

**PERIODONTAL STATUS OF WOMEN ON HORMONAL CONTRACEPTIVES
VISITING MATERNAL CHILD HEALTH AND FAMILY PLANNING CLINIC AND
YOUTH CLINIC AT KENYATTA NATIONAL HOSPITAL**

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V60/74381/14

**A THESIS SUBMITTED IN PARTIAL FULFILLMENT FOR THE AWARD OF THE
DEGREE OF MASTER OF DENTAL SURGERY IN PERIODONTOLOGY OF THE
UNIVERSITY OF NAIROBI**

DECLARATION

I declare that this thesis is my original work and has not been presented for the award of a degree in any other university.

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DEDICATION

I dedicate this thesis to my parents Laxmi and Ram Naresh Saini. You are my inspiration to pursue knowledge and success in life with your unconditional love, support and strength.

ACKNOWLEDGEMENT

Foremost, I thank God for giving me positive direction to pursue my MDS degree to completion.

I thank the University of Nairobi for this opportunity and Chairman of the Department of Dental sciences for the administrative support.

I express profound gratitude to my supervisors for their consistent teaching throughout the process from beginning to completion. I am very grateful for their tireless patience, guidance and encouragement thanks to which this is a reality.

My appreciation goes to the staff at the Maternal Child Health and Family planning clinic, Youth Clinic at Kenyatta National Hospital for their support while carrying out the research.

Finally I thank my family for being my academic champions throughout this journey.

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LIST OF ABBREVIATIONS

- WHO - World Health Organization
- AAP - American Academy of Periodontology
- NHANES - National Health and Nutrition Examination Survey
- PMNL - Polymorphonuclear leucocytes
- GCF - Gingival Crevicular Fluid
- PMA - Performance Monitoring for Action
- CEJ - Cemental Enamel Junction
- PD - Probing Depth
- GI - Gingival Index
- PS - Plaque Score
- KDHS - Kenya Demographic Health Survey
- APHRC - African Profile and Health Research Centre

ABSTRACT

Introduction

Periodontal disease is a form of oral disease commonly including gingivitis and periodontitis. The primary etiologic factor for periodontal disease is microbial plaque, however the disease is multifactorial and modified by various factors including female sex steroid hormones. Hormonal contraceptives based on these hormones may influence the periodontal disease in women. Thus, the periodontal health of women on hormonal contraceptives must be understood to improve knowledge on hormonal contraceptives.

Objective

The objective of this study was to investigate periodontal status of women on hormonal contraceptives visiting the Maternal Child Health and Family Planning Clinic and Youth Clinic at Kenyatta National Hospital.

Materials and Methods

This was a descriptive cross-sectional study with an analytical component conducted among 218 women aged 18-45 years who were recruited using systematic random sampling. A questionnaire was administered to collect socio-demographic details and oral hygiene practices. The mode and duration of hormonal contraceptive was obtained from records and full mouth clinical examination carried out to determine the periodontal status. The clinical parameters investigated included plaque score (PS), gingival index (GI) and clinical attachment loss (CAL) calculated to determine periodontitis. The data was analyzed using SPSS. Spearmans correlation test and logistic regression analysis was carried out.

Results

The mean age of the women was 33.3 years and the implant mode of hormonal contraceptive was the most dominant (56.9%) followed by the oral pill (20.6%). The gingival status showed a mean gingival index of 1.36 and majority of the women (77.5%) had moderate gingivitis. The mean clinical attachment loss was 3.23mm and majority(65.1%) of the women had mild periodontitis. Logistic regression showed a statistically significant relationship between injectable and implant modes of hormonal contraceptives and periodontitis. It was noted the women on injectable (OR=4.16, $p=0.005$) and implants (OR=2.73, $p=0.020$) had higher odds of periodontitis than women on oral pills. There was a positive correlation between mode of hormonal contraceptive and periodontitis ($\rho=0.208$, $p=0.002$) where implants and injectables correlated to increased severity of periodontitis. The duration of hormonal contraceptive use and periodontitis also showed a positive correlation ($\rho=0.240$, $p<0.001$) where the women who had used hormonal contraceptives for a longer period were more likely to exhibit periodontitis.

Conclusion

The women on hormonal contraceptives had mild to moderate forms of periodontitis and gingivitis respectively. The use of the injectable and implant mode of hormonal contraceptives particularly for longer durations had adverse effects on the periodontal health of the women.

CHAPTER ONE: INTRODUCTION AND LITERATURE REVIEW

1.1 INTRODUCTION

Oral diseases related are known to affect 3.9 billion people globally ¹. The diseases commonly include dental caries and periodontal diseases amongst others. Reports from WHO indicate that severe periodontitis is the sixth most prevalent disease worldwide and the global burden of severe periodontitis is shown to be on a predictable increase ^{2,3}. Periodontal disease is one of the common forms of oral disease that is largely preventable and it broadly includes gingivitis and periodontitis. In Kenya, dental caries is known to be the commonest cause of tooth loss at 52.6%, followed by periodontal disease at 27.6%⁴. Broadly, up to 90% of the Kenyan population suffers from gingivitis and 1-10% suffers from chronic periodontitis ⁵.

Periodontal diseases are complex, involving an immunoinflammatory response due to perio pathogenic microbes. The ongoing discoveries of various clinical, microbiological, genetic and radiographic investigations have improved the understanding of periodontal diseases and the disease is currently considered as a multifactorial disease. Microbial plaque has been identified as the primary etiologic factor in periodontal disease however sex steroid hormones are known to act as a modifying or aggravating factor in the disease ^{6,7}. Hence periodontal diseases as a result of the interaction with sex steroid hormones is classified as conditioned enlargement under enlargement associated with systemic conditions or as gingival diseases modified by medications such as oral contraceptives based on the hormones ⁸.

The variations in the levels of female sex steroid hormones influence the endocrine status of women through various stages of their life. This in turn affects not only the systemic health of women but also their oral health⁹. Hormonal contraception based on these sex steroid hormones were introduced in the early 1900s with oral contraceptives being introduced in the 1960s. They contained high doses of estrogens (150 ug) and progestins (9.85 mg) and multiple epidemiologic research on these hormonal contraceptives demonstrated to have adverse effects on the systemic health and periodontal health of women¹⁰.

Consequently, the modern hormonal contraceptives rely on effective, lowered doses of the hormones but majority of the information on the effects of the hormonal contraceptives on the periodontium is based on the older high dose formulations. Various studies on women using the current low dose formulations also report higher levels of gingival inflammation, increased pocket depth and attachment loss^{11, 12}. Furthermore the research conducted on current low dose formulations of hormonal contraception tends to focus largely on oral contraceptives however the Kenyan population shows a very high use of the injectable and implant forms of hormonal contraception^{13,14}. The contraception prevalence rate in Kenya is persistently high with documented increase in hormonal contraception over the years, yet limited information is available on the periodontal health of Kenyan women on hormonal contraceptives.

The purpose of this study was to investigate the periodontal health of women on the current low dose hormonal contraceptives in the Kenyan population. This information will update the knowledge regarding the effects of hormonal contraceptives on the periodontium of women regionally. The knowledge will allow informed education of

women regarding the use of hormonal contraceptives and their periodontal health and will also serve as a basis of improved and efficient periodontal management of patients by dentists during treatment.

1.2: LITERATURE REVIEW

1.2.1 Overview of Periodontal Diseases

The normal periodontium refers to the structures supporting the teeth during function. The principal components of the periodontium include the gingiva, periodontal ligament, cementum and alveolar bone which function as single harmonious unit. Periodontal disease is an inflammatory process of the gingival tissues and/or periodontal membrane of the teeth, which when left untreated results in gingival recession, deep periodontal pockets, loss of supporting alveolar bone causing tooth loss and masticatory failure¹⁵.

Periodontal diseases broadly encompass a group of diseases and conditions, with the most common being gingivitis and periodontitis. Gingivitis is the early phase of inflammation of gingiva without loss of connective tissue. When this inflammatory process persists, there is subsequent clinical attachment loss which is the hallmark of Periodontitis.

