The Comparison of Periodontal Health Status and Metabolic Control in Diabetic Children and Adolescents at Tygerberg Hospital.

A Thesis for the degree of Master of Science in Dental Sciences

In

Periodontics at the Faculty of Dentistry

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Keywords:

Diabetes Mellitus (DM)

Diabetic Type 1 (T1DM)

Diabetic Type 2 (T2DM)

Monogenic diabetes syndromes such as neonatal diabetes and maturity-onset diabetes of the young (MODY)

Glycated haemoglobin (HbA1C %)

Insulin pen or syringe, Insulin pump

Body Mass Index (BMI) in children and adolescents

Puberty

Periodontal disease

Classification of Periodontal and Peri-Implant Diseases and Conditions

Basic Periodontal Examination (BPE)

Children

Adolescents

Abstract:

Overview:

Diabetes Mellitus (DM) is a well-known risk factor for Periodontal disease. Research has established that the prevalence of Periodontal disease is directly related to the glycaemic control of DM in adults and only a few research studies explore this prevalence in diabetic children and adolescents in South Africa.

Aim (General objective):

The aim of this study is to determine the periodontal health status of diabetic patients which include children and adolescents attending the Paediatric Diabetic Clinic at Tygerberg Hospital and compare periodontal status with diabetic control.

Research Methodology:

A cross-sectional study was employed to determine periodontal status and data relating to the HbA1c% level, the type and duration of DM, the body mass index (BMI) percentile, age, sex, and puberty and treatment regimens were collected from patient records and entered into data collection sheets. A basic periodontal examination was conducted to determine the periodontal status of diabetic patients at the Paediatric Diabetic Clinic at Tygerberg Hospital. Data was analyzed in Microsoft Excel and The STATA (Stata Corp. 2017. Stata Statistical Software: Release 15. College Station, TX: Stata Corp LLC) The data was presented via statistical diagrams such as histograms, bar charts, number (percentage), mean (SD - standard deviation) or median [Interquartile Range] or 95% CI [confidence interval] depending on the distribution of data.

Results:

The mean (SD) age of the DM participants was 11.5 (SD ± 3.74) years. The sample included 52 % (n=93) females and 48% (n=87) males. The majority of the 180 DM participants had basic periodontal examination (BPE) score of 0-2, (n=130) compared to the participants with BPE score of 3 (n=50). The HbA1c% levels in males was 9.7 (SD ±2.17) and in females it was 9.9 (SD ±2.08) with no statistically significant difference (p = 0.5446) in HbA1c% levels. Similarly, no association between puberty and HbA1c% levels were found, 9.5 (SD ±1.93) for pubescent participants and 10.0 (SD ±2.27) in those who were not undergoing puberty (p = 0.0858). There was no statistically significant difference between Type I and Type II

DM HbA1c% levels (p =0.1167). The HbA1c% levels in participants with BPE score of 3 was 11.7 (SD ±2.11); 95% CI [11.09, 12.29] compared to those with BPE score 0-2, 9.0 (SD ±1.62); 95% CI [8.76, 9.32] This difference was statistically significant, $p < 0.001$.

Conclusion:

Findings confirm that there is an association between the periodontal health status, as determined by BPE, and metabolic control in DM children and adolescents. The prevalence of periodontitis increased with an increase in HbA1c % level in children and adolescents with DM. Educational programs designed to promote periodontal disease prevention and treatment should be provided to children and adolescents with diabetes. Periodontal care should form part of holistic management strategies in children and adolescents with DM.

Declaration:

I declare that “The Comparison of Periodontal Health Status and Metabolic Control in Diabetic Children and Adolescents at Tygerberg Hospital.” is my own work, that it has not been submitted for any degree or examination in any other university, and that all the sources I have used or quoted have been indicated and acknowledged by complete references.

Name: Lèzaan Scholtz - Evans Date: 03 December 2021

Signed: 

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Abbreviations, Glossary and Definitions

Diabetes Mellitus (DM) - a disease in which the body's ability to produce or respond to the hormone insulin is impaired, resulting in abnormal metabolism of carbohydrates and elevated levels of glucose in the blood.

