and Energy Delivery Form.*
11. Compression: The gingival tissues will be compressed against the tooth surfaces to thin the clot using wet, gloved fingers for approximately 3 minutes.
12. Occlusal adjustment: Occlusal adjustment will be performed in a dry field using the LANAP criteria. Double-thick articulating paper will be used to mark the

occlusal contacts in maximum intercuspation and excursive mandibular movements. After adjustment of occlusion, the teeth will be polished to a clinically acceptable surface smoothness.

13. Periodontal Dressing: A periodontal dressing (Coe-Pak) will be used for all active smokers and/or when deemed clinically necessary by the clinician for patient comfort.
14. Post-operative Instructions: Written and verbal post-operative instructions will be given following treatment with customized recommendations that will promote success for each unique patient.
    1. **Prescriptions:** The following drugs will be prescribed in a standardized manner after reviewing the patient's allergies and medical history.
        a) Pain medication consisting of any of the following alone or in combination:
            i. Ibuprofen 800 mg – 1 tablet every 6-8 hours
            ii. Acetaminophen 325 mg – 1 to 2 tablets every 4 hours
        b) Antibiotics consisting of any of the following alone:
            i. Amoxicillin 500 mg – 1 tablet every 8 hours for 8 days
            ii. Clindamycin 300 mg – 1 tablet every 8 hours for 8 days
            iii. 0.12% Chlorhexidine Gluconate – 1 tbsp. twice daily for 2 weeks
    2. **Diet:** Diet should be limited to soft foods until the P1 appointment and possibly longer as dictated by the patient's healing progress. Chewing

should be directed to the side of the dentition opposite of the side of surgery.

3. **Oral Hygiene:** There should be no brushing, flossing, irrigation, or other mechanical cleansing of the teeth on the side of surgery until after the P1 appointment and possibly longer as dictated by the patient's healing progress. Plaque control will be managed through the use of twice daily rinsing with 0.12% chlorhexidine gluconate.
4. **Physical Activity:** There should be no strenuous physical activity for 72 hours following LANAP treatment.
5. **Smoking:** Smoking should be discontinued for as long as possible after LANAP treatment.

15. VAS Questionnaire to Patient: The patient will be given the appropriate questionnaire *(VAS Pain Form Right Side or VAS Pain Form Left Side)* to complete at home. The completed form will be returned at the P1 appointment.

1st Post-Operative Appointment (P1) – Day 7-14

1. Vitals/History/Subjective Assessment: The patient will be seated in the operatory and have vitals taken as described previously. The patient's medical history, surgical history, family history, social history, current medications, and allergies will be reviewed. The patient's level of pain (0/10 scale) and chief complaint will be recorded.

2. VAS Questionnaire Submitted by Patient: The completed VAS questionnaire *(VAS Pain Form Right Side or VAS Pain Form Left Side as applicable)* will be filed in the research log.
3. Occlusal Adjustment: Any areas with increased tooth mobility, fremitus, and/or asymmetrical gingival healing will be considered for a possible occlusal adjustment as previously described.
4. Objective Exam and Assessment: An extraoral and intraoral exam will be performed noting the pattern of healing and any complications from treatment. Complications will be documented and treated appropriately.

LANAP Surgery Procedure (L2) – Day 7-28

1. Informed Consent/Surgical Timeout: As described previously in L1
2. Pre-medication: As described previously in L1
3. Sedation (if applicable): As described previously in L1
4. Local Anesthesia: As described previously in L1
5. Bone Sounding: As described previously in L1
6. Fiber Cleavage and PerioLase Nd:YAG Laser Settings: As described previously in L1
7. First Pass PerioLase Nd:YAG Laser: As described previously in L1
8. SRP and Blunt Dissection: As described previously in L1
9. Fiber Cleavage and PerioLase Nd:YAG Laser Settings Adjustment: As described previously in L1
10. Second Pass PerioLase Nd:YAG Laser: As described previously in L1
11. Compression: As described previously in L1

12. Occlusal Adjustment: As described previously in L1
13. Periodontal Dressing: As described previously in L1
14. Post-operative Instructions: As described previously in L1
15. VAS Questionnaire to Patient: The patient will be given the appropriate questionnaire *(VAS Pain Form Right Side or VAS Pain Form Left Side)* to complete at home. The completed form will be returned at the P2 appointment.