Microbial plaque is the primary etiological factor in periodontal diseases. These microorganisms cause destruction of periodontal tissues directly and indirectly by eliciting a host immune response that contributes to the destructive pathway. Hence periodontal disease is as a result of the inflammatory response of the host immune system to the periodontal pathogens found in microbial plaque⁷.

However bacterial plaque is not the sole determinant of the nature of periodontal disease. A multitude of genetic, systemic and environmental factors influence the interaction between the microbes and host immune response. This is a key determinant in disease progression and clinical manifestations.

Currently periodontal disease is understood as a multifactorial disease involving local, genetic, systemic and environmental modifying factors¹⁶. Comprehensive literature review, shows that female sex steroid hormones influence the pathogenesis of periodontal diseases and hormonal contraceptives are also under research. This is evident in the American Association of Periodontology (AAP) 1999 classification of periodontal diseases includes the following disease categories: Puberty associated gingivitis, Pregnancy associated gingivitis and under gingival diseases modified by medications specifically oral contraceptive associated gingivitis⁸.

Worldwide the epidemiologic burden shows periodontal disease as the 12th most prevalent pathology with a slightly higher burden in the female sex and elderly. An update on the prevalence of periodontitis in adults in the United States in the NHANES 2009 – 2012 reported that 46% of adults representing 64.7 million people had periodontitis, with 8.9% having severe periodontitis.

In Kenya, Kaimenyi reported that 0.2 - 90% of the Kenyan population suffers from gingivitis and 1-10% suffers from chronic periodontitis⁵. Recently, the Kenya National Oral Health survey 2015 among 1,462 adults and 2,298 children reported that gingival inflammation was found in 98.1% of the persons examined. The prevalence of gingival inflammation in the age group 35- 44 years was 96.1% and with respect to gender the prevalence of gingivitis amongst the males and females was 98.4% and 97.7% respectively¹⁷.

1.2.2 Sex Steroid Hormones and Periodontal health

The female sex steroid hormones play an important role in periodontal health and disease and this effect on the periodontal tissues has been studied extensively over years. The hormones, estrogen and progesterone are responsible for changes in the oral cavity during specific phases of life of women as early as puberty, during pregnancy and even in menopause.

The physiological changes in these sex steroid hormones in women during puberty, menstruation and pregnancy appear to be a modifying factor for the response of the gingiva to dental plaque ¹⁸.

Clinical observations suggested the effect of female sex steroid hormones on the periodontium. The process of tissue specificity hormone localization and identification of the hormone receptors identified that periodontal tissues are target sites for these female sex steroid hormones estrogen and progesterone¹⁹. The receptors were located in the periosteal fibroblasts, scattered fibroblasts of the lamina propria, periodontal ligament (PDL) fibroblasts and osteoblast like cells in bone²⁰.

The mechanism of action of the hormones on the periodontal tissues is directly through the receptors and indirectly by altering the microvascular topography, microbial flora and the host inflammatory response²¹.

Estrogen influences the cytodifferentiation of stratified squamous epithelium, decreases keratinization thus reducing the effectiveness of the epithelial barrier to microbial insult. It increases the cellular proliferation in blood vessels, increases the gingival inflammation without increase in plaque, stimulates Polymorphonuclear leucocytes

(PMNL) phagocytosis and stimulates the proliferation of gingival fibroblasts and connective tissue.

Progesterone increases vascular dilatation and permeability, increases production of PMNL and prostaglandin E2 (PGE2) in gingival crevicular fluid (GCF). It inhibits collagen synthesis in PDL fibroblast and gingival fibroblast proliferation. The alteration in collagen production causes reduced repair and maintenance of the periodontium.

During puberty, elevated levels of the hormones increase gingival inflammation without increase in plaque levels and can increase the prevalence of *Prevotella Intermedia* and *Capnocytophaga* species implicated in periodontal disease. The metabolites of the hormones provide nutritional requirements to the pathogens enabling their proliferation. In menstruation the hormonal peak levels are associated with increased gingival exudates, gingival edema and bleeding. A longitudinal study in 1972 first demonstrated a relationship between puberty and the development of gingivitis in 127 children between 11-17 years. A similar study by Nakagawa showed a significant increase in gingival inflammation and the proportion of specific periopathogens during puberty and the findings were correlated to the increased levels of estrogen and progesterone. The severity of the inflammatory reaction decreases during adulthood despite the persistence of local factors²².

The most noted hormone related oral changes are seen in pregnancy and were first described by Pinard in 1877. Gingivitis in pregnancy ranges between 30 to 100% of pregnant women and the severity of gingivitis varies with the hormonal levels during pregnancy. The symptoms usually increase from the 2nd to 3rd trimester and then abruptly reduce after parturition with reduced levels of the hormone production²³.

Clinical manifestations range from increased gingival bleeding, increased probing depths, tooth mobility and pyogenic granulomas. The bacterial hormonal interaction during pregnancy may change the composition of plaque with increased levels of P. intermedia with increased levels of estrogen and progesterone²⁴.

The pregnancy associated pyogenic granuloma is due to the exaggerated inflammatory response to the local factors. The effects have been earlier classified as gingival enlargement associated with systemic condition or conditioned enlargement⁸.

All these effects of the female sex steroid hormones on the gingival vasculature, microflora, immune response and specific cells exaggerates the gingival response to microbial plaque and alters the pattern and severity of periodontal disease. This strongly indicates the modifying role of female sex steroid hormones in the development of gingivitis and periodontitis that may be independent of the dental plaque²⁵.

1.2.3 Hormonal Contraceptives and Periodontal health

Hormonal contraceptives are agents based on the effects of the female sex steroid hormones estrogen and progesterone. Hormonal contraceptives for women were researched in the early 1900s and the first hormonal contraceptive pill named Enovid was approved in 1961. These contraceptives contained high doses of estrogen (150 ug) and progestin (9.85 mg). Several epidemiologic studies identified the high risk of systemic adverse effects with the high dose formulations. Initial studies on the effects of high dose formulation oral pills on the periodontal health were first started on experimental animals and subsequent clinical studies in humans demonstrated

increased GCF flow, gingival inflammation and Bacteroides species in these women. These studies linked oral contraceptive use to gingival diseases and that it also depended on duration of use. By 1990s, all these unwanted side effects resulted in the modification of the high dose hormonal contraceptives to the current low dose hormonal contraceptives with 20-35 ug/day estrogen and 0.5-1.0 mg/day progestin²⁶.

However, even with low dose hormonal contraceptives there is evidence of the effects of oral contraceptive pills on the gingival status and periodontal health of women. Multiple studies show increased gingival inflammation, increased probing depth and attachment loss with the use of the oral contraceptive pills^{11,12,28}.

Kalkwarf K L researched hundred women between 17-35 years taking birth control pills for two years compared to seventy five of those not taking an oral contraceptive. The experimental group on oral contraceptives showed increased gingival inflammation and gingival bleeding with a lower oral debris index compared to the control group^{10, 29}. The increased inflammatory response seen was attributed to the elevated levels of progesterone which affect the microvasculature topography and permeability. A study by Ardakani AH et al comparing two groups showed that women on the low dose oral contraceptive pill had more extensive gingivitis than the control group. A similar study in 2014 also reported the effects of oral pills on increased gingival inflammation.

Apart from the noted inflammatory effects on the gingival status of these women, several studies remarkably also report deeper pocket depths, higher attachment loss with use of oral pills compared to non-users and of note with their prolonged usage^{29,30,31}. However there is inconclusive information on the distinction of disease

outcome between gingivitis and periodontitis with the use of hormonal contraceptives. The influence of oral contraceptives on the occurrence of specific periodontopathogens has shown increased *P.gingivalis*, *P.Intermedia*, AA and specific *Candida* which are implicated in periodontal disease and may increase the risk of severe periodontitis³².

However, there are experimental studies on the effects of oral contraceptive pills on periodontal health that report no difference in oral contraceptive users with respect to their gingival status, probing depth and attachment loss. Preshaw et al carried out a prospective study on the impact of low-dose oral contraceptives on the development of gingivitis and reported no such effect. Another prospective, split-mouth, experimental gingivitis model on pre-menopausal women was carried out and concluded that the current oral contraceptives did not affect the inflammatory response of the gingiva to dental plaque²⁷.