Diabetic Type 1 (T1DM) - (formerly known as insulin-dependent diabetes or juvenile diabetes) is a condition in which the body stops making insulin. This causes the person's blood glucose level (blood sugar) to increase.

Diabetic Type 2 (T2DM) - is a condition in which cells cannot use blood sugar (glucose) efficiently for energy. This happens when the cells become insensitive to insulin and the blood sugar gradually gets too high.

Monogenic diabetes syndromes such as neonatal diabetes and maturity-onset diabetes of the young (MODY) - Neonatal diabetes mellitus (NDM) and maturity-onset diabetes of the young (MODY) are the two main forms of monogenic diabetes. NDM occurs in new-borns and young infants. MODY is much more common than NDM and usually first occurs in adolescence or early adulthood.

Glycated haemoglobin (HbA1c%)- The term HbA1c refers to glycated haemoglobin. It develops when haemoglobin, a protein within red blood cells that carries oxygen throughout your body, joins with glucose in the blood, becoming 'glycated'. By measuring glycated haemoglobin (HbA1c), clinicians are able to get an overall picture of what our average blood sugar levels have been over a period of weeks/months. HbA1c is also referred to as haemoglobin A1c or simply A1c.

Basic Periodontal Examination (BPE)- Careful assessment of the periodontal tissues is an essential component of patient management. The BPE is a simple and rapid screening tool that is used to indicate the level of further examination needed and provide basic guidance on treatment needed.

Body Mass Index (BMI) in children and adolescents- Body mass index (BMI) is a person's weight in kilograms divided by the square of height in meters. It is an inexpensive and easy-to-perform method of screening for weight categories that may lead to health problems. For children and teens, BMI is age- and sex-specific and is often referred to as BMI-for-age.

Fasting plasma glucose- Fasting is defined as no caloric intake for at least 8 hours.

Insulin pen or syringe- look like large writing pens and can help prevent under- and overdosing. They also don't require refrigeration, are conveniently prefilled, and are more durable than syringes.

Insulin pump- is attached to a thin tube that's implanted under your skin. Pumps are computerized or motorized, and some models also act as glucose monitors. They deliver insulin before each meal along with small amounts through the course of the day.

Risk factors may be environmental, behavioral, or biological factors that, when present, increase the likelihood that an individual will get the disease.

Risk factors are identified through longitudinal studies of patients with the disease of interest.

Children- Medically they are persons between birth and puberty onset of secondary sexual characteristics, usually at 11 yrs. in girls, 12 yrs. in boys.

Adolescents- Medically a person is considered an adolescent when puberty commence until the cessation of physical growth; roughly from 11 to 19 years of age. The World Health Organization (WHO) defines adolescents as those people between 10 and 19 years of age. The great majority of adolescents are, therefore, included in the age-based definition of "child", adopted by the Convention on the Rights of the Child,4 as a person under the age of 18 years.

Periodontal disease - are mainly the result of infections and inflammation of the gums and bone that surround and support the teeth. In its early stage, called gingivitis, the gums can become swollen and red, and they may bleed. In its more serious form, called periodontitis, the gums can pull away from the tooth, bone can be lost, and the teeth may loosen or even fall out.

Classification of Periodontal and Peri-Implant Diseases and Conditions - A classification scheme for periodontal and peri-implant diseases and conditions is necessary for clinicians to properly diagnose and treat patients as well as for scientists to investigate etiology, pathogenesis, natural history, and treatment of the diseases and conditions.

Incidence - the number of new cases that develop in a given period of time.

Participants - a person who takes part in or becomes involved in a particular activity.

Prevalence- the fact or condition of being prevalent; commonness.

Comparison- a consideration or estimate of the similarities or dissimilarities between two things or people.

