Oral Health Status of Patients on Hemodialysis in Zliten-Libya

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DECLARATION

I, Muftah A.A Swisialgdar declare that this research report is my own work. It is being submitted for the degree of MSc Dent in the branch of Community Dentistry in the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other university.

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[Signature]

16th day of May, 2016.
DEDICATION

To my family Thuraya and Rashid, my mother and brothers.
Abstract

Introduction

Chronic Kidney Disease (CKD) is an emerging health problem worldwide. Furthermore, 90% of CKD patients have been shown to have oral manifestations related to the disease. The prevalence of CKD in Libya is 624 per million population. There is a lack of literature on the oral health status of CKD patients in Libya, and oral health practitioners are increasingly likely to encounter these patients.

Aims and objectives

The purpose of this study was to assess the dental and periodontal health of CKD patients on hemodialysis at the Zliten dialysis centre in Libya. The objectives were to determine the prevalence of dental caries, the periodontal status and the treatment needs of the patients, and to compare the effect of hemodialysis duration on oral health status.

Methodology

Data was collected by means of a structured interview questionnaire focusing on demographic information, medical history and dental information of an adult cohort. This was followed by an oral examination using two indices: Decayed Missing Filled Teeth (DMFT) and the Community Periodontal Index of Treatment Need (CPITN).
Results

Seventy-two (N=72) adults consented to participate in the study. The prevalence of dental caries was 86%, and the mean DMFT was 5.96 (SD 5.41). The CPITN results showed that the majority of the participants (44.4%) had scored 3, indicating the presence of 4-5mm shallow pockets. There was no significant effect of hemodialysis duration on the DMFT (p=0.5) or the CPITN (p=0.8).

Conclusion

Though the oral health status of the patients was poor, the effect of duration of hemodialysis on the dental and periodontal status was not significant.
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# TABLE OF CONTENTS

DECLARATION .................................................................................................................. I
DEDICATION .................................................................................................................. II
ABSTRACT ....................................................................................................................... III
ACKNOWLEDGEMENTS .................................................................................................. V
TABLE OF CONTENTS .................................................................................................... VI
LIST OF FIGURES .......................................................................................................... VII
LIST OF TABLES ............................................................................................................. VII
LIST OF APPENDICES .................................................................................................. VIII
NOMENCLATURE ............................................................................................................. IX

1.0 INTRODUCTION ........................................................................................................ 01
1.1 Description of Chronic Kidney Disease (CKD) ......................................................... 01
1.2 Epidemiology of Chronic Kidney Disease .......................................................... 03
1.3 Treatment modalities of Chronic Kidney Disease............................................... 04

2.0 REVIEW OF LITERATURE .................................................................................... 07
2.1 Oral manifestation of CKD .................................................................................... 07
2.2 Dental caries ........................................................................................................... 09
2.3 Periodontal disease in CKD patients ................................................................... 13
2.3.1 Plaque and calculus ....................................................................................... 13
2.3.2 Gingivitis and gingival bleeding ................................................................... 15
2.3.3 Probing pocket depth ................................................................................... 17
2.3.4 CPITN ............................................................................................................ 18
2.4 Effect of duration of hemodialysis on oral health .................................................. 19
2.5 Rational ................................................................................................................ 22

3.0 METHODOLOGY ................................................................................................... 24
3.1 Aim ......................................................................................................................... 24
3.2 Objectives .............................................................................................................. 24
Appendices

Appendix A (participants information sheet) ................................................................. 57
Appendix B (consent form) ............................................................................................. 58
Appendix C (medical history) ......................................................................................... 59
Appendix D (oral exam) .................................................................................................. 61
Appendix E (approval letter) ........................................................................................... 64
Appendex F( approval from Libyan National Committee for Biosafety and Bioethics; certificate from Human Research Ethics Committee (Medical) ) ............ 65
Appendex H (a report from“Turn it in” of scrutiny for evidence of plagiarism in this report) ......................................................................................................................... 67
Nomenclature:

CKD: Chronic Kidney Disease

ESRD: End Stage Renal Disease.

DM: Diabetes Mellitus.

HD: Hemodialysis.

HTN: Hypertension.

RRT: Renal Replacement therapy.

SFR: Salivary Flow Rate.

RF: Renal Failure.
CHAPTER 1.0 INTRODUCTION

1.1 Description of Chronic Kidney Disease.

Chronic Kidney Disease (CKD) is a major problem worldwide. It is a condition where there is either kidney damage or a decrease in its function lasting three months or longer (Levey et al., 2003; USRDS, 2012). The condition can progress to kidney failure, where 90% of the kidney’s function is lost (Levey et al., 2003).

There are many conditions that lead to the development of the disease. Hypertension (HTN) and Diabetes Mellitus (DM), particularly type 2, these constitute the main causes, followed by glomerulonephritis (Shaheen et al, 2005; USRDS, 2012; Craig & Kotanko, 2009). In the USA 44% of newly diagnosed cases had a primary diagnosis of diabetes, and 28% had a primary diagnosis of hypertension (USRDS, 2012).

The progression from kidney damage to renal failure occurs in five stages. Stages 1 to 4 comprise the pre-dialysis stages, where there is a kidney damage with normal function (stage 1), mild decrease in renal function (stage 2), moderate decrease in renal function (stage 3), and in stage 4 there is kidney damage with severe decrease in renal function, beyond which kidney failure occurs, that places the patient in the dialysis stage (5); (Levey et al, 2003). CKD stage 5 is also known as renal failure (RF). It is not synonymous with the commonly-used term End Stage Renal Disease ESRD (USRD, 2012). The latter is used administratively to describe the method of payment for health care by the Medicare ESRD Program in the United States, indicating that
CKD stage 5 patients are treated with Renal Replacement Therapy (RRT), and does not include patients who do not receive that treatment (Levey et al., 2003).

Four main functions are performed by kidneys: removal of end products, especially urea, secretion of erythropoietin, a hormone responsible for production of red blood cells, regulation of blood volume and electrolytes, and transforming Vitamin D3 to its active form in order to participate in calcium homeostasis (Fogo & Kon, 2004; Sulejmanagić et al, 2005).

Loss of kidney function has its consequences for health, including hematological abnormalities, most prominently anemia (Naylor & Fredericks, 1996). Furthermore, bleeding diathesis occurs as a result of dysfunction in platelet adhesion and aggregation (Remuzzi and Pusineri, 1988). Immunological disorders also occur due to dysfunction and suppression of leukocytes (WBC), which places a CKD patient at high risk of contracting a number of infections (Naylor & Fredericks, 1996; De Rossi & Glick, 1996).

Hyperparathyroidism, an endocrine disorder associated with CKD can result in high phosphorus and low calcium concentrations in serum. The latter is also caused by decreased Vitamin D3 production that alters the bone quality, resulting in bone resorption (Hamid et al, 2006). Psychologically, the patient suffers anxiety and depression. Murtagh, et al, (2007) conducted a systematic review to report symptom prevalence in ESRD populations on dialysis. Data on the prevalence of anxiety were extracted from six studies, where they found the prevalence of anxiety ranging from
12% to 52% in the total sample of 597 patients. The prevalence of depression was 5% to 58% in the total sample of 7307 patients on dialysis (Murtagh, et al, 2007). Weighted mean prevalence of anxiety and depression were 38% and 27% respectively (Murtagh, et al, 2007).

Aggravation of renal disease can lead to congestive heart failure resulting from pulmonary edema, ascites, arrhythmias, arteriosclerosis, cardiomyopathy and pericarditis. Severe chronic kidney disease can further cause hypertension as result of fluid overload. (Herzog et al, 2011; Naylor & Fredericks, 1996).

1.2 Epidemiology of Chronic Kidney Disease.

Literature on CKD shows a continuous increase in the prevalence of the disease globally (Al-Sayyari & Shaheen, 2011; USRDS, 2012). This rise is caused by a very high rate of diabetic nephropathy, followed by hypertension, and the shift in age demographics (Al-Sayyari & Shaheen, 2011).

The global annual CKD population increase has been estimated to be 7% (Al-Sayyari & Shaheen, 2011). In Saudi Arabia the affected population increased from 361 per million population (pmp) in 1995 to 874 pmp in 2008 (Al-Sayyari & Shaheen, 2011). In the USA an increase was recorded from 1150 pmp to 1698 pmp over a period from year 1995 to 2007 (Al-Sayyari & Shaheen, 2011). At the end of 2010 there were 594,374 dialysis and transplant patients receiving treatment for CKD stage 5, which was a 4% increase from 2009 (USRDS, 2012). In the USA there were 116,946 new cases of ESRD reported, 0.47 percent more than in 2009 (USRDS, 2012).
One hundred per million population in sub-Saharan African countries, and 430 pmp in Northern African countries are affected by the disease (Barsoum, 2006; Barsoum, 2003). Overall, Latin America has approximately 300 patient pmp (Codreanu et al, 2006). However, there is a variation in the reported annual incidence of patients with CKD in Latin America, from as low as 34 pmp in Bolivia to 300 pmp in Brazil (Codreanu et al, 2006). In India, roughly 100 000 patients progress to a stage requiring them to undergo dialysis annually (Codreanu et al., 2006). Recent epidemiological data has shown an incidence of end stage kidney disease (ESRD) of 181 per million populations in central India (Rajapurkar & Dabhi, 2010). In China the incidence has been estimated as low as 5 pmp in less-developed areas, and 102 pmp in urbanized and more developed areas of that country (Codreanu et al, 2006).