A current systematic review on the effect of hormonal contraceptives, specifically the oral pills, points to an inconclusive outcome due to the large heterogeneity of results obtained^{33,34}. The studies on the effects of hormonal contraceptives largely focus on association of combined oral contraceptive pills on the periodontal health of women with limited information on any other forms of hormonal contraceptives which were introduced later. The biologic effects of sex steroid hormones provide a plausible explanation to hormonal contraceptives acting as modifying factors of periodontal disease and thus the current low dose contraceptives may still act as an aggravating factor of periodontal disease.

Contraceptive use has been defined as the percentage of currently married women ages 15 to 49 years who are using any form of contraception. The main contraceptive methods currently available include the pill, injectables, Intra-uterine device (IUD), hormonal implants, barrier methods (condom, diaphragm, cervical cap, spermicides and sponge), voluntary surgical contraception (VSC) or sterilization, and natural family planning (NFP). Hormonal contraception is available in the form of oral contraceptive pills, injectables, implants, intrauterine devices and herbal formulations.

According to the United Nations in 2015, 64 per cent of married or in-union women of reproductive age worldwide were using some form of contraception and particularly in Africa at 33 percent. In Kenya, modern methods of contraception have been available since 1957 through facilities of Ministry of Health, private sector and NGO's and Kenya was the first country to introduce family planning in its national policy in 1967.

The 1998 Demographic Health Survey showed a four-percentage point increase in contraceptive prevalence from 26 percent to 39 percent between 1993 to 2003 and Kenya had the highest contraceptive prevalence rate in sub – Saharan Africa. Current information on sub-Saharan Africa, reports that more than one-third of contraceptive users rely on injectable contraceptives and a dramatic increase in the injectable method and long acting methods such as Implants has been noted in Kenya.

The PMA (Performance for Monitoring Action) survey data in 2015 reports the prevalence of modern contraceptive use among married women 15-49 years of age is 63.1 % with the injectables being the dominant method at 46.2%, implants 25.5%, pills

11.9% and IUD 7.6%. The modern contraceptive use among unmarried women 15-49 years is 65.6% with injectables at 25.9%, pills 19.9% and implants at 10.8%.

According to the Kenya Demographic & Health Survey (KDHS) 2008–2009, prevalence of contraceptive use was 46% in women 15-49yrs¹⁶. KDHS 2014 showed that among hormonal contraceptives, the injectable was the most preferred method at 45.8%, followed by implant (16.4%), oral pill (12.0%), other modern method (10.8%).

In Kenya, Injectable method of hormonal contraceptives continues to dominate the market, with 26.4% of married women of reproductive age using the method in 2014 and 29.2% in 2015. The implant method also increased from 1.9% in 2008–2009 to 9.9% in 2014 to 16.1% in 2015. Most recently the PMA Survey data from 2017 shows 45.2% of women 15-49yrs use modern contraception methods with 19% on the Injectable method, 14.9% on Implant and 3.5% on the pill.

The extensive literature points to the importance that women should be aware of the influence that hormonal contraceptives may have on their periodontal health. The information obtained on the effect of hormonal contraception is also beneficial to clinicians to focus on preventative programs incorporating enhanced plaque control to establish control of local factors during hormonal contraceptive use in women thus mitigate any adverse effects on their oral health.

CHAPTER TWO: PROBLEM STATEMENT AND JUSTIFICATION

2.1 PROBLEM STATEMENT

Periodontal disease is known to affect a significant part of the Kenyan population with the prevalence of gingivitis recorded at 0.2-90% and periodontitis at 1-10%. Periodontal disease is multifactorial with microbial plaque well understood as the primary etiologic factor. However, hormones which are the basis of hormonal contraception act as a modifying factor of periodontal disease.

There is evidence of increased gingival inflammation and gingival bleeding in women on contraceptive pills which increases with prolonged use . Studies also report that women on oral contraceptives have deeper pocket depth, attachment loss and risk of severe periodontitis.

Thus, the impact of hormonal contraceptives must be well understood and documented in a given population. Failure to correctly diagnose and manage periodontal disease in women on hormonal contraceptives will allow progression of periodontal disease and eventually lead to loss of teeth.

The sequelae of tooth loss compromise the quality of life, aesthetics of individuals in society and increases the cost of health services. This qualifies as a public health problem and contributes to the burden of a disease that is largely preventable with early identification of modifying factors³⁶.

2.2 JUSTIFICATION

Previous studies show the effects of hormonal contraceptives on the periodontium of women. The high dose hormonal contraceptives introduced in the 1960s had 150ug estrogen and 9.85mg progesterone which had increased risk of adverse cardiovascular events and gingivitis. This led to the development of the low dose contraceptives with 20-35ug estrogen and 0.5-1mg progestin.

However, majority of the information available on the effect of hormonal contraceptives on the oral health is still based on earlier high dose formulation reviews. The influence of the low dose formulations on the periodontium is limited and inconclusive as the results obtained are varied in the different populations investigated.

In addition, the studies focus on the effects of oral pills on the periodontium yet the Kenyan population largely relies on the injectable and implant form of hormonal contraception.

Furthermore, there is no regional information regarding the periodontal status of the Kenyan population on hormonal contraceptives yet 37.4% of the female population aged 15-49 years uses hormonal contraceptive methods.

Thus, this study will contribute to baseline knowledge on periodontal health of Kenyan population on hormonal contraceptives. It will substantiate the oral health education of patients on hormonal contraceptives by policy makers and family health care providers. It will also allow for comprehensive clinical care of women by oral health care providers with management based on updated information on hormonal contraceptives and their effect on periodontal health.

2.3 OBJECTIVES

2.3.1 Broad Objective

To investigate the periodontal status of women on hormonal contraceptives visiting the Maternal Child health and Family planning clinic and Youth Clinic at Kenyatta National Hospital.

2.3.2 Specific Objectives

1. To determine the prevalence of women on oral, injectable, implant and other modes of hormonal contraceptives.
2. To determine the gingival status of women on hormonal contraceptives.
3. To determine the periodontal clinical attachment loss in women on hormonal contraceptives.
4. To relate the mode of hormonal contraception to the periodontal clinical attachment loss and gingival status.
5. To relate the duration of hormonal contraception to the periodontal clinical attachment loss and gingival status.

CHAPTER THREE: MATERIALS AND METHODS

3.1 STUDY AREA

The study was carried out in the Maternal child health and family planning clinic and the Youth clinic in Kenyatta National Hospital. This is the largest referral and teaching hospital in the country located in Nairobi, Kenya. It has a total bed capacity of 1800, 50 wards, 24 theatres, Accident and emergency department and 22 outpatient clinics. The hospital caters to millions of the Kenyan population from all socioeconomic backgrounds including the urban, peri-urban and rural areas to provide healthcare services.

The Maternal Child Health and Family Planning (MCH) clinic caters to providing family planning services to women age 21 years and above among other maternal health services. The clinic operates on an appointment and walk in basis regarding the same from Monday to Friday from 8:00am to 12:00pm with an average of 15 women per day. The Youth clinic offers family planning services targeting women below 21 years and similarly operates on weekdays.

3.2 STUDY DESIGN

Data for this study was collected at a single point in time using the appropriate data collection tools. This was therefore a descriptive cross-sectional study with an analytical component.

3.3 STUDY VARIABLES

VARIABLES	MEASUREMENT
SOCIODEMOGRAPHIC VARIABLES	
1. Age	i. Number of years
2. Marital status	ii. Single, Married, Other
3. Education level	iii. Primary, Secondary, Tertiary Level
INDEPENDENT VARIABLES	
1. Type of Hormonal Contraceptive Use	i. Progesterone only ii. Combined
2. Mode of Hormonal Contraceptive Use	i. Oral ii. Injectable iii. Implants iv. Intrauterine devices
DEPENDENT VARIABLES	
1. Gingivitis	i. Gingival Index
2. Periodontitis	ii. Clinical Attachment Loss(mms)
CONFOUNDERS	
1. Smoking	i. Yes OR No
2. Oral hygiene	ii. Plaque Score

3.4 STUDY POPULATION

The study population for this study was all adult women aged between 18-45 years on hormonal contraceptives attending both the Maternal Child health and Family planning clinic and the Youth clinic in Kenyatta National Hospital.