Second Post-Operative Appointment (P2) – 7-14 days following L2

1. Vitals/History/Subjective Assessment: As described previously in P1
2. Objective Exam and Assessment: As described previously in P1
3. Occlusal Adjustment: As described previously in P1
4. VAS Questionnaire Submitted by Patient: As described previously in P1

Third Post-Operative Appointment (P3) – 1 month following L2

1. Vitals/History/Subjective Assessment: As described previously in P1
2. Impressions for Occlusal Guard Fabrication: An occlusal guard will be fabricated by the dental laboratory utilizing maxillary and mandibular alginate impressions along with a bite registration. Details of the laboratory submission will be recorded.
3. Occlusal Adjustment: As described previously in P1
4. Supragingival Polish: A full-mouth supragingival polishing will be performed with a rubber cup and prophy paste.
5. Objective Exam and Assessment: As described previously in P1

Fourth Post-Operative Appointment (P4) – 2 months following L2

1. Vitals/History/Subjective Assessment: As described previously in P1
2. Objective Exam and Assessment: As described previously in P1
3. Supragingival Polish: As described previously in P3
4. Occlusal Adjustment: As described previously in P1
5. Delivery of Occlusal Guard: The occlusal guard will be adjusted in order to achieve proper fit, patient comfort, and function. Upon delivery, the final contacts of the occlusal guard should include bilateral pinpoint contacts in centric relation and narrow protrusive and laterotrusive contact by the anterior teeth.

Fifth Post-Operative Appointment (P5) – 3 months following L2

1. Vitals/History/Subjective Assessment: As described previously in P1
2. Objective Exam and Assessment: As described previously in P1
3. Perio Maintenance: Plaque control will be assessed with the aid of a disclosing agent and subsequently recorded on the *Plaque Control Record* (NAVMED 6600/1). Oral hygiene instructions will be given to patient and a full-mouth supragingival scaling will be performed with ultrasonic and/or hand instrumentation, along with a full-mouth polishing with a rubber cup and prophy paste.
4. Occlusal Adjustment: As described previously in P1

Sixth Post-Operative Appointment (P6) – 6 months following L2

1. OHIP-14 (6-month) Form Completed by Patient: The patient will complete the *OHIP-14 Form 6-Month* in the waiting room prior to the dental appointment. The completed form will be filed in research log.
2. Vitals/History/Subjective Assessment: As described previously in P1
3. Objective Exam and Assessment: As described previously in P1
4. Perio Maintenance: As described previously in P5
5. Occlusal Adjustment: As described previously in P1

Seventh Post-Operative Appointment (P7) – 9 months status following L2

1. Vitals/History/Subjective Assessment: As described previously in P1
2. Objective Exam and Assessment: As described previously in P1
3. Perio Maintenance: As described previously in P5
4. Occlusal Adjustment: As described previously in P1

Eighth Post-Operative Appointment (P8) and Second Periodontal Evaluation/Charting Appointment (E2) – 12 months following L2

1. OHIP-14 (12-month) Form Completed by Patient: The patient will complete the *OHIP-14 Form 12-Month* in the waiting room prior to the dental appointment. The completed form will be filed in research log.
2. Vitals/History/Subjective Assessment: As described previously in P1
3. Radiographs: An updated FMX will be captured to document the status of the dentition following LANAP treatment. To minimize angulation and/or positioning errors, all radiographs will be captured with the aid of XCP-DS® devices for

holding the digital sensor and XCP-ORA® arms and rings for ideal positioning and alignment.