Advances in medical treatment have resulted in a decrease of the mortality rate of CKD patients. Thus the likelihood of dentists treating these patients is growing (Klassen & Krasko, 2002; Craig & Kotanko, 2009; Al-Sayyari & Shaheen, 2011). Patients with CKD often experience the negative effects of renal failure and its treatment modalities (Jover Cerveró et al, 2008). Consequently, special consideration and care should be taken by dentists when treating this category of patients, as they require specialized management (Jover Cerveró et al 2008; De Rossi & Glick, 1996).
1.3 Treatment modalities of CKD:

At its early stages treatment of Chronic Kidney Disease requires the patients to adjust their diet and fluid intake in order to compensate for the reduced excretory capacity of the organ; sodium intake is restricted, and it might be necessary to minimize protein consumption to reduce nitrogenous end-products, like urea (Proctor et al., 2005). Unfortunately, the majority of Chronic Kidney Disease patients progress to Renal Failure (dialysis stage) despite compliance with the dietary approach treatment (Proctor et al., 2005).

Renal failure is fatal unless treated. When renal function drops to a level that threatens health, renal replacement treatment (RRT) is essential (Craig & Kotanko, 2009; Couser et al., 2011). RRT has two forms: Dialysis and renal transplantation (Couser et al, 2011). There are two types of Dialysis: hemodialysis and peritoneal Dialysis (De Rossi & Glick, 1996). Most new patients begin therapy on hemodialysis (USRDS, 2012). It is an artificial process of removal of nitrogenous and other toxic end-products of metabolism from the blood (Klassen & Krasko, 2002).

Typically the hemodialysis session lasts for three to five hours, repeated three times per week at specialized hemodialysis units. However, only 10-20% of the normal kidney’s function can be provided by this procedure. The patient therefore remains at the stage of renal failure and its associated symptoms (Craig & Kotanko, 2009; Davidovich et al, 2005; Kho et al., 1999).
Peritoneal dialysis is another form of renal replacement treatment. A peritoneal membrane of the patient is used to act as a dialysis membrane to remove urea and other waste products. It also provides 10-20% of renal function (Craig & Kotanko, 2009; De Rossi and Glick, 1996). This modality of treatment has the advantage over hemodialysis that it can be done at home. Thus the patient is not required to attend the specialised hemodialysis units, and consequently has greater mobility (Craig & Kotanko, 2009; De Rossi and Glick, 1996). However, peritoneal dialysis is time-consuming: slower than hemodialysis, and it carries a great risk of infection around the peritoneal area where the shunt is placed. It is thus prescribed less often than hemodialysis (Craig & Kotanko, 2009; De Rossi and Glick, 1996).

The ideal treatment for renal failure would be renal transplant, as it restores the kidney functions to normal borderline values, and the oral health characteristics would consequently be similar to those of healthy subjects (De Rossi and Glick, 1996). However, despite its great expense; renal transplantation carries the risk of rejection failure (Agarwal et al, 2007). In addition, the patient becomes dependent on immunosuppressive therapy in order to prevent the immune system from rejecting the new kidney, resulting in increased susceptibility to infection (Agarwal et al, 2007).
CHAPTER 2.0 REVIEW OF LITERATURE

2.1 Oral manifestations of CKD

We included in the Literature review studies in which oral health was evaluated in adults who had stage 5 CKD. A search of the PubMed and Medline databases was performed using the key words “dental caries”, “periodontal disease” and “chronic renal failure” to be eligible for entry in our study.

Oral health is integral with general health. For example, periodontal conditions are related to conditions such as diabetes. Patients with systemic conditions are vulnerable to developing oral disease that further complicates their general health (Peterson, 2003; Peterson & Ogawa, 2005). Some systemic conditions have oral manifestations which may be used as markers for serious immunodeficiency diseases. In addition, oral health and function can be compromised as result of side-effects of medications used in treating some conditions. For example, Hemodialysis patients are repeatedly exposed to systemic anti-coagulation with high-dose heparin during blood purification procedures (Gautam et al, 2014). This predisposes them further to gingival bleeding, and facilitates bacterial colonization and growth; this may subsequently lead to periodontal disease (Gautam et al, 2014).

Ninety percent of affected patients have oral manifestations (Tiwari et al, 2013; Jover Cervero et al, 2008). Most of these reflect the consequences of CKD. Pallor of the oral mucosa, which is most frequently observed, is caused by the decrease in the number of circulating red blood cells (Eigner et al, 1986). Moreover, in cases of
severe anaemia, a patient may develop neuropathy, manifested by tingling or numbness of the tongue (Scally & Cawson, 1987). Furthermore, bleeding, petechia and ecchymosis of the oral mucosa often occur due to abnormal platelet aggregation (Remuzzi and Pusineri, 1988).

Chronic patients become susceptible to infections such as oral candidiasis and angular cheilitis, resulting from general weakening and suppression of the immune system (Bayraktar et al, 2008; Scally & Cawson, 1987).

Xerostomia and parotitis, are believed to result from a combination of direct gland involvement, chemical inflammation, dehydration and mouth breathing (Eigner et al, 1986; De Rossi and Glick, 1996). Other oral manifestations of CKD patients include an ammonia–like taste and smell, oral ulcerations, tongue coatings and pain (Swapna et al, 2013).

In addition to the oral manifestations of CKD, gingivitis and periodontitis observed in these patients are considered as sources for systemic infection and inflammation (Bayraktar et al, 2009). These oral diseases may contribute to the development of atherosclerotic lesions that cause cardiovascular complications (Akar et al, 2011; Bayraktar et al, 2009; Craig and Kotanko, 2009). Both cardiovascular disease and infection are the leading causes of mortality in CKD patients (Craig and Kotanko, 2009; USRDS, 2012). In turn, change of taste, dry mouth and pain resulting from CKD have been proposed as contributing factors to reduced nutrient intake (Akar et al, 2011). These lead to protein energy wasting (Akar et al., 2011), which in turn is a risk
factor for accelerated cardiovascular disease and mortality in this population. (Ruospo et al, 2014).

2.2 Dental caries

Dental caries is defined as a localized, post eruptive, pathological process of external origin, involving softening of the hard tissue and proceeding to the formation of a cavity (WHO, 1962).

The incidence of dental caries is principally governed by factors of time, host, environmental, and microbial agent factors. Alterations in the host factor components such as saliva, dental plaque, oral hygiene, emotional disturbances, as well as alterations in diet have been reported in patients with CKD (Epstein et al., 1980; Al-Wahadni & Al-Omari, 2003; Thorman et al, 2009; Chamani et al., 2009).

Saliva plays an important protective role against dental caries (Bayaktar et al, 2009). It possesses properties like debridement/lavage, mechanical cleansing, and maintenance of mucosal and tooth integrity. Saliva may have a neutral or alkaline pH, depending on its bicarbonate concentration (Bayraktar et al, 2009). Thus, it has neutralizing and buffering capacities that counteract the acidity required for hard tissue demineralization and caries incidence.

Diminished salivary flow rate (SFR) has been reported in patients with CKD (Kho, et al., 1999; Gavaldá et al., 1999; Oyetola et al, 2015; Anuradha et al, 2015). Anuradha et al measured the salivary flow rate in a study group comprised of 24 hemodialysis
patients and found the mean SFR was 0.41, compared with a normal rate (mean 0.68) in a control group of 50 subjects (Anuradha et al., 2015).

Oyetola et al. (2015) compared the stimulated and unstimulated SFR of 90 CKD patients with 90 controls. The study found diminished SFR in CKD patients: the mean unstimulated and stimulated SFRs were (2.34 ml/5min and 4.07 ml/5 min), compared with 3.82 ml/5 min and 8.05 ml/5 min for the controls. However, there was no data on statistically significant difference between the two groups (Oyetola et al., 2015).

It is stated that salivary pH and salivary buffer capacity in CKD patients are statistically higher than in healthy populations in spite of the reduced SFR (Bayraktar et al., 2009). The major difference in the composition of saliva in CKD patients is the increased urea concentration enzymatically metabolized into ammonia, which explains the high salivary pH (Epstein et al., 1980; Kho et al., 1999; Kaushik et al., 2013).

Plaque encourages caries development by assisting bacteria to stick to teeth and allowing acids to accumulate around them. Plaque also prevents saliva from reaching the tooth surface in order to wash and neutralize the surface (Marya, 2011). Oral hygiene procedures such as dental brushing and flossing at least once daily could reduce dental plaque accumulation and subsequently dental caries development. Oral conditions such as dental caries could affect the oral health of reduced oral self-
Klassen & Krasko, 2002 conducted a study that sought to determine the dental health status of 94 hemodialysis and peritoneal dialysis patients in Central and Northern Saskatchewan. One of his objectives was to investigate the oral hygiene habits. They found that most of the dentate patients (97%) involved in the study brushed their teeth once or more daily, with an infrequent or no use of dental floss. The majority of patients (93%) reported that they had never used dental floss (Klassen & Krasko, 2002).

The oral hygiene status of individuals receiving hemodialysis can be poor particularly those that neglected self care. For example, unsatisfactory daily oral hygiene habits and insufficient awareness of the importance of oral health were found among Turkish dialysis patients (Gurkan et al, 2008). A very high percentage (56.4%) reported irregular or no brushing habit and a small percentage (14.3%) reported brushing twice a day (Gurkan et al, 2008). Only 2.4% of the dentate patients reported using dental floss for interdental cleaning. Plaque score was more than 50% in most of the patients (93.7%) indicating a poor oral hygiene regimen.

