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EVALUATION OF DENTAL IMPLANTS PLACED IN PATIENTS ATTENDING THE UNIVERSITY OF NAIROBI HOSPITAL 2006-2017

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A research report submitted to the Faculty of Health Science, University of the Witwatersrand, Johannesburg in partial fulfilment for the degree of Master of Science in Dentistry (Prosthodontics).

Nairobi 2018

DECLARATION

I, **Dr Catherine Njeri Gichangi** declare that this research report is my own work. It is being submitted for an MSc degree in Dentistry (Prosthodontics) at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University, and all the sources I have used or quoted have been indicated and acknowledged by complete references.

Signature: 

Date: ……05-08-2019…….

DEDICATION

I dedicate this research report to the Lord Almighty for making it all possible and to my family for the support especially my husband Dr Linus Wachira Ndegwa and sons David Ndegwa Wachira and Lucas Gichangi Wachira.

PRESENTATIONS ARISING FROM THIS RESEARCH PROJECT

Preliminary results presented at the 48th Scientific meeting of the International Association of Dental Research- South Africa Division Conference held at Glenburn Lodge, Johannesburg South Africa, 30th August -1st September 2018.

ABSTRACT

Aim. Clinical long-term studies have shown that dental implant therapy has predictable outcomes with very high survival and success rates recorded. The objective of this study was to evaluate all the dental implants placed in patients attending the University of Nairobi Dental Hospital for survival, success and complications as well as to determine patient experience and satisfaction with the dental implants and implant prostheses.

Method and Materials. The records of all the patients who received implants at the University of Nairobi Dental Hospital between 2006 and 2017 were reviewed and attempts were made to recall all these patients. Demographic, implant, surgical and restorative details were obtained from patient records, and a questionnaire was administered to those patients participating to determine patient satisfaction and to carry out a clinical and radiographic examination. Survival rates were calculated by Kaplan-Meier plots and associations between patient satisfaction, demographic variables and prosthesis material were determined by appropriate parametric and non-parametric tests. The strength of the associations was measured by Cohen's d and the r-value where appropriate.

Results. It proved impossible to recall and examine all patients: eventually 28 patients participated, representing 53 of the 105 implants that had been placed between 2006 and 2017. The majority of the implants displayed optimum health, one had compromised survival with high occlusal load and one had failed but had been replaced successfully. There was generally acceptable bone loss (< 2mm) with the exception of one or two implants, but these were considered to be clinically acceptable. The soft tissue health as determined by the absence of signs of inflammation and bleeding on probing, was also good even though very

few patients reported that they did not use dental floss as part of their oral hygiene routine. There were no major complications observed in the restorations, but fracture of veneering material was present in a few cases. Patient satisfaction was high, (>90%). Most (66%) of the implants were placed in the aesthetic zone and bone grafting was carried out in 60% of the cases; 85% used synthetic bone graft material Osteon (Genos from Korea) and 15% used bovine bone graft material Bio-Oss (Gestlich Pharma, Switzerland).

Conclusions. Although the small sample size of this study did not allow for multiple statistical comparisons, the study has provided valuable base-line information on the treatment and recall protocols for implant therapy carried out at the University of Nairobi Dental Hospital. The study has shown that there is much that can be improved in the provision of an implant therapy service at the dental hospital, and it is recommended that clear protocols be developed for every stage in the provision of this service. In addition, alternative implant systems and types should be explored, such as the use of angulated implants in the anterior region, so that more of the implant supported restorations can be screw-retained.

ACKNOWLEDGEMENTS

I wish to acknowledge my supervisors from the University of the Witwatersrand, Prof. Peter Owen and Prof. Dale Howes who gave me invaluable support and guidance throughout the research and report writing process.

I also wish to acknowledge Dr Nelson Matu from the University of Nairobi for the support and guidance.

Mr Allan Esolio for assistance with tracing of patient files and contacts and Mr Evans and Gitonga Chege from Radiology.

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NOMENCLATURE/ DEFINITION OF TERMS

Implant: Artificial tooth root analogue prosthesis used to replace either one or more missing teeth in a partially dentate or completely edentulous individual

Survival: Presence of dental implant and or implant prosthesis at time of evaluation

Success: How well a dental implant fairs with regards to set criteria for success

Failure: Loss of dental implant/ implant prosthesis or presence of a condition that will necessitate replacement of the prosthesis.

Complications: Any secondary disease or condition that may require management around the implant/implant prosthesis

Osseointegration: direct functional and structural connection of living bone with a foreign body/surface of a dental implant

GPT 9: Glossary of Prosthodontic Terms 9th edition

ITI: International Team of Implantologists

CHAPTER 1: INTRODUCTION

1.1 General Introduction

Dental implants are artificial tooth root analogues that are used to replace missing teeth either in a partially dentate or completely edentulous individuals with the aim of restoring function, speech and aesthetics. The implants are inserted into the bone through a surgical procedure and an abutment prosthesis placed onto the implant at varying intervals after placement, depending on a number of different variables.

Loss of teeth is a common problem worldwide caused by severe dental decay, fracture of teeth due to trauma and untreated periodontal disease. According to a systematic review and meta-analysis of the global burden of severe tooth loss (Kassebaum et al., 2014), 2.3% of a global population representing 158 million people, were edentate in 2010. In Kenya, out of a population of 42 million 6% of the adults were completely edentulous (Gathece et al., 2015). Dental caries prevalence was 46.4% in children and 34.3% in adults. If left untreated the high incidence of dental caries will lead to further increases in tooth loss.

There are several ways of replacing missing teeth, *inter alia*, partial or complete dentures, fixed partial dentures/bridges and implant therapy. Placement of implants has slowly grown and has emerged as a viable alternative for the replacement of missing teeth. Edentulism results in accelerated bone loss in denture wearers and a reduction in bite force as well as a diminished sense of taste. Abutment teeth of fixed prostheses are prone to caries and endodontic failures. The goal of dentistry is to return an individual to oral health in a predictable manner (Misch et al., 2008). Implant prostheses can return patients to near normal function and aesthetics.

Complications are common in implant therapy and they include biological, mechanical and technical / prosthetic complications. Biological complications are typically related to osseointegration i.e. failure of an implant to osseointegrate due to lack of primary stability (clinician related) or interference (patient related) and loss of osseointegration due to factors such as parafunction or introduction of a biofilm. Mechanical complications are those that are related to the manufacture of the components such as fracture of the implant itself. Technical / prosthetic complications are those that are related to the implant prosthesis and may be technical or clinical. To avoid complications and resultant failure, all implants should be maintained on a regular basis. This entails radiographic as well as clinical evaluation of implants at intervals. Clinical evaluation should be carried out after 1,3 and 6 months of placement and subsequently every year. Radiographic evaluation should be done at 3-6 months and thereafter every 12-18 months. Proper monitoring and maintenance of dental implants is essential to ensure the longevity of the implant and prosthesis as dental implants are foreign bodies inserted into the oral tissues and bear masticatory forces of up to 450 Newtons (Morneburg and Proschel 2002) during function.

In Kenya, the use of dental implants is new. The first dental implant at the only postgraduate training center, University of Nairobi Dental Hospital, was placed in 2006. No clinical evaluation or maintenance of these implants has ever been done. The purpose of this study was therefore to evaluate all the dental implants placed to date for success, survival, failure and complications as part of the maintenance of the implants. This evaluation will form a baseline for future recall and maintenance as well as play a major role in establishing protocols for follow-up of dental implant patients in the country. Currently, there is a paucity of data on dental implants in the region. There are also no guidelines on implant therapy from the Ministry of Health.

1.2 Literature review

The search for artificial teeth started many years ago with wood, bones and even shells used to replace missing teeth. However, the ancient tooth replacement options were not functional and therefore the search continued until osseointegration was discovered by Branemark when using titanium chambers to investigate the anatomy and physiology of tissue injury. He observed that titanium chambers were firmly attached to the bone and they could not be removed from the bone once it healed. Branemark developed the concept of osseointegration in 1952 and applied it to dental implants (Albrektsson et al., 1986). He defined osseointegration as “bone to implant contact at light microscopic level” in 1969.

Clinical long-term studies have shown that dental implant therapy has predictable outcomes with very high survival and success rates recorded (Rasmusson *et al.*, 2005; Simonis *et al.*, 2010). Survival rate refers to a measure of the presence of an implant at time of assessment. It does not indicate the condition of the implant such as whether there is loss of alveolar crestal bone height or any pathology pertaining to the implant. Success rate on the other hand, describes the implant in relation to defined success criteria through radiological examination as well as clinical examination of the implant and abutment prosthesis (Albrektsson et al.,1986; Smith and Zarb 1989).

The first success criteria for dental implants were reported by Schnitman and Shulman, in 1979. For a dental implant to be successful, the criteria required that the “mobility of an implant be less than 1 mm in any direction; no radiologically observed radiolucency; bone loss of no greater than a third of the vertical height of the implant; absence of symptoms and infection; absence of paraesthesia and anaesthesia or violation of the mandibular canal,

maxillary sinus or floor of the nasal passage; and lastly functional service for 5 years in 75% of the cases".

Albrektsson *et al.*, (1986a) published success criteria that have been used for many decades. These stipulated that: an individual implant should be immobile when tested clinically; a radiograph does not demonstrate any evidence of peri-implant radiolucency; vertical bone loss of less than 0.2mm annually following the implant's first year of service; individual implant performance characterised by the absence of persistent and of irreversible signs and symptoms such as pain, infections, neuropathies, paraesthesia or violation of the mandibular canal. In addition, a success rate of 85% at the end of a five-year observation period and 80% at the end of a ten-year period were also the minimum criteria for success.

The criteria above classify dental implants as clinically successful or failed. A natural tooth is not classified in this manner. Misch (1993) opined that as a quality of health scale is used to describe natural teeth and intraoral clinical conditions, then a dental implant, being a tooth root analogue, should be analysed in the same way a natural tooth is analysed.

In 1993 James (Misch 1993) established implant quality factors and these were further developed by Misch (1998). The modified James–Misch Health Scale (Misch et al., 2008) was presented at a consensus conference and approved four clinical categories that contain conditions of implant success, survival, and failure. Survival conditions for implants had two different categories: satisfactory survival which described an implant with less than ideal conditions yet did not require clinical management; and compromised survival which included implants with less than ideal conditions, but which required clinical treatment to reduce the risk of implant failure. Implant failure was the term used for implants that required

removal or had already been lost. The tabulation for the health scale for dental implants is as per Table 1.

Table 1 The James-Misch Health Scale

I. Success (optimum health): o No pain or tenderness upon function o No mobility o 2 mm radiographic bone loss from initial surgery o No exudates history
II. Satisfactory survival: • No pain on function • No mobility • 2–4 mm radiographic bone loss • No exudates history
III. Compromised survival: o May have sensitivity on function o No mobility o Radiographic bone loss more than4 mm (less than1/2 of implant body) o Probing depth more than 7 mm o May have exudates history
IV. Failure (clinical or absolute failure) any of following: • Pain on function • Mobility • Radiographic bone loss of more than1/2 length of implant • Uncontrolled exudate • No longer in mouth

The James Misch health scale is useful in evaluation of the implant at implant level and partly at the peri-implant soft tissue level. Many clinical studies have used implant and peri-implant soft tissue parameters for measuring success while prosthodontic and patient satisfaction parameters are rarely incorporated. According to Papaspyridakos (2012) “success in implant prosthodontics should ideally evaluate a long-term primary outcome considering the implant-prosthetic complex as a whole and patient satisfaction”. This was concluded from a

systematic review to evaluate the most frequently used criteria to define success of treatment in implant dentistry. It was found that when one parameter was used to evaluate success, the success rate was almost always 100%, and that the reverse was true. The use of more success parameters led to a reduction in success rate.

Dental implants therefore have been shown to have high survival and success rates, but the incidence of complications which could lead to failure is also high. The incidence of complications was reported as high as 33.6% in a systematic review done in 2012 (Pjetursson et al, 2012). A total of 464 patients were examined and 4.6% had failed implants, 66.4% were successful. Complications in implant therapy include biological and technical/mechanical complications. For biological complications, which include peri-implant mucositis, peri-implantitis and loss of osseointegration, Derks and Tomasi (2015) reported a prevalence of 43% for peri-implant mucositis (inflammation of soft tissues) and 22% for peri-implantitis (inflammation of soft tissues and bone loss).

Loss of osseointegration usually occurs later, at least, six months' post implant placement. This could result from occlusal overload and factors such as parafunction and poor bone quality. Mechanical complications are those that are related to the manufacture of fabricated components whereas prosthetic/technical complications are related to the fabricated components of the prosthesis. Pjetturson et al in 2007 reported that the incidence of technical complications on implant supported prostheses was higher than in tooth supported prostheses. Over 5 years the implant supported prostheses had an incidence of complication in 38.7% cases while the tooth supported prosthesis' incidence was 15.6%. Mechanical complications included implant fracture whose incidence was less than 1% and mostly occurred in narrow implants.

It is imperative that all implants are maintained through regular clinical and radiographic evaluation. Maintenance of implants entails the recall of patients and assessment of implant prosthesis, peri-implant tissue health, oral hygiene and plaque control, periodontal health, remaining dentition and the radiographic assessment of marginal bone around an implant. If early diagnosis and treatment of complications is not done, failure of the implant may ensue. Failure refers to a missing dental implant or implant prosthesis as well as severe complications that necessitate removal of the implant/implant prosthesis.