4. Full-Mouth Periodontal Exam: As described previously in E1
5. Perio Maintenance: Full-mouth supragingival scaling will be performed with piezo-ultrasonic instrumentation and hand curettes. Subgingival scaling and root planing with will be limited to select areas with PD ≥ 5 mm with BOP and/or purulence. Full-mouth polishing will be performed with a rubber cup and prophy paste.
6. Occlusal Adjustment: As described previously in P1

DATA COLLECTION

As subjects are enrolled in the study, they will be assigned a chronological patient number (1-30) based on their date of enrollment. The patient number will be cross-referenced to an electronic spreadsheet (*LANAP Subject PII Master List*) that contains the patient's full name, date of birth, DOD identification number, last 4 digits of social security number, phone number, email address, and home address. The *LANAP Subject PII Master List* will be maintained in the principal investigator's locked office on a CAC-enabled, password-protected, government desktop computer. This digital file will serve as the master copy that links a subject's PII to their data and contact information. Only the principal investigator will have access to the master list. The data from all physical forms gathered throughout the study will be linked to the patient number only. Any additional data collection will also be linked exclusively to the patient's number. The corresponding data from necessary documents will be transferred to an electronic spreadsheet (*LANAP Data Collection Sheet)* and the physical documents will be stored in

a locked drawer along with the corresponding consent form. The individual *LANAP Data Collection Sheet* will contain the following information:

1. Patient Demographics:
    a. Sex (male, female)
    b. Age (numerical variable)
    c. Race (American Indian or Alaskan Native, Asian, African American, Native Hawaiian or other Pacific Islander, White, Hispanic, Latino, Other Race, or two or more races).

    *This information will be collected from a patient questionnaire.
2. Medical History:
    a. Anticoagulant use (no, yes (vitamin K antagonist), yes (direct oral anticoagulant), yes (LMWH), yes (antiplatelet), yes (multiple drug classes))
    b. Smoking status (never, current light smoker < 10 cigs/day, current heavy smoker ≥ 10 cigs/day, former smoker, current smokeless tobacco use, current vape or e-cigarette use)
    c. Diabetic status (no, yes (Type 1 with controlled HbA1c < 8), yes (Type 1 non-controlled HbA1c ≥ 8), yes (Type 2 controlled HbA1c < 8), yes (Type 2 non-controlled HbA1c ≥ 8))
    d. BMI (underweight < 18.5, normal 18.5-24.9, overweight 25.0-29.9, class I obesity 30.0-34.9, class II obesity 35.0-39.9, class III obesity ≥ 40)
    e. Arthritis (no, yes (RA), yes (OA), yes (both RA and OA))
    f. Inflammatory bowel disease (yes, no)

g. Osteoporosis (yes, no)

h. Bisphosphonate use (current, former, never)

*This information will be collected from a combination of the patient questionnaire and a medical record review.

3. Full-mouth Clinical Variables:

    a. The Plaque Control Record Index is documented at E1, P5, P6, P7, and E2. The presence or absence of plaque on mesial, distal, facial, and lingual surfaces at the gingival margin is noted. The index is calculated by dividing the number of plaque-containing surfaces by the total number of surfaces.

    b. An overall bleeding score is recorded at E1 and E2. The bleeding score is calculated by dividing the number of bleeding sites by the total number of sites.

4. Site-level Clinical Variables:

    a. Probing depth (PD) for individual sites is recorded at E1 and E2. Measured at six sites per tooth, PD is calculated by measuring the distance from the free gingival margin to the base of the periodontal pocket.

    b. Clinical Attachment Level (CAL) for individual sites is recorded at E1 and E2. Measured at six sites per tooth, CAL is calculated by measuring the distance from the cemento-enamel junction to the base of the periodontal pocket.

c. Recession (REC) for individual sites is recorded at E1 and E2. Measured at six sites per tooth, REC is calculated by measuring the distance from the cemento-enamel junction to the free gingival margin.

d. Bleeding on Probing (BOP) for individual sites is recorded at E1 and E2. Measured at six sites per tooth, BOP is recorded as positive or negative based on the presence or absence of bleeding after withdrawal of the UNC-15 probe from the base of the pocket during PD measurements.

e. Furcation Involvement (FI) for individual sites is recorded at E1 and E2. Measured at three sites per maxillary molar (mesial (M), buccal (B), and distal (D)), and two sites per mandibular molar (buccal (B) and lingual (L)), FI is measured with a Nabers probe utilizing grading criteria described by Glickman (Grade 0-4).

5. Tooth-level Clinical Variables:

   a. Individual tooth mobility is recorded at E1 and E2 using the classification described by Miller (Class 0-4).

   b. Individual tooth fremitus is recorded at E1 and E2. Fremitus is recorded as positive or negative based on the presence or absence of palpable or visible mobility of the tooth when subjected to occlusal forces.