Chamani et al (2009) found 27.2% of 55 HD patients did not brush their teeth at all, and 98.1% did not use dental floss. Infrequent dental visits were reported by 56.3% of patients. CKD patients tend to spend much time and concern on their primary health problem, to the detriment of oral health. The dialysis treatment is frequent
and often leaves the patient exhausted; and this discourages them from attending a dental clinic (AL-Sebaie et al, 2013; Al-Wahadni and Al-Omari, 2003). Furthermore, they are also affected by financial limitations, making oral health still less of a priority (Galili et al., 1983; AL-Sebaie et al, 2013; Al-Wahadni and Al-Omari, 2003; Attasi et al, 2001). In addition, adult self-rated oral health and oral health-related regimens are negatively influenced by anxiety and depression which are common in CKD patients (Dumitrescu et al, 2009).

Concerning diet adjustments, especially in terms of a recommended pharmacodiary approach, CKD patients are required to reduce the intake of protein-rich diet and shift to frequent and high intake of carbohydrates. This may affect the dental status as sugar and other fermentable carbohydrates act as a substrate for the oral bacteria, and the resultant acid lowers the pH of salivary and plaque (Thorman et al., 2009). This in turn leads to the beginning of demineralization of hard tooth structure.

The DMFT index (Decayed, Missed, and Filled Teeth) has been used frequently in assessing dental status of CKD patients. DMFT is considered very low if it is < 5; low if it is between 5 and 8.9, moderate if 9 to 13.9 and high when above 13.9 (Peterson et al, 2003).

The prevalence of dental caries in adult patients with CKD varies. Some studies found a low approximate mean DMFT of 6.5 (Tiwari et al, 2013; Muhan & Gupta, 2000), while
others reported high scores of approximately mean 17 (Sobrado Marinho et al, 2007) to mean 20.6 (Souza et al, 2008).

A systematic review and meta-analysis of observational studies in which oral health was evaluated in adults with CKD revealed that the mean DMFT index in adults with CKD was proportional to the disease stages (Ruospo et al, 2014). There was a variation in the reported DMFT in adult patients with CKD stage 5 according to different geographical regions, with the lowest DMFT index [DMFT: 9.0 (CI 8.2–9.8)] reported in studies from the Eastern Mediterranean (Ruospo et al, 2014). In Europe an increasing index was reported [DMFT: 14.2 (CI, 13.8–14.7)]; the Western Pacific [DMFT: 16.5 (CI, 14.9–18.0)] and United States [DMFT: 17.9 (CI 17.2–18.6)], p < 0.001 for subgroup difference (Ruospo et al., 2014).

2.3 Periodontal disease in CKD patients

2.3.1 Plaque and calculus

Among the direct causes of gingivitis is the deposition of dental plaque and calculus (Marya, 2011; Krishna&Dasar, 2010). Plaque is the soft non-mineralized bacterial accumulation on the inadequately cleaned tooth surface. Once mineralized, the plaque results in formation of calculus, in which the inorganic components account for 70-90 percent. This inorganic component of the calculus consists mainly of crystalline and amorphous calcium phosphate. Calculus is always covered with a non-mineralized layer of plaque (Al-Wahadni and Al-Omari, 2003). It was reported
that calculus in the CKD patient was thicker than that in individuals not medically compromised (Epstein et al., 1980).

In CKD patients increased plaque and calculus deposition have been reported in many studies (Bayraktar et al, 2007; Bots et al., 2006; Gavaldá et al, 1999; Klassen & Krasko, 2002; Ruospo et al, 2014). The increased calculus and plaque deposition in these patients was attributed to poor oral hygiene (Klassen&Krasko, 2002; Al-Wahadni & Al-Omari, 2003; Bayraktar et al, 2007). Furthermore, the changed serum calcium-phosphorous balance, which alters the salivary composition, has been identified as a cause of this increase (Epstein et al., 1980; Gavaldá et al., 1999).

In addition, the heavy calculus accumulation could be caused by the high urea concentration, and should be considered when determining supportive periodontal therapy intervals (Al-Wahadni& Al-Omari, 2003).

Bots et al (2006) found high calculus deposition in CKD patients on hemodialysis maintenance therapy in spite of their good oral hygiene. The authors attributed it to factors other than poor oral hygiene, such as salivary changes in composition (Bots et al., 2006).

In Poland, Borawski et al (2007) enrolled 35 CKD patients and reported that the median plaque index was 2.5(0-3). 0 is the minimum and 3 is the maximum. In Holland, Bots et al (2006) found that of the mean total number of examined surfaces of teeth (5.4±1.0), almost half of the surfaces were covered with dental plaque (2.4 ± 1.6) in the 42 dentate dialysis patients examined. Only 4% of the assessed surfaces
had a score of 0, while 32.6% had a score of 1, and the rest had either score 2 or 3.

Torkzaban et al (2009) examined 31 Iranian patients for plaque prevalence using the Plaque Control Record Index (PCRI). Plaque was detected on more than 50% of the total examined tooth surfaces in nearly all patients: 21 had plaque accumulation of 81-100% of the total examined tooth surface.

In Arabic countries two studies were conducted. The first was performed in Saudi Arabia, where the researcher enrolled 90 patients and found a PI score of 2.04±0.53. The other researcher enrolled 47 dentate Jordanian patients and found a PI score of 1.59±0.60 (Attasi et al, 2001; Al-Wahadny & Al-Omri, 2003).

In conclusion, Plaque and calculus are prevalent in CRF patients. Many indices were used to determine these accumulations and the levels varied in patients from different regions of the world. Reasons as poor oral hygiene, changed serum calcium-phosphorous balance, high urea concentration and salivary changes in composition were considered to explain the increased plaque and calculus deposition in these patients.

**2.3.2 Gingivitis and bleeding:**

Gingivitis is inflammation of the gingival tissue, where the disease alters the junctional epithelium without changing the level of its attachment to the tooth (Marya, 2011).

In established gingivitis the inflammation becomes overt clinically with signs such as gingival swelling and bleeding. However, the gingival inflammation could be
detected infrequently in CKD patients because of the uremic state that may suppress the inflammatory reaction in gingival tissue (Jenabian et al, 2013; Hamissi et al, 2009). On the other hand, it has been suggested that the immunosuppressed state caused by uremic condition would not retard the gingival response against bacterial load found in dental plaque (Bots et al., 2006).

The effect of uremia on gingival inflammatory response to increased bacterial plaque was assessed (Kitsou et al, 2000). The author enrolled six uremic patients and a group of six, age and gender-matched non-uremic controls. Participants were required to refrain from any mechanical or chemical oral hygiene care for 3 weeks. The findings indicated no difference in gingival indices of either group. However, these results must be interpreted with caution due to the small sample size (n=6).

Prevalence of moderate to severe gingivitis was reported in CKD patients. Mild gingivitis was observed. In Poland the mean gingival index (GI) in 35 hemodialysis patients was found to be 1.37±0.23 (Borawski et al, 2007). In Turkey, Iran and Saudi Arabia the mean GI in three studies conducted were 1.9±0.3; 1.14±0.97 and 1.81±0.56 respectively (Cengiz et al 2009; Chamani et al 2009; Attasi et al, 2001) Severe gingivitis, gingival index scores of between 2.1-3, was detected in Jordan and Saudi (Al-Wahadni& Al-Omari, 2003; Al-Sebaie et al 2013).

The number of teeth with gingivitis and bleeding were found to correlate strongly with the number of teeth with dental plaque and calculus (Oshrain et al 1979; Bots et al, 2006). However, the anticoagulant therapy taken by the hemodialysis patients
exacerbated bleeding on probing, indicating that the intake of these medications may interfere with the direct reflection of the actual gingival and periodontal inflammation (Marakoglu et al, 2003; Bots et al 2006). In contrast, it has been proposed that bleeding might attributable to other factors than anticoagulant therapy (Hamissi et al., 2009; De Rossi & Glick, 1996). Changes in the quality and quantity of platelets and low hematocrit level are the most common causes of oral bleeding in CKD patients (Hamissi et al, 2009; De Rossi & Glick, 1996).

2.3.3 Probing Pocket Depth

The traditional theory is that gingivitis could progress and affect the periodontium, leading to the development of periodontitis, in which loss of attachment and bone destruction take place. Periodontitis is caused by bacteria that cause chronic inflammatory disease, leading to the destruction of connective tissue and bone that supports the teeth (Marya, 2011). This may result in episodes of bacteremia, especially in immune-compromised patients (Manjunath et al, 2013). In periodontitis apical migration of junctional epithelium occurs and results in formation of the so called “periodontal”, or true, “pocket” (Marya,2011). Thus, in epidemiological research the pocket depth can determine the presence or absence of periodontal disease (Leroy et al,2010). Probing pocket depth (PPD) was also assessed in many studies on CKD. In Jordan Al-Wahadni &Al-Omri, (2003) found a mean PPD for 47 CKD patients of 2.86mm (SD =0.58). In the same country Al-Sebaie et al, (2014) assessed 126 CKD patients and found a mean of (4.62mm ±1.25). Cengiz et al(2009)
examined 68 Turkish CKD patients and reported a mean PPD score of 2.3mm±0.6. Chamani et al (2009) reported a PPD of 55 Iranian CKD patients of 2.2mm±1.03.

2.3.4 CPITN

The Community Periodontal Index for Treatment Needs (CPITN) has been used in epidemiological studies to assess the periodontium of CKD patients. It is an index used to detect and monitor the extent of periodontal disease and treatment needs in communities. The indicators for the CPITN include presence or absence of gingival bleeding; supra- or sub- gingival calculus, and shallow (4-5mm) or deep (>6mm) periodontal pockets (Sheiham & Spencer, 2002). However, the index has limitations, such as it does not measure tooth mobility or attachment loss. Despite this, it is still being used for its simplicity, and no other appropriate indices have been developed to replace it.

