Risk factors associated with peri-implant mucositis

**A mini-thesis submitted in partial fulfilment of the requirements
for the degree of Magister Chirurgiae Dentium
in Oral Medicine and Periodontics at the Faculty of Dentistry
University of the Western Cape**

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Abstract

Peri-implant disease is a collective term for inflammatory lesions involving the implant supporting periodontal tissues which if not diagnosed early can progress to loss of osseo-integration and late implant failure (Heitz-Mayfield, 2008: 292). Peri-implant disease encompasses peri-implant mucositis and peri-implantitis. Peri-implant mucositis is a reversible inflammatory lesion only affecting the soft tissue around an implant, similar to gingivitis around the natural dentition. If the pathological condition is left untreated progression to peri-implantitis may occur (Heasman *et al*, 2010:511; Grusovin *et al*, 2010: 3). The increasing amount of patients treated with implant-restored fixtures may contribute to a higher incidence of peri-implant infections (Renvert and Persson, 2009: 9), especially in the absence of a supportive maintenance care programme. Early identification of the signs and symptoms of peri-implant disease are crucial in preventing further disease progression (Karbach *et al*, 2009: 492). When reviewing the literature it is apparent that this is a large scale problem among implant restored patients. Prevalence rates of peri-implant mucositis are high affecting roughly 50% of implant sites and 80% of patients (Lindhe and Meyle, 2008: 284; Heasman *et al*, 2010: 512). **Aim:** To determine the prevalence of peri-implant mucositis and the association between systemic and local risk factors. **Method:** An analytical cross-sectional study was carried on 74 patients with restored single implants treated at the Oral Medicine and Periodontology (OMEDP) Department of the Faculty of Dentistry of the University of the Western Cape, in the period 1st January 2005 until end October 2011. The various risk factors for peri-implant disease that were evaluated included gender, smoking, diabetes, implant position in dental arch, implant connection, implant diameter, type of implant restored crown, keratinized gingival width, and oral hygiene. Peri-implant mucositis around implants was evaluated by visual examination as measured by bleeding on probing (BOP) in the peri-implant sulcus. A positive response to bleeding on probing (BOP) was considered a positive sign for the presence of peri-implant mucositis using a Vivacare TPS® periodontal probe. Data was transferred onto a Microsoft Excel® spread sheet and analysed using the Microsoft Excel® program. The prevalence of peri-implant mucositis in the sample population and the null hypothesis was tested with a statistical test, the chi-squared test for not normally distributed data. **Results:** There was an overall prevalence of peri-implant mucositis in the study population of 70.3% per implant site. The null hypothesis was rejected by four risk factors which had a statistically significant association with peri-implant mucositis: anterior dental arch position; wider keratinized gingival widths; poor to fair oral hygiene status; and prior oral hygiene instructions. Analysis of the data revealed that the majority (77.27%) of implant-supported cement retained restorations in the anterior area presented with bleeding on probing. This may be explained by the extrusion of cement

around the margins of a cement-retained restoration which, given time in a vascular environment of peri-implant gingiva could elicit a foreign body inflammatory reaction. **Conclusion and recommendations:** The high prevalence rate obtained from the study population highlights the need for implant maintenance in general. To ensure optimal long term mucosal health around dental implants caution needs to be exercised when planning cement-retained restorations. Further research is necessary on the various risk factors associated with the onset of peri-implant disease, however a larger sample size is recommended.

Keywords: peri-implant mucositis, prevalence rate, risk factors

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Declaration

I, the undersigned hereby declare that the work contained in this mini-thesis is my original work, that it has not been submitted before for any degree or examination in any university, and that all the sources I have used or quoted have been indicated and acknowledged by complete references.

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             Suzette Stander   Date

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Dedication

This mini-thesis is dedicated to my mentor Professor J Marnewick in appreciation for all that he has taught me.

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CHAPTER 1:
INTRODUCTION

1.1.   Structure of the report

This mini-thesis consists of seven chapters relating to the various aspects investigated in this analytical cross-sectional study.

Chapter 1 summarizes the background and purpose of the study. Chapter 2 provides a comprehensive literature review and includes recent definitions, prevalence rates and criteria for the diagnosis of peri-implant disease. It concludes with a list of the various systemic and local risk factors associated with peri-implant disease.

Chapter 3 describes the study aim, objectives and null hypothesis. Chapter 4 describes the research design and methodology. It elaborates on the research tool, data collection procedures and instruments used. It elucidates on the calibration of the researcher, data management and analysis as well as ethical considerations.

Chapters 5 to 7 detail the results, discussion, conclusion and recommendations respectively.

1.2.   Background and purpose of the study

The increasing amount of patients treated with implant-supported prosthesis may contribute to a higher incidence of peri-implant infections (Renvert and Persson, 2009: 9). Early identification of the signs and symptoms of peri-implant disease are crucial in preventing further disease progression (Karbach *et al*, 2009: 492).

When reviewing the literature, it is apparent that peri-implant infections are a large scale problem among patients restored with implant prosthesis. Most of the literature reporting on the prevalence rates of peri-implant disease originates from international studies and to date, this is the first South African prevalence study to report on the prevalence of peri-implant disease. The prevalence of peri-implant mucositis is reported to range between 30.7% - 50% of implant sites and 63.4% - 80% of patients (Lindhe and Meyle, 2008: 284; Heasman *et al*, 2010: 512; Atieh *et al*, 2012). Atieh *et al,* 2012, found this to occur with or

without any supportive periodontal maintenance care. Rinke *et al* (2011) evaluated the frequency of peri-implantitis and found that implant patients not enrolled in a supportive maintenance care program had an 11 fold greater risk for developing peri-implant disease.

The rationale for this research project is to determine the prevalence rate of peri-implant mucositis and the relationship between various risk factors among patients with restored single implants at the Oral Medicine and Periodontology Department (OMEDP) of the Faculty of Dentistry of the University of the Western Cape (UWC).

The study population comprised of patients with single implants placed at the OMEDP and restored at the UWC Prosthetic Department, during the period 01 January 2005 to end of October 2011 (a period of 6 years and 10 months).

To date, neither stringent follow-up protocols, nor maintenance programs are employed at the OMEDP. As previously mentioned, the risk of developing peri-implant disease is increased if patients do not participate in a regular maintenance program. Peri-implant disease is difficult and costly to manage and if left untreated, will result in late implant failure. The initiation of a maintenance program will prove to be beneficial for these patients.

CHAPTER 2:
LITERATURE REVIEW

2.1.   *Background:*

Peri-implant disease encompasses inflammatory changes within the periodontal tissues surrounding an implant. Loss of osseo-integration and late implant failure can follow if not diagnosed and treated early (Heitz-Mayfield, 2008: 292).

Dental implants are at risk of bacterial colonization as the micro flora found are similar to that of the adjacent teeth and are formed within the first week of implant insertion. Periodontal pathogens are similar in peri-implant disease but differ from those found around teeth with a healthy dentogingival unit. These periodontal pathogens are present in the peri-implant micro flora within the first two weeks after implant exposure. It was proposed that the natural dentition acts as a bacterial reservoir for the colonization of implants (Thöne-Mühling *et al*, 2010: 506; Greenstein *et al*, 2010: 116).

The surface characteristics of the implant directly affect the amount of bacteria attaching on the surface of the implant when the implant is exposed. Rougher implants promotes more surface adherence of bacteria. Rough implant surfaces are very difficult to clean and are often repopulated by the regrowth of the residual biofilm of bacteria, after their rough surfaces have been cleaned (Khammissa *et al*, 2012: 72).

The formation of an adherent layer of plaque on the implant appears to be vital in the formation of peri-implant diseases and could be the reason for the change in the biocompatibility of implant surfaces. Gram-negative anaerobic bacteria are primarily linked with peri-implant diseases (Renvert *et al,* 2008: 309). A large quantity of recognized periodontal pathogens such as *Porphyramonas gingivalis*, *Prevotella intermedia*, *Treponema denticola, Aggregatibacter actinomycetemcomitans* and *Fusobacterium nucleatum*, has been related with the onset of peri-implant disease. *Staphylococcus aureus* may also be associated with peri-implant disease as titanium surfaces favour their attachment (Shumaker *et al,* 2009: 392; Khammissa *et al*, 2012: 72). As a result, peri-implant infections are caused by a disproportion between bacterial load and host defence (Heitz-Mayfield, 2008: 292).

When the healing or prosthetic abutment is attached to the implant body, bacteria become imprisoned within the microgap (of various dimensions) at the implant-abutment interface.

The microgap is a source of contamination and therefore results in inflammation in the peri-implant marginal soft tissue unit (Khammissa *et al,* 2012: 72).

2.2. *Definitions and terms:*

Peri-implant disease can be divided into peri-implant mucositis and peri-implantitis. Peri-implant mucositis is a reversible inflammatory lesion restricted to the soft tissues around an implant. It is similar to gingivitis around the natural dentition. If left untreated, progression to peri-implantitis may ensue (Heasman *et al,* 2010:511; Grusovin *et al*, 2010: 3; Khammissa *et al*, 2012: 70). Peri-implantitis is an inflammatory condition of the gingiva around the implant which spreads apically and may result in the progressive destruction of the osseo-integrated bone, increased probing depth with exudation (Karbach *et al,* 2009: 492; Shumaker *et al*, 2009: 392). This bone loss can result in the failure of the implant (Nogueira-Filho *et al,* 2010: 1).

2.3. *Prevalence of peri-implant disease:*

There is inconsistent data in the literature regarding the prevalence of peri-implant disease. This may be due to the different clinical criteria used to evaluate and define the disease or the different observation periods in the previous international studies or different surface enhancements (Ferreira *et al*, 2006: 932; Atieh *et al*, 2012: 3).

There is a paucity of the cross-sectional studies reporting on the prevalence of peri-implant infections. Some studies show that peri-implant mucositis affects roughly 50% of implant sites and 80% of patients, however peri-implantitis affects roughly 12 – 43% of implant sites and 28 -56% of patients (Lindhe and Meyle, 2008: 284; Heasman *et al*, 2010: 512; Khammissa *et al*, 2012: 70). However, Atieh *et al* (2012: 1 -12), in a recent systematic review, found the prevalence of peri-implant mucositis and peri-implantitis to be 63.4% of participants; 30.7% of implants and 18.8% of patients; 9.6% of implants respectively. These findings were independent of patient follow-up.

This high prevalence rate of peri-implant disease emphasises the need for maintenance care (Heasman *et al*, 2010: 512; Atieh *et al*, 2012: 1, 8). If peri-implant disease is left untreated the condition may cause implant failure (Heitz-Mayfield, 2008: 292). Implant failure can occur during the early (less than 6 weeks) or late (after 3 months) healing period after implant placement. However, the primary reason for late implant failures (after 3 months of placement) is peri-implant infections (Karbach *et al,* 2009: 491; Chen and Darby, 2003: 212).

2.4. *Diagnosis of disease:*

The diagnosis of peri-implant mucositis is achieved by using both visual and tactile examination of the peri-implant marginal soft tissue. Under healthy conditions the soft tissue layer directly next to the implant is less vascular, less cellular, and has an increased amount of collagen scar tissue when compared to normal gingival tissue.

With peri-implant mucositis the peri-implant marginal soft tissues appears erythematous (Lindhe and Meyle, 2008: 284; Heasman *et al,* 2010: 512) with the presence of bleeding on probing and or suppuration (Figure 1). Bleeding on probing is a sign of inflammation in the peri-implant sulcus and the absence thereof is indicative of peri-implant health (Chen and Darby, 2003:214). Histologically, peri-implant mucositis resembles gingivitis. After the bacterial biofilm accumulates, the inflammatory cell infiltrate in the peri-implant soft tissue are similar to that seen in the dentogingival unit in gingivitis (Khammissa *et al*, 2012: 124).