3.5 INCLUSION CRITERIA

- i. Age 18 – 45 years
- ii. Women on continuous hormonal contraception for at least 6 months prior to recruitment.
- iii. Women who give written voluntary consent.

3.6 EXCLUSION CRITERIA

- i. Menopause (Amenorrhea): Hormonal imbalance during menopause alter the periodontal status of women.
- ii. Pregnancy: Physiological hormonal changes during pregnancy result in gingival changes.
- iii. Hormone replacement therapy: Use of hormonal contraceptives for e.g. acne, menopause
- iv. Known systemic diseases e.g. Hypertension, Diabetes mellitus are known to modify the periodontal disease status.
- v. Known dietary deficiencies: Deficiencies such as vitamin C affect gingival status.
- vi. Antibiotic or anti-inflammatory medication use
- vii. Use of drugs inducing gingival enlargement i.e. calcium channel blockers, cyclosporines, anticonvulsants

viii. Periodontal Therapy: Non-surgical or surgical therapy

3.7 SAMPLE SIZE DETERMINATION

The Fischer's formula was used to calculate sample size:

$$n = \frac{Z^2 P(1-P)}{D^2}$$

Z = Normal standard deviate is 1.96 at 95% confidence interval

P = Expected proportion of women with moderate periodontitis on hormonal contraceptives in population is unknown thus taken as 50%

D = Significance level at 5%

$$n = \frac{1.96^2 \times 0.5(1-0.5)}{0.05^2} = 384.2$$

Considering the target population is less than 10,000; the final sample size requires sample adjustment using the formula:

$$nf = \frac{n}{1+n/N}$$

nf = Adjusted sample size for population less than 10,000

n = Original sample size calculated i.e. 385

N = Population size i.e. 500

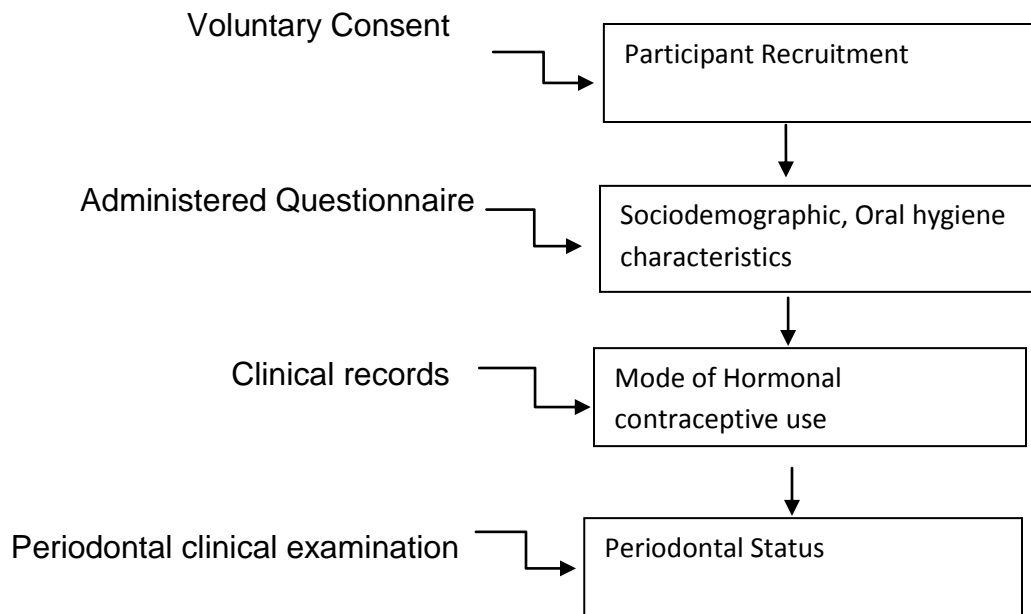
$$nf = \frac{385}{1+385/500}$$

Therefore sample size = **218** individuals.

3.8 SAMPLING METHOD

Systematic sampling method was used to obtain the sample size. This was done by the selection of every third patient attending the clinic.

3.9 DATA COLLECTION



3.9.1 Participant Recruitment and Consent

The KNH clinics operate on weekdays between 8:00am to 12:00am on an appointment booking arrangement and walk in patients. With the assistance of the department nurses, patients were met and using a checklist, participants recruited for the study following written voluntary informed consent.

3.9.2 Socio-demographic data and Hormonal Contraceptive Use

The socio-demographic data was collected using an interviewer administered and serialized questionnaire (Appendix 1). Data about the mode, type and duration of hormonal contraceptive use was collected using the patients file records.

3.9.3 Periodontal Clinical Examination

Data on the periodontal variables was collected by clinical examination carried out by the principal investigator. The participants were seated in a well-lit room and draped with a disposable bib. Infection control protocol was observed to use disposable gloves and sterile dental instruments pre-autoclaved at the dental school for the clinical examination.

The full periodontal clinical examination was carried out at as follows:

Gingival Index

This was carried out with a Williams periodontal probe, under light finger pressure at the gingival sulcus of the designated Ramjford teeth and recorded after 15 seconds. Gingivitis was assessed based on the Gingival Index by Loe and Silness 1963 (Appendix 2)

Plaque Score

Plaque score was assessed using plaque disclosing tablets and the Tureskys modification of Quigley Hein Index 1970 (Appendix 3)

Probing Depth

This was measured using a dental mirror and periodontal probe with Williams markings in millimeters. Probing depth was measured as the distance between the gingival

margin to base of gingival sulcus. The probing depth was assessed and recorded at six points around each tooth namely mesiobuccal, buccal, distobuccal, lingual, mesiolingual and distolingual (Appendix 4).



Gingival Recession

This was measured in millimeters as the distance between the cementoenamel junction (CEJ) and gingival margin.

Clinical Attachment Loss

Clinical attachment loss was calculated in millimeters as the sum of probing depth and gingival recession.

3.10 PERIODONTITIS

The severity of Periodontitis was then determined as per the CDC/AAP Definitions³⁸.

Disease Category	Clinical Attachment Loss	Periodontal Pocket Depths
Severe periodontitis	More than 2 interproximal sites with CAL of more or equal to 6 mm (not on the same tooth)	AND 2 or more interproximal sites with PPD of more than or equal to 5mm
Moderate periodontitis	More than 2 interproximal sites with CAL of more or equal to 4 mm (not on the same tooth)	OR 2 or more interproximal sites with PPD of more than or equal to 5mm
Mild periodontitis	More than 2 interproximal sites with CAL of more or equal to 2 mm (not on the same tooth)	OR 2 or more interproximal sites with PPD of more than or equal to 4mm
No periodontitis	No evidence of mild, moderate or severe periodontitis	

3.11 ETHICAL CONSIDERATIONS

Ethical approval was obtained from the Kenyatta National Hospital and University of Nairobi Ethics and Research Standard Board (KNH-UON ERC); Ref: KNH-ERC/A/130 (Appendix 5).

Voluntary informed consent was obtained from all participants after the purpose of the study had been well explained (See Appendix 6). Women requiring treatment were advised accordingly and referred for management.

3.12 DATA MANAGEMENT

Data coding was carried out and then entered into the computer. The data was cleaned and the analyzed using Statistical Package for Social Sciences (SPSS) 21 for Windows and Microsoft Excel.

Descriptive statistics such as sociodemographic variables, oral hygiene characteristics, mode of hormonal contraceptive, periodontal status including gingivitis and periodontitis were generated. Spearman's correlation test and logistic regression analysis was done to determine any relationship between the variables.

CHAPTER FOUR: RESULTS

This chapter presents the results obtained from the study. The results presented include the socio demographic characteristics, oral hygiene practices, mode of hormonal contraceptive use and the periodontal status including gingivitis and periodontitis.