All the reviewed studies that employed CPITN in assessing the extent of periodontal disease among CKD have shown that from 97% to 100% of patients had periodontal disease, ranging from score 1 to score 4 on CPITN. These scores can be interpreted as follow: Score 1 means the presence of gingival bleeding, score 2 indicates that there is a plaque and calculus, score 3 implies a shallow pocket 4-5 mm and score 4 is the <6 mm pocket.

CPITN score 1 was observed less frequently, except for a study conducted by Tiwari et al., 2013 in central India, that found a score 1 frequency of 30% of the whole population. Score 4 was also observed less frequently except for a study by
Dencheva 2009 in Bulgaria, that found that 13.5% of the total examined population had score 4 (Dencheva.,2009). The majority of the studied population fell in scores 2 and 3, as reported in studies in India and Turkey (Duran & Erdemir, 2004; Manjunath et al, 2013).

2.4 The effect of duration of hemodialysis on oral health

The literature has established that renal failure has a negative impact on the oral health of hemodialysis patients. However, the effect of the duration of hemodialysis is controversial. Some researchers, (Al-Wahadni and Al-Omari, 2003; Chamani et al, 2009; Naugle et al, 1998) concluded that there was no statistically significant difference in the effect of the duration of hemodialysis on the periodontal health of patients. In contrast, other researchers found that the greater the duration of hemodialysis, the less favourable was periodontal health (Cengiz et al, 2009; Attasi et al, 2001; Bayraktar et al 2007).

In their attempt to determine the effect of duration of hemodialysis on dental and periodontal health researchers divided the samples of hemodialysis patients into groups based on the period that patients had spent since the first session on dialysis (Naugle et al, 1998; Atassi et al, 2001; Al-wahadny&Al-Omri, 2003; Gautam et al 2014).

Attasi et al (2001) enrolled 90 hemodialysis patients, divided into three groups as follows: 1 less than one year; 2 for 1 to 3 years, and 3 longer than 3 years. Four clinical parameters were studied: debris index DI, calculus index CI, plaque index PI,
and gingival index GI. Using the One-way analysis of variance (ANOVA) to determine significant differences in the 4 indices among the 3 groups at 5% level, and using Tukey’s post hoc test to compare between groups, the researcher detected a significant difference between groups 1 and 2 in the all the indices. The GI was 1.42±0.67 for the group 1, and 2.96±0.38 for group 2. Similarly, a significant difference between groups 1 and 3 was also detected at the all indices. No significant difference was found between groups 2 and 3 (Attasi et al., 2001).

Al-Sebaie et al. (2013) conducted a study in Jordan, where they divided 126 HD patients into four groups according to their history of dialyses as follows: group 1 comprised patients on dialysis for less than one year, group 2 included patients on dialysis for between 1 and 3 years, group 3, where the patients had been on dialysis for between 3 and 6 years, and finally those who had been on dialysis for more than 6 years made up group 4. They used four parameters to determine periodontal health: plaque index (PI), gingival index (GI), probing pocket depth (PPD) and gingival recession (GR). Only statistically significant differences in GR index was detected between the groups. The mean GR was 2.53 (SD 1.46) for group 1, 2.22 (SD 1.59) for group 2, 1.04 (SD 1.04) for group 3 and 1.48 (SD 0.90) for group 4 (P<0.05). However, the difference was not statistically significant between the four groups in the other three indices (P >0.05).

Gautam et al. (2014) examined 206 Indian hemodialysis patients, using the Community Periodontal Index CPI as a parameter to assess the periodontal status. They divided the whole sample into 3 groups, based on of duration of dialysis as
follows: less than a year (144 subjects); one to three years (28), and more than three years (34). The researchers concluded that the duration of hemodialysis had no effect on the periodontal status, as the duration was not statistically associated with CPI score (P=0.999).

Al-Wahadni and Al-Omari(2003) enrolled 47 dentate hemodialysis patients in a study undertaken in Jordan. They found no correlation between the duration of dialysis and the severity of periodontal disease, since the analysis of variance showed no statistically significant difference among PI, GI, GR and PDD taken for the three groups. However, there was some difference amongst the DMFT scores. The pooled DMFT found that the 47 subjects had 240 carious teeth, 86 missing teeth, and 79 filled teeth, with a mean DMFT of 8.47 (SD, 2.8). Patients on hemodialysis for less than a year had low levels of caries (DMFT=6.64; SD, 3.0) in comparison to those who had been on hemodialysis for longer than a year (DMFT=9.1, SD2.6) or more than 3 years (DMFT= 9.5; SD2.9; p=0.003; 0.005).

**Summary of the literature review**

In summary, oral and general health of CKD patients are interrelated, with many oral signs and symptoms reported to be related to the loss of kidney function. These include hematological disorders such as anemia, bleeding; immunological deficiency; oral candidiasis, angular chelitis; and conditions such as dry mouth, ammonia-like taste and smell, and tongue coating.
CKD patients carry other risk factors contributing to dental caries, such as diminished salivary flow rate and increased carbohydrate consumption. In contrast, anti-caries activities like high salivary pH and increased salivary buffer capacity have been reported among the patients. However, poor oral hygiene practices have been reported in these patients, especially in low- and middle-income countries, as a result of time and financial constraints, and anxiety, all of which cause oral health care neglect.

The DMFT index has been used to assess the dental status of CKD patients. CKD patients have a low, moderate to high prevalence of dental caries. The results regarding the prevalence of dental caries varied considerably among different CKD cohorts in different regions of the world.

As showed by the different indices used to assess gingival and periodontal status, conditions such as gingivitis, plaque formation, calculus deposition and formation of periodontal pocket were reported. The severity of these conditions varied across populations from different countries. A large proportion of patients scored either 2 or 3 on CPITN, while a small proportion scored 1 or 4. Finally, the duration of hemodialysis was found not to affect the oral health, as reported by some studies.

### 2.5 Rationale

Libya has a high prevalence (624/million population) of patients with dialysis-treated ESRD (Al-Ashek et al, 2012). Eighty five per cent (85%) of the patients are younger than 65 years and 58% of them are male. The prevalence of ESRD varies
considerably with age, with a peak at 55–64. There is a lack of literature in Libya on the effects of renal failure and hemodialysis on oral health. This study, therefore, will contribute to the understanding of oral health status of renal dialysis patients in Libya, and will provide baseline information that will be useful for planning on the oral health needs of hemodialysis patients.
CHAPTER 3.0 METHODOLOGY

3.1 Aim

The aim of the study was to determine the oral health status of patients receiving hemodialysis at the Zliten hemodialysis Centre in Zliten Teaching Hospital, Libya.

3.2 Objectives

- To determine the prevalence of dental caries in adult patients on hemodialysis.
- To determine the periodontal status of patients on hemodialysis.
- To determine the dental and periodontal treatment needs of this population.
- To investigate whether duration of hemodialysis impacts on the caries and periodontal status of CKD patients in Libya.

3.3 Study design:

This was a cross-sectional study design with an analytical component.

3.4 Study population

The study has been undertaken in Zliten hemodialysis centre attached to Zliten Teaching Hospital. The centre has been offering dialysis for CRF patients since 1996 and receives approximately 133 ESRD patient of different ages and gender.

The population sample was obtained from an adult population receiving treatment at the centre. The sampling procedure was convenient, and obtained within one month.
Patients who did not meet the inclusion criteria were excluded. The exclusion criteria were:-

- Patients under 18.
- Patients with psychiatric problems.
- Those who did not provide signed informed consent.
- Extremely uncooperative patients.

3.5 Measurement method/instrument

Data was collected by means of a structured questionnaire, followed by an oral examination.

3.6 Questionnaire

The questionnaire was developed using questions from instruments used in similar published studies (Tiwari et al 2013; Al-Wahadani A & Al-Omari, 2003). It consisted of closed-ended questions comprising of demographic information, medical history and dental information (Appendix C). The researcher administered the questionnaire to the patients via an interview.

Pre-Testing of tools

Piloting: This questionnaire was piloted in a sample of approximately 10 patients not included in the study. This was done to check the feasibility of the questionnaire. As
a result of the pilot study, all questions were considered for recording in the final study.

*Calibration:*

The oral examination was conducted by one investigator. Intra-examiner reliability was measured by carrying out a reproducibility test, and the Kappa statistics test was utilized to determine the difference between the scored and rescored records.

### 3.7 Clinical oral exam

Clinical data were collected using 2 dental indices: the Decayed Missing Filled Teeth (DMFT) and the Community Periodontal Index of Treatment Need (CPITN) (*Appendix D*). The DMFT records the number of decayed, missing and filled teeth. It provides an account of the prevalence of dental caries. The CPITN is an index used to detect and monitor the extent of periodontal disease and treatment needs in communities. The indicators for the CPITN include presence or absence of gingival bleeding; supra- or sub-gingival calculus; shallow periodontal pockets (4-5mm) and deep periodontal pockets (>6mm) (Sheiham & Spencer, 2002)

### 3.8 Data Collection:

The subjects were examined in a seated position in a well-lit room using a light and mouth mirror. When using the DMFT index, probes were not used, and teeth were assessed visually with a mouth mirror and light. The scores were recorded according

For the CPITN a lightweight 0.5mm ball-ended probe was utilized, not more than 20 grams probing pressure was applied, and 6 points on each tooth were examined. These included the mesio-buccal/lingual; mid-buccal/lingual and disto-buccal/lingual surfaces (WHO, 1987). The examination was carried out by a calibrated dentist from the Department of Pediatric and Community Dentistry of Zliten Dental School. The oral examination data were recorded on a dental examination form developed by the Department of Community Dentistry at the university of Witwatersrand, WITS. (Appendix D).