Figure 1:   **Peri-implant mucositis: Erythematous marginal soft tissue around 14 which bled after probing.**

The clinical picture of peri-implantitis is associated with peri-implant marginal soft tissue erythema, probing depths of more than 5mm and bleeding on probing, suppuration and radiographic evidence of marginal bone loss - more than 0.2 mm annually or progressively (Figure 2). Sites with peri-implantitis show the presence of plaque and histological evaluation of the inflammatory infiltrate in the connective tissue around the implants includes macrophages, lymphocytes, plasma cells and several neutrophil granulocytes (Lindhe and Meyle, 2008: 284; Atieh *et al*, 2012: 3).
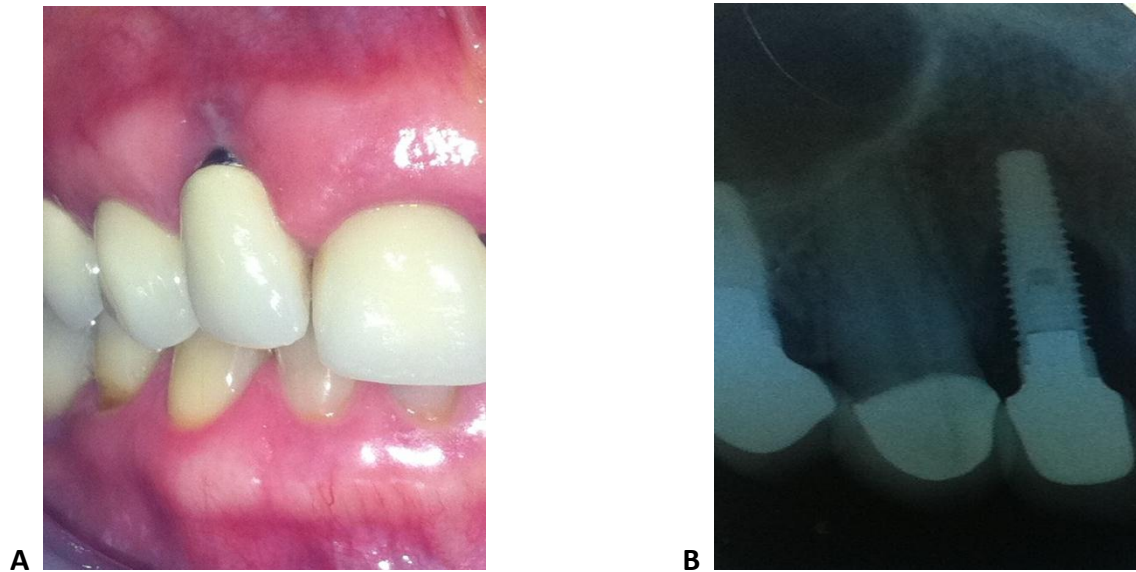
Figure 2: **Peri-implantitis: The 12 implant presents with an erythematous peri-implant marginal soft tissue, recession and suppuration (A); as well as loss of osseo-integrated marginal bone (B) seen on the peri-apical radiograph.**

2.5. *Risk factors associated with peri-implant disease:*

Risk factors are defined as the various factors reported to be associated with the development of peri-implant disease and also referred to as risk variables (Lindhe and Meyle, 2008: 284). When treating patients with peri-implant disease, early recognition of associated risk factors is essential even before initiating treatment. In so doing, these causative factors may be addressed to improve the prognosis of the treatment (Karbach *et al,* 2009: 491; Nogueira-Filho *et al,* 2010: 5).

1. Bacterial plaque

The composition of bacterial plaque on dental implants is similar to the microbiology of the natural dentition (Chen and Darby, 2003: 212). Soft tissue around dental implants react to the bacterial plaque accumulation and inflammatory lesions will develop as a result in the peri-implant soft tissue (Grusovin *et al,* 2010: 3). It has been shown (Ferreira *et al* in 2006) that subjects with poor oral hygiene and an increased plaque accumulation have a higher association with peri-implant disease. Furthermore, the implant site accessibility for oral hygiene can influence the presence of peri-implant disease (Serino and Ström, 2009: 170). Poor oral hygiene is therefore an risk factor for peri-implant disease.

2. Keratinized gingival width

Conflicting evidence has been reported on the effect of keratinized gingival width and peri-implant health. Numerous studies (sited in Greenstein *et al*, 2010: 115) reported peri-implant mucositis in patients with a lack of keratinized gingiva. Similarly other studies (sited in Greenstein *et al*, 2010: 115) maintained the contrary. This may be explained by the observation that with proper oral hygiene, peri-implant health can be preserved regardless of the extent of keratinized gingival tissue around the implant. However, if there is meagre oral hygiene in the oral cavity, sufficient amount of keratinized gingiva may prove valuable (Greenstein *et al*, 2010: 115). All of these studies did not elaborate on the effect that muscle pull had on the amount of keratinized gingival width and peri-implant health.

3. Periodontally compromised patients

Patients who lose teeth due to periodontal disease are also managed with dental implant fixtures (Heitz-Mayfield, 2008: 296). Several studies have looked at the association between periodontally compromised patients and peri-implant infections. A periodontally compromised patient is defined as a subject with a history of either chronic or aggressive periodontitis but without active disease at the time of implant placement. These patients had undergone periodontal therapy (i.e. non-surgical or surgical) before implant placement.

The systematic review of Karoussis *et al* (2007) investigated 15 prospective studies and examined the implant survival rates in periodontally compromised subjects and compared the short-term and long-term studies as well as subjects with chronic and aggressive periodontitis with each other. The short-term studies were conducted over a period of less than 5 years while the long-term studies were conducted over a period of 5 years or more. The short-term studies stressed a stringent individual maintenance programme after implant placement. Longer-term studies showed an increase in probing depths, peri-implant bone loss and incidence of peri-implantitis. They concluded that in long-term follow-up studies, subjects with a history of chronic periodontal disease were at an increased risk for the development of peri-implantitis, however further research is necessary as evidence is limited and confounding factors in these long-term studies such as diabetes and smoking in patients with periodontal disease makes it difficult to determine the effects of periodontitis history alone. Their second conclusion was that short-term studies in subjects with chronic periodontal disease had an implant survival rate similar to periodontally healthy individuals; however these subjects were placed under an individual maintenance care programme subsequent to implant placement. Studies on implants placed in patients with a history of aggressive periodontitis are restricted to short-term follow-up, with favourable survival rates. Long term results are however not available.

In a retrospective study (Rinke *et al*, 2011: 828) the frequency of peri-implantitis amongst participants with a history of periodontal disease was comparable to those without. In this retrospective study was found that regular maintenance proved favourable in maintaining peri-implant health and that the lack thereof resulted in an eleven fold increase in the risk of peri-implant disease.

4. Uncontrolled Diabetes Mellitus

Diabetes mellitus is a chronic metabolic disorder that occurs when the glucose in the blood cannot be absorbed into the cells of the body. This occurs when the pancreas fails to produce sufficient amount of insulin or the cells discontinue responding to the insulin that is produced. Uncontrolled diabetes is considered a risk variable for implant failure and a contraindication for implant therapy. Chronic hyperglycaemia results in chronic inflammation which can lead to bone resorption. Furthermore, diabetics are at a higher risk for infection due to being in an immune-suppressed state, which results in delayed wound healing. Local infection post-surgically and the inability to protect against infection in these patients may play a role in implant complications seen in these patients (Zupnik *et al*, 2011: 4; Heitz-Mayfield, 2008: 296). In a study done by Ferreira *et al* (2006) subjects were considered diabetics if they had an individual fasting blood sugar of ≥ 126 mg/dl or had been using anti-diabetic drugs for the past two weeks. They concluded that poor metabolic control in diabetics was associated with a higher risk for peri-implantitis.

5. Smoking

Smoking has a profound effect on the periodontium with regards to implant patients' wound healing. The mechanism by which smoking influences wound healing can be divided into four categories (Liddelow and Klineberg, 2011: 422):

a) The carbon monoxide produced by the cigarette reduces the oxygen levels in the blood of the healing tissues;
b) Nicotine acts as a vasoconstrictor and reduces the blood flow to the wound site;
c) The cytotoxic activity of the fibroblasts and acute inflammatory cells disrupts cell repair and defence;
d) And wound healing is impaired leading to a greater risk for post-operative complications.

Heterogeneity exists with regards to the definition of smoking described in the various studies. In a systematic review (Strietzel *et al*, 2007: 523 - 544) any patient who smoked cigarettes was considered a smoker, irrespective of number or frequency. They found smokers were at greater risk for peri-implant disease development and subsequent implant

failure, when compared to non-smokers. These findings were supported by Rinke *et al* (2011).

Karbach *et al* (2009) found smoking to be the key risk variable for the development of peri-implant mucositis. Furthermore, tobacco smoking negatively influences the outcome of preventative and management programmes for peri-implant disease, because smoking increases marginal bone loss around implants (Heasman *et al*, 2010: 512).

6. Restoration type (cement vs. screw-retained)

Cement-retained implant restorations are a popular prosthetic treatment modality amongst clinicians. During placement of the restoration, complete elimination of the excess cement from peri-implant soft tissues is extremely difficult. The deeper the sub-gingival margins of the implant restoration (especially 2mm or deeper) the more challenging it becomes to adequately remove excess cement. Residual cement will act as an irritant to peri-implant soft tissues or cause a potential delayed toxic response to the peri-implant tissues. Excess cement deposits irritate peri-implant tissues, triggers an inflammatory response and therefore shows a strong association with the development of peri-implant disease (Linkevicius *et al,* 2011: 1, 3, 5).

Screw-retained implant restorations have less untoward peri-implant soft tissue reactions as no cement is required during placement thereof (Linkevicius *et al,* 2011: 1, 3, 5).

7. Alcohol

There is a paucity of evidence relating alcohol consumption to peri-implant disease. A study by Galindo-Moreno *et al* (2005) assessed the effect of alcohol and tobacco use on peri-implant bone resorption. In subjects with a daily alcohol intake of more than 10g, an increased risk for peri-implantitis was found. Secondly, they concluded that alcohol consumption resulted in greater peri-implant marginal bone loss, when compared to tobacco use.

2.6. *Management of peri-implant disease:*

Implants, like natural teeth, require regular follow up visits to verify the health of the soft and hard tissues as well as the status of the prosthesis. Periodontal health must be re-established and maintained before implant therapy can proceed. However, even in a healthy peri-implant environment, peri-implant supportive care is essential not only to improve the long-term survival of implant-restored fixtures but also for the early detection of possible peri-implant complications. The goal of peri-implant supportive care is to reduce

the amount of plaque and thereby reduce the risk for further disease progression. To this end, patient motivation for proper oral hygiene is crucial (Shumaker *et al*, 2009: 389; Heasman *et al,* 2010: 515). In a retrospective follow-up study (Costa *et al,* 2012), a high incidence of peri-implant mucositis was found in patients not following a supportive maintenance care programme.

- **Most effective therapeutic intervention**

Prevention is the most effective treatment modality for peri-implant conditions (Khammissa *et al,* 2012: 122). When peri-implant disease is diagnosed, identification of risk factors is vital to devise patient specific treatment regimens (Grusovin *et al*, 2010: 3; Heasman *et al*, 2010: 515).

The long-term success and prognosis of the implant is directly related to maintaining the lowest implant bacterial content through good oral hygiene (Feller *et al*, 2012: 128). This was supported by (Atieh *et al* in 2012) who showed that consistent supportive periodontal care reduced the incidence of peri-implantitis with no one management protocol reported to be more clinically effective than the other.

- **Frequency of intervention**

The frequency of peri-implant supportive care is dependent on the individual susceptibility of the patient to various risk factors. With reference to the time interlude between maintenance visits, a three month interval is recommended for patients with periodontitis requiring supportive care, with some requiring additional visits (Greenstein *et al,* 2010: 120). The general guideline is that bleeding on probing can be used to establish the frequency of maintenance intervals in susceptible patients. If bleeding on probing occurs in more than 16% of the sites (implant/ teeth/ teeth and implants), then maintenance intervals should decrease by one month, however if bleeding on probing presents at less than 10% of the sites, then the frequency of the maintenance intervals may be increased by one month (Shumaker *et al,* 2009: 395 – 396).

2.7.   *Future recommendations:*

Nogueira-Filho *et al* (2010) suggested the formulation of a specific prognostic classification system to help guide treatment planning for dental implant fixtures. They proposed that it be based on the stability of the peri-implant tissues and probability of implant failure. However limited information is available and further investigation into a rational systematic prognostic classification system for the management of peri-implant infections is necessary.