Many studies have reported the presence or absence of an implant but not its status. This means that some of the implants rated as successful due to their presence in the mouth may indeed be failed if the status of the implants necessitates its removal.

Absence of regular care is a risk factor for peri-implantitis. A 5 year follow-up study done by Costa et al in 2012 revealed that patients who had undergone regular maintenance care had an 82% success rate with 18% diagnosed with peri-implantitis, whereas 44% of the ones without care were diagnosed with peri-implantitis. Another study (Rocuzzo et al, 2012) also revealed a distinct difference in marginal bone loss of more than 3mm in 63.3% of patients who had no regular care compared with 11% of those who had regular care.

Supportive care begins once the treatment commences with the aim of maintaining health, preventing complications and therefore ensuring long term success of the implants.

Treatment outcomes involve both the clinician and the patient. Patient satisfaction is therefore key in determining the success of dental implants. The patient's ability to chew or function with the prosthesis as well as aesthetic satisfaction are crucial. Pjettursson et al, 2005

found that 90% of patients with oral implants were satisfied with function and aesthetics in a 10 year follow-up prospective study.

Most studies focus on performance of the implant body over time for success. A few studies have included implant prosthesis evaluation as well as patient satisfaction. Two such studies included an assessment of the implant prosthesis at 4 levels as well as patient satisfaction assessment (Papaspyridakos 2012; Galluci 2015). The implant was evaluated with the use of an intraoral radiograph to determine crestal bone levels and status of bone to implant contact. The peri-implant tissues were evaluated for peri-implant disease. The implant prosthesis was evaluated for function, aesthetics and ability to clean. Patient satisfaction was assessed for ability to function and aesthetic perception.

1.3 Justification of the study

An evaluation of the different outcomes of dental implant therapy done at the University of Nairobi Dental School is necessary to provide scientific evidence that will inform treatment planning and patient education for consent acquisition in the future. The study should be the basis for an audit of the clinical work done at the Dental School giving an insight as to the success, survival, failure rate and complications of dental implants and implant prostheses. This also should reveal areas that need improvement in the various stages of the treatment from treatment planning through to delivery. The goal would be to establish a maintenance protocol for implant patients seen at the Dental School by using these baseline records and to promote early diagnosis and treatment of complications to improve success and longevity of implant therapy in the institution.

CHAPTER 2: AIMS AND OBJECTIVES

2.1 Aims

1. To assess the status of implants placed at the University of Nairobi Dental School in the period 2006 to 2017.
2. To assess the patients' experiences and satisfaction with the implant and prosthetic treatment received.

2.2 Objectives

1. To evaluate success of the dental implants
2. To measure the survival rates and reasons for complications and / or loss of implants.
3. To evaluate patient satisfaction with the treatment they received.
4. To assess factors associated with success, survival, failure and patient satisfaction

2.3 Null hypothesis

The null hypothesis is that there were no significant associations found between patient satisfaction and all other measurements, nor on the effect of implant survival and all other relevant factors.

CHAPTER 3: MATERIALS AND METHODS

3.1 Study design

Retrospective cohort study

3.2 Study population

The patients were identified from the department records and were asked under their own cognisance, to attend the dental school for a check-up, and for their consent to participate in the study. All patients who were identified, and gave their consent were included in the study.

3.3 Sample size

Approximately 105 implants were placed in the study period. The anticipated recall rate was 50%, i.e. the anticipated sample size was 53 implants. Sample size estimation was based on the estimation of proportions (e.g. the proportion of females in the study group), and the association between categorical patient satisfaction variables and the selected demographic / clinical variables. Based on a worst-case (for sample size) estimate of 50%, 5% precision and the 95% confidence level, a sample size of 385 would normally be required. The anticipated sample size of 53 corresponds to a precision of 13.2% (rather than 5.0%) and was therefore a limitation of the study.

Sample size for prevalence was determined using the formula (Daniel 2013):

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

where n = sample size,
Z = Z-statistic for the chosen level of confidence,
P = expected prevalence or proportion
d = precision

Sample size calculations were carried out in G*Power (Faul et al 2007).
Associations between variables required the use of the chi-square test. For 80% power at the 5% significance level, small, medium, and large effect sizes (w = 0.1, 0.3, 0.5 respectively) require sample sizes of 785, 87 and 31. The anticipated sample size of 53 in this study means that only large effect sizes, were detected unless greater participation could be obtained.

3.4 Data Collection

The original patient records were used to obtain the following information:

- Reason for tooth loss
- Dental status-periodontal, occlusal, oral hygiene
- Implants Details: type of implant, implant length and diameter
- Surgical details:
    - Stages (one or two stage),
    - Bone Grafting (yes/no),
    - Loading: immediate, early or delayed.
- Restorative details:
    - Prosthesis design
    - Prosthesis material
    - Prosthesis retention: screw/cement retained
    - Restorative platform: bone level/abutment level

3.4.1 Clinical examination

- The clinical examination comprised of the following parameters:
    - Plaque status using the modified Plaque Index (Mombelli et al 1987)
        - Score 0: No detection of plaque

        - Score 1: Plaque only recognised by running a probe across the smooth surface of the implant
        - Score 2: Plaque can be seen by the naked eye
        - Score 3: Abundance of soft matter
- Occlusion assessed as follows:
    - General occlusal schemes. Balanced occlusion, group function (immediate and progressive), mutually protected occlusion or a combination.
    - Characteristics of occlusion related to the implant supported prosthesis measured with 8-micron shim stock.
        - The patients were asked to bite on to an 8μm shim stock in light contact and in heavy contact/firmly. The degree of the hold of the shim stock was recorded. The tooth was deemed to be in infra-occlusion if the shim stock pulled through very easily, in occlusion if the shim stock just pulled through and in hyper-occlusion if it held and did not pull through (Kim et al. 2005)
        - Excursion: Protected Yes/No
        - Adjacent teeth: hyper occlusion, occlusion or infra-occlusion
        - Contacts: open, tight or loose as measured with unwaxed floss
- Presence or absence of implant *in situ*
- Status of the implant prosthesis evaluated for success, need for prosthetic maintenance and failure using the following parameters: aesthetics of the prosthesis; fracture of the abutment, abutment screw, crown or veneer; decementation; loosening of abutment screw or crown. Success criteria

defined at 4 levels as per the systematic review of success criteria in implant dentistry reported by Papaspyridakos et al (2012) (Table 2).

Table 2 Success criteria at Prosthetic level (Papaspyridakos et al 2012)

Level 1	Prosthesis with major complications / failed that requires a new prosthesis. Missing/fractured superstructure
Level 2	Prosthesis with minor complication that can be fixed at the chairside. Abutment or screw loosening, veneer chipping
Level 3	Aesthetic prosthesis. No need for intervention and patient satisfied with aesthetics
Level 4	Functional prosthesis. No need for intervention and patient can function with it.

- Status of tissues surrounding the implant/peri-implant health examined using the modified sulcus bleeding index (Mombelli et al 1987)
    - Score 0: No bleeding when periodontal probe was passed along the gingival margin
    - Score 1: Isolated bleeding spots present
    - Score 2: Blood forms a confluent red line on margin
    - Score 3: Heavy or profuse bleeding
- Probing pocket depth performed at six points of all implants (mesio-buccal, buccal, disto-buccal, disto-lingual, lingual, mesio-lingual) with a Williams Probe.
- Probing attachment level related to the implant shoulder.

3.4.2 Radiological examination

- Radiographic evaluation is one of the most important measures in evaluating peri-implant alveolar bone status during the maintenance phase of dental implants (Misch 1993). This should be done yearly for healthy individuals and every 6 months when indicated or in individuals with peri-implantitis. The patients who had received dental implants at the Dental School were not on any maintenance protocol.
- Radiographic examination was done by standardised periapical radiographs using the intraoral paralleling technique. The initial postoperative implant radiographs were used to compare with radiographs at the time of evaluation. This radiograph will serve as a baseline record for patients with missing or inadequate records in the files. They can be used in the future for further analysis and maintenance of the implants.
- Presence or absence of peri-implant radiolucency was recorded.

3.4.3 Questionnaire

- Personal and demographic parameters were recorded which include age, gender, occupation, area of residence, smoking habits, reasons for tooth loss, any relevant medical history.
- Patient satisfaction was evaluated with a set of 10 questions to elicit their experience in terms of overall comfort of the prosthesis, aesthetics, and ability to eat and speak, as well as their satisfaction with the procedure carried out.

3.5 Data Analysis

Categorical variables were summarised by frequency and percentage, tabulation and illustrated by means of bar charts. Continuous variables were summarised by the mean,

standard deviation, median and interquartile range, and their distribution illustrated by means of histograms. Survival rates were analysed by Kaplan-Meier plots.

The associations between categorical patient satisfaction variables and age (categorised), level of education and prosthesis material were determined by the t-test or Analysis of Variance, or if non-parametric, the Wilcoxon rank sum test (or the Kruskal-Wallis test were used. The strength of the associations was measured by the Cohen's d for parametric tests and the r-value for the non-parametric tests. The following scale of interpretation was used:

0.80 and above	large effect
0.50 to 0.79	moderate effect
0.20 to 0.49	small effect
below 0.20	near zero effect

Data analysis was carried out in SAS. The 5% significance level used.

CHAPTER 4: RESULTS

4.1 Response

The recall rate was 51%: although 105 implants were placed in the study period, only 53 were able to be evaluated, from 28 patients. All these implants were placed between 2010 and 2017. The recall of the patients who received implants prior to this period proved to be impossible, because they could not be traced.

4.2 Demographic data

Age

The median age of the patients was 45 years (IQR 33-56 years; range 22-63 years). The distribution is shown in Fig. 1.

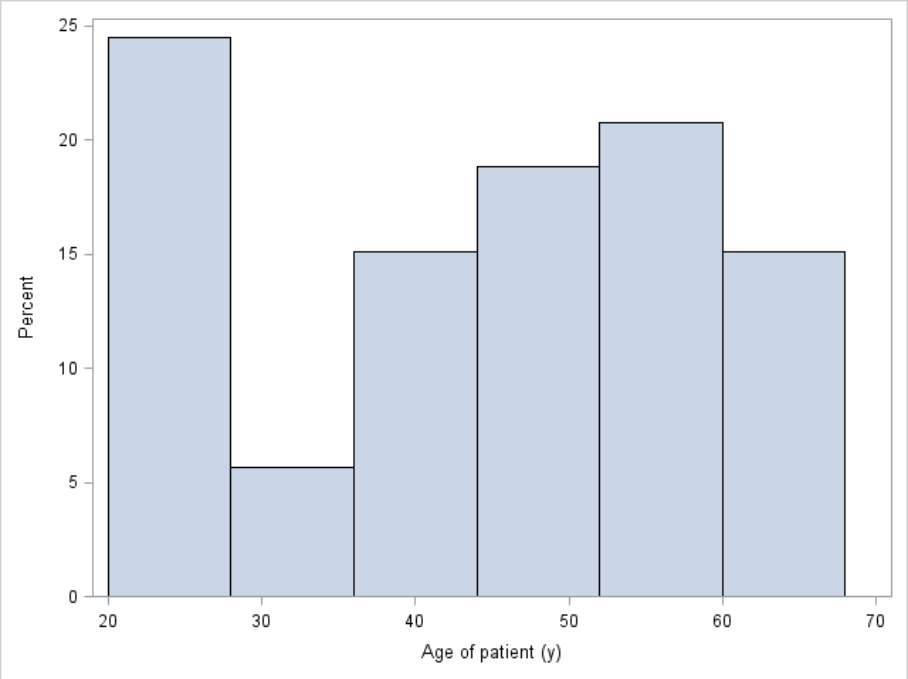
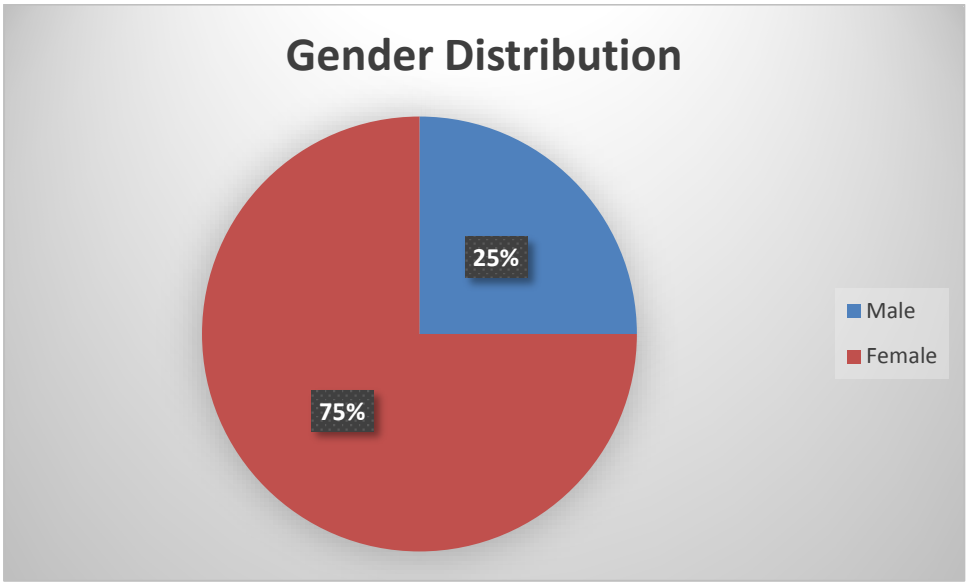


Figure 1 Demographics of the study population (age)

Gender

Female patients received 79% of the implants.