6. Treatment complications:

   Treatment complications will be recorded during the objective evaluations by the treating periodontist or periodontal resident as follows:

   a. Excessive bleeding during or after LANAP (L1 or L2)

   b. Unretrievable broken fiber tip during LANAP

c. Newly diagnosed irreversible pulpitis or pulpal necrosis within 60 days of LANAP (L1 or L2)
d. Post-operative infection requiring surgical intervention or additional antibiotics within 14 days of LANAP (L1 or L2)
e. Development of soft tissue necrosis with exposure of underlying alveolar bone following LANAP (L1 or L2)

7. OHIP-14 Questionnaire: OHIP-14 responses will be collected from patient questionnaires in order to evaluate perceived improvements in oral health.
8. VAS Questionnaire: VAS responses will be collected from patient questionnaires in order to evaluate pain following LANAP treatment.

DATA ANALYSIS

The data analysis plan includes the use of descriptive statistics to analyze and compare patient demographics and medical history information for the patients enrolled. In addition, paired t-tests will be used to compare the means and standard deviations of clinical variables measured at baseline and 12 months. The clinical variables to be analyzed include: full-mouth (plaque control record index and overall bleeding score), tooth-level (tooth mobility and fremitus), and site-level (probing depth, clinical attachment level, recession, bleeding on probing, and furcation involvement) clinical variables, respectively. With regard to the post-operative pain questionnaires completed after each LANAP therapy visit, descriptive statistics will be used to analyze the patient reported pain levels. Lastly, the repeated measures analysis of variance (ANOVA) statistical procedure will be utilized to analyze the patient's perceived improvement in oral health via OHIP-14 questionnaires collected at baseline, 6 months, and 12 months.

CHAPTER 3: Results/Discussion

This human research clinical outcomes study is still pending approval by the WRNMMC Institutional Review Board. The anticipated data gathered from the collection of clinical variables measured at baseline and 12 months will allow for assessment of the typical healing response following LANAP. While there has been at least one study outlining healing after treatment with the LANAP protocol,[9] the overall number of patients enrolled were relatively low, and the clinical measurements were limited to probing depth, clinical attachment level, and recession. This study will not only provide data related to how LANAP influences PD, CAL, and recession, but also add additional information related to secondary variables (e.g., mobility, fremitus, and FI) not measured in previous studies. The one-year data gathered in this study may be used to compare LANAP with other conventional therapies employed for the treatment of periodontal disease. Conventional therapies of interest for comparison include scaling and root planing, osseous surgery, and modified Widman flap.[20] In addition, through the collection of baseline demographic and medical history, the impact of specific factors, such as smoking status, diabetic status, or BMI, may be analyzed to determine if there is an effect on the LANAP healing response. The patient-reported outcome measures of pain and perceived improvements in oral health will be measured through the VAS and OHIP-14 questionnaires, respectively. The collection of this information will provide insight into the patient's overall experience with LANAP therapy and their perceived changes in oral health.

APPENDIX A

OHIP-14 FORM (Baseline) **Patient #_____**

Please circle one number for each question.

Scale: 0 = never, 1 = hardly ever, 2 = occasionally, 3 = fairly often, 4 = very often

Functional limitations					
Have you had trouble *pronouncing any words* because of problems with your teeth, mouth or dentures?	0	1	2	3	4
Have you felt that your *sense of taste* has worsened because of problems with your teeth, mouth or dentures?	0	1	2	3	4
Physical pain					
Have you had *painful aching* in your mouth?	0	1	2	3	4
Have you found it *uncomfortable to eat any foods* because of problems with your teeth, mouth, or dentures?	0	1	2	3	4
Psychological discomfort					
Have you been *self-conscious* because of your teeth, mouth, or dentures?	0	1	2	3	4
Have you *felt tense* because of problems with your teeth, mouth or dentures?	0	1	2	3	4
Physical disability					
Has your *diet been unsatisfactory* because of problems with your teeth, mouth, or dentures?	0	1	2	3	4
Have you had to *interrupt meals* because of problems with your teeth, mouth, or dentures?	0	1	2	3	4
Psychological disability					
Have you found it *difficult to relax* because of problems with your teeth, mouth, or dentures?	0	1	2	3	4
Have you been a bit *embarrassed* because of problems with your teeth, mouth, or dentures?	0	1	2	3	4
Social disability					
Have you been a bit *irritable with other people* because of problems with your teeth, mouth, or dentures?	0	1	2	3	4
Have you had *difficulty doing your usual jobs* because of problems with your teeth, mouth, or dentures?	0	1	2	3	4
Handicap					
Have you felt that life in general was *less satisfying* because of problems with your teeth, mouth, or dentures?	0	1	2	3	4
Have you been *totally unable to function* because of problems with your teeth, mouth, or dentures?	0	1	2	3	4