CHAPTER 3:
AIMS AND OBJECTIVES

3.1. Aim

To determine the relationship between the prevalence of peri-implant mucositis and local and systemic risk factors associated with single implant supported crowns.

3.2. Objectives

1. To determine the prevalence of peri-implant mucositis as measured by clinical examination.

2. To determine the prevalence of systemic risk factors associated with peri-implant mucositis including gender, smoking, and diabetes.

3. To evaluate various local implant related risk factors. This includes the position in the dental arch; internal or external connection; the association between a standard versus a wide diameter; screw- or cement-retained implant restored crowns.

4. To evaluate local risk factors related to periodontal parameters around the implant site. This includes bleeding on probing and keratinized gingival width around the implant.

5. To determine the relationship between the bacterial plaque and peri-implant mucositis through the use of a plaque-index (modified Sillness and Loë, 1964).

3.3. Null hypothesis

There is no association between the proposed risk factors and the prevalence of peri-implant mucositis associated with single implant-supported crowns.

CHAPTER 4:
MATERIALS AND METHODS

4.1. Study design

This is an analytical cross-sectional study to determine the relationship between the development of peri-implant mucositis and the presence of different risk variables.

The study utilized both a standardized data collection form and an intra-oral examination for each patient (Appendix 1, 2, 3, and 4 respectively).

4.2. Study population

The study sample comprised of patients with restored single implants placed at the OMEDP Department and restored at the Prosthetic Department of the Faculty of Dentistry of the University of the Western Cape, in the period ranging from the 1st January 2005 up and until the end of October 2011.

Patients included in the study:

- Single implants in partially edentulous mouths;

- Implants of all diameters (irrespective of make or brand);

- Bone level implants with an internal or external connection;

- Implants that were restored for a minimum of one year.

Patients excluded in the study:
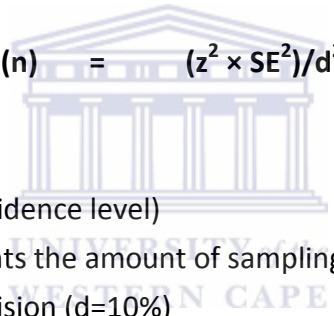
- Those that underwent any bone or soft tissue grafting procedure at the implant site at time of surgical placement;

- Those with immediately placed implants;

- Those with splinted implants or implant bridges;

- Those with tissue level implants.

Data for all patients who receiving implants was captured in a record book in the OMEDP Department. The data from suitable candidates was captured in Microsoft Excel® spread sheet and the latter program was used to select a random sample. Patients were provided with a complimentary check-up and oral prophylaxis.

4.3. Sample size

Cross-sectional studies report the prevalence of peri-implant mucositis to be approximately 50% of implant sites and amongst 80% of implant patients (Lindhe and Meyle, 2008: 284; Heasman *et al*, 2010: 512).

$$(n) = (z^2 \times SE^2)/d^2$$

n = sample size

Z= Z value (e.g. 1.96 for 95% confidence level)

SE = standard error (e.g. represents the amount of sampling variability)

d = desired level of absolute precision (d=10%)

Therefore sample size (n) = $(1.96 \times SE^2)/d^2$

SE for percentage peri-implant mucositis = 50 (e.g. if taken a 50% prevalence of peri-implant mucositis)

Sample size (n) = $(1.96^2 \times 50^2)/10^2$

= $(3.8416 \times 2500)/100$

= 96. 04

Require 97 participants for study to fall within 90% confidence interval.

As the estimate of peri-implant mucositis in this study was expected to be around 50% or even higher, the maximum proportion of 50% was used to estimate the sample size. The study sample necessary to reach this estimate with a 95% confidence interval to fall within 10 % of the estimate was 97. In the event of possible exclusion of patients during the data collection phase a sample of 100 patients was to be selected.

The list of patients in the record book eligible for the study was 120 patients of whom 100 were randomly selected using the Microsoft Excel® program. Each patient from the selected group of 100 was contacted and provided a complimentary check-up and oral prophylaxes at the time of the appointment, however only 74 patients was willing to partake in the study.

4.4.   Data collection procedures and instruments

A standardized data collection (Appendix 1) form as well as an intra-oral examination was completed for each patient.

 It was used to record information regarding:

1. *The patient's gender and health:*

   - *Smoking:*
   Patients who had been smoking tobacco during the implant check-up appointment was categorised as smokers.

   - *Diabetes:*
   The presence of diabetes was based on the patient's report and no differentiation was made between type 1 and 2 diabetes. No further chemical blood tests were done.

2. *Data related to the implant site:*

   - *Position in dental arch:*
   The position of the implant in the dental arch was categorised as either anterior or posterior. Anterior implants were positioned in the incisors to canine area. Posterior implants were positioned in the premolar to molar region.

   - *Implant diameter:*
   The diameter of the implant was divided into either standard or wide. Standard diameter implants ranged between 3.7mm and 4.2mm. Wide diameter implants ranged between 5 mm and 6 mm.

   - *Type of implant restoration placed:*
   The type of implant restored crown used on each implant was categorised as either being a screw-retained or cement-retained crown.

- *Follow-up time from implant placement*

The elapsed time from implant placement to prosthesis placement was calculated for each participant and divided into two groups: 1 to 2 years; and more than 2 years.

3. *Clinical periodontal parameters for the implant site:*

The intra-oral examination recorded by the primary researcher evaluated the clinical parameters at the implant site. The clinical parameters at the implant site were measured with a Vivacare true pressure-sensitive (TPS)® periodontal probe applied at a light pressure of 20 g (see Figure 3). The Vivacare TPS®periodontal probe has a 0.5 mm ball tip with a tactile rim to reduce tissue trauma. The tip of the probe is connected to a spring mechanism which regulates the pressure extended to the probe tip. The force indicator lines overlap at approximately 20 g force. The probe tip has detailed millimetre measurements (Bergenholtz *et al*, 2000: 93 – 94). The clinical parameters recorded around the implant site included (Serino and Ström, 2009: 170; Lindhe *et al*, 2008: 130):

- *Keratinized gingival width*:

This was measured with the Vivacare TPS® periodontal probe and the amount of keratinized gingiva measured was categorized into three groups: less than 1mm; equal to and more than 1mm but less than 2mm; equal to and more than 2mm.

- *Bleeding on probing (BOP):*

The Vivacare TPS® periodontal probe was passed along the gingival margin around the implant and measurements were recorded at 6 sites (mesio-buccal, mid-buccal, disto-buccal, mesio-palatal/ lingual, mid-palatal/ lingual, disto-palatal/ lingual). The peri-implant tissue was subsequently observed for 30 seconds to determine the presence or absence of bleeding.

Figure 3: In photograph (A) the disto-buccal sulcus of the 14 implant is measured with the Vivacare TPS® probe and bleeding in the same site is observed shortly afterwards in photograph (B). In photograph (C) the 21 implant disto-buccal sulcus is measured with the Vivacare TPS® probe and bleeding is detected in photograph (D) subsequently. The mirrored image captured in photograph (E) the mid-palatal peri-implant sulcus of the 11 implant is measured with the Vivacare TPS® probe and in photograph (F) bleeding of the peri-implant soft tissue is noted soon afterwards.

A positive response to bleeding on probing (BOP) in any of the six sites tested around the implant was recorded as positive for the presence of peri-implant mucositis. The latter was based on the diagnostic criteria for peri-implant mucositis which is dependent on visual evaluation of the peri-implant marginal soft tissue which will appear erythematous, as well as bleeding on probing (BOP) (Lindhe and Meyle, 2008: 284; Heasman *et al*, 2010: 512; Chen and Darby, 2003: 214).

4. *Oral hygiene of the patient:*

▪ *Oral hygiene status*:

The general oral hygiene of the patient was measured using a plaque index (PI) (modified Sillness and Löe 1964). It evaluated the extent of soft plaque deposits at the vestibular and lingual gingival margin of selected teeth in the dentition. The plaque index for the oral cavity was then calculated by totalling the two (vestibular and lingual) plaque scores per tooth and then adding the plaque scores for each tooth and dividing it by the number of teeth examined (Bayne *et al*, 2006: 837).

Plaque score:

Score 0:   no plaque in gingival margin or tooth;
Score 1:   plaque only noticed by running probe over tooth surface;
Score 2:   moderate accumulation of plaque on gingival margin and tooth and plaque can be observed by naked eye;
Score 3:   abundance of plaque on gingival margin and tooth.

Interpretation of the plaque index (PI) (modified Sillness and Löe 1964):

PI 0:   excellent
PI 0.1– 0.9: good
PI 1.0– 1.9: fair
PI 2.0– 3.0: poor

▪ *Brushing frequency:*
The brushing frequency for each patient was categorised into: never, or every other day, or twice daily.

- *Flossing frequency* :

The flossing habit for each patient was divided into the following categories: never, or every other day, or twice daily.

- *Rinsing with mouthwash*:

It was not established what type of mouthwash each patient was using, only the frequency of rinsing. The rinsing frequency was divided into: never, or seldom (every other day), or twice daily.

- *Other oral hygiene aids:*

The use of any additional oral hygiene aids was established. These included: water pick, interdental brush, or none.

- *Oral hygiene instructions received prior to implant therapy.*

Each participant was asked if they received instructions on how to clean around the implant before the implant and crown on the implant was placed.

4.5. Calibration of instrument and researcher

- ### Vivacare TPS® probe's reproducibility of a constant probing force

Initially the ability of the Vivacare TPS® probe tips (Figure 4) to reproduce a constant probing force was tested with the use of a mechanical testing machine, the Zwick Material Prufeng 1446 Test Xpert Machine® (Figure 5).

Three of the metal Vivacare TPS® probe tips adapted to one handle was selected to test whether there were differences in force between the probe tips. Each metal probe tip was tested three times (Figure 6).

The probe tip was balanced perpendicularly towards the flat weighing surface of the electronic balance arm (Figure 7). The electronic balance arm was under manual control at a speed of 5 mm/min and a downwards pressure was applied through the electronic balance arm and onto the spring arm of the probe until the line on the probe tip and handle were on the same level.

Figure 4: The Vivacare TPS® periodontal probe consists out of a handle and three different probe tips: metal, plastic and flexible. The tip has a spring system that controls the pressure which is transferred to the probe tip.