There were 75% female patients and 25% male.



Highest level of education

74% of the implants were placed in patients with tertiary education (Table 3).

Table 3 Highest level of education of the participants

Highest level of education	**Number**	**Percentage %**
Primary	3	6
Secondary	11	21
Tertiary	39	74

Occupation

The occupation of the participants was classified according to the International Standard Classification of Occupations 2012 (ISCO-2012) and is shown in Table 4

Table 4 Classification of occupations of the participants

Occupation	Number	Percentage%
Professionals	28	53
Managers	11	21
Clerical support workers	4	8
Plant and machine operators, and assemblers	2	4
Craft and related trades workers	2	4
Service and sales workers	1	2
Technicians and associate professionals	0	0
Skilled agricultural, forestry and fishery workers	0	0
Elementary occupations	0	0
Armed forces occupations	0	0

Area of residence

The majority of the participants (64%) resided within a radius of 20 km from the Dental School, some (29%) within a radius of 50km and 2 came from very far, more than 300km from the school; one from Kampala (Uganda) and one form Kericho, 300kms away.

4.2.1 Reason for tooth loss

The predominant reasons for tooth loss were caries (43%) and trauma (40%). Periodontal disease was the least (17%) cause of tooth loss (Fig. 2).

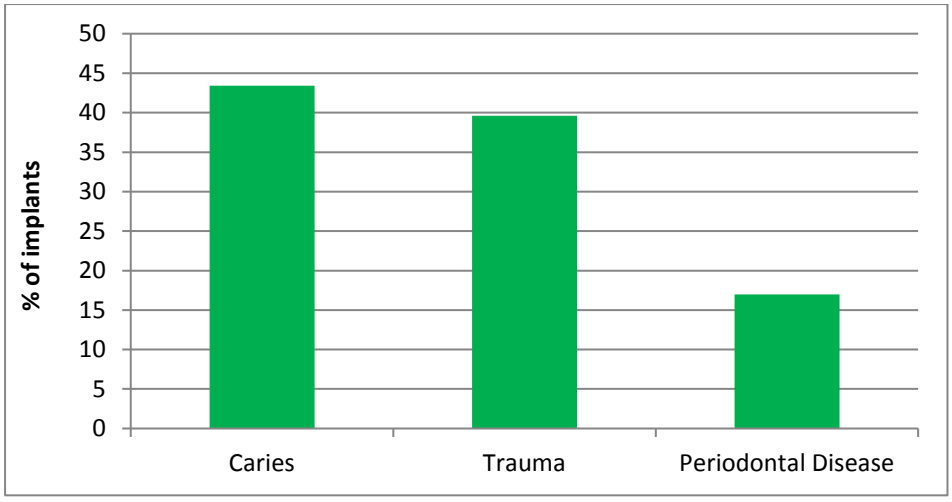


Figure 2 Reasons for tooth loss

4.2.2 Medical and Dental history of the patient

Fifteen percent of the implants were placed in patients with hypertension. No patient reported with heart disease or diabetes (Fig. 3).

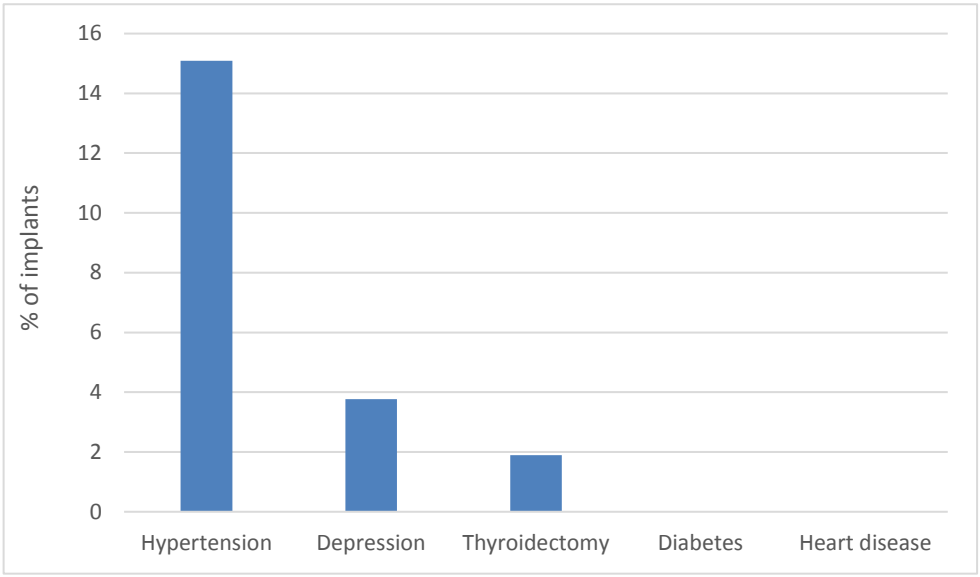


Figure 3 Medical history of the participants

Medications currently used by the patients as well as at the time of implant placement were low (Table 4). No patient was found to be on anticoagulants or bisphosphonates during implant placement.

Table 5 Medications used by the participants

Current medications	Asomex, Atenolol	2	4
	Enalapril Nebivolol	2	4
	Coaprovel	1	2
	Thyroxine	1	2
	Anticoagulants	0	0
	Bisphosphonates	0	0
Medications at implant placement	Junior aspirin	3	6
	Asomex, Atenolol	2	4
	Enalapril Nebivolol	2	4
	Coaprovel	1	2
	Thyroxine	1	2
	Anticoagulants	0	0
	Bisphosphonates	0	0

All patients had had previous dental treatment: 70% conservative treatment, 53% endodontic treatment and 38% periodontal treatment (Fig 4).

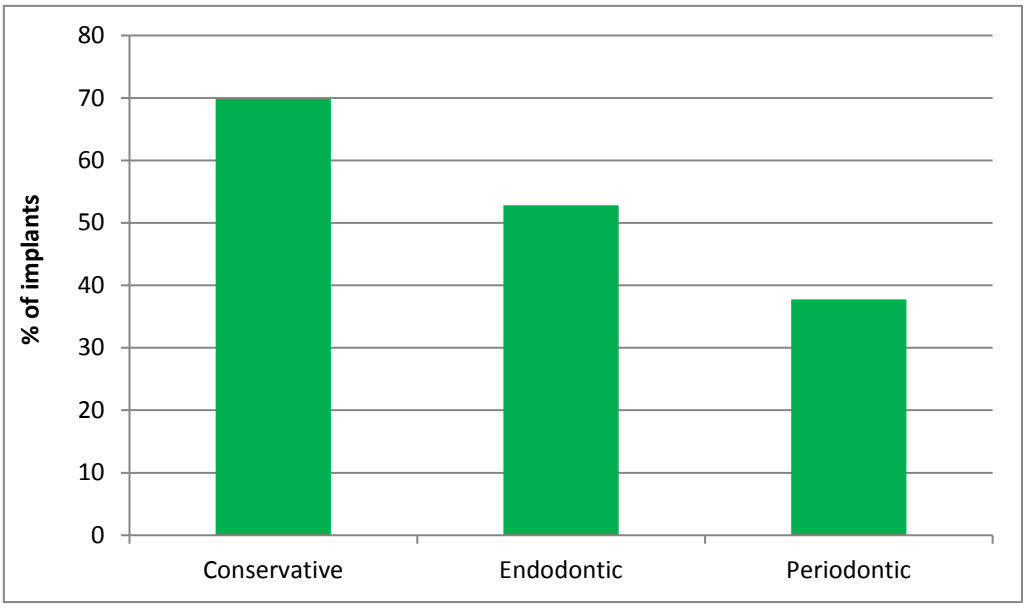


Figure 4 Previous dental treatment of the participants

4.2.3 Smoking and alcohol intake habits

Only 1 implant was placed in a patient who smoked while 75% of implants were placed in patients who used alcohol.

4.3 Clinical data

One implant had failed after 2 months and 6 months later it was replaced successfully.

4.3.1 Implant data

Implant location

The most frequently replaced tooth was the upper central incisor, and 66% of the implants were replacing anterior teeth (Fig. 5) The majority of the implants (79%) were placed in the maxilla.

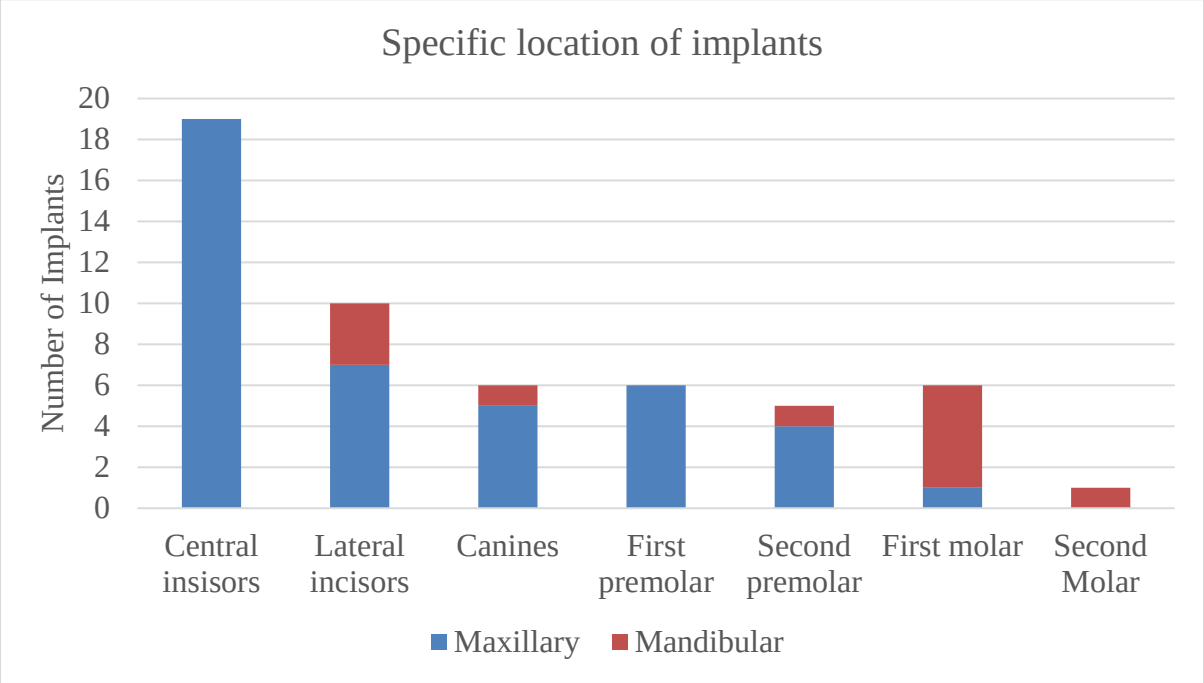


Figure 5 Location of the implants

Type of implant

Implants were predominantly MIS (MIS Implants Technologies Ltd., Bar-Lev, Israel) type (66%) (Fig. 6). Others were Any Ridge (Megagen Implant Co., Seoul, Korea A), Zimmer TSV (Tapered Screw Vent) (Zimmer Biomet, Switzerland), and Megagen (Megagen Implant Co., Seoul, Korea).

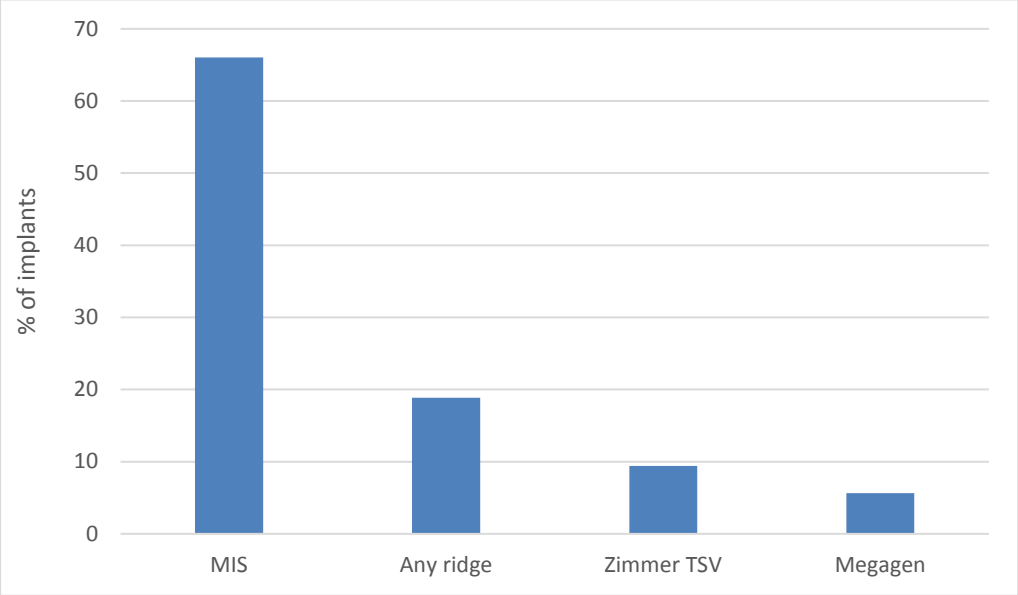


Figure 6 Implant type

Implant dimensions

The average widths and lengths of the implants placed were as shown in Table 6. No short implants were used.