4.1 SOCIODEMOGRAPHIC CHARACTERISTICS

A total of 218 women were recruited in the study. The mean age of the women was 33.3 years. Majority (56.9%) of the women were between the age 19-34 years and 43.1% of women were of the age 35 years and above. In terms of employment, majority (33.5%) of the women at were employed, 27.5% were self-employed as business owners, 22.5% were housewives and 12.5% were students as shown in table 1.

Majority(60.6%) of the women had attained a tertiary level qualification, 27.5% had completed secondary education and 11.9% had completed primary level education. 76.6% of the women reported to be married and 22% were single as shown in table 1.

TABLE1: Sociodemographic Characteristics

VARIABLES	CATEGORY	FREQUENCY (n)	PERCENTAGE(%)
Age	19-34 years	124	56.9
	35 years and above	94	43.1
	Employed	73	33.5
	Business/self-employed	60	27.5
Occupation	Housewife	49	22.5
	Student	28	12.8
	Not specified	8	3.7
	Primary	26	11.9
Education Level	Secondary	60	27.5
	Tertiary	132	60.6
	Single	48	22.0
Marital Status	Married	167	76.6
	Other	3	1.4

4.2 ORAL HYGIENE PRACTICES

Tooth brushing and interdental cleaning habits were assessed using a questionnaire for all participants. Majority (99.1%) reported brushing their teeth daily while 0.9% did not brush daily. A significant number of women, 63.4% reported brushing twice a day, 35.2% reported brushing once a day and 1.4% brushed three times a day. Majority (99.9%) reported using a commercial toothbrush for toothbrushing while a minority of 0.9% used a chewing stick.

Interdental cleaning was practiced by 78% of the participants while 22% did not practice interdental cleaning. Ninety percent reported using a toothpick while only 5.3% used dental floss. The frequency of interdental cleaning for majority of the participants 72.4% was reported as a weekly routine while 17.6% reported interdental cleaning on a daily basis as shown in table 2.

The mean plaque score among participants was 1.52 which indicates that there was presence of flecks or a continuous band of plaque at the cervical margins of the tooth. The women had an overall plaque score range of 0.42 to 2.83.

TABLE 2: Oral Hygiene Practices

VARIABLES	CATEGORY	FREQUENCY(n)	PERCENTAGE(%)
Tooth Brushing	Yes	216	99.1
	No	2	0.9
Frequency of Brushing	Once a day	76	35.2
	Twice a day	137	63.4
	Three times a day	3	1.4
	Commercial toothbrush	216	99.1
Brushing tool	Chewing stick	2	0.9
	Yes	170	78.3
Interdental cleaning	No	48	21.7
	Toothpick	153	90
Interdental cleaning tool	Dental Floss	9	5.3
	String	2	1.2
	Other	6	3.5
	Daily	30	17.6
Frequency of Interdental cleaning	Weekly	123	72.4
	Monthly	17	10

4.3 MODE OF HORMONAL CONTRACEPTIVES

The hormonal contraceptive methods outlined were implant, injection, pills, patch and intrauterine device. The majority 56.9% of the women used an implant, 20.6% used the

pills, 17.4% used the injection, 0.5% used a patch, 0.9% used an intrauterine device and 2.8% used the emergency form of hormonal contraception as shown in table 3.

Out of the 124 implant users, 53.2% used Jadelle and 46.8% used Implanon. The 38 women on the injection method used Depoprovera. Out of the 45 pill users, 91.1% used the combined oral contraceptive pills namely Femiplan and Microgynon and 8.8% used the progestin only pill namely Microlut. Only 2 women used a hormonal intrauterine device called Mirena. The 6 women who used emergency form of contraception used various brands.

TABLE 3 : Prevalence and Mode of Hormonal Contraceptives

VARIABLES	CATEGORY	FREQUENCY (n)	PERCENTAGE (%)
Mode of Hormonal Contraceptive	Pill	45	20.6
	Implant	124	56.9
	Injection	38	17.4
	Patch	1	0.5
	Intrauterine Device	2	0.9
	Emergency Contraception	6	2.8

4.4 GINGIVITIS

The degree of gingival inflammation was assessed using the Gingival Index. The mean gingival index was 1.36 with an overall range between 0.25 – 2.08. Majority of the

women, 77.5% had moderate gingivitis, 12.8% had mild gingivitis and 9.6% had severe gingivitis as shown in table 4.

TABLE 4 Prevalence and Severity of Gingivitis

VARIABLE	CATEGORY	FREQUENCY(n)	PERCENTAGE(%)
GINGIVITIS	Mild gingivitis	28	12.8
	Moderate gingivitis	169	77.5
	Severe gingivitis	21	9.6

There was a correlation between plaque and gingival inflammation that was statistically significant ($\rho=0.649$, $p<0.001$) with higher levels of gingival inflammation seen in those with higher levels of plaque. There was no statistically significant correlation between the mode of hormonal contraceptive and gingivitis. There was also no statistically significant relationship between duration of hormonal contraceptive and gingivitis ($\rho=0.143$, $p= 0.035$) as shown in table 5.

TABLE 5: Spearmans correlation for Mode, Duration and Periodontal status

	Spearmans Correlation Coefficient Values					
VARIABLE	Gingivitis	Periodontitis	CAL	Plaque	Duration	Mode
Gingivitis	1					
Periodontitis	0.309**	1				
CAL	0.314**	0.985**	1			
Plaque	0.649**	0.356**	0.350**	1		
Duration	0.076	0.240**	0.255**	0.001	1	
Mode	0.008	0.0208**	0.220**	0.135*	0.075	1

***p<0.05 , **p<0.01**

The participants with basic education (primary, secondary) had 2.76 times higher odds of having gingivitis than those with tertiary education (OR=2.76, p=0.03). In addition, the participants who did not practice interdental cleaning had 3.81 higher odds of having gingivitis (OR=3.04, p=0.02). The logistic regression analysis showed no statistically significant relationship between mode, duration of hormonal contraceptive and gingivitis as shown in table 6.

TABLE 6: Logistic Regression model for Gingivitis

Characteristic	Category	OR	p-value
Age	19-34 years	1.01	0.980
	35+ years		
Education	Basic education	2.76	0.032
	Tertiary		
Marital status	Married	1.33	0.622
	Single/other		
Interdental cleaning	No	3.04	0.020
	Yes		
Mode of Contraceptive	Implant	0.94	0.907
	Injection	0.69	0.622
	Other	0.00	0.999
	Pill		
Duration of contraceptive use		1.09	0.115

4.5 PERIODONTITIS

The mean probing depth of the participants was 1.53mm (± 0.34 SD) and the mean clinical attachment loss was 1.57mm (± 0.38 SD). Periodontitis was then categorised

using the CDC/AAP classification. Majority (65.1%) of the women, had mild periodontitis and 33.9% had moderate periodontitis as shown in table 7.

TABLE 7 : Prevalence and Severity of Periodontitis using CDC/AAP Classification 2012

VARIABLE	CATEGORY	FREQUENCY(n)	PERCENTAGE(%)
PERIODONTITIS	Mild periodontitis	142	65.1
	Moderate periodontitis	74	33.9
	Severe periodontitis	1	0.5

There was a moderate correlation between plaque and clinical attachment loss that was statistically significant ($\rho=0.350$, $p<0.001$) and similarly the association between plaque and periodontitis was statistically significant ($\rho=0.356$, $p<0.001$) as shown in table 5.

There was a positive correlation between implant mode of hormonal contraceptive and periodontitis ($\rho=0.208$, $p=0.002$). The duration of hormonal contraceptive use and periodontitis showed a positive correlation that was statistically significant ($\rho=0.240$, $p<0.001$) where the women who had used hormonal contraceptives for a longer period were more likely to exhibit moderate to severe periodontitis as shown in table 5.

The odds of periodontitis increased with age (OR=5.44, $p=0.001$). The women on injectable (OR 4.16, $p=0.005$) and implant mode of hormonal contraceptive had higher odds of periodontitis (OR=2.73, $p=0.020$). The women on hormonal contraceptives for

longer duration of also had higher odds of periodontitis (OR=1.14, p=0.002) as shown in table 8.