Figure 5: The Zwick Material Prufeng 1446 Test Xpert Machine's® electronic balance arm which was under manual control at a speed of 5 mm/min.
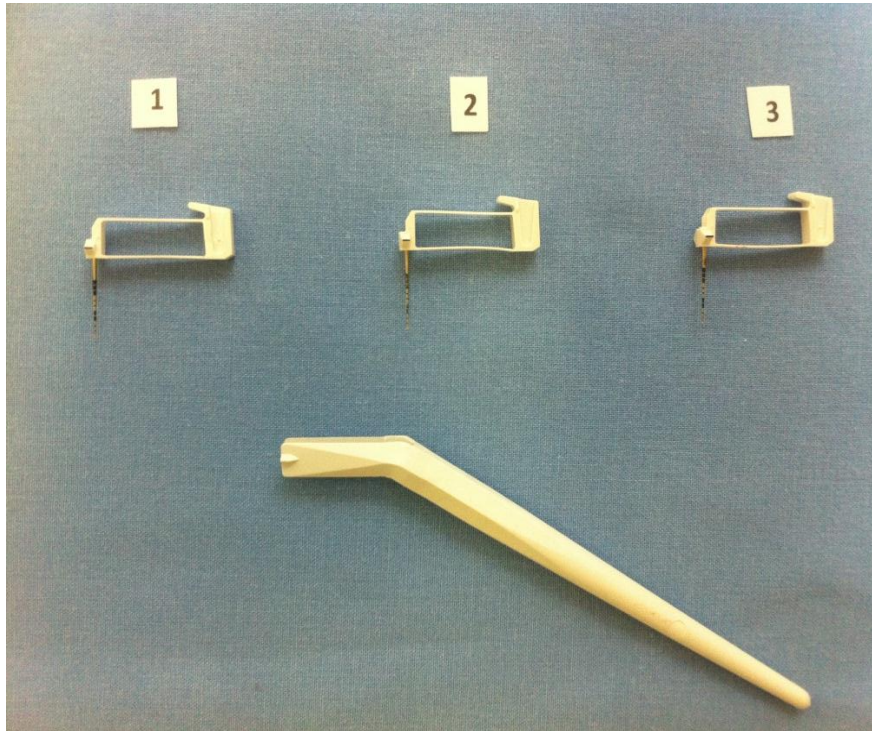
Figure 6: Three Vivacare TPS® metal probe tips which was each measured separately on the same handle.
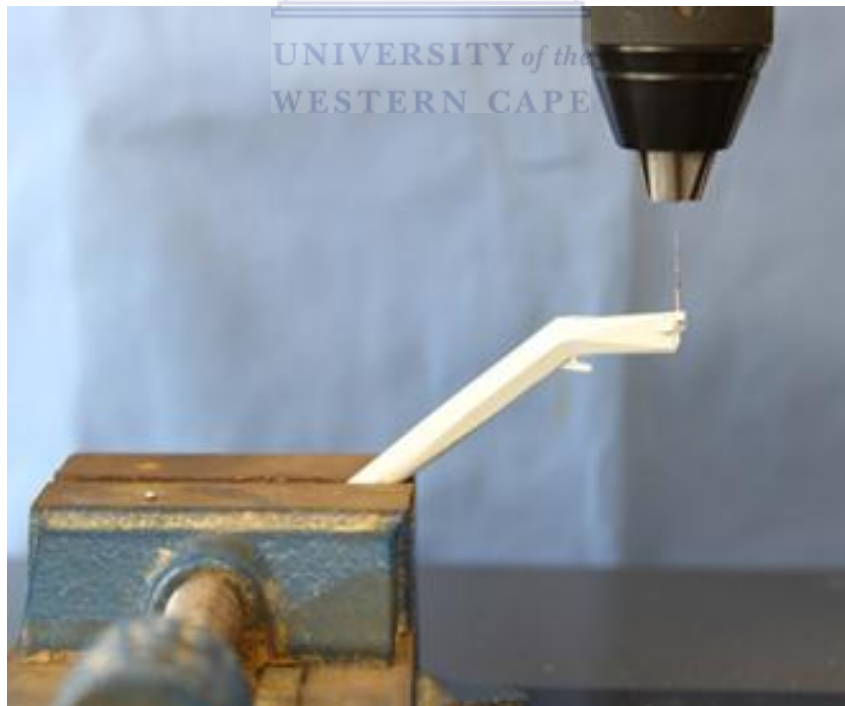
Figure 7: The metal probe tip is adjusted perpendicularly towards the flat weighing surface of the electronic balance arm of the machine.

Two examiners (examiner 1 and 2) took the measurements independently. Examiner 1 was positioned at the level of the probe and flat weighing surface of the electronic balance arm. This examiner indicated to examiner 2 when the lines on the handle and probe tip coincided. Examiner 2 was positioned in front of the computer and read and recorded the force (N), on the verbal command of examiner 1.

Table 1: **The average measurements and force evaluated for Vivacare TPS® probe tip number 1.**

Probe Tip number 1		
Force (N)	*Begin measurement (mm)*	*End measurement (mm)*
0.33	222.523	220.365
0.33	222.749	220.462
0.30	222.383	220.331

Table 2: **The average measurements and force evaluated for Vivacare TPS® probe tip number 2.**

Probe Tip number 2		
Force (N)	*Begin measurement (mm)*	*End measurement (mm)*
0.25	216.339	214.706
0.23	216.537	214.704
0.25	216.360	214.808

Table 3: **The average measurements and force evaluated for Vivacare TPS® probe tip number 3.**

Table 3: Probe Tip number 3		
Force (N)	*Begin measurement (mm)*	*End measurement (mm)*
0.16	216.005	214.585
0.15	217.532	215.904
0.18	217.662	216.152

After the three probe tips was tested, it was decided to used probe tip number 3 as a mean force of 0.163 N was obtained. This is less than the 0.2 N, which is the approximate estimate given by the manufacturer.

Furthermore, in concurrence with the study by Bergenholtz *et al* (2000), reproducible measurements of the Vivacare TPS® probe was high when the same probe tip was used with the same handle. Therefore to ensure standardization the same handle and probe tip number 3 was used for each peri-implant examination.

Throughout the study, after every ten patients evaluated, the Vivacare TPS® probe tip number 3's ability to reproduce the same force was evaluated with the Zwick Material Prufeng 1446 Test Xpert Machine® using the above mentioned method and a mean force of less than the required 0.2N was obtained throughout.

- *Inter-examiner calibration*

The primary researcher's ability to reproduce a consistent positive result for bleeding which was in agreement with a second more experienced clinical supervisor (i.e. golden standard) was evaluated by determining the kappa values. The latter can be defined as the actual measure of agreement with the degree of agreement which would have occurred by chance:

Kappa = (Observed Agreement – Expected Agreement) / 1 – Expected Agreement

To this end patients without implants were examined at six peri-sulcular sites around either the upper or lower first molars. Bleeding on probing was measured. The six peri-sulcular sites around the first molar evaluated included the mesio-buccal, mid-buccal, disto-buccal, disto-palatal/lingual, mid-palatal/lingual, and mesio-palatal/lingual.

The primary researcher evaluated the patient first and allowed a period of 15 minutes to elapse before the more experienced clinical supervisor (i.e. golden standard) evaluated the same patient's tooth. In-between each exam the patient rinsed with 0.2% digluconate chlorhexidine mouth rinse (alcohol based) to remove any residual blood from the peri-sulcular area.

After the examination by the experienced clinical supervisor a period of 15 minutes elapsed before the primary researcher evaluated the same patient's tooth for the second time. In-between each exam the patient rinsed with 0.2% digluconate chlorhexidine mouth rinse (alcohol based) to remove any residual blood from the peri-sulcular area.

The kappa statistic was then evaluated for the readings at the six sites between the two examiners.

Complete agreement between the examiners resulted in a kappa value = 1. Total disagreement the kappa statistic = 0. If the kappa value is more than 0.8 then there is good agreement between examiners. A kappa statistic between 0.6 and 0.8 indicated substantial agreement; however a value between 0.4 and 0.6 indicates moderate agreement.

Table 4: **The kappa values for the first inter-examiner calibration between the primary researcher and the golden standard.**

Peri-sulcular sites	Kappa-values	Quality of agreement
Mesio-buccal	0.634	Substantial agreement
Mid-buccal	1	Total agreement
Disto-buccal	0.7	Substantial agreement
Mesio-palatal/lingual	0.815	Good agreement
Mid-palatal/lingual	0.667	Substantial agreement
Disto-palatal/lingual	0.526	Moderate agreement

Table 5: **The kappa values for the second inter-examiner calibration between the golden standard and the primary researcher.**

Peri-sulcular sites	Kappa-values	Quality of agreement
Mesio-buccal	1	Total agreement
Mid-buccal	1	Total agreement
Disto-buccal	0.667	Substantial agreement
Mesio-palatal/lingual	1	Total agreement
Mid-palatal/lingual	1	Total agreement
Disto-palatal/lingual	1	Total agreement

The majority of the above listed kappa values (Tables 1 and 2) interpreting the quality of agreement was found to be more than substantial agreement, which is considered to be satisfactory to establish inter-examiner calibration.

- *Intra-examiner calibration*

The primary researcher's skill to reproduce a consistent positive result for bleeding was measured. The primary researcher evaluated the patient first and a period of 30 minutes elapsed before evaluating the same patient's tooth for a second time. After each

measurement the patient rinsed with 0.2% digluconate chlorhexidine mouth rinse (alcohol based) to remove residual blood from around the tooth.

The kappa statistic was then evaluated for the readings at the six sites between the two examinations conducted by the primary researcher.

Table 6: **The kappa values for the intra-examiner calibration of the primary researcher.**

Peri-sulcular sites	Kappa-values	Quality of agreement
Mesio-buccal	0.634	Substantial agreement
Mid-buccal	1	Total agreement
Disto-buccal	0.7	Substantial agreement
Mesio-palatal/lingual	0.815	Good agreement
Mid-palatal/lingual	0.667	Substantial agreement
Disto-palatal/lingual	0.526	Moderate agreement

The majority of the kappa values listed in Table 3 above is more than substantial agreement which is considered satisfactory to establish intra-examiner calibration.

4.6. *Disinfection and sterilization of instruments*

Disinfection completely destroys micro-organisms on non-living objects which may cause disease, except for the bacteria spores. Sterilization completely eradicates micro-organisms on non-living objects by means of a physical or chemical procedure (Rutala and Weber, 2004: 702).

High level disinfectants are used to eradicate all micro-organisms on instruments after an exposure time of less than 45 minutes.

Centre for Disease Control and Prevention (CDC) recommends high level disinfectants may inactivate the human immunodeficiency virus (HIV), hepatitis B virus (HBV) as well as secretions contaminated with pulmonary tuberculosis (Rutala and Weber, 2004: 702, 704).

Since only one Vivacare TPS probe handle and specific probe tip number 3 was used throughout the study, there was insufficient time available between patients to gas sterilize the instrument. To this end a high level disinfectant (MedDis®) was used in between patients and at the end of the day the Vivacare TP®S probe was taken for gas sterilization

with ethylene oxide. After each patient the probe was mechanically cleaned with a brush and running water, and then immersed in a tray containing MedDis® for a period of 30 minutes after which the instrument was rinsed under running water.

MedDis® (Figure 8) is explicitly indicated for the chemical reprocessing of thermo-sensitive surgical instruments. The chemical disinfects within 10 minutes and sterilizes after 30 minutes of soaking. It is bactericidal, fungicidal, virucidal, mycobactericidal and sporicidal.

Figure 8:   MedDis® container (A); (B) illustrates the reverse of the container with the manufacturer instructions.

At the end of each day, the Vivacare TPS® probe underwent ethylene oxide (ETO) sterilization (Figure 9 and 10). The full sequence of ETO sterilization begins with pre-conditioning and humidification, gas introduction, exposure, evacuation, and air washes. The full duration of the complete cycle may take between 2 to 5 hours after which an additional ventilation time of 8 to 12 hours is required. Major drawbacks of this process are the extended cycle duration, and the harmful effect on staff exposed to the gas (Rutala and Weber, 2004: 268).

Figure 9: Ethylene oxide (ETO) is used to sterilize medical instruments that cannot be steam sterilized. The picture above illustrates the machine into which the instruments are placed overnight for a complete cycle. Note the ventilation channel at the back of the machine to evacuate the harmful gas.
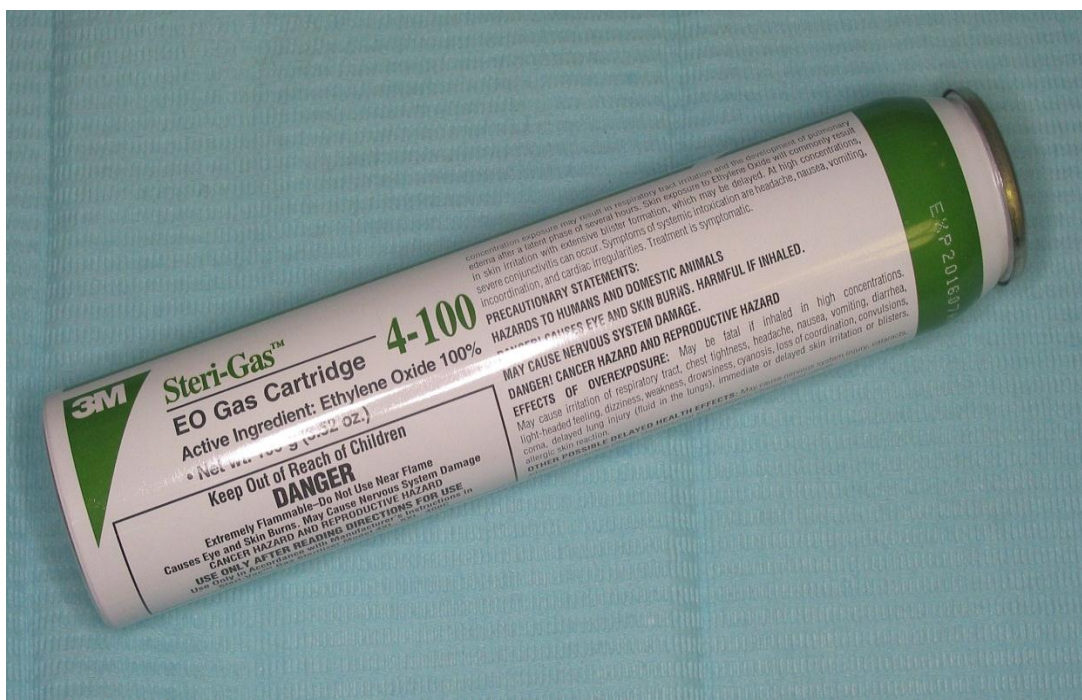
Figure 10: **Ethylene oxide (ETO) gas cartridge. ETO gas is colourless, flammable, and poisonous to staff.**

4.7. Data processing and analysis

The source of the data was the information gathered on the standardized data information form collected during the clinical examination. The data was captured by the principal investigator on the standardized data information form and analysed using the Epi Info® and Microsoft Excel® statistical program. The data was backed up on two different devices. One device was kept in the office and the other device was taken home every night to ensure that it was not at the same site as the computer used for the data capturing.