Table 6 Implant widths and lengths used and their location

Maxillary	**Average width**	**Average Length**
Central incisor	3.8	13.5
Lateral incisor	3.9	13.9
Canine	4.1	12.8
First premolar	4.1	12.3
Second Premolar	4.2	11.1
First Molar	4.1	11
Mandibular		
Lateral incisor	3.96	14
Canine	4.1	13
Second Premolar	4.5	10
First Molar	5.0	11.1
Second molar	5	8.5

No implants were placed in the mandibular central incisor and first premolar region.

4.3.2 Surgical details

All implants were placed in two surgical stages. Bone grafting was done in 60% of implants, 85% of which used the synthetic bone graft material Osteon (Genos Co., South Korea) and the remainder (15%) used the bovine bone graft material Bio-Oss (Gestlich Pharma, Switzerland).

The majority of the implants (52, 98%) were loaded after osseointegration (delayed loading) and only one was loaded immediately. All implant restorations were placed at abutment level.

4.3.3 Restorations

Eighty-three percent of the implants were restored with single crowns and the remaining 17% were fixed partial dentures. There were two 4-unit bridges in the anterior region of the maxilla and mandible, at 12-22 and 32-42 regions respectively. One 3-unit Fixed Partial denture was placed in the 21-23 region.

The implant restorations were predominantly metal ceramic (85%). Seven were all ceramic, of which 6 were Zirconia. Only 10 implants had screw retained restorations (one restoration was not recorded) (Table 7). The distribution of the screw retained restorations within the different jaws was equal however, the majority of the screws were found in the first mandibular molar.

Table 7 Distribution of cement and screw-retained restorations

Maxillary	**Screw retained**	**Cement retained**
Central Incisor	1	18
Lateral Incisor	0	7
Canine	1	4
First Premolar	2	4
Second Premolar	1	3
First molar	0	1
Second molar	0	0
Total	**5**	**37**
Mandibular		
Central Incisor	0	0
Lateral Incisor	0	2
Canine	0	1
First Premolar	0	0
Second Premolar	1	0
First molar	4	1
Second molar	0	1
Total	**5**	**5**

4.3.4 Occlusal evaluation

Ninety-eight percent of the prostheses were excursion protected and no working or non-working side interferences during lateral or protrusive excursions were observed. The distribution of occlusion types as indicated by the shim stock hold under heavy and light contact is shown in Fig. 7. Two of the adjacent teeth were in hyper-occlusion and one was in infra-occlusion; all others presented with normal occlusal contacts.

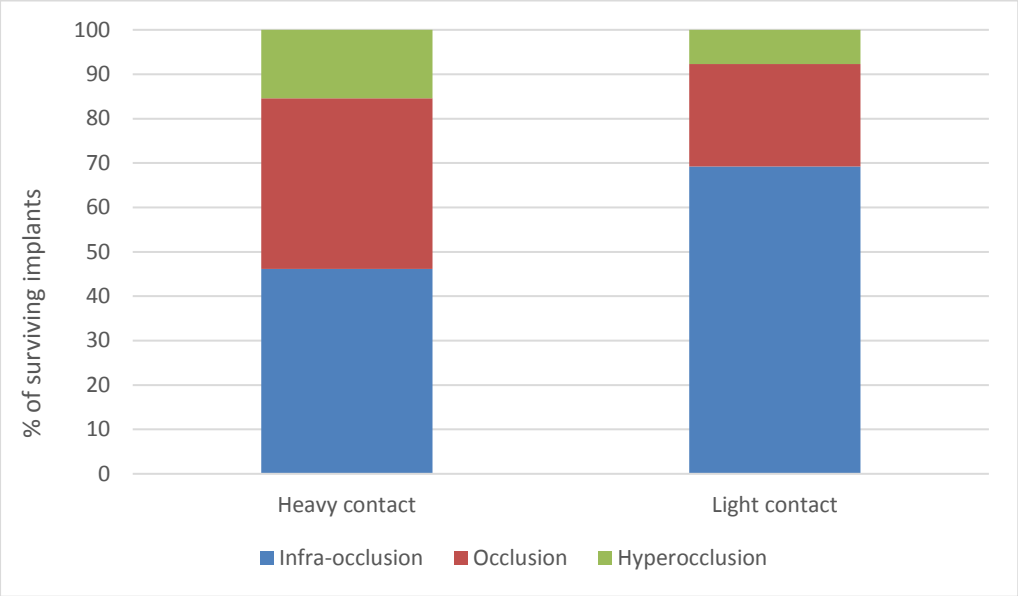


Figure 7 Distribution of occlusion types as indicated by the shim stock test

4.3.5 Interproximal contacts evaluation

Dental floss was used to analyse the interproximal contacts and it was found that 50% of the implants had tight contacts (Fig. 8).

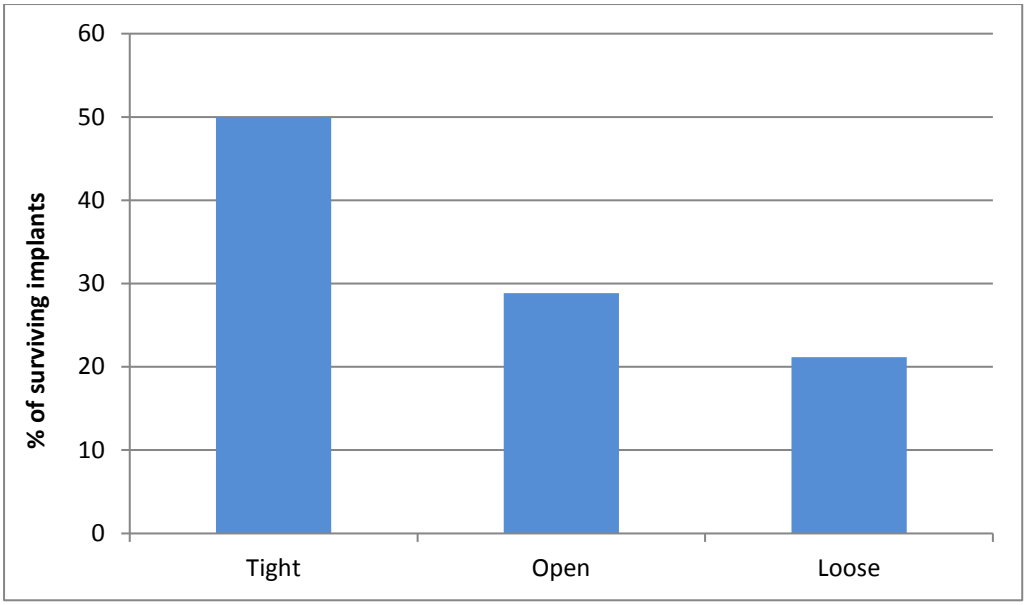


Figure 8 Interproximal contacts as measured with dental floss

4.3.6 Periodontal evaluation

The modified Mombeli plaque index score and bleeding index score were used to analyse the periodontal status of the peri-implant tissues. The modified plaque score was 0 in all implants, and the modified sulcus bleeding index was 0 in 85% of the cases and score of 1 in the remainder of the cases. The distribution of the pocket depth is shown in Fig. 9.

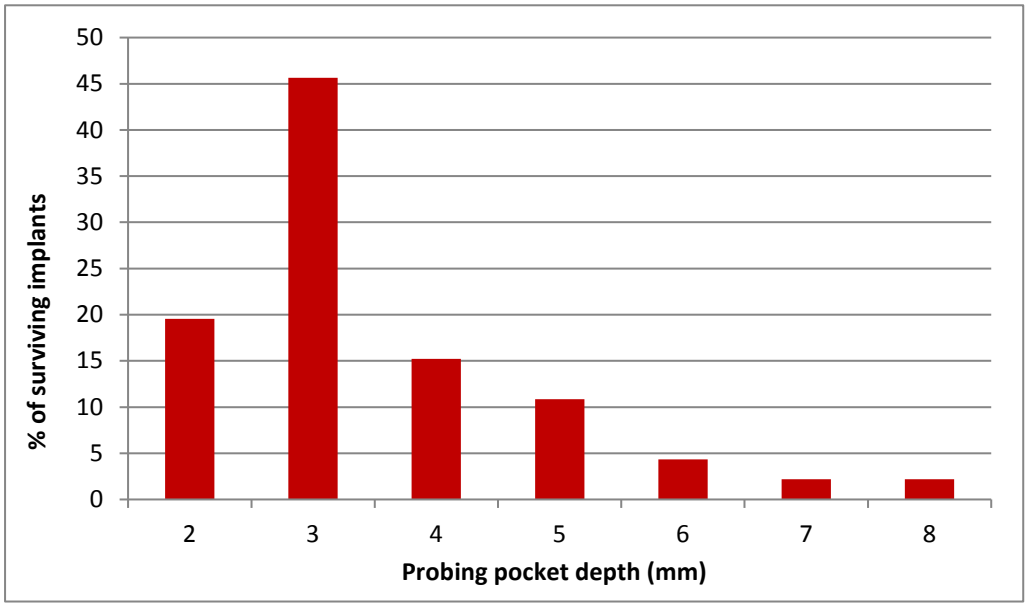


Figure 9 The distribution of the pocket depth

4.4 Radiological evaluation

Intraoral periapical radiographs (45) were taken for all the patients who gave consent (see Fig. 10). These were compared with the initial 29 radiographs found in the patient's records. Only 29 out of the 53 implants evaluated had initial radiographs in their records. Therefore, changes in bone level between initial and evaluation radiograph were not possible to evaluate for the remaining 24 implants.

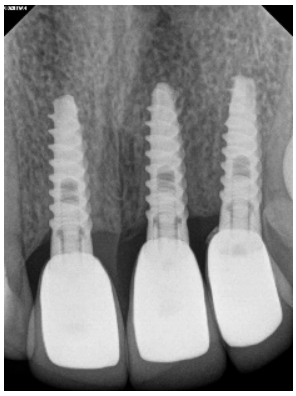


Figure 10 Example of intra-oral radiograph taken at evaluation

Table 8 Evaluation of bone loss vs duration of implant in the mouth

Implant Location	Bone Level Initial X ray in mm	Bone level evaluation in mm	Bone loss	Time implant in situ in years
32	1	3.5	-2.5	3.6
22	0	2.4	-2.4	3.4
42	0.5	2.6	-2.1	3.9
21	0	2	-2	3.4
13	3.5	5.4	-1.9	4.3
11	0	1.5	-1.5	2.5
21	0	1.3	-1.3	2.4
21	0	1.2	-1.2	2.9
11	1	2	-1	5.3
21	0	1	-1	5.4
25	0.3	1.1	-0.8	1.5
46	0.2	0.8	-0.6	1.2
11	0	0.6	-0.6	2.9
22	1	1.5	-0.5	5.4
46	0.7	1	-0.3	1.1
11	0	0.3	-0.3	4.2
22	0	0.2	-0.2	5.8
13	0	0.2	-0.2	5.0
11	0	0.2	-0.2	3.2
24	0.8	1	-0.2	1.5
22	0.8	1	-0.2	2.4
12	0	0	0	2.5
11	0	0	0	5.0
21	2.1	2	0.1	2.5
25	1	0.8	0.2	3.3
21	0.7	0.5	0.2	3.2
13	2	1.7	0.3	3.1
36	0.8	0.5	0.3	1.3
11	2	0.6	1.4	2.4

Most of the implants recorded bone loss of less than 2 mm. Three out of the 29 implants had bone loss of more than 2mm but less than 3mm and had been in the mouth for an average of 3.5 years.

Peri-implant radiolucency was found in 12 of the implants that were examined radiologically (Table 9). Four of these with radiolucency had no initial radiographs present thus only bone height could be measured.

Table 9 Bone loss in implants exhibiting radiolucency (PAP: peri-apical pathology)

Implant site	Bone loss in mm	Other Anomaly	Time implant in years	Probing Pocket Depth	Bleeding Index
21	1	None	5.4	6	1
13	1.9	PAP on 12 (Adjacent)	4.3	5	0
11	0.2	None	3.2	3	0
11	0.6	None	2.9	3	0
21	1.2	None	2.9	2	0
11	1.5	None	2.5		0
42	2.1	None	3.9	2	0
32	2.5	None	3.6	2	0

The only implant with a radiographic anomaly on the adjacent tooth (periapical radiolucency) was in the 13-region. It had a peri-implant radiolucency as well as deep pockets, bone loss of 1.9mm and was in hyper-occlusion on light contact. This implant had been in the mouth for 4 years and 3 months and was symptomless. The occlusion scheme also indicated that the restoration was not protected during excursive movements. This was the only restoration which was not protected.

The restoration was immediately equilibrated and removed from hyper-occlusion during light contact by filing down the high spot and patient informed of the compromised state of the implant and need for further investigations and management. The patient lives in Kampala

which is in Uganda, more than 600km from the Dental School and therefore was referred to the nearest dental clinic for continuation of the treatment and maintenance.

Radiolucency vs probing depth

One of the participants who had some radiolucency did not consent to probing. One of the remaining 11 had a probing depth of 6mm and one of 5mm. According to the James-Misch Health scale none of these were unfavourable probing depths.