3.9 Statistical Analysis

Data was statistically described in terms of mean, standard deviation (±SD), frequencies and proportions when appropriate. Data was checked for normality using the Kolmogorov-Smirnov analysis. The age variable showed normal distribution. Hence, One-Way ANOVA was used to compare between subgroups on mean age. All other tested parameters showed non-normal distribution, and hence nonparametric tests, such as the Kruskal-Wallis test, were used to compare between different subgroups. Statistical analysis was performed with IBM® SPSS® (SPSS Inc., IBM Corporation, NY, and USA) Statistics Version 22 for Windows and MedCalc® Version 12.2.1.0 for Windows.

3.10 Ethical Consideration
All volunteers were provided information about the study, all who agreed to participate provided written consent and confidentiality was ensured.

Ethical approval for this study was obtained from ethics committee of Libyan Society for Biological Research, as well as from the Human Research Ethics Committee (Medical) at the University of the Witwatersrand (WITS). The ethical approval reference number for WITS was M141034.

3.11 Limitations

This study was conducted in one centre, which was of a relatively small sample size and hence the findings may have limited generalizability.

CHAPTER 4.0 RESULTS
Of 133 hemodialysis patients in the centre, 72 adult dentate patients agreed to participate in the survey. The response rate was 54%.

The results of the Kappa statistics were 0.8. This was done before the start of the study by re-examining a randomly selected sample of about 10% of the proposed total sample (Joubert & Ehrlich, 2007).

I. Demographic data: Table 1 shows the demographic data including mean age, gender, the causes of renal failure and the comorbidities that some patients have with the renal failure and its underlying cause.

Table 1. Demographic Data.

<table>
<thead>
<tr>
<th>Total number of participants</th>
<th>N= 72</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (in years)</td>
<td>44.44</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>47</td>
</tr>
<tr>
<td>Female</td>
<td>25</td>
</tr>
<tr>
<td>Cause of ESRD:</td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>25</td>
</tr>
<tr>
<td>Diabetes</td>
<td>23</td>
</tr>
<tr>
<td>Glomerulonephritis</td>
<td>18</td>
</tr>
<tr>
<td>Genetic Disorder</td>
<td>2</td>
</tr>
<tr>
<td>Autoimmune</td>
<td>2</td>
</tr>
<tr>
<td>Unknown cause</td>
<td>2</td>
</tr>
<tr>
<td>Other comorbidities:</td>
<td></td>
</tr>
<tr>
<td>HCV</td>
<td>4</td>
</tr>
<tr>
<td>Condition</td>
<td>Count</td>
</tr>
<tr>
<td>----------------------------</td>
<td>-------</td>
</tr>
<tr>
<td>HBV</td>
<td>1</td>
</tr>
<tr>
<td>Cardiovascular Disease</td>
<td>3</td>
</tr>
<tr>
<td>Physical disabilities</td>
<td>2</td>
</tr>
<tr>
<td>Visual disturbances</td>
<td>6</td>
</tr>
<tr>
<td>Allergy</td>
<td>2</td>
</tr>
<tr>
<td>Bleeding disorders</td>
<td>1</td>
</tr>
</tbody>
</table>

Patients who indicated that they had been on dialysis for a period less than one year were 13 and allocated to subgroup 1. Patients who spent period on dialysis for 1-3 years and for longer than three years were allocated to subgroups 2 and 3 that consist of 17 and 42 patients respectively. This allocation of patients was done to compare between subgroups of different duration on hemodialysis later on.

No significant difference in age was found between the subgroups when tested for mean age (p=0.585) and gender (p= 0.170). In addition, there was no statistical significance between the subgroups groups in terms of Diabetes Mellitus (DM) (p=0.479). Only 4 cases (30.8%) had DM in <1 Year subgroup, 8 cases (47.1%) in 1–3 Years and 13 cases (31%) in the >3 Years subgroup. Finally, there was a significant difference in smoking habits among the three subgroups (0.001%): only 2 cases (15.4%) were smokers in <1 Year subgroup, 0 in the 1–3 Years subgroup and 9 (21.4%) in the >3 Years subgroup. No patients involved in this study consumed alcohol.
ii. Clinical parameters

1- Total DMFT

Data on the prevalence of dental caries showed that of the 72 participants, 62 had dental caries, making the caries prevalence of the study population 86%.

The total DMFT was 429 teeth. 219 were decayed (ratio 0.51); mean (3.04; SD3.1); 175 were missing (ratio 0.41); (mean 2.43; SD3.2); and 35 had been filled (ratio 0.081) mean( 0.49;SD1.6). Table 2 shows total mean DMFT of the study population.

Table 2: The mean DMFT of the study population.

<table>
<thead>
<tr>
<th>DMFT</th>
<th>No.</th>
<th>Mean</th>
<th>SD</th>
<th>95% CI</th>
<th>Min.</th>
<th>Max.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>72</td>
<td>5.96</td>
<td>5.41</td>
<td>4.689 to 7.231</td>
<td>0.00</td>
<td>24.00</td>
</tr>
</tbody>
</table>

2-Difference between all tested subgroups in DMFT

Data on DMFT showed that the subgroup on dialysis longer than 3 years had the highest mean DMFT, and the subgroup on dialysis for less than 1 year had the lowest. Results of the Kruskal-Wallis test for comparison of DMFT for subgroups showed no significant difference between mean DMFT values between the subgroups at p=0.502. Data for DMFT are presented in Table 3 and Figure 1.
Table 3 Mean DMFT of the subgroups in relation to hemodialysis duration.

<table>
<thead>
<tr>
<th>Duration</th>
<th>&lt; 1 Yr</th>
<th>1-3yrs</th>
<th>&gt;3 Yrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>No.</td>
<td>13</td>
<td>17</td>
<td>42</td>
</tr>
<tr>
<td>Mean</td>
<td>4.62</td>
<td>5.94</td>
<td>6.38</td>
</tr>
<tr>
<td>SD</td>
<td>4.43</td>
<td>6.11</td>
<td>5.44</td>
</tr>
<tr>
<td>95% CI</td>
<td>1.943 to 7.297</td>
<td>2.799 to 9.08</td>
<td>4.685 to 8.07</td>
</tr>
<tr>
<td>Min.</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Max.</td>
<td>14</td>
<td>20</td>
<td>24</td>
</tr>
<tr>
<td>p-value</td>
<td>0.502</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 1: Histogram showing the mean DMFT values in the subgroups

3- Dental treatment needs (DT)

Unmet treatment needs was calculated as follows: UTN= mean number of decayed teeth/mean number of decayed teeth that had been filled × 100=86% (Jong 1981).
Data for Dental Treatment needs are presented in Table 4. Out of 133 patient there were 16 patients, 22% needed DT1 (one surface filling), 33 patients 46% needed DT2 (two-surface filling), 8 patients ,11% needed DT3 (Pulp care and restoration). Only one patient needed DT4 (veneer or laminate), 25 patients 35% needed DT5 (Crown for any reason),37 patients, 51% needed DT6 (extractions) and 40 patients, 56% needed DT7 (dental prosthesis) as shown in table 4 figure 2.

**Table 4:** Dental treatment needs for the hemodialysis patient at Zliten hospital, Libya

<table>
<thead>
<tr>
<th>N</th>
<th>DT1</th>
<th>DT2</th>
<th>DT3</th>
<th>DT4</th>
<th>DT5</th>
<th>DT6</th>
<th>DT7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>16</td>
<td>33</td>
<td>8</td>
<td>1</td>
<td>25</td>
<td>37</td>
<td>40</td>
</tr>
<tr>
<td>22%</td>
<td></td>
<td>46%</td>
<td>11%</td>
<td>1%</td>
<td>35%</td>
<td>51%</td>
<td>56%</td>
</tr>
<tr>
<td>No</td>
<td>56</td>
<td>39</td>
<td>64</td>
<td>71</td>
<td>47</td>
<td>35</td>
<td>32</td>
</tr>
<tr>
<td>78%</td>
<td></td>
<td>54%</td>
<td>89%</td>
<td>99%</td>
<td>65%</td>
<td>49%</td>
<td>44%</td>
</tr>
<tr>
<td>Mean</td>
<td>1.3750</td>
<td>1.6061</td>
<td>3.6250</td>
<td>11.0000</td>
<td>2.2000</td>
<td>2.9459</td>
<td>4.7000</td>
</tr>
<tr>
<td>Std. Deviation</td>
<td>.61914</td>
<td>.89928</td>
<td>5.28982</td>
<td>0</td>
<td>1.38444</td>
<td>3.62051</td>
<td>4.23780</td>
</tr>
</tbody>
</table>
Figure 2: The number of patients requiring various dental treatment needs at Zliten hemodialysis centre, Libya

4-Total CPITN

Figure 3 shows the CPITN scores for the total sample. The majority of the patients (44.4%) had a score of 3, which indicated shallow pocketing, and only 2.8% of the population had a score of 1 for bleeding.
Figure 3: Histogram showing the total CPITN scores.