- ### *Data analysis*

The information assimilated was used to determine a prevalence of peri-implant mucositis in the sample population and its association with various risk variables.

The null hypothesis was tested with a statistical test, the chi-squared test for not normally distributed data. This was used to determine if there was a statistically significant relationship between the presence of peri-implant mucositis and the various systemic and local risk factors as well as the gender of the patients.

4.8.   Ethics

- ### Ethics concerning research approval

The research proposal was approved by the Senate Ethics Research Committee of the University of the Western Cape (Appendix 5).

- ### Patient autonomy

Participation of patients in the study was voluntary. The patient had the right to withdraw from the study at any stage, without prejudice. Patients were required to understand the information that was provided by the researcher and social differences or learning disabilities were addressed when obtaining informed consent (Appendix 2 and 4). Patients received a scale and polish even if he or she did not want to participate in the study.

- ### Management of potential implant complications

When any implant complications or disease was identified in the study population, the researcher informed the patient of such complications and appropriately referred after explanation and education of possible causes therefore.

- ### Treatment options and time aspects regarding management

The researcher was not obliged to provide treatment for the patient, but appropriate referral was arranged therefore

- ### Patient confidentiality

Patient information was kept confidential. Information was collected on a data collection form (Appendix 1) that excluded the patient's name. The data collection form only had the patients study number and file number with a list of corresponding names only on file in the researcher's office. The personal information of the patients was destroyed once the data analysis was completed and the results of the study was discussed and written up.

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CHAPTER 5:
RESULTS

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5.1. Introduction

A study sample of 74 implant patients was investigated to determine the relationship between the presence of peri-implant mucositis and the various systemic and local risk factors. Different variables were compared and the appropriate statistical tests employed to analyse data.

A 95% confidence interval was accepted throughout the statistical analysis and a p-value of less than 0.05 was accepted as statistically significant.

Table 7: **Odds ratios; 95% confidence intervals (C/I); and statistical significance; for developing bleeding on probing when responding to various local and systemic risk factors.**

Risk fackors	Odds Ratio	C/I Lower Limit	C/I Upper Limit	Chi square	P-value
Gender	1.081	0.355	3.292	0.019	0.891
Smoking	0.449	0.142	1.416	1.921	0.166
Diabetes	1.286	0.126	13.086	0.045	0.831
Dental Arch Position *	**7.333**	**1.550**	**34.696**	**7.784**	**0.005**
Diameter Implant	1.895	0.387	9.277	0.638	0.425
Follow-up time after placement	1.350	0.383	4.764	0.219	0.640
Implant retained crown	1.708	0.603	4.833	1.027	0.311
Keratinized Gingival Width *	**0.322**	**0.110**	**0.940**	**4.492**	**0.034**
Oral Hygiene Status *	**3.808**	**1.223**	**11.855**	**5.692**	**0.017**
Brushing Frequency	1.508	0.372	6.111	0.334	0.563
Flossing Frequency	1.108	0.401	3.063	0.039	0.844
Mouthwash Frequency	0.589	0.147	2.357	0.570	0.450
Other Oral Hygiene Aids	0.983	0.320	3.013	0.001	0.975
Water pick	1.064	0.19	5.949	0.005	0.944
Interdental Brush	0.942	0.257	3.456	0.008	0.928
Prior Oral Hygiene Instructions *	**4.267**	**1.432**	**12.716**	**7.266**	**0.007**

(regarded as statistically significant.)*

5.2. General prevalence of peri-implant mucositis

The prevalence rate of peri-implant mucositis was of 70.3%.

5.3. Demographics of the study population

Of the seventy four (74) patients evaluated, fifty three (53) patients were female of which 69.8% was positive for peri-implant mucositis. Twenty one (21) males were included into the study of which 71.4% were positive for peri-implant mucositis.

There was no statistically significant prevalence difference between the two groups (gender and bleeding on probing).

The age distribution of the study sample was comprehensive and ranged from 20 to 84 years. The patient's age was allocated into various age groups and the succeeding pie chart (Figure 11) illustrates the age distribution of the study sample. Those younger than 49 years represented 19 participants (36.54%) of the sample and those 50 years and older represented 33 participants (63.46%) of the sample.

Percentage allocation for age distribution of sample

	Legend	KEY FOR AGE:
1.92		
9.62	■ 1	
11.54	■ 2	
9.62	■ 3	
15.38	■ 4	KEY FOR AGE:
17.31	■ 5	1 = 20 to 29 years
34.62	■ 6	2 = 30 to 39 years
	■ 7	3 = 40 to 49 years
		4 = 50 to 59 years
		5 = 60 to 69 years
		6 = 70 to 79 years
		7 = 80 to 89 years
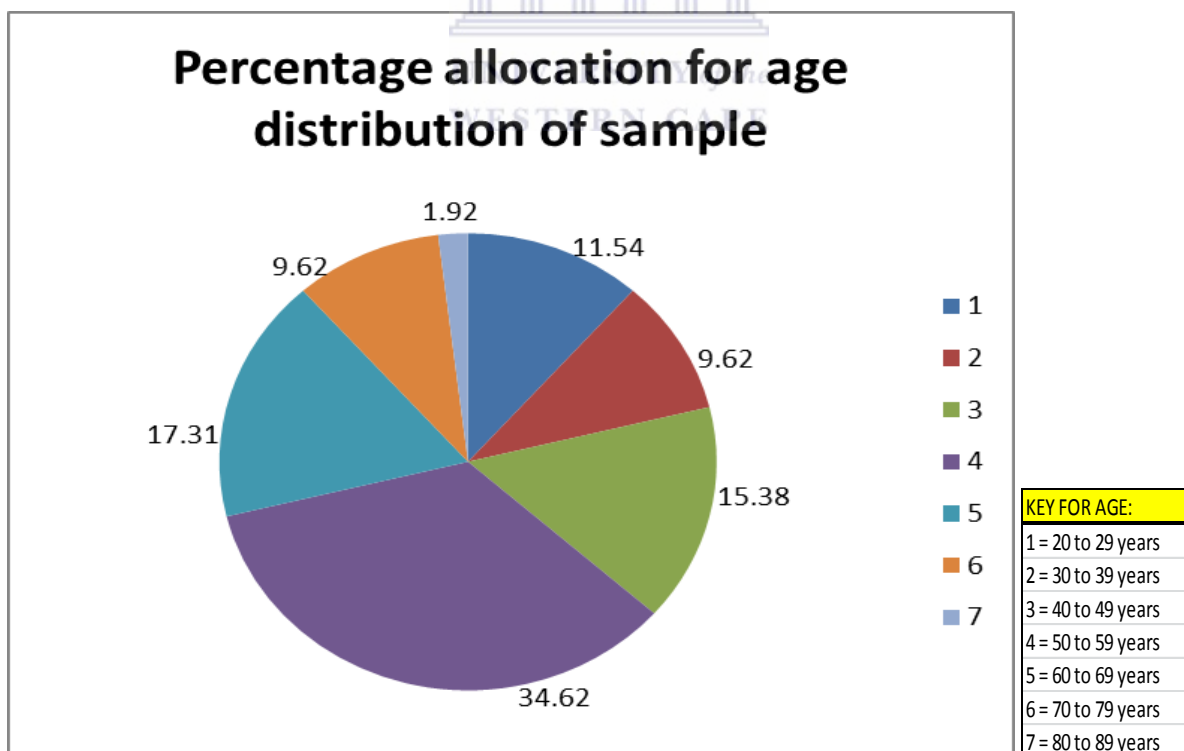
Figure 11: Age distribution of study sample positive for peri-implant mucositis.

5.4. Systemic factors' association with peri-implant mucositis

Diabetes and smoking were two systemic risk factors which were investigated. There were no statistically significant differences between these two groups and peri-implant mucositis. Sample sizes of diabetics and smokers' positive for peri-implant mucositis was too small for any inferences to be made.

- **Smoking**

A patient was considered a smoker when they reported smoking tobacco at the time of the implant check-up.

Table 8:   A frequency table for smoking and peri-implant mucositis.

SMOKING	Bleeding		Total
	Positive	Negative	
Yes	9	7	16
No	43	15	58
TOTAL	52	22	74

- ➢ Chi-square = 1.921
- ➢ P-value = 0.166

The Chi-square statistic of 1.921 represented a probability of 0.166 which was more than 0.05; therefore there was no significant difference between the groups.

- **Diabetes**

The presence of diabetes was based on the patient's report and no differentiation was made between type 1 and 2 diabetes. No further diagnostic chemical blood tests were done.

Table 9:   **A frequency table for diabetes and peri-implant mucositis.**

	Bleeding		
DIABETIC	**Positive**	**Negative**	**Total**
Yes	3	1	4
No	49	21	70
TOTAL	52	22	74

- ➢ Chi-square = 0.045
- ➢ P-value = 0.831

The Chi-square statistic of 0.05 represented a probability of 0.83 which was more than 0.05; therefore there was no significant difference between the groups.

5.5. *Local risk factors related to the implant and their association with peri-implant mucositis*

▪ *Dental arch position*

Implants placed in the incisor to canine region of the dental arch where categorised as being anterior implants. Posterior implants were implants placed in the premolar to molar regions of the dental arch.

Table 10:   **A frequency table for dental arch position of the implant and bleeding on probing.**

	Bleeding		
ARCH POSITION	**Positive**	**Negative**	**Total**
Anterior	22	2	24
Posterior	30	20	50
TOTAL	52	22	74

- Chi-square = 7.784
- P-value = 0.005

The Chi-square statistics of 7.784 represented a probability of 0.005 which was less than 0.05; therefore there was a significant difference between the groups.

- ■ *Diameter implant*

The implant diameter was categorised into standard (between 3.7mm and 4.2 mm) or wide (5 mm and 6 mm).

Table 11:   A frequency table for implant diameter and peri-implant mucositis.

	Bleeding		
IMPLANT DIAMETER	**Positive**	**Negative**	**Total**
Standard	48	19	67
Wide	4	3	7
TOTAL	52	22	74

- Chi-square = 0.638
- P-value = 0.425

The Chi-square statistic of 0.638 represented a probability of 0.425 which was more than 0.05; therefore there was no significant difference between the groups.

- ■ *Implant retained crown*

The type of implant restored crown used on each implant was categorised as either being a screw-retained or cement-retained crown.

Table 12: A frequency table for implant retained crown and peri-implant mucositis.

CROWN RETENTION	Bleeding		
	Positive	Negative	Total
Cement	37	13	50
Screw	15	9	24
TOTAL	52	22	74

- Chi-square = 1.027
- P-value = 0.311

The Chi-square statistic of 1.027 represented a probability of 0.311 which was more than 0.05; therefore there was no significant difference between the groups.