Radiolucency vs occlusion

Twenty five percent of the implants with radiolucency were in hyper-occlusion in light contact, 33% were in occlusion whereas 42% were in infra-occlusion. (Table 10).

Table 10 Occlusion exhibited in those implants with radiolucency

Implant Heavy contact	**Implant Light contact**	**Implant Location**	**Adjacent teeth**
Hyper-occlusion	Hyper-occlusion	24	Occlusion
Hyper-occlusion	Hyper-occlusion	21	Occlusion
Hyper-occlusion	Hyper-occlusion	13	Hyper-occlusion
Hyper-occlusion	Occlusion	42	Hyper-occlusion
Hyper-occlusion	Occlusion	32	Occlusion
Hyper-occlusion	Occlusion	21	Occlusion
Infra-occlusion	Infra-occlusion	11	Occlusion
Infra-occlusion	Infra-occlusion	11	Occlusion
Occlusion	Infra-occlusion	25	Occlusion
Occlusion	Infra-occlusion	11	Occlusion
Occlusion	Infra-occlusion	21	Occlusion
Occlusion	Occlusion	11	Occlusion

Half of all the implants with radiolucency were found to be in hyper-occlusion during heavy contact. The remaining 4 were in occlusion and 2 were in infra-occlusion.

4.5 Implant restorations

The implant restorations were evaluated for any complications. All implants were found to have the restoration *in situ* and none required removal of the restoration due to major faults. Therefore, no restoration was found to have a major complication. However, 3 had ceramic chipping and were therefore classified as minor complications. This accounted for 6% of the implant restorations.

4.6 Overall evaluation

4.6.1 Implant survival

Presence of implant at time of evaluation was denoted as survival rate. Only one implant was lost during the follow-up period.

The Kaplan-Meier plot is shown in Fig. 11.

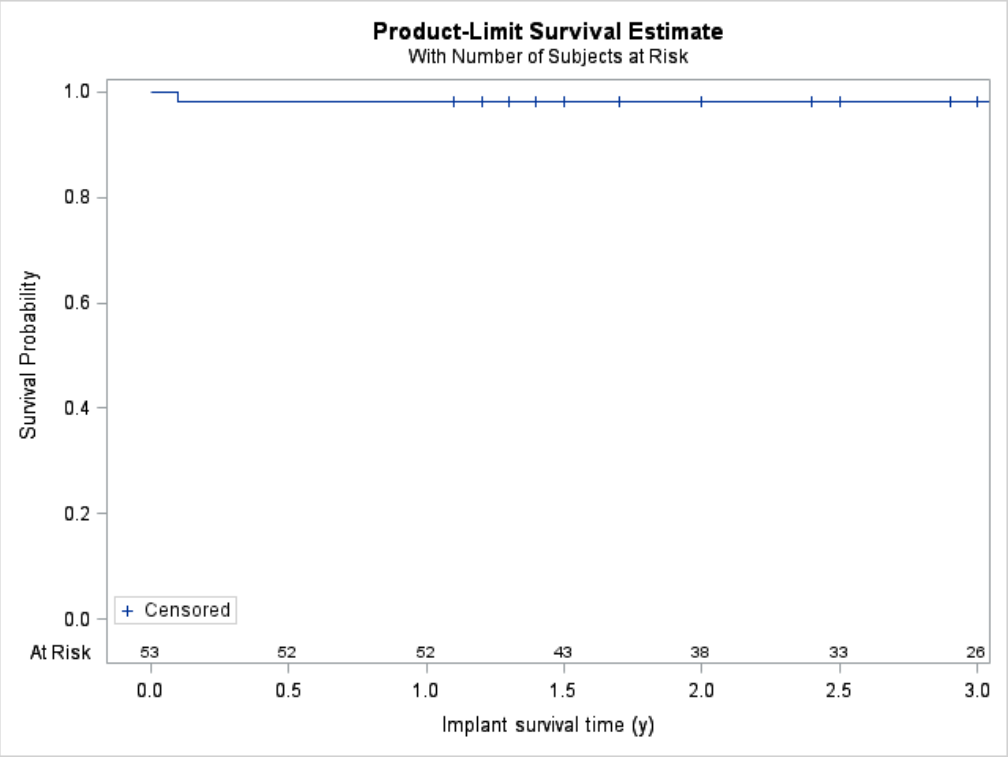


Figure 11 Kaplan-Meier plot of survival estimate

The survival estimates together with their 95% confidence intervals are shown in Table 11.

Table 11 Implant survival estimates

Time (y)	Survival estimate (%)	95% CI for survival estimate (%)
1	98	87-99
2	98	87-99

4.6.2 Implant success and complication rate

It is important to note that some patients did not consent to radiographs, one was pregnant at the time of assessment while others had no baseline records therefore analysis of marginal bone level could not be done. A total of 31 implants were examined radiologically and these are the ones classified under the James Misch Health scale (Misch et al., 2008).

The success rate of these implants was 98%. Ninety percent were classified under the James-Misch scale as 'optimally healthy' and 8% of the implants were classified under 'satisfactory survival'. These implants had a radiographic bone loss within the range of 2-4mm. Only one implant had a probing depth of more than 7 mm and this implant was classified under level III i.e. compromised survival and needed further management.

4.7 Patient satisfaction

An interview administered questionnaire was used to evaluate patient satisfaction with the implant treatment. This included a set of 10 questions; 6 of which were scored on a Visual Analogue Scale (VAS).

Most patients reported that they would undergo this treatment again while 3 felt that they would rather not. Two of these patients cited advanced age and one preference to keep natural teeth as the reasons.

All patients reported that they would recommend implant therapy treatment to others and only one patient felt that the cost of the implant was not justifiable.

Satisfaction scores are shown in Table 12 and Fig. 12 show the median satisfaction with each attribute (the error bars denote the IQR). The median satisfaction was high (>90%) for all measures except flossing.

Table 12 Patient satisfaction results. SD: Standard Deviation. IQR: Inter-quartile range

VARIABLE	N	MEAN	SD	MEDIAN	IQR		MIN	MAX
Overall comfort	52	87	15	90	82	98	13	100
Eating comfort	52	88	16	91	82	100	19	100
Speech comfort	52	81	30	96	84	100	13	100
Appearance	52	80	25	91	71	98	16	100
Brushing ability	52	90	18	96	90	100	17	100
Flossing ability (if patient flosses)	48	69	29	79	51	92	0	100

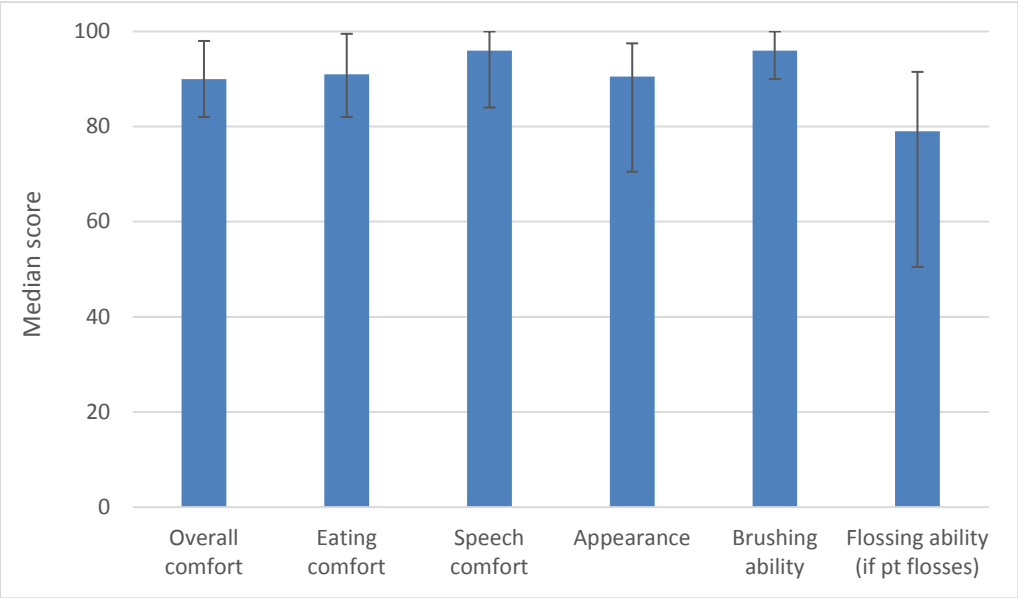


Figure 12 Median satisfaction with each attribute of the patient satisfaction visual analogue scale

The participants were asked to comment on the food they were unable to eat since receiving implants. The results are shown in Fig. 13. Sixty-nine percent of the implants were not associated with any difficulty.

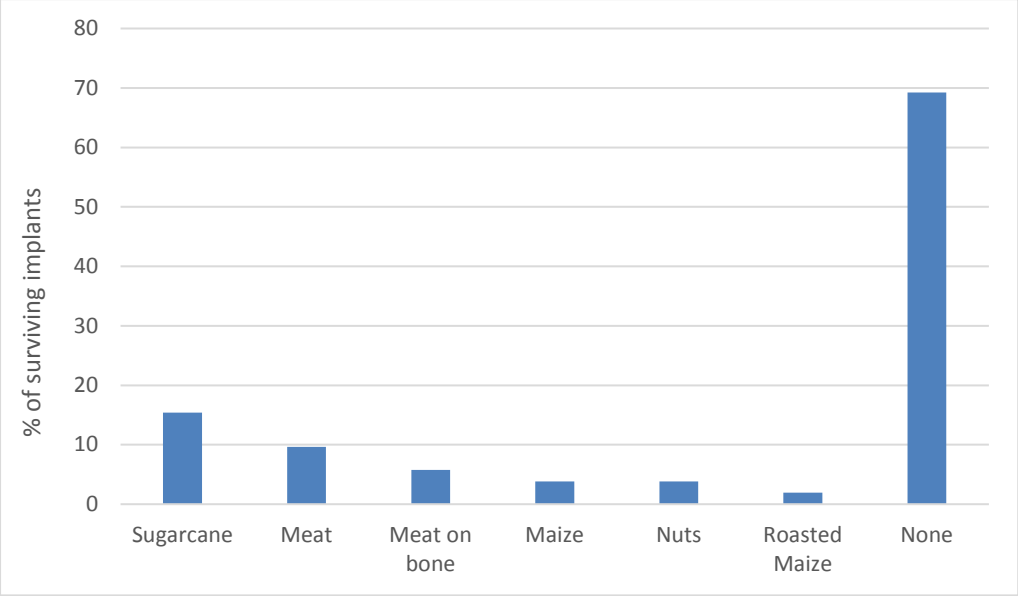


Figure 13 Difficulty with eating food types

Patient satisfaction found in this study was compared to a study done by Pjetursson et al in 2005 and these are shown in Table 13.

Table 13 Patient satisfaction parameters compared with Pjetursson et al (2005)

Parameter	Pjetursson study	This study
Survival rate	93%	98%
Chewing and function satisfaction	97%	91%
Phonetics	96%	96%
Aesthetics	97%	91%
Cleansability	93%	96%
Overall satisfaction	92%	90%
Undergo same treatment	94%	94%
Recommend to relative	89%	100%
Cost justifiable	87%	98%

CHAPTER 5: DISCUSSION

5.1 Study population

Many studies have shown that dental implant therapy has predictable outcomes. However, no study had been done in Kenya to date. A sample taken from patients attending the University of Nairobi Dental School revealed that the majority of the patients who sought treatment for dental implants were women (75%) and had a tertiary level of education (74%).

The Recall rate was 50 % and this is in tandem with the findings of the Kenyan National Oral Health Survey (Gathece et al, 2015). It indicated that 83% of the patients would only visit a dentist if they were in pain or discomfort; 4.4% would go for follow-up treatment and 3.65% would go for routine check-up. This clearly indicates that the oral health seeking behaviour of Kenyans is very low.

The pool of patients came from a diverse region. Most (64%) resided within Nairobi or at least within a radius of 20km from the Dental School. There were, however, a few individuals who came from as far as 300km (Kericho) and another 660km (Kampala) from the Dental School. This can also explain the low recall rate. Accessibility of specialized dental services in Kenya is limited to major towns and cities.

Most of the participants were professionals (53%) and managers (21%). They ranged from business owners, doctors, teachers to advocates. These participants also reported that they felt that the cost of the treatment was justifiable. Only one person felt that the cost was not justifiable, and this person was among the few (6%) whose highest level of education was primary education and whose occupation was categorised under the service and sale workers

category according to the International Standard Classification of Occupation. Implant therapy seems to be affordable mainly to high to middle-class citizens.

Implant therapy requires regular reviews post treatment. It is therefore important to notify the patients prior to placement of implants of the necessity of regular reviews.

5.2 Medical History

This referred to any pre-existing medical condition or use of medication at the time of implant placement. The focus was on the presence of diabetes, heart disease or hypertension and the use of anticoagulants and bisphosphonates. None of the patients in this study had a history of diabetes or heart disease. A few had controlled hypertension. There is, however, no absolute contraindication for implant placement in medically compromised patients (Gómez-de Diego et al 2014). It is important to note that patients on bisphosphonates are partially contraindicated as this may have a negative impact on osseointegration thus slowing down the healing process or leading to a lack of osseointegration. In this study there were no patients on bisphosphonates.