APPENDIX B

OHIP-14 FORM (6 mos. POT) Patient #_____	Please circle one number for each question. Scale: 0 = never, 1 = hardly ever, 2 = occasionally, 3 = fairly often, 4 = very often				
Functional limitations Have you had trouble *pronouncing any words* because of problems with your teeth, mouth or dentures?	0	1	2	3	4
Have you felt that your *sense of taste* has worsened because of problems with your teeth, mouth or dentures?	0	1	2	3	4
Physical pain Have you had *painful aching* in your mouth?	0	1	2	3	4
Have you found it *uncomfortable to eat any foods* because of problems with your teeth, mouth, or dentures?	0	1	2	3	4
Psychological discomfort Have you been *self-conscious* because of your teeth, mouth, or dentures?	0	1	2	3	4
Have you *felt tense* because of problems with your teeth, mouth or dentures?	0	1	2	3	4
Physical disability Has your *diet been unsatisfactory* because of problems with your teeth, mouth, or dentures?	0	1	2	3	4
Have you had to *interrupt meals* because of problems with your teeth, mouth, or dentures?	0	1	2	3	4
Psychological disability Have you found it *difficult to relax* because of problems with your teeth, mouth, or dentures?	0	1	2	3	4
Have you been a bit *embarrassed* because of problems with your teeth, mouth, or dentures?	0	1	2	3	4
Social disability Have you been a bit *irritable with other people* because of problems with your teeth, mouth, or dentures?	0	1	2	3	4
Have you had *difficulty doing your usual jobs* because of problems with your teeth, mouth, or dentures?	0	1	2	3	4
Handicap Have you felt that life in general was *less satisfying* because of problems with your teeth, mouth, or dentures?	0	1	2	3	4
Have you been *totally unable to function* because of problems with your teeth, mouth, or dentures?	0	1	2	3	4

APPENDIX C

OHIP-14 FORM (12 mos. POT) Patient #_____	Please circle one number for each question. Scale: 0 = never, 1 = hardly ever, 2 = occasionally, 3 = fairly often, 4 = very often				
Functional limitations Have you had trouble *pronouncing any words* because of problems with your teeth, mouth or dentures?	0	1	2	3	4
Have you felt that your *sense of taste* has worsened because of problems with your teeth, mouth or dentures?	0	1	2	3	4
Physical pain Have you had *painful aching* in your mouth?	0	1	2	3	4
Have you found it *uncomfortable to eat any foods* because of problems with your teeth, mouth, or dentures?	0	1	2	3	4
Psychological discomfort Have you been *self-conscious* because of your teeth, mouth, or dentures?	0	1	2	3	4
Have you *felt tense* because of problems with your teeth, mouth or dentures?	0	1	2	3	4
Physical disability Has your *diet been unsatisfactory* because of problems with your teeth, mouth, or dentures?	0	1	2	3	4
Have you had to *interrupt meals* because of problems with your teeth, mouth, or dentures?	0	1	2	3	4
Psychological disability Have you found it *difficult to relax* because of problems with your teeth, mouth, or dentures?	0	1	2	3	4
Have you been a bit *embarrassed* because of problems with your teeth, mouth, or dentures?	0	1	2	3	4
Social disability Have you been a bit *irritable with other people* because of problems with your teeth, mouth, or dentures?	0	1	2	3	4
Have you had *difficulty doing your usual jobs* because of problems with your teeth, mouth, or dentures?	0	1	2	3	4
Handicap Have you felt that life in general was *less satisfying* because of problems with your teeth, mouth, or dentures?	0	1	2	3	4
Have you been *totally unable to function* because of problems with your teeth, mouth, or dentures?	0	1	2	3	4