- *Follow-up time from implant placement*

The time that elapsed from implant placement till implant follow-up for each participant, was calculated afterwards from the date of implant placement recorded in the implant record book kept in the OMEP Department and the date of the implant follow-up appointment. The mean follow-up time for each of the 52 participants evaluated with bleeding after probing was 3 years and 4 months.

The follow-up time was divided into two groups: 1 to 2 years; and more than 2 years.

Table 13: A frequency table for follow-up time from implant placement and bleeding after probing.

FOLLOW UP TIME	Bleeding		
	Positive	Negative	Total
1 to 2 years	12	4	16
More than 2 years	40	18	58
TOTAL	52	22	74

- ➢ Chi-square = 0.219
- ➢ P-value = 0.640

The Chi-square statistic of 0.219 represented a probability of 0.640 which was more than 0.05; therefore there was no significance between the groups.

5.6. Local risk factors related to the keratinized gingival width around the implant and its association with peri-implant mucositis

Keratinized gingival width was divided three categories: less than 1mm; equal to and more than 1mm but less than 2mm; equal to and more than 2mm. However, due to a small sample (five cases) of keratinized gingival width less than 1 mm, the three categories were collapsed into two categories: less than 2 mm; 2mm and more.

Table 14: **A frequency table for keratinized gingival width and peri-implant mucositis.**

KERATINIZED GINGIVAL WIDTH	Bleeding		
	Positive	Negative	Total
Less than 2mm	11	10	21
2mm and more	41	12	53
TOTAL	52	22	74

- ➢ Chi-square = 4.492
- ➢ P-value = 0.034

The Chi-square statistic of 4.492 represents a probability of 0.034 which was less than 0.05; therefore there was no significant difference between the groups.

5.7. Local risk factor related to oral hygiene and its association with peri-implant mucositis

▪ Oral Hygiene Status

The oral hygiene status of the patient was divided into three categories: poor, fair or good. For statistical evaluation the categories for oral hygiene status of the patient was collapsed into two categories: poor to fair oral hygiene; and good oral hygiene.

Table 15:   **A frequency table for oral hygiene status and peri-implant mucositis.**

	Bleeding		
ORAL HYGIENE STATUS	**Positive**	**Negative**	**Total**
Poor to fair	44	13	57
Good	8	9	17
TOTAL	52	22	74

- ➢ Chi-square = 5.692
- ➢ P-value = 0.017

The Chi-square statistic of 5.692 represented a probability of 0.017 which was less than 0.05; therefore there was a significant difference between the groups.

- ▪ *Brushing frequency*

The brushing frequency was divided into two categories: never or every other day; or twice daily.

Table 16:   **A frequency table for brushing and bleeding after probing.**

	Bleeding		
BRUSHING FREQUENCY	**Positive**	**Negative**	**Total**
Once	10	3	13
Twice	42	19	61
TOTAL	52	22	74

- ➢ Chi-square = 0.334
- ➢ P-value = 0.563

The Chi-square statistic of 0.334 represented a probability of 0.563 which was more than 0.05; therefore there was no significant difference between the groups.

- *Flossing frequency*

The flossing frequency was divided into two categories: never or every other day; and every day.

Table 17:   Frequency table for flossing and peri-implant mucositis.

FLOSSING FREQUENCY	Bleeding		
	Positive	Negative	Total
Never to seldom	32	13	45
Every day	20	9	29
TOTAL	52	22	74

- ➢ Chi-square = 0.039
- ➢ P-value = 0.844

The Chi-square statistic of 0.039 represented a probability of 0.844 which was more than 0.05; therefore there was no significant difference between the groups.
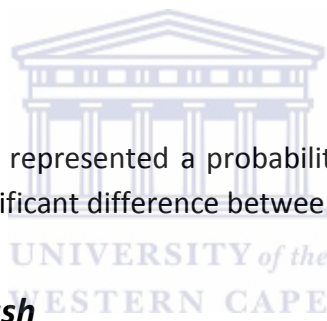
- *Rinsing with mouthwash*

It was not established what type of mouthwash each patient was using, only the frequency of rinsing. The rinsing frequency was divided into: never or seldom; and twice daily.

Table 18:   Frequency table for rinsing and peri-implant mucositis.

RINSING FREQUENCY	Bleeding		
	Positive	Negative	Total
Never - every other day	41	19	60
Everyday	11	3	14
TOTAL	52	22	74

- ➢ Chi-square = 0.570

The Chi-square statistic of 0.57 represents a probability of 0.45 which is more than 0.05; therefore no significant difference between the groups.

- ***Other oral hygiene aids***

From each participant it was assimilated if any additional oral hygiene aids other than brushing, flossing and using a mouthwash was used. Patients were given three options: water pick, interdental brush, or none.

For statistical evaluation three separate frequency tables was made: other oral hygiene aids; water pick; and interdental brush.

Table 19:   The frequency table of other oral hygiene aids and bleeding on probing.

	Bleeding		
OTHER ORAL HYGIENE AIDS	**Positive**	**Negative**	**Total**
Yes	14	6	20
No	38	16	54
TOTAL	52	22	74

- Chi-square = 0.001
- P-value = 0.975

The Chi-square statistic of 0.001 represented a probability of 0.975 which was more than 0.05; therefore there was no significant difference between the groups.

Table 20:   A frequency table for the use of a water pick and bleeding after probing.

	Bleeding		
WATERPICK	**Positive**	**Negative**	**Total**
Yes	5	2	7
No	47	20	67
TOTAL	52	22	74

- Chi-square = 0.005
- P-value = 0.944

The Chi-square statistic of 0.005 represents a probability of 0.944 which was more than 0.05; therefore there was no significance between the groups.

Table 21: **A frequency table for the use of an interdental brush and bleeding after probing.**

INTERDENTAL BRUSH	Bleeding		
	Positive	Negative	Total
Yes	9	4	13
No	43	18	61
TOTAL	52	22	74

- Chi-square = 0.008
- P-value = 0.928

The Chi-square statistic of 0.008 represented a probability of 0.928 which was is more than 0.05; therefore there is no significance between the groups.

- *Oral hygiene instructions prior to commencing implant treatment*

Each participant was asked if they received instructions how to clean around the implant before the implant and crown on the implant was placed.

Table 22: **Frequency table representing pre oral hygiene instructions and bleeding on probing.**

PRE ORAL HYGIENE INSTRUCTIONS	Bleeding		
	Positive	Negative	Total
Yes	32	6	38
No	20	16	36
TOTAL	52	22	74

- ➢ Chi-square = 7.266
- ➢ P-value = 0.007

The Chi-square statistic of 7.27 represents a probability of 0.007 which is more than 0.05; therefore there is a significant difference between the groups.

**Figure 12:   Pre oral hygiene instructions and bleeding on probing.**

5.8. Inter-relationship between peri-implant mucositis and selected risk factors

- ▪ *Anterior implants associated with implant crown retention and bleeding after probing*

Table 23:   Frequency table for anterior implants associated with implant crown retention and peri-implant mucositis.

	Bleeding		
CROWN RETENTION	**Positive**	**Negative**	**Total**
Cement	17	1	18
Screw	5	1	6
TOTAL	22	2	24

- ➢ Chi-square = 0.727
- ➢ P-value = 0.394
- ➢ Odds ratio = 3.400

The majority of anterior cement-retained crowns (77.27%) were positive for bleeding after probing. The majority of cement-retained crowns (94.44%) in the anterior dental arch were positive for bleeding after probing.

The Chi-square statistic of 0.727 represented a probability of 0.394 which is more than 0.05; therefore there was no significant difference between the groups.

- ▪ ***Posterior implants associated with implant retained crown and peri-implant mucositis***

Table 24: **Frequency table for posterior implants associated with implant retained crown and peri-implant mucositis.**

	Bleeding		
CROWN RETENTION	**Positive**	**Negative**	**Total**
Cement	20	12	32
Screw	10	8	18
TOTAL	30	20	50

- ➢ Chi-square = 0.232
- ➢ P-value = 0.630
- ➢ Odds ratio = 1.333

The majority of posterior implants had cement-retained crowns (62.50%) positive for bleeding. However the majority of crowns on posterior implants positive for bleeding were 66.67%.

The Chi-square statistic of 0.232 represented a probability of 0.630 which was more than 0.05; therefore there was no significant difference between groups.

- **Peri-implant mucositis associated with keratinized gingival width and dental arch position**

The majority of patients (95.83%) with bleeding after probing and anterior placed implants had a keratinized gingival width of 2 mm and more.

Table 25: **Frequency table of peri-implant mucositis associated with keratinized gingival width and dental arch position.**

ARCH POSITION	Keratinized Gingival Width		Total
	Less than 2mm	2mm and more	
Anterior	1	23	24
Posterior	20	30	50
TOTAL	21	53	74

- Chi-square = 10.245
- P-value = 0.001
- Odds ratio = 0.065
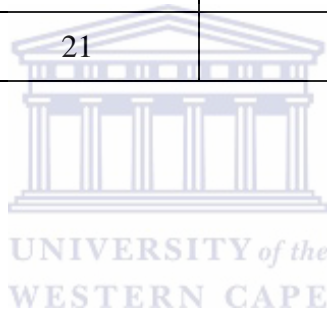
The odds for having keratinized gingival width of less than 2mm around anterior implants are 0.07 times the odds of posterior implants.

Therefore the odds for having keratinized gingival width of less than 2mm around an anterior implant are 93% less than the odds for those around posterior implants.

The Chi-square statistic of 10.24 represented a probability of 0.001 which is less than 0.05; therefore there was a significant difference between the groups.

- **Peri-implant mucositis associated with flossing and receiving prior oral hygiene instructions**

The majority of participants (53.33%) who did receive oral hygiene instructions prior to implant placement never or seldom flossed.

Table 26: Frequency table of peri-implant mucositis associated with flossing frequency and receiving prior oral hygiene instructions.

	Prior Oral Hygiene Instructions		
FLOSSING	No	Yes	Total
Never to seldom	21	24	45
Every day	15	14	29
TOTAL	36	38	74

- ➢ Chi-square = 0.181
- ➢ P-value = 0.671
- ➢ Odds ratio = 0.817

The Chi-square statistic of 0.181 represented a probability of 0.671 which was more than 0.05; therefore there was no significant difference between the groups.
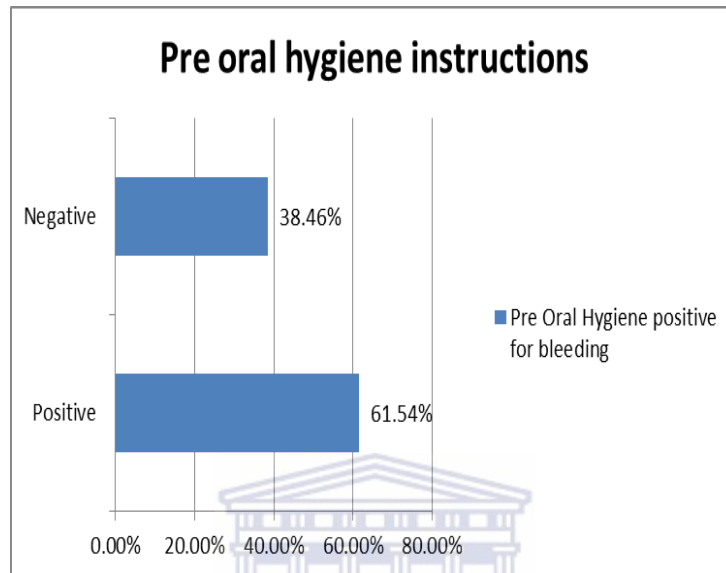
- ▪ *Peri-implant mucositis associated with oral hygiene status and flossing frequency*

Table 27: Frequency table of peri-implant mucositis associated with oral hygiene status and flossing frequency.

	Flossing Frequency		
Oral Hygiene Status	Never to seldom	Every day	Total
Poor to fair	38	19	57
Good	7	10	17
TOTAL	45	29	74

- ➢ Chi-square = 3.570
- ➢ P-value = 0.058
- ➢ Odds ratio = 2.857

The majority of participants (66.67%) with poor to fair oral hygiene status flossed never or seldom.