Diabetes is a metabolic disease which may influence osseointegration through reduction of bone formation as well as induction of bone resorption. Uncontrolled hyperglycaemia influences the production of osteoblast matrix through inhibition of the differentiation of the osteoblasts, therefore leading to reduced bone formation and alteration of the response of the parathyroid hormone and thus metabolism of phosphorus and calcium. Human studies are yet to be done to correlate any reduced bone formation around implants with this state. Fortunately, in this study, no patient had a history of diabetes.

Cardiac disease leads to a reduction in oxygen and nutrients to the osseous tissues and this may affect osseointegration. These patients are also highly susceptible to infective endocarditis as the implant therapy entails introduction of a foreign object into the bone. Gómez-de Diego et al (2014), indicated that neither diabetes nor cardiac disease are an absolute contraindication to implant placement. Both conditions require proper control as well as the appropriate antibiotic prophylaxis for successful outcomes.

Use of anticoagulant is on the rise due to an increase in cardiac disease. Patients with normal clotting parameters have an INR (International Normalized Ratio) of 0.7-1.2 while patients on anticoagulants range from 2-4. There is increased risk of bleeding during or a few days after the surgical insertion of the dental implants in patients on anticoagulants. On the other hand, there is increased risk of thrombosis if the INR is lowered to normal levels. There has, therefore, been controversy as to whether to stop oral anticoagulants and lower the INR to 2 instead of the therapeutic levels of 2-4. While some studies (e.g. Al Mubarak et al 2006) have shown that there is an increased risk (52%) of bleeding in patients who continue use of anticoagulants during dental surgery, others (Wahl et al 2015) have shown that the risk is low (1%). Madrid and Sanz (2009) concluded that there is no need to stop oral anticoagulants prior to performing minor oral surgery so long as this does not involve the use of autogenous bone grafts and or extensive flaps and osteotomy preparations. Guidelines published in the British Dental Journal (Perry et al 2007) indicate that use of oxidised cellulose (surgicel), collagen sponges and sutures should be used to minimise bleeding in patients on anticoagulants and that analgesics containing Non-Steroidal Anti-Inflammatories (NSAIDs) or Cyclooxygenase COX 2 inhibitors should be avoided due to risk of over anticoagulation. No patients reported use of anticoagulants prior to the implant therapy in this study.

5.3 Tooth loss

The most common reason for tooth loss was dental caries followed by trauma. This is in accord with the 2.3 billion people globally suffering from dental caries in their permanent dentition (Global Burden of Disease 2018). There is clearly an ongoing need to sensitise the public on preventive measures as well as early diagnosis of oral disease.

The most commonly replaced tooth was the maxillary central incisor, mostly due to trauma (57%). In fact, the loss of anterior teeth accounted for all teeth lost due to trauma.

Anterior teeth are essential not only for aesthetics but also for speech and phonation thus it was the most highly replaced tooth in this study. Loss of a posterior tooth may not affect the psychosocial aspect of a patient compared with the loss of an anterior tooth.

5.4 Implant Dimensions

Implant length has been shown to play a role in implant survival and success. In the present study all the implants were classified as long with minimum length of 8.5mm and a maximum length of 16mm. The range of implant length in the anterior region was 12-14mm the highest, 14mm being in the canine region. The posterior region had a range of 8.5 to 11mm and the 11mm was in the premolar region.

According to the 6th ITI consensus conference report (Jung et al 2018) a short implant, less than 6mm in length, can be a viable option in cases where there is reduced bone height, however their survival rate varies and is lower. Narrow implants, less than 2.5mm, on the other hand also showed lower survival rates. The recommended diameter from the above conference was more than 4mm. In this study the median diameter was 4.1mm with a

minimum of 3.3mm and maximum of 5.5mm. Comparisons on survival rates between long and short implants were therefore not possible.

5.5 Bone grafting

The success rates of implants placed with simultaneous bone grafting is high. Clementini et al (2011) reported a success rate of 61.5%-100%. In this study 60% of the implants were grafted and this could have led to the high success rate of 98% for the 31 implants that were reported under the James Misch health scale optimum health.

5.6 Occlusion in fixed implant supported prostheses

Occlusal forces influence the dental implant and supporting bone structure. Moderate forces within a certain threshold may lead to increase in bone density and apposition whereas heavy forces may lead to bone resorption. It is difficult to quantify the magnitude and direction of occlusal forces (Isidor 2006). It has been reported that forces during normal mastication stay within a physiologic range compared with forces during parafunction which can be quite extensive and prolonged (Manfredini et al 2011; Heitz-Mayfield et al 2004; Klineberg et al 2007) and it is possible that some of the ceramic veneering fractures observed in this study could have been due to parafunction.

An occlusal design in static occlusion, such that axial loading is through centred contacts in the occlusal fossae (assessed using a shim stock) has been recommended, together with flatter cusp angles and wider occlusal fossae, to increase horizontal freedom and reduce stress from lateral forces (Kim et al 2005; Klineberg et al 2012).

In this study 8% of the implants were found to be in hyper-occlusion as the shim stock foil held firmly in light closure of the teeth. This can lead to complications of a biologic nature as the crestal bone levels may reduce due to bone loss. This in turn can lead to lack of support and eventual implant failure.

In the natural dentition the occlusal feedback from teeth is transmitted through mechanoreceptors found in the periodontal ligament. In contrast, implants do not have a periodontal ligament, and these have a compensatory occlusal feedback mechanism from the bone ('osseoperception'), peri-oral muscles, ligaments and jaw joints. This type of feedback is considerably less than that of teeth. It is for this reason that for anterior guidance, the adjacent teeth are used for proprioception feedback. This means that the anterior implant prosthesis should not be in contact with the opposing tooth and the posterior implant prosthesis should not have working or non-working interferences in dynamic occlusion. In this study 98% of all the implant prostheses were mutually protected during excursion.

5.7 Contacts

The area of tooth that is in close approximation with the adjacent tooth or adjacent fixed prosthesis is referred as the interproximal contact (GPT 9). This area plays a role in maintaining and stabilising the dental arch. Weak or open contacts cause food impaction which predisposes the natural teeth to caries and periodontal disease. It may also lead to undesirable movement of the teeth.

The contact points in this study were evaluated using non-waxed dental floss. If the floss could not easily pass through the contact, it was termed as tight and if the floss could easily pass through it was loose and if the contact was obviously open it was termed at open. 50%

of the implants evaluated had tight contacts; 29 % had open contacts and 21% had loose contacts. This, however, did not seem to play a role in the success of the implant, nor did the fact that the majority of the patients did not floss their teeth.

5.8 Implant prosthesis material

The survival rate for metal ceramic implant supported fixed dental prostheses as reported by Pjetursson et al (2012) was 96.4% after 5 years and 93.9% after 10 years; the most frequent complication was fracture of the veneering material (13.5%) and loss of retention of cemented prosthesis (4.7%). In this study there was no loss of retention of the cemented prostheses despite their being the majority (79%). The fracture of veneering material was also much lower as only 3 implant restorations (6%) had this minor complication. Most of the implants were placed in the aesthetic zone and this would require a cemented prosthesis for improved aesthetic outcome. One of the challenges or limitations of screw retained prostheses is the position of the access hole which can interfere with occlusion in the posterior teeth and aesthetics in the anterior region. This can be overcome by the use of angulated implants or angulated abutments, but these were not used in this study, possibly because of a lack of knowledge of these or a lack of availability.

5.9 Radiographic evaluation of the implant

Radiographic evaluation of the implant is essential in determining the success of the implants as parameters such as bone loss, radiolucency and other anomalies may be observed.

Crestal bone height

Standardized periapical radiographs taken using the paralleling technique were used to evaluate the status of the peri-implant bone. The crestal bone height was observed in relation to the implant shoulder level. If the bone level coincided with the implant shoulder level this

was indicated as 0 and if the crestal bone height was more coronal to the implant shoulder it was positive and if apical to the implant shoulder it was negative. The difference between crestal height at initial x ray and at the evaluation x ray was the amount of bone loss recorded.

In this study 47 implants were evaluated radiographically as the other 6 were in patients who did not consent to having a radiograph taken. Out of these, only 29 had initial periapical radiographs available in their record. Bone loss could therefore only be evaluated in 29 implants. Only 3 out of the 29 implants had a bone loss of 2-3mm. The rest were under 2mm. These 3 implants had been in the mouth for a period of 3 years.

Presence of radiolucency

In this study, 12 implants had radiolucency. Half of these implants were in hyper-occlusion on heavy contact suggesting high occlusal forces. It is difficult to measure the exact extent of the forces exerted on the peri-implant bone, however this correlated with Frost's findings concerning bone changes with mechanical stress (Frost 1994). Normal bone strain was reported to be 50-1500 microstrains and high strain that could lead to favourable apposition of bone was in the range of 1500-3000 microstains while higher forces of more than 3000 microstrains could lead to bone fatigue and therefore bone loss.

One of the implants was in infra-occlusion suggestive of lower mechanical stress and this could result in bone disuse atrophy. 50-100 microstrains leads to disuse of bone and remodeling of bone will lead to bone loss (Frost 1994).

Radiolucency vs probing depth

Probing depths of more than 6mm are associated with bone loss. In this study only one implant with radiolucency had a probing depth of 6mm, and this implant was asymptomatic. There were insufficient numbers to enable any correlation between implants with radiolucency and probing depths to be made.

5.10 Patient satisfaction

Although there were only 28 patients who were able to be interviewed, patient satisfaction in these patients was very high, with only 3 patients reporting that they would not undergo this treatment again. Two cited age as the main reason, and one felt that natural teeth were preferred, though it was not clear if this was a wistful comment as a regret for having lost teeth. Nevertheless, it has been reported elsewhere that age can be a determining factor for refusing implant therapy (Ellis et al 2011).

5.11 Success, survival and complications

Survival is defined as the presence of the implant or reconstruction at the time of follow-up examination without specifying the condition of the element examined. Over the years the terms success and survival have been used interchangeably. According to the third ITI consensus statement (Lang et al 2004), success should be defined as the presence of the implant at the time of evaluation with absence of complications. In this study, survival rates as well as success rates were found to be 98%, which was similar to other studies such as Buser et al (2013) which reported a high survival rate of 98.8% over 10 years and a success rate of 97%.

5.12 Complications

Complications are unfavourable outcomes in implant therapy and can be of biologic in nature or hardware related. Biological complications are those that are associated with peri-implant mucosa and bone loss and relate to the host response to the foreign body. Hardware complications are those that are associated with the implant or prosthetic components. Hardware complications are further divided into mechanical complications which involve the manufacturer fabricated components and the technical complications which involve the laboratory fabricated components of the prosthesis (Salvi and Bragger et al 2009).

Biological complications

Inflammation of the soft tissues around an implant is referred as peri-implant mucositis and when this inflammation occurs in addition to alveolar bone loss it is known as peri-implantitis. According to a systematic review done by Pjetturson et al in 2012, 8.5% of the implants examined had this complication. They also found that the odds of hardware complication relative to biologic complication was 4:1 and that the most common hardware complication was fracture of the veneering material (13.5%). In this study the only minor complication noted was fracture of the veneering material which occurred in 6% of the implant prostheses. The second most common minor complication in the Pjetturson study was loss of the access opening followed by abutment screw loosening. None of which were present in this study since majority of the implant prosthesis (79%) were cement retained.

Technical complications

These are complications that are related to the laboratory fabricated components of the implant prosthesis. Fracture of veneering material is classified as a technical complication.

A few of the restorations in this study were found to have ceramic chipping as a minor technical failure observation, but it was not possible to ascertain the exact cause which can relate to a variety of factors.

Mechanical complications

These are complications that are related to the manufacturer fabricated components and include fracture of abutment or abutment screw and fracture of the implant. No implant in this study had abutment screw fracture but only 6% of the restorations were secured with screws.

Implant failure

Only one implant failed during the study period. This was an anticipated failure as osseointegration did not take place and the implant was ex-planted after 2 months and replaced successfully.

CHAPTER 6: CONCLUSIONS

Although the small sample size of this study did not allow for multiple statistical comparisons, the study has provided valuable base-line information on the treatment and recall protocols for implant therapy carried out at the University of Nairobi Dental School.

Despite some inexperience in these protocols, the patients recalled and interviewed reported very high levels of satisfaction. In addition, all implants but one were in situ, and functioning satisfactorily. There was generally acceptable bone loss with the exception of one or two implants, but these were considered to be clinically acceptable.

The soft tissue health was also surprisingly good even though very few patients reported that they used dental floss as part of their oral hygiene routine. This again highlights the need for regular recall and maintenance visits.

The study has shown that there is much that can be improved in the provision of an implant therapy service at the dental hospital, and it is recommended that clear protocols be developed for every stage in the provision of this service. In addition, alternative implant systems and types should be explored, such as the use of angulated implants in the anterior region, so that more of the implant supported restorations can be screw-retained without the need for bone augmentation.

The main limitation in this study was the recall rate, related in part to the distance the patients lived from the hospital. Most of the patients were also under the impression that once the implant was placed there was no need for follow-up treatment since this was a permanent

solution to missing teeth. Clearly, patients should be informed of the need for follow-up treatment prior to commencement of implant therapy.

Another limitation in this study was the lack of adequate medical records. Some patient records were not available and even when they were there, some contained, for example, incorrect contact details.

Despite the above limitations this study has obtained much valuable information regarding dental implant therapy in Kenya. This information will be used as baseline records for future reviews and recall of the dental implant patients.