APPENDIX D

Visual Acuity Pain Score (Left Side)

Patient #_____

Please rate your average pain experienced on each day

Day 0 (Day of Surgery – 2 hours after procedure until midnight)

Day 1 (1st Day after Surgery)

Day 2 (2nd Day after Surgery)

Day 3 (3rd Day after Surgery)

Day 4 (4th Day after Surgery)

Day 5 (5th Day after Surgery)

Day 6 (6th Day after Surgery)

APPENDIX E

Visual Acuity Pain Score (Right Side)

Patient # _____

Please rate your average pain experienced on each day

Day 0 (Day of Surgery – 2 hours after procedure until midnight)

Day 1 (1st Day after Surgery)

Day 2 (2nd Day after Surgery)

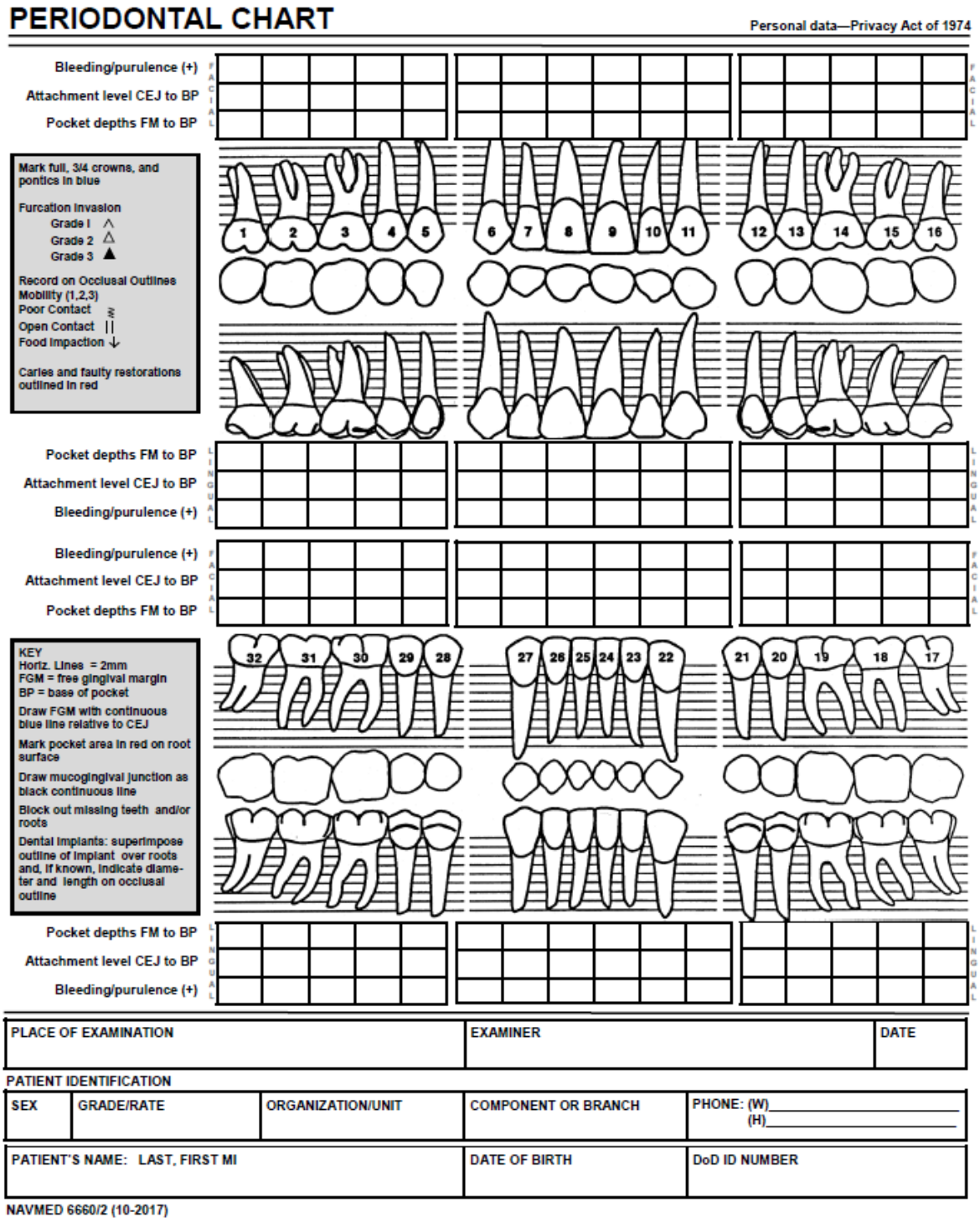
Day 3 (3rd Day after Surgery)