The Chi-square statistic of 3.570 represents a probability of 0.058 which was more than 0.05; therefore there was no significant difference between the groups.

5.9. Description of statistically significant findings:
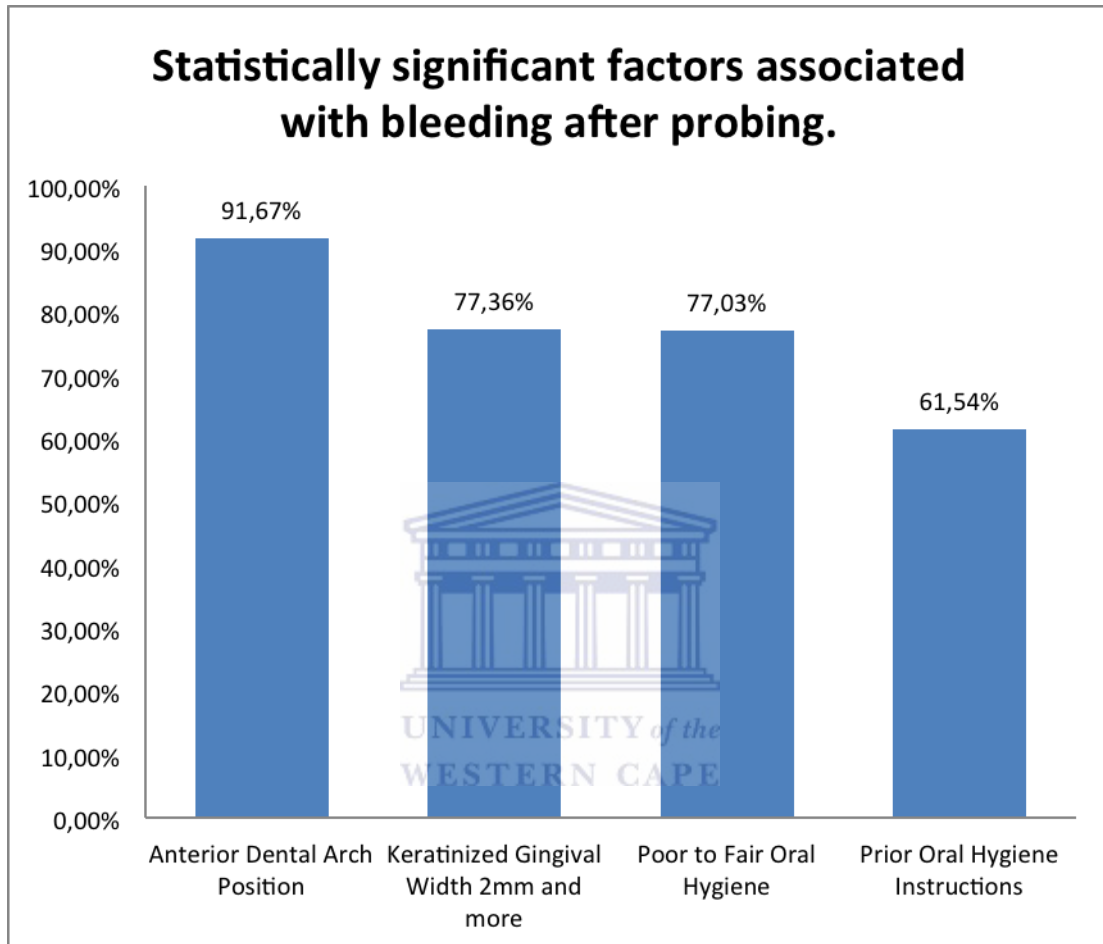
Figure 13: **Statistically significant factors associated with bleeding on probing.**

- *Dental arch position*

Participants with anterior implants that presented with bleeding after probing were 20 (91.67%) while only 30 (60%) participants with posterior implants presented with bleeding after probing.

The odds for having an anterior placed implant of bleeders were 7.33 times the odds of non-bleeders.

- ***Keratinized gingival width***

Participants with a keratinized gingival width of 2mm and more who was positive for bleeding after probing was 41 (77.36%) and only 11 (52.38%) participants with a keratinized gingival width of less than 2mm had bleeding after probing.

The odds of participants having a keratinized gingival width of less than 2 mm of non-bleeders were 68% less the odds of bleeders.

Participants that did not present with bleeding after probing are 0.68 times more likely to have a keratinized gingival width of less than 2mm compared to those who did bleed.

- ***Oral hygiene status***

The majority of participants (77.03%) had poor to fair oral hygiene while less than a third of the sample (22.97%) had good oral health. Participants with poor to fair oral hygiene 44 (77.19%) were positive for bleeding after probing, while only 8 (47.06%) participants with good oral hygiene were positive for bleeding after probing.

The odds for having a poor to fair oral hygiene status of bleeders were 3.808 the odds of non-bleeders.

Participants that did not present with bleeding after probing are 1.64 times more likely to have poor to fair oral hygiene status compared to those who did not bleed.

- ***Prior oral hygiene instructions***

The majority of participants (61.54%) who presented with bleeding after probing did receive oral hygiene instructions before implant therapy.

The odds for not having pre oral hygiene instructions of bleeders are 4.267 times the odds of non-bleeders.

Participants that did not present with bleeding on probing are 1.52 times more likely to have not received oral hygiene instructions prior to implant placement compared to those who did present with bleeding.

5.10. Null hypothesis

The null hypothesis was therefore rejected when considering the four selected risk factors:

- Anterior dental arch position

- Wider keratinized gingival widths

- Poor to fair oral hygiene status

- Prior oral hygiene instructions

CHAPTER 6:
DISCUSSION

This cross-sectional study aimed to determine the prevalence of peri-implant mucositis and its associated risk factors in patients treated with single implants, which were restored for a minimum of one year in the Department of OMEDP at UWC.

The findings of this study reveal the prevalence rate of peri-implant mucositis to be 70.3% per implant site. It is considerably higher in comparison to international studies whose prevalence rates of peri-implant mucositis range between 30.7 - 50% of implant sites and 63.4 - 80% of patients (Lindhe and Meyle, 2008: 284; Heasman *et al,* 2010: 512).

No significant gender predilection with regard to the prevalence of peri-implant mucositis was found, which is in concordance with the findings of other such studies.

To date there is no available South African literature reporting on the prevalence of peri-implant disease. A plausible reason for the high prevalence rate found in this study population could be the absence of a defined maintenance program for patients receiving implant restorations. In the present study the follow-up period for participants ranged from one year to seven years (mean of 3 years and 4 months). The majority of participants (76.92%) with bleeding on probing only presented for a follow-up examination, 2 years following placement of the implant prosthesis. Most participants did not comply with the recommended maintenance care and others only presented when prosthodontics maintenance or repair was required. It can therefore not be uniformly stated that the follow-up appointment given to participants as part of the study was the first maintenance care appointment for all the participants. In the literature the frequency of maintenance visits to prevent disease progression is still unclear. In addition, the fact that there are fewer studies on peri-implant mucositis than peri-implantitis means that there is a lack of follow-up of the disease progression in general. Another possible reason for the high prevalence rate in this study population may be as a result of a small sample size. The study included 74 implant patients from the initial list of 100 suitable candidates. Not all randomly selected suitable candidates were included for analysis in the study. This is because:

• Eight patients did not want to come in for a follow-up evaluation.

- Three patients moved to different provinces and could not come in for a follow-up evaluation.

- Six patients were not contactable for various reasons.

- Nine patients did not receive the prosthetic components and crown after their implant surgery was completed due to financial constraints.

Of all the risk factors evaluated in this study, only four were found to be statistically significant and included: if the position of the implant crown was in the anterior dental arch position; wider keratinized gingival widths; poor to fair oral hygiene status; and prior oral hygiene instructions.

The role of local risk factors, i.e. "position of dental implant in the arch" and "width of keratinized gingival tissue", in the development of peri-implant mucositis was an unexpected finding, because studies in the literature reveal different results.

In contrast, this study has revealed that at long term follow-up there is a statistically greater prevalence of peri-implant mucositis (diagnosed by bleeding after probing) around implants in the anterior area of the mouth. The anterior area also has a greater prevalence of wider dimensions of keratinized gingiva. A study by Greenstein *et al* (2010: 115) maintained the contrary and found that wider keratinized gingival widths around the implant site may prove valuable to the peri-implant soft tissue health. Furthermore, in the literature there is no evidence with regards to what effect the position of the dental implant in the dental arch will have on the development of peri-implant disease.

Additionally, analysis of the data has revealed that the majority (77.27%) of implant-supported cement retained restorations in the anterior area have presented with bleeding on probing. This is also in direct contrast with the literature. A systematic review and meta-analysis (De Brandão *et al,* 2013: 287 – 295) has shown that there is no evidence to support differences in the marginal bone loss through indirect comparison between cement and screw-retained restorations. A randomized controlled trial with 10 year follow-up has shown that, within the limitations of the study, there was no evidence of a significant difference in the clinical behaviour of the peri-implant marginal soft tissues when cemented or screw-retained single-tooth implant restorations were provided (Vigolo *et al*, 2012: 355 -364). Other long term follow-up studies have shown better peri-implant soft tissue reactions around cement-retained implant supported restorations compared to screw-retained restorations (Nissan *et al*, 2011: 11-2 – 1107).

An explanation for the greater prevalence of peri-implant mucositis in the anterior area might be the extrusion of cement around the margins of a cement-retained restoration which, given time in a vascular environment of peri-implant gingiva could elicit a foreign body inflammatory reaction which is clinically diagnosed as peri-implant mucositis. This would explain the lack of effect of good plaque control instruction on peri-implant mucositis as the mucositis is a foreign body reaction and not a plaque-induced lesion. Animal studies on root canal fillers (Silva-Herzog *et al,* 2011: 440 -446) have shown reactions in connective tissue to these materials and it is feasible that peri-implant tissues will also react to extruded cement materials resulting in inflammation in these tissues. Further research to investigate this theory is difficult to do as the ideal diagnostic method to determine whether there has been extrusion of cement around a crown margin is direct visual inspection which would mean crown removal. Another possible reason explaining the majority of cement-retained crowns presenting with peri-implant mucositis, is that the participants in this study had their cement-retained crowns placed by different prosthodontic dental registrars. Their lack of experience may have contributed to possible excessive amounts of cement being used, eliciting a foreign body reaction in the peri-sulcular tissues.

Poor oral hygiene and bacterial plaque is considered to be the major risk variable for peri-implant disease. Peri-implant soft tissues react to the bacterial plaque and result in local inflammation. Studies have proven that patients with poor oral hygiene and high numbers of bacterial plaque are strongly associated with peri-implant disease (Grusovin *et al,* 2010: 3). Results in this study are in agreement with the literature and shows a statistically significant association between poor to fair oral hygiene and peri-implant mucositis. Less bleeding occurred in participants with good oral hygiene. In addition, the majority of the sample (63.46%) was 50 years and older and may give a possible explanation for poor to fair oral hygiene being so high. A possible lack in dexterity in this age group may have resulted in a lack of proper home cleaning around the implants. This may be the possible cause for the bulk of patients not flossing around the implants and the increase in peri-implant mucositis around implants. Furthermore the brushing frequency, flossing habit, rinsing frequency, or other oral hygiene aids used did not have a statistically significant effect on the overall oral hygiene of the participants. Interestingly the majority of participants (54%) did not use any other oral hygiene aids than brushing and flossing. However, it can be postulated that even if these participants were flossing around the anterior cement-retained implant crowns, it still would not have made a difference as the excessive cement would not have been removed or dislodged.

With regards to the participants who received oral hygiene instructions prior to the initiation of implant therapy, the results in this study found a statistically significant association (p= 0.007) between the groups. The majority of participants (61.54%) who presented with bleeding after probing did receive oral hygiene instructions before implant therapy. The odds for not having pre oral hygiene instructions of non-bleeders were 4.267

times the odds of bleeders. This result was unexpected and may be possibly related to the loss of dexterity in the majority of the sample being over 50 years of age. The latter could be explained by the majority of participants (53.33%) who did receive oral hygiene instructions prior to implant placement who never or seldom flossed. In addition the bulk of participants (66.67%) with poor to fair oral hygiene status also flossed never or seldom. However one must bear in mind that a participant will not be able to remove the excess cement in the peri-sulcular area eliciting a foreign body reaction with flossing.