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APPENDICES

Appendix 1 Ethical clearance certificate from the University of Witwatersrand Human Research Ethics Committee (HREC)

Appendix 2 Approval by University of Nairobi to conduct study

Appendix 3 Data collection sheet

Appendix 4 Questionnaire

Appendix 5 Informed Consent document

Appendix 6 Informed Consent form

Appendix 7 List of variables

Appendix 8 Informed consent document translated in Swahili

Appendix 9 Informed consent form translated in Swahili

Appendix 10 Questionnaire translated to Swahili

Appendix 1: Ethical clearance, University of the Witwatersrand

R14/49 Dr Catherie Njeri Gichangi

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M170813

NAME: (Principal Investigator)	Dr Catherie Njeri Gichangi
DEPARTMENT:	Oral Rehabilitation Community Dentistry and Periodontology Department School of Dental Sciences, University of Nairobi
PROJECT TITLE:	Evaluation of Dental Implants Placed in Patients Attending the University of Nairobi Hospital 2006-2016
DATE CONSIDERED:	25/08/2017
DECISION:	Approved unconditionally
CONDITIONS:	South African Human Research Ethics Committees (HRECs) have no standing outside South Africa. Ethics approval is also required from local HRECs in Nigeria
SUPERVISOR:	Prof CP Owen
APPROVED BY:	Professor P. Cleaton-Jones, Chairperson, HREC (Medical)
DATE OF APPROVAL:	15/11/2017

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

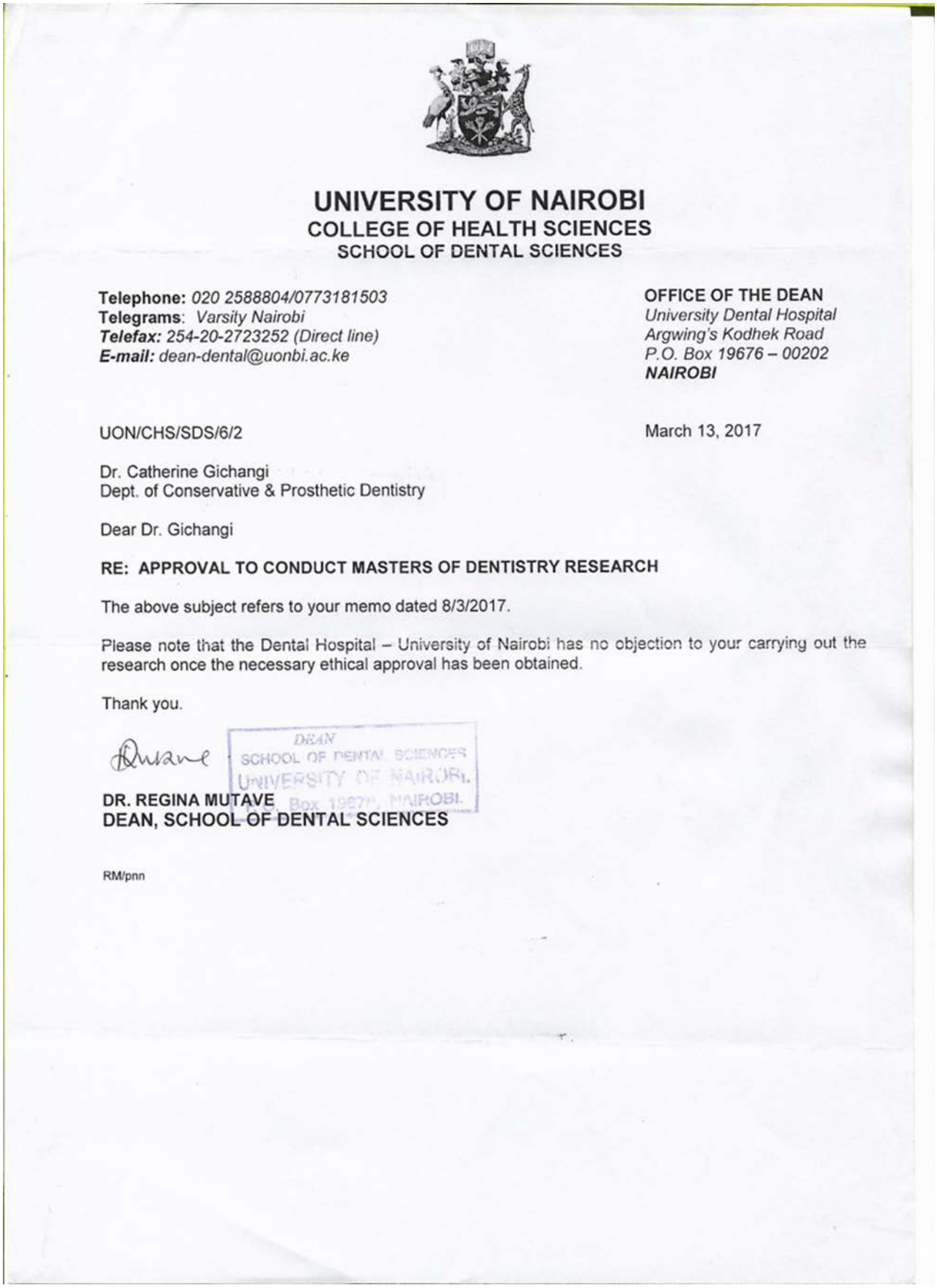
DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on the 3rd floor, Phillip Tobias Building, Parktown, University of the Witwatersrand. I/We fully understand the conditions under which I am/we are authorised to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit to the Committee. **I agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. in this case, the study was initially review August and will therefore be due in the month of August each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix 2: Approval by University of Nairobi to conduct study



UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
SCHOOL OF DENTAL SCIENCES

Telephone: *020 2588804/0773181503*
Telegrams: *Varsity Nairobi*
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E-mail: *dean-dental@uonbi.ac.ke*

OFFICE OF THE DEAN
University Dental Hospital
Argwing's Kodhek Road
P.O. Box 19676 – 00202
NAIROBI

UON/CHS/SDS/6/2

March 13, 2017

Dr. Catherine Gichangi
Dept. of Conservative & Prosthetic Dentistry

Dear Dr. Gichangi

RE: APPROVAL TO CONDUCT MASTERS OF DENTISTRY RESEARCH

The above subject refers to your memo dated 8/3/2017.

Please note that the Dental Hospital – University of Nairobi has no objection to your carrying out the research once the necessary ethical approval has been obtained.

Thank you.

DEAN
SCHOOL OF DENTAL SCIENCES
UNIVERSITY OF NAIROBI
P.O. Box 19676, NAIROBI

DR. REGINA MUTAVE
DEAN, SCHOOL OF DENTAL SCIENCES

RM/pnn

Appendix 3: Data collection sheet

Demographics: this information will be kept in a separate securely stored file and will be used for statistical associations' calculations only.

File Number: _____

Date of birth: _____

Gender: Male ☐ Female ☐

Occupation: _____ _____

Highest level of education: Primary ☐

Secondary ☐

Tertiary ☐

Area of Residence: _____

Reason for tooth loss: Periodontal disease ☐

Caries ☐

Trauma ☐

Medical History:

Do you suffer from any of the following chronic illness?

Diabetes ☐

Hypertension ☐

Heart Disease ☐

Other ☐ Specify _____

Do you currently take any of the following medicaments?

Anticoagulants ☐

Bisphosphonates ☐

Other ☐ Specify _____

History of medication during implant placement:

Anticoagulants ☐

Bisphosphonates ☐

Other ☐ Specify _____

Dental History: Specify

Endodontic treatment ☐ _____

Periodontal treatment ☐ _____

Conservative treatment ☐ _____

Social history: Smoking Yes ☐ No ☐

Alcohol intake: Yes ☐ No ☐

Location of the Implant: Anterior ☐ Posterior ☐

- Implant Details: Type of implant _____

Implant dimensions_____

- Surgical details:
  a) Stages: One stage ☐ Two stage ☐
  b) Bone Grafting: Yes ☐ No ☐
     If yes specify which type_____
  c) Loading: Immediate ☐ Early ☐ Delayed ☐
- Restorative details:
  a) Prosthesis design_____
  b) Prosthesis material All ceramic ☐
     Specify_____
     All metallic ☐ Metal ceramic ☐
  c) Prosthesis retention: Screw retained ☐ Cement retained ☐
  d) Restorative platform: Bone level ☐ Abutment level ☐

Clinical examination

1) Occlusal evaluation

General occlusal schemes. Balanced occlusion ☐ Group function ☐

mutually protected occlusion☐combination☐ Specify _____

Characteristics of occlusion:

a) In heavy contact: Hyper occlusion☐Occlusion☐ Infra-occlusion ☐
b) light contact: Hyper occlusion ☐Occlusion☐Infra-occlusion ☐
c) Excursion: Protected Yes☐No ☐
d) Adjacent teeth: Hyper-occlusion☐ Occlusion ☐Infra-occlusion☐
e) Contacts: Open☐ Tight☐ Loose ☐

2) Periodontal evaluation of tissues surrounding the implant.

Implant Location	Modified Plaque Index	Sulcus Bleeding Index	Probing Depth Pocket	Probing Attachment level

3) Implant prosthesis evaluation

Level 1	Major complications	Missing superstructure	Fractured superstructure	
Level 2	Minor complications	Abutment loosening	Screw loosening	Ceramic chipping
Level 3	Aesthetic			
Level 4	Functional			

4) Radiological evaluation

Implant Location	Bone level at initial x ray in mm	Bone level at evaluation date in mm	Presence of peri-implant radiolucency	Other anomaly

Appendix 4

QUESTIONNAIRE

Please answer the following Questions

1. Would you undergo this treatment again with the experience you have now?

No ☐ Yes ☐

1a. If No, why not?

2. Would you recommend the procedure to others in a similar situation?

No ☐ Yes ☐

2a. If No, why not?

3. Was the cost of the implant justifiable?

No ☐ Yes ☐

4. Please indicate on the line below how you experience the overall comfort of your crown on the implant.

0 ——————————————————————— 100

Very uncomfortable Comfortable

5. How comfortable is your crown on the implant when you eat?

0 ——————————————————————— 100

Very uncomfortable Comfortable

6. Do you feel the crown and implant have affected your speech?

0 ——————————————————————— 100

Not at all Considerably

7. How do you feel about the appearance of your crown on the implant?

0 ——————————————————————— 100

Poor Excellent

8. Have you experienced any difficulty with brushing your crown on the implant?

0 ——————————————————————— 100

Difficult Easy

9. Have you experienced any difficulty with flossing your crown on the implant?

0 ——————————————————————— 100

Difficult Easy

10. Are there any foods you find you are unable to eat because of the crown on the implant?

Appendix 5

PARTICIPANT INFORMATION AND CONSENT FORM

INTRODUCTION

I Dr Catherine Njeri Gichangi, Tutorial fellow at the University of Nairobi School of Dental Sciences currently registered for a master's program at the University of Witwatersrand South Africa would like to tell you about a study being conducted by myself. The purpose of this consent form is to give you the information you will need to help you decide whether or not to be a participant in the study. Feel free to ask any questions about the purpose of the research, what happens if you participate in the study, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide to be in the study or not.

This process is called 'informed consent'. Once you understand and agree to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in a medical research:

i) Your decision to participate is entirely voluntary
ii) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal
iii) Refusal to participate in the research will not affect the services you are entitled to in this health facility or other facilities.

We will give you a copy of this form for your records. May I continue?

YES / NO

This study has approval by The Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Protocol No. P584/10/2017 and the human and research ethical committee (HREC) from the University of Witwatersrand Clearance certificate number: M170813

WHAT IS THIS STUDY ABOUT?

I will be interviewing and examining individuals who have had dental implants done at the University of Nairobi Hospital.

The purpose of this study is to find out how satisfied you are with the implant treatment you received. This will involve my examining you and asking you to complete a short questionnaire. This will help us to improve our service to you and others who have and will have, implant procedures. During the clinical examination which will be at no cost to you, you will receive a full check-up and a radiographic evaluation of the implant prosthesis. The total time will be no more than one hour. In addition, we will be retrieving some information from your hospital records.

There will be approximately 50 participants in this study selected from the patient record register at the University of Nairobi Dental hospital. We are asking for your consent to consider participating in this study.

WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH STUDY?

If you agree to participate in this study, the following things will happen:
You will be interviewed regarding satisfaction of the dental implant. Clinical and radiological examination of the dental implant will be carried out. The interview and examination will last approximately 1 hour. The interview will cover topics such as ability to chew with the implants, ability to clean the implant and aesthetics.

After the examination, you will be notified of any complications noted on the dental implant and a comprehensive treatment plan provided.

We will ask for a telephone number where we can contact you if necessary. If you agree to provide your contact information, it will be used only by people working for this study and will never be shared with others. The reasons why we may need to contact you include:
Future recall and maintenance of the implants

ARE THERE ANY RISKS, HARMS DISCOMFORTS ASSOCIATED WITH THIS STUDY?

There are no risks involved in this study as no invasive procedures will be done.

CONFIDENTIALITY

All information obtained during the course of this study, including personal data and research data will be kept strictly confidential. All your responses to the questionnaires will remain anonymous: the hardcopy questionnaires will be coded.

Data that may be reported in scientific journals will not include any information that identifies any of the participants in this study.

ARE THERE ANY BENEFITS BEING IN THIS STUDY?