Table of Contents

List of Tables and Figures

Tables

Figures

Chapter 1: Introduction:

Diabetes Mellitus

Diabetes Mellitus (DM) is a well-known chronic metabolic disease, characterized with chronic hyperglycaemia that leads to carbohydrate, fat and protein metabolism disturbances. (Chertan 2018) Pancreatic beta- cell destruction leads to a deficiency or insufficient amount of insulin hormone secretion, and thus chronic hyperglycemia ensues... Alternatively, insulin production is effective but the target cells are insensitive to the action of insulin. (WHO: World Health Organization 1999)

Diabetes Mellitus is thus classified into four groups: (American Diabetes Association: ADA 2018)

- Type 1 diabetes (T1DM)/ Insulin dependent diabetes: absolute insulin deficiency or insufficient amount of insulin produced due to autoimmune beta-cell destruction. (ADA 2018, Skyler *et al* 2017)
- Type 2 diabetes (T2DM)/Insulin resistant Diabetes: A progressive loss of beta-cell insulin secretion frequently on the background of insulin resistance. (The body cells inability to bind to insulin to activate glucose uptake by body cells) (ADA 2018, Skyler *et al* 2017)
- Gestational diabetes mellitus (GDM): diabetes diagnosed in the second or third trimester of pregnancy that was not clearly overt diabetes prior to gestation. (ADA 2018)
- Specific types of diabetes due to other causes (ADA 2018):
  - Monogenic diabetes syndromes such as neonatal diabetes and maturity-onset diabetes of the young [MODY].
  - Diseases of the exocrine pancreas such as cystic fibrosis and pancreatitis.
    Drug- or chemical-induced diabetes such as with glucocorticoid use, in the treatment of HIV/AIDS, or after organ transplantation

Uncontrolled DM can lead to various organ damage or dysfunction e.g. kidneys, heart, eyes. It can also lead to damage of blood vessels and nerves. (WHO, 2006) Generalized symptoms observed with diabetes are weight loss, polydipsia (increase thirst), polyuria (increase urination) and the blurring of vision. Severe symptoms may result in stupor and coma due to diabetic ketoacidosis (DKA) or hyperosmolar hyperglycaemia state and if not treated can lead to death. (Chinnaboina *et al* 2018, Chiang *et al* 2014)

Diabetes Mellitus is a global disease, prevalent in 425 million people worldwide and in South Africa, 6% of the overall population suffers from this chronic metabolic disease. (IDF, 2017) Diabetes Mellitus is more prevalent between the ages of 21 and 79 years and consists of approximately 3.85 million people in this age group. (CDE: The Centre for Diabetes and Endocrinology 2018) (IDF 2015)

Periodontal Disease

Periodontal disease is characterized as an inflammatory disease, which affects the periodontium. (Kinane *et al* 2017)

The disease starts with the inflammation of the free gingival tissue with no clinical attachment loss and in the early stage or phase is known as gingivitis. If disease is not diagnosed and treated appropriately it can progress and affect the attached gingival structures. The disease in this later stage or phase, is known as Periodontitis and causes clinical attachment loss, which includes alveolar bone and periodontal ligament destruction, and if the disease remains undiagnosed and untreated, it can eventually result in tooth mobility and tooth loss. (FDI World Dental Federation 2018)

Tonetti, M. (2017) stated that, according to the global burden of disease study done from 1990-2010, the prevalence of periodontal disease globally increased from 1990 to 2010 by 57, 3%. Severe periodontitis is worldwide the sixth most prevalent disease and affects 11.2% or 743 million people globally. (Tonetti, 2017)

Periodontal disease was reclassified in a world workshop in 2017 by the American Academy of Periodontology and European Federation of Periodontology and implemented in 2018. The classification includes four major groups and classifies according to various aetiologies. (Caton *et al* 2018).

The 2018 Classification of Periodontal and Peri-Implant Diseases and Conditions (Caton *et al* 2018)

- Periodontal Health, Gingival Diseases and Conditions (Chapple 2018)
    - Periodontal Health and Gingival Health
    - Gingivitis: Dental Biofilm-Induced
    - Gingival Diseases: Non-Dental Biofilm-Induced

- ❖ Periodontitis (Papapanou 2018) (Tonetti 2018)
    - Necrotizing Periodontal Diseases
    - Periodontitis
    - Periodontitis as a Manifestation of Systemic Disease
    - Periodontal Abscesses and Endodontic-Periodontal Lesions