1 = Bleeding. 2 = Calculus. 3 = Pocket (4-5 mm). 4 = Pocket (6mm)

**Total CPITN**

As shown in Figure 4 and Table 5, subgroups of patients on hemodialysis <1 year and on hemodialysis 1-3 years showed a greater number of subjects (about 53%) scoring 2 on CPITN, while the subgroup on hemodialysis >3 years showed 35.7% of its total subjects scoring 2 on the CPITN. The half of subjects in the subgroup on hemodialysis >3 years (50%) scored 3 on CPITN depicting mild periodontitis,
compared with 38.5% and 35.3% in subgroups on hemodialysis <1 year and 1-3 years respectively. Score 1 and score 4 were the least prevalent among the subgroups.

**Figure 4:** The distribution of CPITN scores on subgroups

The results of Kruskal-Wallis test for comparison of the total CPITN for the subgroups showed no significant difference between mean total CPTIN values of the subgroups at p=0.77, Table 5.
Table 5: CPITN of the subgroups in relation to hemodialysis duration

<table>
<thead>
<tr>
<th>Duration</th>
<th>No.</th>
<th>Mean</th>
<th>SD</th>
<th>95% CI</th>
<th>Min</th>
<th>Max</th>
<th>bleeding</th>
<th>calculus</th>
<th>3-5 mm pocket</th>
<th>Deep pocket</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 1 Year</td>
<td>13</td>
<td>2.54</td>
<td>.66</td>
<td>2.1 to 2.9</td>
<td>2</td>
<td>4</td>
<td>0</td>
<td>7</td>
<td>5</td>
<td>1</td>
<td>0.776</td>
</tr>
<tr>
<td>1 Year – 3 Years</td>
<td>17</td>
<td>2.59</td>
<td>.71</td>
<td>2.2 to 2.9</td>
<td>2</td>
<td>4</td>
<td>0</td>
<td>9</td>
<td>6</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>&gt;3 Years</td>
<td>42</td>
<td>2.64</td>
<td>.73</td>
<td>2.4 to 2.8</td>
<td>1</td>
<td>4</td>
<td>2</td>
<td>15</td>
<td>21</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>72</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>100</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5-Periodontal treatment need:

In this study 63 patients (87.5%) required periodontal treatment need 2, which is the need for professional tooth cleaning as well as improvement of personal oral hygiene. Furthermore, 10% required periodontal treatment need 3, which is the need for more complex periodontal treatment, such as removal of infected tissue. Only about 2.5% are in need of periodontal treatment need 1, need for improving personal oral hygiene.
CHAPTER 5.0 DISCUSSION

The literature has reported that the oral health status of CKD patients is generally poor. Oral conditions mirroring the deterioration of systemic health of CKD, as well as dental and periodontal disease, are prevalent (Ruospo et al., 2014). These conditions, although largely preventable, affect oral health-related quality of life, and further complicate the patient’s general health (Craig & Kontanko, 2009; Guzeldemir et al., 2009). In addition, inflammatory oral disease such as periodontitis has been proposed as a possible risk factor for developing fatal cardiovascular disease in CKD patients (Ruospo et al., 2014; Craig & Kontanko, 2009).

This study was aimed at assessing the dental and periodontal status and dental treatment needs of CKD patients on hemodialysis, and to determine whether the duration on hemodialysis had an impact on the oral health status of hemodialysis patients at Zliten Dialysis Centre, Libya. The results of the study provided baseline data on the oral status of these patients, and this information can be used to contribute to the development of a preventive and therapeutic oral health care protocol for this special population, and to reduce the need for crisis dental management.

Zliten is a coastal city in Northwest Libya, with a population of 231000. There is only one dialysis centre in the city. This centre serves 133 patient with ESRD. Thus, the prevalence of ESRD in the city is 133 per 231000 which means that approximately 576 pmp had ESRD in Zliten. This proportion is similar to the rates reported by Al-
Ashek et al (2013), who found that 624 pmp in Libya had ESRD. The chief cause of ESRD, as reported by patients, was hypertension, followed by diabetes mellitus and glomerulonephritis Table 1. Although one of the limitations of our study was being dependent on the patient response to indicate the cause of renal failure, previous studies varied in their assessment of the cause of ESRD, and most considered diabetes mellitus the most common cause, followed by hypertension.

In this study more patients were found to have been on dialysis for longer than three years, suggesting improvement in the prognosis of the disease, as hemodialysis is a successful modality that prolongs the lives of CKD patients. Consequently, this increases the likelihood of dentists encountering such patients in their clinics. Among the other comorbidities associated with the renal failure is the hepatitis C and hepatitis B infection. Patients on hemodialysis are at an increased risk for acquiring hepatitis C infection as a result of cross-contamination from the dialysis circuits. In our study, there were 4 patients (5%) with hepatitis C infection and one patient with hepatitis B infection table 1. Another study of a sample size of 206 patients in Guntur, India by Gautam et al, (2014) found hepatitis C was seen in 82 subjects (39.8%) whereas hepatitis B was seen in 8 subjects (3.88%) (Gautam et al, 2014). This reveals that the prevalence of viral hepatitis in our study is far less than that found in the study conducted in Guntur, India. However, the prevalence of HBV surface antigen (HBsAg) and anti-HCV in Libya were 2.2% and 1.3% respectively (Elzouki et al., 2013). Furthermore, hemodialysis patients in Zliten dialysis centre undergo a routine viral screening on monthly basis. The screening was found to dramatically
decrease the risk of viral transmission (Krasteva & Panov., 2008). Both the low prevalence of viral hepatitis nationwide and the infection control measures implemented by the centre could explain the low prevalence of the disease in our study.

The liver performs many biochemical functions such as synthesis of coagulation factors and drug metabolism. In case of liver diseases, such functions may be adversely affected (Krasteva & Panov., 2008). Additionally, dentists and their staff should know well the risk of infection from their patients, the risk of cross-infection between patients, and the risk of infecting each other (Krasteva & Panov., 2008).

Seventy two hemodialysis patients out of 133 participated in the study. The response rate was 54%. The rest did not meet the inclusion criteria, were edentulous, critically ill or were unwilling to participate might be due to dental fear.

5.1 Dental caries

The prevalence of dental caries was found to be high in the study population, affecting 62 of the 72 patients (85.5%). Our finding is higher than that found in a study conducted in Virginia, where the prevalence was 64% among hemodialysis patients. In studies conducted in Guntur, India, far fewer (56%) of hemodialysis patients were reported as having active decay (Naugle et al, 2001; Gautam et al, 2014).

However, the mean DMFT is 5.96 ±SD 5.41. and according to the WHO criteria is classified as very low (Peterson et al, 2003). This DMFT is lower than that reported
in studies undertaken in Arab countries such as Jordan, where the mean DMFT in 47 dentate patients was 8.47 (±SD 2.88) (Al-Wahadani & Al-Omari, 2003). In another study (Al-Sebaie et al, 2014) the mean DMFT for 126 dentate Jordanian patients was 12.26 (Max15-Min8.17). Our DMFT records were close to those reported in studies from India (Mohan & Gupta, 2011), where the mean DMFT was 6.19 (± SD 6.40); Table 6 demonstrates that the mean DMFT in our study population was low in comparison to other developing countries.

Table 6. DMFT scores for CKD patients from cited studies.

<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Year</th>
<th>Sample size</th>
<th>DMFT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Present study</td>
<td>Libya</td>
<td>2015</td>
<td>72</td>
<td>5.96±5.41</td>
</tr>
<tr>
<td>Naugle et al</td>
<td>USA</td>
<td>1998</td>
<td>45</td>
<td>11.77±7.55</td>
</tr>
<tr>
<td>Mohan &amp; Gupta</td>
<td>India</td>
<td>2013</td>
<td>26</td>
<td>6.19±6.40</td>
</tr>
<tr>
<td>Tiwari et al</td>
<td>India</td>
<td>2013</td>
<td>30</td>
<td>6.37±4.26</td>
</tr>
<tr>
<td>Al-Sebaie et al</td>
<td>Jordan</td>
<td>2014</td>
<td>126</td>
<td>12.6(15-8.17)</td>
</tr>
<tr>
<td>Al-Wahdani</td>
<td>Jordan</td>
<td>2003</td>
<td>47</td>
<td>8.47±2.88</td>
</tr>
<tr>
<td>Cengize et al</td>
<td>Turkey</td>
<td>2009</td>
<td>68</td>
<td>12.7±8.1</td>
</tr>
<tr>
<td>Chamaniet al</td>
<td>Iran</td>
<td>2009</td>
<td>68</td>
<td>11.33±8.44</td>
</tr>
<tr>
<td>Tilaki et al</td>
<td>Iran</td>
<td>2014</td>
<td>95</td>
<td>15.47±7.85</td>
</tr>
</tbody>
</table>

The significant role of socio-behavioural and environmental factors in oral disease and health is demonstrated in a large number of epidemiological surveys (WHO, 2003; Petersen, 2003). In light of the environmental factors, Zliten is located in a drought region in Africa and dry regions generally have higher fluoride levels in their
water. In addition, the percentage of population in Libya with optimally fluoridated water is only 22%, the remainder would shift towards the ground water which is enriched with fluoride, regardless of its side effect, it increases caries resistance (Water System Council; British Fluoridation Society, 2013).

Decayed scores of the patients in our study indicate that there were unmet dental treatment needs, which has been highlighted in previous studies (Naugle et al, 1998; Al-Wahdani & Al-Omari, 2003; Al-Sebaie, 2014). Unmet treatment need for caries was 86%. Furthermore, the following treatments were required: restorative (DT1, DT2, and DT3) and surgical intervention (DT6 - extraction of hopelessly carious teeth) in order to prevent further progression of the active dental caries.