Day 4 (4th Day after Surgery)

Day 5 (5th Day after Surgery)

Day 6 (6th Day after Surgery)

APPENDIX F


PERIODONTAL CHART
Personal data—Privacy Act of 1974
Bleeding/purulence (+)
Attachment level CEJ to BP
Pocket depths FM to BP
FACIAL
Mark full, 3/4 crowns, and pontics in blue
Furcation Invasion
Grade I
Grade 2
Grade 3
Record on Occlusal Outlines
Mobility (1,2,3)
Poor Contact
Open Contact
Food Impaction
Caries and faulty restorations outlined in red
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16
Pocket depths FM to BP
Attachment level CEJ to BP
Bleeding/purulence (+)
LINGUAL
Bleeding/purulence (+)
Attachment level CEJ to BP
Pocket depths FM to BP
FACIAL
KEY
Hortz. Lines = 2mm
FGM = free gingival margin
BP = base of pocket
Draw FGM with continuous blue line relative to CEJ
Mark pocket area in red on root surface
Draw mucogingival junction as black continuous line
Block out missing teeth and/or roots
Dental implants: superimpose outline of implant over roots and, if known, indicate diameter and length on occlusal outline
32 31 30 29 28 27 26 25 24 23 22 21 20 19 18 17
Pocket depths FM to BP
Attachment level CEJ to BP
Bleeding/purulence (+)
LINGUAL
PLACE OF EXAMINATION
EXAMINER
DATE
PATIENT IDENTIFICATION
SEX
GRADE/RATE
ORGANIZATION/UNIT
COMPONENT OR BRANCH
PHONE: (W)
(H)
PATIENT'S NAME: LAST, FIRST MI
DATE OF BIRTH
DoD ID NUMBER
NAVMED 6660/2 (10-2017)

APPENDIX G

PLAQUE CONTROL RECORD

Personal data—Privacy Act of 1974

D 1 2 3 4 5 6 7 8 F M F 9 10 11 12 13 14 15 16 D
L L
D 32 31 30 29 28 27 26 25 L M L 24 23 22 21 20 19 18 17 D
F F

PREVIOUS INDEX__________ PRESENT INDEX__________ DATE____________

D 1 2 3 4 5 6 7 8 F M F 9 10 11 12 13 14 15 16 D
L L
D 32 31 30 29 28 27 26 25 L M L 24 23 22 21 20 19 18 17 D
F F

PREVIOUS INDEX__________ PRESENT INDEX__________ DATE____________

D 1 2 3 4 5 6 7 8 F M F 9 10 11 12 13 14 15 16 D
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D 32 31 30 29 28 27 26 25 L M L 24 23 22 21 20 19 18 17 D
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PREVIOUS INDEX__________ PRESENT INDEX__________ DATE____________

D 1 2 3 4 5 6 7 8 F M F 9 10 11 12 13 14 15 16 D
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D 32 31 30 29 28 27 26 25 L M L 24 23 22 21 20 19 18 17 D
F F

PREVIOUS INDEX__________ PRESENT INDEX__________ DATE____________

D 1 2 3 4 5 6 7 8 F M F 9 10 11 12 13 14 15 16 D
L L
D 32 31 30 29 28 27 26 25 L M L 24 23 22 21 20 19 18 17 D
F F

PREVIOUS INDEX__________ PRESENT INDEX__________ DATE____________

PATIENT IDENTIFICATION

SEX	GRADE/RATE	ORGANIZATION/UNIT	COMPONENT OR BRANCH	PHONE: (W)__________ (H)__________

PATIENT'S NAME: LAST, FIRST MI	DATE OF BIRTH	DoD ID NUMBER

NAVMED 6660/1 (10-2017)

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