You will benefit by receiving free dental check-up including an x ray that will reveal the status of your dental implant, which is embedded in bone and therefore can only be seen by means of a radiograph. The evaluation will ensure that all implant complications are diagnosed and treated early resulting in long term survival and success of the treatment. Minor complications that can be treated on the chairside will be addressed immediately while major complications that necessitate laboratory input will be referred accordingly.

Also, the information you provide will help us better understand dental implant therapy and assist in formulating a recall and maintenance protocol at the University of Nairobi Dental Hospital.

This information is a contribution to science and technology.

WILL BEING IN THIS STUDY COST YOU ANYTHING? NO

WILL YOU GET REFUND FOR ANY MONEY SPENT AS PART OF THIS STUDY?

YES. Transport to the University of Nairobi Dental Hospital will be refunded to a maximum of 1000 Kenya shillings.

WHAT IF YOU HAVE QUESTIONS IN FUTURE?

If you have further questions or concerns about participating in this study, please call or send a text message to the study staff at the number provided at the bottom of this page.

For more information about your rights as a research participant you may contact:

Secretary/Chairperson, Kenyatta National Hospital-
University of Nairobi Ethics and Research Committee
Telephone No. 2726300 Ext. 44102
Email uonknh_erc@uonbi.ac.ke

Human Research Ethics Committee (HREC):

The chairperson of the committee is Prof P Cleaton-Jones whose email address is:
peter.cleaton-jones1@wits.ac.za
The administrators are Ms ZaneleNdlovu/ Mr RhulaniMkansi/ Mr Lebo Moeng
Tel +27-11 717 2700/2656/1234/1252
Email: HREC-Medical.ResearchOffice@wits.ac.za

WHAT ARE YOUR OTHER CHOICES?

Your decision to participate in research is voluntary. You are free to decline participation in the study and you can withdraw from the study at any time without injustice or loss of any benefits.

Appendix 6

CONSENT FORM

Participant's statement

I have read this consent form or had the information read to me. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw any time. I freely agree to participate in this research study.

I understand that all efforts will be made to keep information regarding my personal identity confidential.

By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

I agree to participate in this research study:

Yes No

I agree to have an x ray/radiograph of the dental implant taken

Yes No

I agree to provide contact information for follow -up:

Yes No

Participant printed name: _____

Participant signature _____

Date _____

Researcher's statement:
I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has willingly and freely given his/her
consent.

Researcher 's Name: _____

Date: _____Signature _____

In case of any clarifications or concerns regarding the study you may contact the investigator, the supervisors, the KNH/UON Ethics, Research and Standards Committee or HREC using the following contacts:

Dr Catherine Njeri Gichangi
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Dr Nelson Matu
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University of Nairobi, School of Dental Sciences
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KNH/UON-ERC: Tel- 020 726300-9
Email address- uonknh_erc@uonbi.ac.ke

Human Research Ethics Committee (HREC):
Prof P Cleaton-Jones whose email address is: peter.cleaton-jones1@wits.ac.za

Ms ZaneleNdlovu/ Mr RhulaniMkansi/ Mr Lebo Moeng
Tel +27-11 717 2700/2656/1234/1252
Email: HREC-Medical.ResearchOffice@wits.ac.za

Appendix 7

List of Variables

SOCIO-DEMOGRAPHIC	**INDEPENDENT**	**DEPENDENT**
Age	Type of implant	Survival
Gender	Dimension of implant	Success
Level of education	Implant location	Failure
Occupation	Loading	Complications
Area of residence	Bone graft	
	Investigations done	
	Medical History	
	Dental History	
	Medication Before/During	
	Smoking habits	

Appendix 9

HABARI YA WASHIRIKI

UTANGULIZI

Mimi, Dr Catherine Njeri Gichangi, mshirika wa mafunzo katika Chuo Kikuu cha Nairobi Shule ya Sayansi ya meno sasa waliosajiliwa kwa shahada ya uzamili katika Chuo Kikuu cha Witwatersrand Afrika Kusini ningependa kukuambia kuhusu utafiti unaofanywa na mimi mwenyewe. Madhumuni ya fomu hii ya idhini ni kukupa taarifa unayohitaji ili kukusaidia uamuzi au ikiwa ni mshiriki katika utafiti. Jisikie huru kuuliza maswali yoyote kuhusu madhumuni ya utafiti, kinachotokea ikiwa unashiriki katika utafiti, hatari na faida iwezekanavyo, haki zako kama kujitolea, na kitu kingine chochote kuhusu utafiti au fomu hii ambayo haijulikani. Tunapojibu maswali yako yote kwa kuridhika kwako, unaweza kuamua kuwa katika utafiti au la.

Utaratibu huu unaitwa 'kibali cha habari'. Mara unapoelewa na kukubali kuwa katika utafiti, nitawaomba usaini jina lako kwenye fomu hii. Unapaswa kuelewa kanuni za jumla zinazotumika kwa washiriki wote katika utafiti wa matibabu:

i) Uamuzi wako wa kushiriki ni kikamilifu kwa hiari

ii) Unaweza kujiondoa kwenye somo wakati wowote bila ya kutoa sababu ya uondoaji wako

iii) Kukataa kushiriki katika utafiti hautaathiri huduma unazostahili katika kituo hiki cha afya au vifaa vingine.

Utafiti huu una kibali na Kliniki ya Kenyatta ya Taifa ya Chuo Kikuu cha Nairobi Itifaki Nambari P584 / 10/2017 na Kamati ya Maadili ya Binadamu na Utafiti (HREC) kutoka Chuo Kikuu cha Witwatersrand Clearance Certificate: M170813

NI NINI KUJIFUZA KUFANYA?

Nitawahi kufanya mahojiano na kuchunguza watu ambao wamekuwa na implants za meno kufanyika kwenye Hospitali ya Chuo Kikuu cha Nairobi.

Kusudi la utafiti huu ni kujua jinsi umeridhika na matibabu ya kuingiza ambayo umepata. Hii itahusisha kukuchunguza na kukuuliza kukamilisha swala fupi. Hii itatusaidia kuboresha huduma zetu kwako na wengine ambao wana na watakuwa na taratibu za kuingiza. Wakati wa uchunguzi wa kliniki ambao hautakuwa na gharama yoyote kwako, utapokea upimaji kamili na tathmini ya radiografia ya uingizaji wa mazao. Wakati wote utakuwa si zaidi ya saa moja. Kwa kuongeza, tutapata habari fulani kutoka kwenye rekodi za hospitali.

Kutakuwa na washiriki 50 hivi katika utafiti huu waliochaguliwa kutoka kwenye usajili wa rekodi ya mgonjwa katika hospitali ya meno ya Chuo Kikuu cha Nairobi. Tunakuomba idhini yako

fikiria kushiriki katika somo hili.

Je, utapata rejea kwa kila kitu cha kifedha kama sehemu ya kujifunza hii? NDIYO. Usafiri kwa Hospitali ya Madaktari ya Chuo Kikuu cha Nairobi utarejeshwa kwa kiwango cha juu cha shillingi elfu moja.

NINI UNA MAFUNZO KATIKA KWANZA?

Ikiwa una maswali zaidi au wasiwasi juu ya kushiriki katika somo hili, tafadhali piga simu au tuma ujumbe wa maandishi kwa wafanyakazi wa kujifunza kwa idadi iliyotolewa chini ya ukurasa huu.

Kwa habari zaidi kuhusu haki zako kama mshiriki wa utafiti unaweza kuwasiliana na:

Katibu / Mwenyekiti, Hospitali ya Taifa ya Kenyatta-

Chuo Kikuu cha Nairobi Kamati ya Maadili na Utafiti

Simu Namba 2726300 Ext. 44102

Barua pepe uonknh_erc@uonbi.ac.ke

Kamati ya Maadili ya Utafiti wa Binadamu (HREC):

Mwenyekiti wa kamati ni Prof P Cleaton-Jones ambaye barua pepe ni:

peter.cleaton-jones1@wits.ac.za

Watawala ni Bi Zanele Ndlovu / Mr Rhulani Mkansi / Mr Lebo Moeng

Tel + 27-11 717 2700/2656/1234/1252

Barua pepe: HREC-Medical.ResearchOffice@wits.ac.za

USHIRIKI

Uamuzi wako wa kushiriki katika utafiti ni wa hiari. Wewe ni huru kupungua kushiriki katika utafiti na unaweza kujiondoa kwenye utafiti wakati wowote bila udhalimu au kupoteza faida yoyote.

Appendix 9

FORM YA SHAHA

Taarifa ya Mshiriki

Nimesoma fomu hii ya idhini au nilisoma habari. Nimekuwa na maswali yangu akajibu kwa lugha ambayo ninayoelewa. Hatari na faida zimeelezewa kwangu. Ninaelewa kuwa ushiriki wangu katika utafiti huu ni hiari na kwamba nipate kuchagua kuchagua wakati wowote. Ninakubali kwa hiari kushiriki katika utafiti huu wa utafiti.
Ninaelewa kuwa jitihada zote zitafanywa ili kuweka habari kuhusu siri ya utambulisho wangu binafsi.

Kwa kutia saini fomu hii ya kibali, sijaacha haki yoyote ya kisheria ambayo mimi nishiriki katika utafiti wa utafiti.

Nakubali kushiriki katika utafiti huu wa utafiti:

Ndio_____ la_____

Nakubali kuwa na ray ray / radiograph ya kuingiza meno kuchukuliwa

Ndio_____ la_____

Nakubali kutoa maelezo ya mawasiliano kwa kufuatilia:

Ndio_____ la_____

Jina la kuchapishwa la mshiriki:

_____

Sahihi ya mshiriki _____

Tarehe _____

Taarifa ya Mtafiti:
Mimi, mshirikiwaji, nimeelezea kikamilifu maelezo muhimu ya utafiti huu wa utafiti kwa mshiriki aliyechaguliwa hapo juu na kuamini kwamba mshiriki ameelewa na ametoa kwa hiari na kwa uhuru wake
idhini.

Jina la Mtafiti: _____
Tarehe: _____ Sahihi _____

Ikiwa kuna ufafanuzi wowote au wasiwasi kuhusu utafiti unaweza kuwasiliana na uchunguzi, wasimamizi, Kamati ya Maadili ya KNH / UON, Kamati ya Utafiti na Viwango au HREC kwa kutumia anwani zifuatazo:

Dr Catherine Njeri Gichangi
Idara: Maalum ya Maumbile na Prosthetic Dentistry
Chuo Kikuu cha Nairobi, Shule ya Sayansi ya meno
Namba ya 0723841390
Barua pepe: cnjeri@uonbi.ac.ke

Prof Prof Owen
Idara: Idara ya Usafishaji wa Kinywa
Chuo Kikuu cha Witwatersrand, Johannesburg Afrika Kusini
Namba ya simu: +27836792205
Barua pepe: peter.owen@wits.ac.za

Dr Nelson Matu
Idara ya Periodontology / Jumuiya na Maambukizi ya Dentistry
Chuo Kikuu cha Nairobi, Shule ya Sayansi ya meno
Barua pepe: nelson.matu@uonbi.ac.ke au nkmatu@yahoo.com
Simu: 0722793909

KNH / UON-ERC: Simu- 020 726300-9

Anwani ya barua pepe- uonknh_erc@uonbi.ac.ke

Kamati ya Maadili ya Utafiti wa Binadamu (HREC):

Prof P Cleaton-Jones ambaye barua pepe ni: peter.cleaton-jones1@wits.ac.za

Bi Zanele Ndlovu / Mr Rhulani Mkansi / Mr Lebo Moeng

Tel + 27-11 717 2700/2656/1234/1252

Barua pepe: HREC-Medical.ResearchOffice@wits.ac.za

Appendix 10

QUESTIONNAIRE IN KISWAHILI

TafadhalijibuMaswaliifuatayo

1. Je! Unapitiamatibabuhiitenanauzoefuunaosasa?

Hapana ☐ ndio ☐

1a. Ikiwa Hapana, kwanini?

_____

_____

2. Je! Unapendekeza utaratibu kwa wengine katika hali kama hiyo?

Hapana ☐ ndio ☐

2a. IkiwaHapana, kwanini?

_____

_____

3. Je! Gharama ya kuingiza imethibitishwa?

Hapana ☐ ndio ☐

4. Tafadhali onyesha kwenye mstari hapa chini jinsi unavyopata faraja ya jumla ya taji yako juu ya kuingiza.

0 ——————————————————— 100

Haisikitishwi Inasikitishwa sana

5. Taji yako ni vizuri sana kwa kuimarisha wakati unakula?

0 ——————————————————— 100

Haisikitishwi Inasikitishwa sana

6. Je, unasikia taji na kuingiza imeathiri hotuba yako?

0 ——————————————————— 100

Sio kabisa Ndio kabisa

7. Unahisi je kuhusu kuonekana kwa taji yako juu ya kuingiza?

0 ——————————————————————————— 100

Sio faa sana Inafaa sana

8. Je! Umekuwa na ugumu wowote kwa kuchanganya taji yako juu ya kuimarisha?

0 ——————————————————————————— 100

Ngumu sana Rahisi

9. Je! Umekuwa na ugumu wowote kwa kupiga taji yako juu ya kuimarisha?

0 ——————————————————————————— 100

Ngumusana Rahisi

10. Je, kuna vyakula ambavyo hukuta huwezi kula kwasababu ya taji ya kuingiza?

Appendix 10: Turnitin Report