TABLE 8: Logistic Regression model for Periodontitis

Characteristic	Category	OR	p-value
Age	19-34 years		
	35+ years	5.44	0.001
Education	Basic education	2.21	0.006
	Tertiary		
Marital status	Married	2.61	0.013
	Single/other		
Mode of Contraceptive	Implant	2.73	0.020
	Injection	4.16	0.005
	Other	1.73	0.481
	Pill		
Duration of contraceptive use		1.14	0.002

4.6 LIMITATIONS

The study was subject to limitations such as the lack of a hormonal profile to determine the hormone levels systemically or in the oral cavity. The subgingival microflora or specific biomarkers were not assessed and could have provided an adjunct to describe the periodontal status. There was recall bias as data collection relied on the information provided by the participants and the accuracy of the clinical records for the variables.

The cross sectional nature of data and lack of comparative group limits ability to accurately define any association in terms of causality between hormonal contraceptives and the periodontal status.

CHAPTER FIVE: DISCUSSION, CONCLUSION, RECOMMENDATION

This chapter discusses the findings of the study. The findings of the study are also interpreted with accounts from existing knowledge and literature.

5.1 SOCIODEMOGRAPHIC CHARACTERISTICS

The age of the participants ranged between 18-45 years which ensured that voluntary informed consent was obtained from adult women. It also ensured that the gradual perimenopause phase would be mitigated based on the average age of menopause for women in western Kenya³⁹.

The education level of majority (60.6%) of the women who were using hormonal contraceptives had a tertiary level education. Gordon et al 2011 in a quantitative study in Ethiopia reported that women's education increased the independence and autonomy to make decisions in contraception choice⁴⁰. The Family Planning in East Africa January report 2018 also highlights that the contraceptive prevalence rate was higher among those with secondary education and above compared to primary education.

5.2 ORAL HYGIENE CHARACTERISTICS

Ninety eight point six percent of the women reported brushing daily using a commercial toothbrush. Dental plaque plays a major role in periodontal disease and dental caries, thus regular oral hygiene practice is a requisite for mechanical plaque removal and healthy oral cavity^{41,42}. Majority of the women practiced interdental cleaning using a toothpick. However, toothpicks allow only point contact with the tooth surface and are more suited for removing food debris after a meal. Only 4.3% used dental floss which is

similar to a study by Warren et al 1996 who found the routine use of dental floss is low (10-30%) among adults as it is technically challenging.

5.3 MODE OF HORMONAL CONTRACEPTIVE

The study found that majority of the women used the implant type of hormonal contraceptive. These implants were namely Implanon for duration of 3 years and Jadelle for 5 years. Multiple health surveys indicate injectables are the dominant hormonal contraceptive method in Kenya however a rising trend in the use of implants has been noted⁴³. This finding is similar to a recent African Profile and Health Research Centre (APHRC) 2018 report that shows that in Kenya, higher proportions of women are using long term methods of contraception which includes implants and injectables. The lower number of injectables in the study population could be explained by the counselling provided at the clinics regarding the adverse effects of the injectable method. These include the lack of immediate discontinuation and the side effects that continue until the Depoprovera is cleared 6-8 months after last injection, thus women may have a 6 to 12 month delay in return of fertility. In addition, the facility being a large referral hospital is well equipped with the implant contraceptives with adequate technical staff training to administer the implants.

5.4 GINGIVITIS /PERIODONTITIS

Majority (77.5%) of the women, had moderate gingivitis and the association between plaque and gingival inflammation was statistically significant with higher levels of gingival inflammation seen in those with higher levels of plaque. This positive correlation between the plaque scores and gingival index concurs with the role of dental plaque in the pathogenesis of periodontal disease⁴⁴.

However, there was no statistically significant difference in the severity of gingivitis between these various types of hormonal contraceptive users. This is in contrast to other studies that showed gingival changes with use of oral pills^{11,27,29}.

Majority (65.1%) of the women, had mild periodontitis. The participants with basic education had higher odds of having periodontitis compared to those with tertiary education. This corroborates with a systematic review on education as a predictor for chronic periodontitis that concluded that low educational attainment was associated with an increased risk of periodontitis³⁵.

The odds of having periodontitis was higher for women aged 35 years and above compared to the 18-34 years age group. This is understood due to the increased duration of exposure of the periodontal tissues to risk factors such as dental plaque and several studies show that the prevalence of periodontal disease increases with age⁴⁶.

There was a positive correlation between periodontitis and mode of hormonal contraceptive use. It was noted that the use of implants and injections was correlated to increasing severity of periodontitis compared to the use of oral pills. This is similar to a study by Taichman et al reported that women who indicate injectable use have a significantly increased risk of prevalence of periodontal conditions as compared to those who did not⁴⁵. Kazerooni et. al also reported increased pocket depth and periodontitis with levonorgestrel implant mode of contraceptives⁴⁷. Largely the studies that investigate a link between hormonal contraceptives and the periodontium focus on oral pill method. There is limited information on the impact of other forms of hormonal

contraceptives such as injectables, implants on the periodontium which need to be further explored.

5.4 CONCLUSION

Based on the findings of the study, the following was concluded :

1. The use of implant and injectable forms of hormonal contraceptives increases the likelihood of suffering from periodontitis.
2. The use of hormonal contraceptives for longer duration also increased the likelihood of periodontitis.

5.5 RECOMMENDATION

Based on the findings of this study, the following are my recommendations :

1. There is need to educate women on possible effects of hormonal contraceptives on the periodontal health by health care providers.
2. There is need for further studies to be done to explain any associations of hormonal contraceptives on the periodontal health of women.

5.6 CONFLICT OF INTEREST

The study was done as a partial fulfilment for the award of Masters of Dental Surgery in Periodontology at the University of Nairobi in addition to scientific purposes. The costs were met solely by the principal investigator and there was no related conflict of interest.

REFERENCES

1. Richards D. Oral diseases affect some 3.9 billion people. *Evid Based Dent.* 2013; 14(2):35.
2. Marcenes W, Kassebaum N, Bernabe E, Flaxman A, Naghavi M, Lopez A et al. Global burden of oral conditions in 1990-2010: a systematic analysis. *J Dent Res.* 2013; 92(7):592-597.
3. Kassebaum NJ, Bernabé E, Dahiya M, Bhandari B, Murray CJ, Marcenes W. Global burden of severe periodontitis in 1990–2010: a systematic review and meta-regression. *J Dent Res.* 2014; 93:1045–1053.
4. Sanya BO, Nganga, PM, Nganga RN. Causes and pattern of missing permanent teeth among Kenyans. *East African Medical Journal.* 2004; 81(6):322-325.
5. Kaimenyi J. T.Oral health in Kenya. *International dental journal.* 2004; (6 Suppl 1), 378–382.
6. Kinane, D. F. Causation and pathogenesis of periodontal disease. *Periodontology 2000.* 2001; 25:8–20.
7. Page RC and K.S. Kornman. The pathogenesis of human periodontitis: an introduction. *Periodontology 2000.* 1997; 14(1):91.
8. Armitage GC. Development of a classification system for periodontal diseases and conditions. *Ann Periodontol.*1999; 4:1-6.
9. Markou, E, Eleana, B, Lazaros, T & Antonios, K. The influence of sex steroid hormones on gingiva of women. *The open dentistry journal.* 2009; 3:114.
10. Preshaw PM. Oral contraceptives and the periodontium. *Periodontology 2000.* 2003; 61:125–159.