Therefore oral hygiene instructions alone prior to the initiation of implant therapy are no assurance for a reduced risk of later developing peri-implant disease. There are many other co-founding factors which may also influence the outcome of peri-implant soft tissue health. In the literature there are limited amount of studies that looked at combined risk factors and their synergistic effect on implant survival. These factors may not seem significant when analysed individually, but may become so when they occur together. In this study we found that anterior placed implants with cement restored crowns were at greater risk for developing peri-implant disease. The majority of anterior implants that presented with bleeding after probing (77.27%) had cement-retained crowns. Furthermore anterior implants with a keratinized gingival width of 2 mm and more were also more likely to present with peri-implant disease and showed a significant difference (p = 0.001).

Weaknesses and strengths of study:

- Sampling error: A sample error of 10% was used in this study. With a maximum prevalence rate of peri-implant mucositis of 50% or more expected (as gleaned from the literature) and a 10% margin of sampling error the study utilized the minimal sample required of 97. In the end only 74 participants contacted out of the 97 sampled, agreed to come in for examination. As the population size was 120 there was not the option of using a sampling error of 5% or less.

- During the completion of the calibration of the primary researcher, each participant was asked to rinse with 0.2% Digluconate Chlorhexidine mouth rinse between each examination. The latter was done to remove any residual blood form the peri-sulcular area before the next examiner evaluated the peri-sulcular tissues. In retrospect, this was not required and perhaps over cautious and there is no literature that deems this necessary.

- Three of the significant risk factors found in this study (i.e. dental arch position, oral hygiene status, and prior oral hygiene instructions) each had odds ratio's which was more than 3 indicating a strong association with bleeding after probing. However the range between the lower and upper limits of their confidence intervals was very

wide, indicating a possible weakness in the results. Their small sample may have had an effect on the precision of the results.

- Furthermore the effect that the different implant systems' surface topography and bacterial plaque might have on the peri-implant tissue was not investigated as the study only examined the soft tissue around the implant and not the bone.

Hence while no inferences can be made for the majority of risk factors evaluated, the study highlights the need for initiating a periodontal supportive maintenance care program for patients to ensure optimal long term mucosal health. It can be proposed that a more rigid maintenance programme should be assigned to patients based on the position of the implant in the dental arch (anterior), the type of implant supported restoration used (cement), and the age and manual dexterity of the patient (above the age of 50 years).

CHAPTER 7:
CONCLUSION AND RECOMMENDATIONS

Within the limitations of this cross-sectional study there is a high occurrence of peri-implant mucositis with a 70.3% prevalence rate per implant site.

Four risk factors had a statistically significant relationship on peri-implant mucositis. They included "anterior dental arch position"; "wider keratinized gingival width"; "poor to fair oral hygiene"; and "prior oral hygiene instructions".

Recommendations

The high prevalence rate obtained from the study population illustrates the importance of a regular maintenance programme for patients with implant restored restorations. A more rigid maintenance programme are proposed for implant patients with an anteriorly placed implant, cement-retained implant supported restoration, and those above the age of 50 years with loss of dexterity.

Finally, to safeguard optimal long term mucosal health around dental implants it can be recommended to use screw-retained implant supported restorations rather than cement-retained.

Further research is recommended on the various risk factors associated with the onset of peri-implant disease. The current study had a limited sample size which was sufficient for determining the main aim of the study. A larger sample size is recommended for evaluating the various risk factors associated with peri-implant disease to ensure accuracy and completeness of results.

As suggested in the literature by Nogueira-Filho *et al* in 2010 a prognostic classification system identifying possible risk factors in patients prior to initiating implant therapy may reduce the prevalence of peri-implant mucositis. It can be recommended that future research should focus on this.

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Risk Factors associated with Peri-implant Mucositis

Data Collection Form

Study Reference Number   **Patient Folder Number:**

Mark (X) the appropriate section:

Gender	Male	Female
Smoking	Yes	No
Diabetes	Yes	No

Periodontal Parameters around Implant Site

Keratinized Gingival Width   Less than 1mm   More than 1mm but less than 2mm   More than 2mm

Bleeding on Probing (BOP)		
Mesio-buccal	Mid-buccal	Disto-buccal
Mesio-palatal/lingual	Mid-palatal/lingual	Disto-palatal/lingual

Oral Hygiene

Plaque Index:

Tooth Nr	Vestibular Plaque Score	Lingual Plaque Score	Total Tooth Plaque Score
16			
21			
24			
36			
41			
44			
		Total =	

Have you received oral hygiene instructions before?	Yes	No
Do you brush your teeth twice a day?	Yes	No
If no, how often do you brush?	Once a day	Once every other day
Do you floss your teeth?	Yes	No
If yes, how often do you floss your teeth?	Every day	Every other day
Do you use a mouth rinse?	Yes	No
How often do you rinse?	Every day	Every other day
Do you use other oral hygiene aids?	Yes	No
If yes, does it include the following?	Interdental brush	Waterpick

Implant Evaluation

Position in arch	Anterior (Incisor to canine)	Posterior (Premolar to molar)
Implant connection	Internal	External
Implant diameter	Standard (3.7mm - 4.2mm)	Wide (5mm - 6mm)
Restored crown	Screw-retained	Cement-retained

APPENDICS 2:

Consent Form

Department of

Faculty of Dentistry & WHO Oral Health Collaborating Centre
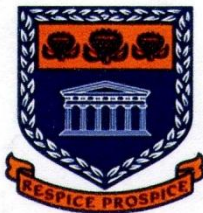
UNIVERSITY *of the*
WESTERN CAPE

Risk Factors associated with Peri-implant Mucositis

Consent form

Mr/Mrs/Miss..

I am willing to participate in the above mentioned study and understand that the study is voluntary.

File no: ....

Date of Birth: ....

This study is approved by the Ethical and Research Committee of the University of the Western Cape and participation in this study is on voluntary basis. I have been adequately informed about the objects of the study. I also know that I have the right to withdraw from the study at any given stage which will not discriminate me in future treatments. My rights will be protected, and all my details will be kept confidential, and no details regarding my identity will be published.

Patient's name: ....

Signature: ....

Witness's name: ....

Signature: ....

Date: ....

Signature of Researcher: ....
                                          Dr. S. Stander

Date: ....

APPENDICS 3:
Patient Information Letter

Department of
Faculty of Dentistry & WHO Oral Health Collaborating Centre

UNIVERSITY of the WESTERN CAPE

Risk Factors associated with Peri-implant Mucositis

Patient Information Letter
Pasiënt informasie
Xhosa

I, Dr S Stander, plan a cross-sectional study to investigate the prevalence of peri-implant mucositis in implant-restored patients as well as to identify the associated risk factors for the development of peri-implant disease. The prevalence of peri-implant mucositis and the association of these variable risk factors can be obtained from information gathered from a clinical oral examination and a standardized data form. Participation in the study is on a voluntary basis and all information will be kept strictly confidential. Your participation will assist us in formulating a prognostic classification system for implant restored patients and to initiate an oral maintenance program for these patients.

Afrikaans
Xhosa

Thank you in anticipation
Dankie vir u samewerking
Xhosa

Dr S Stander
Department of Oral Medicine and Periodontology
Faculty of Dentistry of the University of the Western Cape

APPENDICS 4:

Patient Consent to Clinical Photography and Video Recording

Department of

Faculty of Dentistry & WHO Oral Health Collaborating Centre

UNIVERSITY *of the*
WESTERN CAPE

Risk Factors associated with Peri-implant Mucositis

Patient Consent to Clinical Photography and Video Recordings	Surname:
	Name:
	Date of Birth: Gender:

I, ... consent to photographs or video recordings being taken of me/my child as requested, I understand that these photographs and recordings will be stored appropriately, treated with the utmost confidentiality and be part of my dental record. I hereby give consent for the images or recordings to be used ONLY for the boxes I have indicated with a tick (√):

☐   **Record purposes and for my/my child's future management**

The photographic images and recordings will form part of the information collected for your care and treatment. This information is handled in accordance with the HPCSA Booklet 14: Guidelines on the keeping of patient records.

☐   **Education and training purposes**

The photographic images and recordings may be used for teaching purposes and viewed by health professionals outside of the UWC Faculty of Dentistry. The images may be used for example, in talks, conference presentations, posters or on the Internet to help train other health professionals in the management of dental and oral diseases

☐   **Approved research purposes & publication**

This may involve the photographic images and recordings being used for example in medical or dental publications, journals, textbooks, conference material, e-publications and on the Internet. Images will be seen

by health professionals and researchers who use the publications in their professional education. The images may be seen by the general public. Images will not be used with identifying information such as name, however, full confidentiality is not guaranteed.

☐   **Other purposes** (please specify): ....

•   I understand that all efforts will be made to conceal my identity but that full confidentiality cannot be guaranteed.

•   I understand that my consent or refusal will in no way affect my dental care.

Patient Name & Signature: .... Date: ....

Witness Name & Signature.. Date: ....

Requesting Clinician Name (print): ....

Date: ....

Department: .... Phone: ....

Patient Name (print): ....

Views required ....

Required for: **Records   Teaching/Lectures   Research   Publication**

Images taken by: .... Date...

Location where copies stored: ....

APPENDICS 5:

Approval by Ethics Committee

Office of the Deputy Dean
Postgraduate Studies and Research
Faculty of Dentistry & WHO Collaborating Centre for Oral Health

UNIVERSITY OF THE WESTERN CAPE
Private Bag X1, Tygerberg 7505
Cape Town
SOUTH AFRICA

Date: 2ⁿᵈ March 2012

For Attention: Dr S Stander
Diagnostics Cluster

Dear Dr Stander

STUDY PROJECT: Risk factors associated with peri-implant mucositis

PROJECT REGISTRATION NUMBER: 12/1/19

ETHICS: Approved

At a meeting of the Senate Research Committee held on Friday 3ʳᵈ February 2012 the above project was approved. This project is therefore now registered and you can proceed with the study. Please quote the above-mentioned project title and registration number in all further correspondence. Please carefully read the Standards and Guidance for Researchers below before carrying out your study.

Patients participating in a research project at the Tygerberg and Mitchells Plain Oral Health Centres will not be treated free of charge as the Provincial Administration of the Western Cape does not support research financially.

Due to the heavy workload auxiliary staff of the Oral Health Centres cannot offer assistance with research projects.

Yours sincerely

Professor Sudeshni Naidoo

Tel -27-21-937 3148 (w); Fax -27-21-931 2287 e-mail: suenaidoo@uwc.ac.za

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APPENDICS 6:
Diary of Researcher

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➤ **January 2011 and February 2011:**

Conceptualising research topic and starting with literature review.

➤ **March 2011:**

Submission of literature review in order to complete the research methodology module.

➤ **August 2011:**

Submission of methodology section in order to complete the research methodology module.

➤ **November 2011:**

Protocol presentation and submission to complete research methodology module.

➤ **December 2011:**

Submit protocol for ethics approval by the Research and Ethics Committee of the University of the Western Cape.

➤ **March 2012:**

Obtain ethical clearance from the Research and Ethics Committee of the University of the Western Cape. Project registration number is 12/1/19.

➤ **April 2012:**

Primary researcher calibration as well as calibration of Vivacare TPS probe completed. Initiating study and start with data collection.

> ### July 2012:

Meeting with co-supervisor of mini-thesis to discuss slow progression of data collection: could only manage to evaluate 26 patients. Decide to offer patients a free cleaning after examination for data collection as incentive to come for follow-up. Agree on cut-off date for data collection: November 2012.

> ### November 2012:

Data collection completed on 19 November 2012. Study population is 74 patients. Arrange first meeting with statistician for data analysis.

> ### December 2012:

Final meeting with statistician on 19 December 2012 and statistical analysis completed.

> ### January to June 2013:

Writing of mini-thesis and submission to supervisor and co-supervisor for corrections.

> ### July to August 2013:

Submission of mini-thesis for evaluation by the external examiners.