The most required dental treatment need was DT7, which is the prosthetic need. This might be in the form of dental implant supported prosthesis, fixed partial denture or removable partial denture depending on the patients candidacy for each prosthodontic option. The number of teeth that need to be replaced are 188. When extracting 109 tooth, the sum of teeth to be replaced may become 297.

As large proportion of patients (51%) require dental extraction. The oral health care provider should therefore be familiar with the health impacts of treating a CRF patient.

The unmet treatment needs of CKD population have been attributed to such factors as financial, stress, anxiety, lack of oral health education and awareness which might hinder that population from attending dental clinics (Fraser et al, 2013 A; Al-
In addition, CKD patients spend much time and concern on their primary health problem over their oral health needs. The dialysis treatment is frequent, and often leaves the patients exhausted, making them reluctant to attend dental clinics (Fraser et al, 2013; AL-Sebaie et al, 2013; Al-Wahadani and Al-Omari, 2003). Traditional dental treatment is provided free in the public sector in Libya, and population access to local health services for both rural as well as urban populations during 1999-2012 has remained 100% (Peeran et al., 2014). Thus at least the financial barrier could be excluded.

5.2 Periodontal status

Data on periodontal status have shown that 100% of the examined sample has some form of either gingival or periodontal disease or both. This finding is higher than that found in a healthy population since disease-free gingiva and periodontium was observed as presented in the WHO Global Oral Health Data Bank (Peterson & Ogawa, 2005). However, our findings are in accordance with recently published studies (Gautam et al, 2014; Duran et al, 2004; Dencheva et al, 2009).

The CPITN index was used to assess periodontal status in our study, and those data were presented as the percentage distribution of dentate subjects. Thirty-one patients (43.1 %) scored 2 on CPITN, which indicates the presence of plaque and calculus, suggesting that patients receive inadequate periodontal care. Deposition of plaque and calculus was reported in many studies on periodontal disease in CKD.
patients (Gavalda et al 2009; Al-Wahadani& Al-Omari, 2003; Al-Sebaie et al, 2014; Bots et al, 2006).

A score of 3 has been frequently observed in CKD patients on hemodialysis, indicating moderate periodontitis, presented as a shallow pocket. In our study 35 patients scored 3, (44.4 %). Dencheva et al, (2009) found that the proportion of subjects scoring 3 on CPITN was similar to that scoring 2, which is consistent with our findings (Dencheva et al, 2009). If this trend continues without intervention, in the coming years the severity of periodontal disease might progress, resulting in deep pocket.

The prevalence of score 4 was about 10 %, where 7 CKD patients had deep pocket. This is a low proportion, and is similar to those reported in previous studies (Duran et al, 2004; Dancheva et al, 2009). They likewise found a small portion of the population scoring 4 on CPITN.

Only Two patients had a score of 1 in our study, in contrast to other studies undertaken in developing countries like in India, where a score of 1 had been reported in 30% of patients (Tiwari et al, 2013). Table 7 gives a sample of CPITN scores distribution in different studies.

Bots et al (2006) reported that the number of teeth with gingivitis and bleeding were found to correlate strongly with the number of teeth with dental plaque and calculus (2006). According to those findings, we would correctly assume that all patients scoring 2(43%) would have bleeding, indicating a high prevalence of
bleeding gum in this study. However, Torkzaban et al (2009) reported a low gingival bleeding rate in a cohort of CKD patients, despite the high accumulation of plaque and calculus.

In other literature it has been reported that the majority of population had a score of 3, and that the smallest portion had score 4 on CPITN, WHO (Peterson & Ogawa, 2005). The most recently published report on periodontal status of a Libyan population (Peeran et al, 2012) showed that about half of population, 52.65% (n = 238), were detected with shallow pockets (score 3) followed by 30.08% (n = 136) with calculus (score 2), 12.17% (n = 55) had deep pockets (code 4), 3.31% (n = 15) had bleeding (code 1), and only 1.33% (n = 6) were healthy (code 0). The majority population, both in our study and the Libyan general population, falls into either score 2 or 3, requiring the same periodontal treatment. Thus the periodontal status of CKD patients in Zliten may not differ from that reported by other studies, supporting the suggestion that the immunosuppressed state caused by uremic condition does not retard the gingival response against the bacterial load found in dental plaque (Kituso et al, 2000; Bots et al., 2006).

The assessment of periodontal treatment needs is the prime goal, to facilitate the achievement of which the CPITN was developed. In this study 63 patients (87.5%) required periodontal treatment need 2, which is the need for professional tooth cleaning as well as improvement of personal oral hygiene. Furthermore, 10% required periodontal treatment need 3, which is the need for more complex treatment, such as removal of infected tissue.
Table 7. Distribution of CPTIN scores for CKD patients in different studies

<table>
<thead>
<tr>
<th>Author</th>
<th>Country</th>
<th>Year</th>
<th>Sample size</th>
<th>CPITN</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>x 4</td>
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<tr>
<td>Present study</td>
<td>Libya</td>
<td>2015</td>
<td>72</td>
<td>0% 9.7%</td>
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<tr>
<td>Duran &amp; Edmir</td>
<td>Turkey</td>
<td>2004</td>
<td>342</td>
<td>0% 2%</td>
</tr>
<tr>
<td>Tiwari et al</td>
<td>India</td>
<td>2013</td>
<td>30</td>
<td>7% 0%</td>
</tr>
<tr>
<td>Gautam et al</td>
<td>India</td>
<td>2014</td>
<td>206</td>
<td>4% 39%</td>
</tr>
<tr>
<td>Manjunath</td>
<td>India</td>
<td>2013</td>
<td>234</td>
<td>0% 1%</td>
</tr>
<tr>
<td>Dencheva</td>
<td>Bulgaria</td>
<td>2013</td>
<td>45</td>
<td>13.4% 26.6%</td>
</tr>
</tbody>
</table>

5.3 The effect of the duration of hemodialysis on dental and periodontal health

Hemodialysis treatment has many consequences that alter oral health. The level of severity of oral disease could thus be explained in relation to the chronic nature of renal disease. In our study finding though the DMFT and CPITN, for groups 1, 2 and 3 was 4.62 (±4.43); 5.94 (±6.11), and 6.38 (±5.44) respectively; the Kruskal-Wallis test for comparison of DMFT for tested groups showed no significant difference between mean DMFT values between the tested groups at p=0.502 (Table 3, Figure 1).

Regarding the CPITN, the more advanced periodontal disease (score 3) was observed more frequently in the group on hemodialysis for longer than three years than of lesser duration. Smaller proportions scored 2 on CPITN in the group on hemodialysis for longer than three years than in the other groups of a shorter duration. Thus more patients in the group on dialysis for the longest duration have a tendency to progress to the development of deep pockets unless periodontal treatment is intervened. The
mean CPITN of the three respective groups was 2.54 (±0.66); 2.59(±0.71) and 2.64(±0.73). The results of the Kruskal-Wallis test for comparison of total CPITN for tested groups showed no significant difference between mean total CPITN values between the tested groups at \( p=0.776 \).

According to these results, we could conclude that oral health among the study participants was not affected by the duration of hemodialysis as in previous studies (Naugle et al, 1998; Al-Wahadani & Al-Omari 2003; Gautam et al 2014).

**Limitations**

The small size of our study population could have underestimated the impact of duration of hemodialysis on oral health. Most dialysis patients have complex medical comorbidities such as hypertension and diabetes, which could play the role of important confounding factors in giving a conclusive diagnosis of periodontal disease status.
Conclusion and recommendations

Among the 72 hemodialysis patients in Zliten, Libya, the prevalence of dental caries was found to be high (86%). The periodontal status consisted of predominantly shallow pocketing (score 3) and calculus (score 2). The Unmet Treatment Index was (86%) and most of the treatment required involved complex dental care (56%) and extractions (51%). The duration of dialysis treatment was not found to have had significant impact on the DMFT and CPITN scores. For a better understanding of the effect of hemodialysis on dental and periodontal health, further longitudinal studies of a large sample size would be required.

Meeting these patients’ oral health needs is of paramount importance, since this would improve the oral health-related quality of life and prevent further compromising of their general health. This could be achieved by setting up an integrated oral health intervention involving general health care practitioners and nephrologists.
Bibliography:


Greetings
My name is Dr MuftahSwisi and I am a dentist in the Division of Public Oral Health. I am conducting a study entitled: Oral Health Status of Patients on Hemodialysis.

What is the purpose of the Study?
I would like to invite you to participate in the study. The purpose of the study is to survey your dental and periodontal health and to determine the dental treatment needs.

What the study entails?
An oral health care professional will first interview you by asking you questions that are related to your dental and medical experiences, this will take 15minutes. Upon completing the questions your mouth will be examined.

Confidentiality
If you consent to participating in the study, we assure you that all your information will remain confidential. The information collected will be kept in a secure locked office.

Participation
Participation in this study is voluntary and you are free to refuse or withdraw from the study at any time. Refusal to participate or discontinue will not disadvantage you in any way.

Risks
There are no foreseeable risks in your participation.

Benefits
There are no direct benefits to you but should you require any oral health care, and you will be made aware of your oral health status, you will be referred to the Zliten Dental Clinic should your require dental treatment.

Contact details
If you have any queries or would like more information about the study, please contact:
Dr MuftahSwisi on 0944267467.

If you are not happy with the way this research is being conducted, you are welcome to contact the research ethics office in Zliten Teaching Hospital.

Your cooperation in this regard will be highly appreciated.

Dr Muftah Swisi
Appendix B: Consent Form

Please complete this form after you have read the Information Sheet and/or listened to an explanation about the research.