11. Ahmad Haerian-Ardakani, Amir Moeintaghavi, Mahammadreza Reza Talebi-Ardakani, Keyvan Sohrabi, Shahin Bahmani, Maede Dargahi. The Journal of Contemporary Dental Practice. 2011; 11:33-40.
12. Dominigues, Roberta Santos et al. Influence of combined oral contraceptives on the periodontal condition. J. Appl. Oral Sci. 2012; 20,2.
13. United Nations, Department of Economic and Social Affairs, Population Division 2015. Trends in Contraceptive Use Worldwide 2015(ST/ESA/SER.A/349).
14. Magadi, MA & Curtis SL. Trends and Determinants of Contraceptive Method Choice in Kenya. Studies in Family Planning. 2003; 34(3),149–159.
15. Tonetti MS, Greenwell H, Kornman KS. Staging and grading of periodontitis: Framework and proposal of a new classification and case definition. J Clin Periodontol. 2018; 45(Suppl 20):S149–S161.
16. Könönen, E., Gursoy, M., & Gursoy, U. K. Periodontitis: A Multifaceted Disease of Tooth-Supporting Tissues. Journal of clinical medicine. 2019; 8(8),1135.
17. Gathece L. Kenya National Oral Health Survey Report 2015.
18. Mascarenhas, Paulo, Gapski, Ricardo, Al-Shammari, Khalaf, Wang, Hom-Lay. "Influence of sex hormones on the periodontium." Journal of Clinical Periodontology. 2003; 30(8):671-681.
19. Mariotti A. Sex steroid hormones and cell dynamics in the periodontium. Crit Rev Oral Biol Med. 1994; 5:27-53.

20. Nanba H, Nomura Y, Kinoshita M, Shimizu H, Ono K, Goto H, et al. Periodontal tissues and sex hormones-effects of sex hormones on metabolism of fibroblasts derived from periodontal ligament. *Nippon Shishubyo Gakkai Kaishi*. 1989; 31(1);166-75.
21. Bhardwaj, Amit & Verma, Shalu. Effect of Androgens, Estrogens and Progesterone on Periodontal Tissues. *Journal of Orofacial Research*. 2012; 2:165-170.
22. Nakagawa, S., Fujii, H., Machida, Y., & Okuda, K. A longitudinal study from prepuberty to puberty of gingivitis. Correlation between the occurrence of *Prevotella intermedia* and sex hormones. *Journal of clinical periodontology*, 1994; 21(10),658–665.
23. Wu M, Chen SW, Jiang SY. Relationship between gingival inflammation and pregnancy. *Mediators Inflamm*. 2015; 2015:623427.
24. Kornman KS, Loesche WJ. The subgingival microflora during pregnancy. *J Periodontal Res*. 1980; 15(2):111-22.
25. Güncü G, Tözüm T and Çaglayan F. Effects of endogenous sex hormones on the periodontium — Review of literature. *Australian Dental Journal*. 2005; 50:138–145.
26. Preshaw, P.M. Oral contraceptives and the periodontium. *Periodontology* 2000. 2013; 61:125-159.
27. PM Preshaw, MA Knutsen and A Mariotti. Experimental Gingivitis in Women Using Oral Contraceptives. *J Dent. Res*. 2001; 80: 2011-2015.

28. Sambashivaiah S, Rebentish P D, Kulal R, Bilichodmath S. The influence of oral contraceptives on the periodontium. *J Health Sci.* 2010; 1(1):1.
29. Tilakaratne A, Soory M, Ranasinghe AW, Corea SMX, De Silva M. Effects of hormonal contraceptives on the periodontium, in a population of Sri Lankan women. *J Clin Periodontol.* 2000; 27:753–757.
30. Mullally BH, Coulter WA, Hutchinson JD, Clarke HA. Current oral contraceptive status and periodontitis in young adults. *J Periodontol.* 2007; 78(6):1031-1036.
31. Vijay G. Relationship of duration of oral contraceptive therapy on human periodontium-A clinical, radiological and biochemical study. *Ind J Dent Adv.* 2010; 2(2):168–74.
32. Brusca MI, Rosa A, Albaina O, Moragues MD, Verdugo F & Pontón J. The impact of oral contraceptives on women's periodontal health and the subgingival occurrence of aggressive periodontopathogens and *Candida* species. *Journal of periodontology.* 2010; 81(7),1010-1018.
33. Ali I, Patthi B, Singla A, et al. Oral Health and Oral Contraceptive - Is it a Shadow behind Broad Day Light? A Systematic Review. *J Clin Diagn Res.* 2016; 10(11): ZE01-ZE06.
34. Castro, M.M.L., Ferreira, M.K.M., Prazeres, I.E.E. et al. Is the use of contraceptives associated with periodontal diseases? A systematic review and meta-analyses. *BMC Women's Health.* 2021;48.
35. Fotso et al. Unintended pregnancy and subsequent use of modern contraceptive among slum and non-slum women in Nairobi, Kenya. *BMC Pregnancy and Childbirth.* 2014;14:224.

36. P. Batchelor. Is periodontal disease a public health problem? *British Dental Journal*. 2014; 217:405 – 409.
37. Charan, Jaykaran and Tamoghna Biswas. “How to Calculate Sample Size for Different Study Designs in Medical Research?” *Indian Journal of Psychological Medicine*. 2013; 121–126.
38. Eke PI, Page RC, Wei L, Thornton-Evans G, Genco RJ. Update of the case definitions for population-based surveillance of periodontitis. *J Periodontol*. 2012; 83(12):1449-1454.
39. J. Noreh, C. Sekadde-Kigundu, J. G. Karanja, N. G. Thagana. Median age at menopause in a rural population of western Kenya *East Afr Med J*. 1997; Oct; 74(10):634–638.
40. Gordon C, Sabates R, Bond RTW. Women’s Education and Modern Contraceptive Use in Ethiopia. *International Journal of Education*. 2011; 3(1):1–23.
41. Marsh P, D: Dental Plaque as a Microbial Biofilm. *Caries Res*. 2004; 38:204-211.
42. Menon L, Ramamurthy J. New vistas in plaque control. *IOSR J Dent Med Sci*. 2014; 3:64-8.
43. Performance Monitoring and Accountability 2020 (PMA2020) Project, International Centre for Reproductive Health Kenya (ICRHK). 2014. Detailed Indicator Report: Kenya 2014. Baltimore, MD: PMA2020. Bill & Melinda Gates Institute for Population and Reproductive Health, Johns Hopkins Bloomberg School of Public Health.

44. Y. A. AlJehani, "Risk Factors of Periodontal Disease: Review of the Literature," International Journal of Dentistry, vol. 2014, Article ID 182513, 9 pages, 2014.
45. Taichman LS, Sohn W, Kolenic G, Sowers M. Depot medroxyprogesterone acetate use and periodontal health in 15- to 44-year-old US females. *J Periodontol.* 2012; 83(8):1008-1017.
46. Wu Y, Dong G, Xiao W, et al. Effect of Aging on Periodontal Inflammation, Microbial Colonization, and Disease Susceptibility. *J Dent Res.* 2016; 95(4):460-466.
47. Kazerooni T, Ghaffarpasand F, Rastegar N, Kazerooni Y. Effect of levonorgestrel implants on the periodontium. *Int J Gynaecol Obstet.* 2008; 103(3):255-256.
48. Saini R, Saini S, Sharma S. Oral contraceptives alter oral health. *Ann Saudi Med.* 2010; 30(3):243.
49. Prachi S, Jitender S, Rahul C, Jitendra K, Priyanka M, Disha S. Impact of oral contraceptives on periodontal health. *Afr Health Sci.* 2019; 19(1):1795-1800.
50. Global, regional, and national incidence, prevalence, and years lived with disability for 354 diseases and injuries for 195 countries and territories, 1990–2017: a systematic analysis for the Global Burden of Disease Study 2017. *Lancet* 2018; 392:1789–8583.

APPENDICES

Appendix One: Questionnaire

1. Date _____
2. Serial Number _____
3. File Number _____
4. Age _____
5. Phone No. _____
6. Occupation _____
7. Education Level

1. Primary
2. Secondary
3. College

8. Marital Status 1. Single 2. Married 3. Other

9. How long have you been on the hormonal contraceptive?(Patient File Record)

Duration _____

Mode of Hormonal Contraceptive Use

Pill

Combined Progestin Only

- Implant
- Injection
- Patch
- Intrauterine Device
- Vaginal Ring
- Emergency Contraception

10. Do you brush your teeth? 1. Yes 2. No (if no, proceed to question 12)

11. How often do you brush?

- 1. Once a day
- 2. Twice a day
- 3. Three times a day

12. What do you use to brush your teeth?

- 1. Commercial toothbrush
- 2. Chewing stick
- 3. Charcoal
- 4. Fingers
- 5. Other (specify) _____

Do you practice inter-dental cleaning? Yes No

If yes, what do you use?