Title of Study: Oral Health Status of Patients on Hemodialysis.

- Thank you for considering taking part in this research. The person organizing the research must explain the project to you before you agree to take part.

- If you have any questions arising from the Information Sheet or explanation already given to you, please ask the researcher before you decide whether to join in. You will be given a copy of this Consent Form to keep and refer to at any time.

- I understand that if I decide at any other time during the research that I no longer wish to participate in this project, I can notify the researchers involved and be withdrawn from it immediately.

- I consent to the processing of my personal information for the purposes explained to me.

Participant’s Statement:

I _____________________________________________________________________

Agree that the research project named above has been explained to me to my satisfaction and I agree to take part in the study. I have read both the notes written above and the Information Sheet about the project, and understand what the research study involves.

Signed Date

Investigator’s Statement:

I _____________________________________________________________________

Confirm that I have carefully explained the nature, demands and any foreseeable risks (where applicable) of the proposed research to the volunteer.

Signed Date
Dear Respondent

Thank you for agreeing to participate in the study. The purpose of the questionnaire is to determine your oral health experiences while you are on haemodialysis. Kindly please attempt all the questions.

Name: ...............................................................

Name of hospital: ...................................................

Gender: ...............................................................

Age: .................................................................

Medical History:

Past medical history kindly please tick the medical history that is relevant to you

<table>
<thead>
<tr>
<th>Allergies</th>
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<tbody>
<tr>
<td>High blood pressure</td>
<td>Cardiovascular disease</td>
</tr>
<tr>
<td>Diabetes</td>
<td>Respiratory disease</td>
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<tr>
<td>Renal disease</td>
<td>Bleeding disorders</td>
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<tr>
<td>Learning disabilities</td>
<td>Physical disabilities</td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
</tbody>
</table>

In case of any other illnesses not listed above, please indicate these conditions.

Appendix C

استبيان التاريخ المرضي

Medical History Questionnaire

شكراً لمشاركتكم في هذه الدراسة. وتعتمد هذه الاستبيانات على تحديد حالة صحة الفم والأسنان الخاص.

يرجى التكرم بمحاولة الإجابة على جميع الأسئلة.

Date:

Dear Respondent

Thank you for agreeing to participate in the study. The purpose of the questionnaire is to determine your oral health experiences while you are on haemodialysis. Kindly please attempt all the questions.

Name: ...............................................................

Name of hospital: ...................................................

Gender: ...............................................................

Age: .................................................................

Medical History:

Past medical history kindly please tick the medical history that is relevant to you

<table>
<thead>
<tr>
<th>Allergies</th>
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</thead>
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<tr>
<td>High blood pressure</td>
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<td>Renal disease</td>
<td>Bleeding disorders</td>
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<tr>
<td>Learning disabilities</td>
<td>Physical disabilities</td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
</tbody>
</table>

In case of any other illnesses not listed above, please indicate these conditions.

59
If you have ticked other, please specify………………………………………………………………………………

Current medication:..................................................................................................................

سبب الفشل الكلوي، نرجو وضع علامة أمام السبب الذي أدى إلى الفشل الكلوي
Cause of renal failure, please tick the cause of that led to having renal failure to you

<table>
<thead>
<tr>
<th>Cause of Renal Failure</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>ارتفاع الضغط</td>
<td></td>
</tr>
<tr>
<td>السكري</td>
<td></td>
</tr>
<tr>
<td>التهاب الكبيبات الكلوية</td>
<td></td>
</tr>
<tr>
<td>مناعية</td>
<td></td>
</tr>
<tr>
<td>أسباب أخرى (Others)</td>
<td></td>
</tr>
</tbody>
</table>

Duration on hemodialysis: مدة العميل منذ أول جلسة :

<table>
<thead>
<tr>
<th>Duration</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>أقل من سنة واحدة</td>
<td></td>
</tr>
<tr>
<td>من 1-3 سنوات</td>
<td></td>
</tr>
<tr>
<td>أكثر من 3 سنوات</td>
<td></td>
</tr>
</tbody>
</table>

Dental history: طب الفم والأسنان:

Past dental history: تاريخ أمراض الفم:

Habits: العادات

<table>
<thead>
<tr>
<th>Habit</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you smoke?</td>
<td></td>
</tr>
<tr>
<td>Do you drink?</td>
<td></td>
</tr>
<tr>
<td>Other habits?</td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX D

ORAL HEALTH SURVEY

Name:  
Name of dialysis centre:  
Region:  
Date:  

<table>
<thead>
<tr>
<th>Code no.</th>
<th></th>
<th></th>
</tr>
</thead>
</table>

**General Information**

<table>
<thead>
<tr>
<th>Age</th>
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<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Sex</th>
<th></th>
</tr>
</thead>
</table>

**Periodontal Status (CPITN)**

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
</table>

0 = Healthy  
1 = Bleeding  
2 = Calculus  
3 = Pocket 4-5 mm  
4 = Pocket 6mm  
X = Excluded sextant

**Treatment Needs: TN2**

TN0: no need for treatment the sextant is healthy or missing.  
TN1: need for improve the personal oral hygiene..  
TN2: a) A code of 2 or higher indicates need for professional cleaning of teeth and removal of plaque retentive factors. In addition, patient requires oral hygiene instructions.  
b) Shallow to moderate pocketing (4 to 5 mm) code 3. oral hygiene and scaling will reduce inflammation and bring 4mm or 5mm pocket to value of 3mm or below. Thus sextants with these pockets are placed in the same treatment category TN2.  
TN3: A sextant scoring code 4(6 mm or deeper pockets) may or may not be successfully treated by deep scaling and efficient personal oral hygiene measures. Therefore, it requires a complex treatment which involves deep scaling, root planning and more complex procedure.
## Dental Status & RCI

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 18 | 17 | 16 | 15 | 14 | 13 | 12 | 11 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 |

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 48 | 47 | 46 | 45 | 44 | 43 | 42 | 41 | 31 | 32 | 33 | 34 | 35 | 36 | 37 | 38 |

### Permanent teeth

- 0 = sound
- 1 = decayed
- 2 = filled & decayed
- 3 = filled, no decay
- 4 = missing due to caries
- 5 = missing for any other reasons
- 6 = sealant, varnish
- 7 = bridge abutment/ special crown
- 8 = unerupted tooth
- 9 = excluded tooth
### DMFT

<table>
<thead>
<tr>
<th>DMFT component</th>
<th>Number of Teeth</th>
</tr>
</thead>
<tbody>
<tr>
<td>D</td>
<td></td>
</tr>
<tr>
<td>M</td>
<td></td>
</tr>
<tr>
<td>F</td>
<td></td>
</tr>
<tr>
<td><strong>Total DMFT</strong></td>
<td></td>
</tr>
</tbody>
</table>

**Treatment Need of Individual Teeth:**

0-None

- P- Preventive, caries arresting care.
- F- Fissure Sealant
- 1-One surface filling
- 2-Two or more surface fillings
- 3- Crown for any reason.
- 4- Veneer or laminate.
- 5-Pulp care and restoration.
- 6- Extraction.
- 7- Need for other care.(specify).........
- 8- Need for other care.(specify).........
Dr SA Mufhah
84
Upper Leeuween St
Bookap
8001
South Africa

Dear Dr Mufhah

Master of Science in Dentistry: Approval of Title

We have pleasure in advising that your proposal entitled *Oral health status of hemodialysis patients in Zileni-Libya* has been approved. Please note that any amendments to this title have to be endorsed by the Faculty’s higher degrees committee and formally approved.

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences
HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M141034

NAME: Dr Muffah Swis Algdar
(Principal Investigator)

DEPARTMENT: Community Dentistry
Ministry of Health-Libya
Zitlen Teaching Hospital-Centre for Artificial Kidney

PROJECT TITLE: Oral Health Status of Patients on Haemodialysis
In Zitlen-Libya

DATE CONSIDERED: 31/10/2014

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 the Country in which research will be done.

SUPERVISOR: Dr Mpho Molete

APPROVED BY: Professor Cleaton-Jones, Chairperson, HREC (Medical)

DATE OF APPROVAL: 19/11/2014

This clearance certificate is valid for 6 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and ONE COPY returned to the Secretary in Room 10004, 10th floor,
Senate House, University.

I/we fully understand the conditions under which I/we are authorized 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 the
application to the Committee. I agree to submit a yearly progress report.

Principal Investigator Signature

Date 21/11/2014

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES
State of Libya

Ministry of Higher Education & Scientific Research
Libyan National Committee for Biosafety & Bioethics

Reference No: 15/ 2 Arabic character Seen/ 33
Date: 9/07/2015

Respected Sir

Muftah Swil Algdar

May God’s Peace and Blessing be upon you.

By this letter, we inform you of our approval relating to your application to acquire approval for Ethical Permission relative to the Research Project titled:

“Oral Health Status of Patients on Haemodialysis in Ziten, Libya”

In accordance to documentation forwarded, and which has been reviewed, including that related to the text of Ethical Clearance Certificate issued by the Committee for Human Research Ethics in South Africa.

We wish you success in your research. May God’s Peace and Blessing be upon you.

Signed in the original

Dr. Abd al-Aziz Muhammad al-Buni
Head of the National Committee for Biosafety & Bioethics

Seal

State of Libya – Ministry of Higher Education and Scientific Research
Head of the National Committee for Biosafety & Bioethics

Tel: 0217116082, 0217266274, 0217290727 - info@lnccbb.ly
Dr
by Swisi Muftha
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