- 1. Toothpick Daily Weekly Monthly

Appendix Two: Gingival Index, Loe and Silness 1963

0	Normal, absence of oedema and no bleeding on probing
1	Oedema present with absence of bleeding on probing
2	Oedema present, glazing and bleeding on probing
3	Oedema, ulceration with spontaneous bleeding

Gingivitis Severity

No gingivitis

0.1 – 1 Mild gingivitis

1.1 – 2 Moderate gingivitis

2.1 – 3 Severe gingivitis

Appendix Three: Plaque Score, Tureskys Modification of Quigley Hein Index

0	No plaque
1	Isolated flecks of plaque along gingival margin
2	Continuous band along cervical margin $\leq 1\text{mm}$
3	Plaque up to one third of tooth surface
4	Plaque greater than one third but less than two third of tooth surface
5	Plaque greater than two third tooth surface

Appendix Four: Clinical Examination Form

Date _____

Serial No. _____

GINGIVAL INDEX

16	F		21	F		24	F	
	L			L			L	
44	F		41	F		36	F	
	L			L			L	

PLAQUE SCORE

16	F		21	F		24	F	
	L			L			L	
44	F		41	F		36	F	
	L			L			L	

PERIODONTAL PROBING CHART

Maxillary arch

Tooth	17	16	15	14	13	12	11	21	22	23	24	25	26	27	
Palatal															
Recession															
Pocket Depth															
CAL															
Facial															
Recession															
Pocket Depth															
CAL															
Mobility															

Mandibular Arch

Tooth	17	16	15	14	13	12	11	21	22	23	24	25	26	27
Palatal														
Recession														
Pocket Depth														
CAL														
Facial														
Recession														
Pocket Depth														
CAL														
Mobility														

Appendix Five: Ethics Approval



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Fax: 725272
Telegrams: MFDSUP, Nairobi

Ref: KNH-ERC/A/130

20th April 2017

Dr. Ranjana Saini
Reg. No. V80/7438/14
School of Dental Sciences
College of Health Sciences
University of Nairobi

Dear Dr. Saini

REVISED RESEARCH PROPOSAL- PERIODONTAL STATUS OF WOMEN ON HORMONAL CONTRACEPTIVES VISITING MATERNAL CHILD HEALTH AND FAMILY PLANNING CLINIC AND YOUTH CLINIC AT KENYATTA NATIONAL HOSPITAL (P570/08/2016)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and approved your above revised proposal. The approval period is from 20th April 2017 – 19th April 2018.

This approval is subject to compliance with the following requirements:

- Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
- All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH-UoN ERC before implementation.
- Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
- Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
- Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period (Attach a comprehensive progress report to support the renewal).
- Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
- Submission of an executive summary report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

For more details consult the KNH- UoN ERC website <http://www.erc.uonbi.ac.ke>

"Protect to Discover"

Yours sincerely,



PROF. M. L. CHINDIA
SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Director, CS, KNH
The Assistant Director, Health Information, KNH
The Chair, KNH-UoN ERC
The Dean, School of Dental Sciences, UoN
Supervisors: Dr. Nelson K. Matu, Dr. Veronica Wangari, Dr. Bernard Mwa

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Appendix Six: Consent Form

This is to certify that I, _____
hereby agree to participate in this educational and research study on **“Effect of hormonal contraceptives on the periodontium of women visiting Kenyatta National Hospital”**. The study will be carried out by Dr.Ranjana Saini, a postgraduate student pursuing a Master’s degree in Periodontology at the University of Nairobi, School of Dental Sciences. The consent to carry out this study has been given Kenyatta National Hospital and University of Nairobi Ethics and Research Standard Board.

I understand that this study will involve a full mouth examination using a sterile dental mirror and periodontal probe where all the teeth will be examined for plaque, gum bleeding, mobility and pocket depth. I understand that no dental treatment will be rendered during this appointment rather my current oral health status will be evaluated and I will be referred for treatment as necessary.

Risks and discomforts

There are no anticipated risks associated with this research. Minimal discomfort in the gums and slight bleeding maybe encountered during examination. However care will be taken to minimize any possible discomfort.

Perceived benefits

Perceived benefits from this study include partial fulfillment for the award of masters of dental surgery in periodontology at the University of Nairobi, adding new information to the existing knowledge of the periodontal health of the participants. Personal benefits for participants include knowledge of their periodontal status for which participants may seek voluntary treatment as required. The study will also form a basis for future

research aimed at developing protocols to manage periodontal disease in women on hormonal contraception.

Confidentiality

The information collected will be treated with utmost confidentiality. Participant identity will not be revealed in any publication resulting from this study.

Withdrawal Privilege

I understand that participation is entirely voluntary and I may refuse to participate or withdraw from the study at any time without penalty or prejudice. No monetary compensation or otherwise is to be expected.

Voluntary consent:

I certify that I have read this consent form or it has been read and interpreted to me and that I have understood it. Any questions pertaining to the research have been answered to my satisfaction. I consent to this study by appending my signature below.

Signature of participant _____ **Date** _____

Investigators statement:

I certify that I have explained to the above subject the nature and purpose of this study, potential benefits and possible risks associated with participation in this study. All questions have been answered to the participant's satisfaction.

Signature _____ **Date** _____

For more clarifications and enquiries on the consent please contact

Principal Investigator: Dr. Ranjana Saini

+254772559390

saini_ranjana01@yahoo.com

Periodontology/ Community and Preventive Dentistry

University of Nairobi.

Kiini cha Utafiti

Hii ni kuonyesha ya kwamba mimi _____ nimepatiana ruhusa ya kushiriki katika Utafiti unaochunguza “**Athari za uzazi wa mpango homoni juu ya peridontium ya wanawake kutembelea Kenyatta National Hospital**”. Huu Utafiti unafanywa na Daktari Ranjana Saini, mwanafunzi katika chuo kikuu cha Nairobi. Naelewa kwamba huu utafiti utahusikana kuangalia hali ya ufizi ya meno yangu na hakuna matibabu yeyote ambayo yatatekelezwa. Kama kuna kasoro nitapewa mawaidha kuhusu jinsi ya kupata matibabu kwingine.

Manufaa na madhara ya Utafiti

Nitajulishwa matokeo ya Utafiti baada ya kuangaliwa na nitapewa mawaidha yanayohitajika. Matokeo ya Utafiti huu yatawaisidia wanasayansi wa hapa nchini na wa kimataifa kugundua na kupunguza ugonjwa. Nimeelewa kwamba hakuna gharama yeyote kwa kushiriki katika utafiti huu.

Hifadhi ya Nakala ya Habari Utakayotoa

Habari zote zitakazokusanywa kutoka kwako zitahifadhiwa kwa siri na kutumiwa tu katika utafiti huu. Majina yangu hayataandikwa mahali popote wakati wowote. Nakala zote za habari kukuhusu zitafungiwa katika makabati maalum wakati wote wa utafiti huu. Habari hizi zitawekwa kwenye kompyuta nan mchunguzi pekee yake ndiye atakayetumia kitambulisho cha siri ili kufikia habari hizi.

Tunasistiza usiri huu katika kusimamia habari tutakazopewa ili kuzuia kujulikana kwa watakaoshiriki katika utafiti huu. Hakuna majina yatakayotumika katika vikao vya sayansi kwa umma na ripoti zitakazochapishwa katika majarida ya sayansi.

Idhini na Sahihi

Nimesoma maelezo yaliyoko hapa juu na nimekubali kwa hiari kushiriki katika utafiti huu.

.....

Jina la Mshiriki Sahihi ya Mshiriki na Tarehe

Mimi niliyepewa jukumu la kupeana maelezo kuhusu utafiti huu kwa mshiriki aliyetajwa hapa juu, nimepeana maelezo kamili kulingana na masomo na ujuzi wangu katika kazi hii. Kwa hivyo ninahitimu kufanya jukumu hili.

Jina la mtafiti aliyetoa maelezo: Dr.Ranjana Saini

+254 722 559390

saini_ranjana01@yahoo.com

Periodontology and Community Dentistry

University of Nairobi.