- ❖ Periodontal Manifestations of Systemic Diseases and Developmental and Acquired Conditions (Jepsen 2018)
    - Systemic Diseases or Conditions Affecting Periodontal Supporting Tissues
    - Mucogingival Deformities and Conditions
    - Traumatic Occlusal Forces
    - Tooth- and Prosthesis-Related Factors

- ❖ Peri-Implant Diseases and Conditions (Berglundh 2018)
    - Peri-Implant Health
    - Peri-Implant Mucositis
    - Peri-Implantitis
    - Peri-Implant Soft and Hard Tissue Deficiencies

Diabetes Mellitus and Periodontal Diseases:

The pathogenesis of diabetes mellitus (DM) and periodontal diseases have similarities as both diseases have chronic inflammation as pathogenic mechanisms as well as common risk factors. (Nazir and Amin, 2021). Literature has shown that DM is a major risk factor for periodontal diseases as it has a bidirectional relationship with periodontal diseases. (Madiba and Bhayat 2018) (Stöhr, *et al* 2021). This is evident in the new 2018 classification of Periodontal and Peri-Implant Diseases and Conditions (Caton *et al* 2018) where DM and smoking are important modifying factors in the diagnostic process. The HbA1c% level of DM is used as a descriptor in the staging and grading process when diagnosing periodontitis. (Papapanou P N *et al* 2018)
This study explored the periodontal health status of diabetic children and adolescents attending the Paediatric Diabetic Clinic at Tygerberg Hospital and compared that to their metabolic control of Diabetes Mellitus.

Chapter 2: Literature Review

Diabetes Mellitus in Children and Adolescents

Type 1 DM (T1DM) or Insulin dependent diabetes

Type 1 diabetes mellitus (T1DM) is previously known as juvenile or childhood onset diabetes. (Chetan 2018, Novotna *et al* 2015) It is caused by insufficient or absolute lack of insulin secretion from the beta cells of the pancreas. (Chetan 2018, Novotna *et al* 2015)

The underlying aetiology for this aberrant secretion of insulin is due to auto-immune destruction of the beta cells within the pancreas, triggered by environmental and determined by genetic factors. (Chetan 2018, Novotna *et al* 2015) Symptoms of T1DM include weight loss, fatigue, polydipsia, polyuria, polyphagia (increased hunger), vision change and diabetic ketoacidosis. (Chetan 2018, Novotna *et al* 2015)

Type 2 D M (T2DM) Insulin dependent

Type 2 Diabetes Mellitus (T2DM) was known as non-insulin-dependent or adult-onset diabetes and was considered rare in children and adolescents. (Temneanu *et al* 2016)

However, in the mid-1990s, researchers began to notice a growing increased incidence of T2DM worldwide. (Temneanu *et al* 2016) The traditional paradigms of T2DM occurring only in adults and T1DM only in children were no longer accurate, as both diseases occur in both age-groups. (Temneanu *et al* 2016)

Research indicates that T2DM is not only due to insulin resistance, but can present together with insulin-secretory defects in beta cells with a decrease in the amount of insulin secreted. (Gerich 2003)

Monogenic diabetes syndromes such as neonatal diabetes and maturity-onset diabetes of the young [MODY]

Neonatal and MODY diabetes mellitus in children are usually caused by mutations of a single gene. (Lemelman et al 2018) The gene mutation is present in the pancreatic beta-cells causing a defect in cell function which leads to insulin deficiency. (Lemelman et al 2018) According to Winter (2003), neonatal diabetes is a result of genetic abnormalities in Kir6.2 and SUR1, which form the KATP channel in pancreatic beta-cells and there are five types of MODY with respect to gene abnormalities. These types of MODY (except for MODY2) are due to transcription factor mutations involved in the regulation of insulin gene transcription. (Winter 2003). MODY 1: the gene mutations in hepatocyte nuclear factor-4α (HNF1α);

MODY 2: Glucokinase mutations (GCK /chromosome 7p15-p13/ hexokinase IV); MODY 3: Hepatocyte nuclear factor-1α (HNF-1α); MODY4: Insulin-promoter factor-1 (IPF-1); MODY 5: Hepatocyte nuclear factor1β (HNF-1β). (Winter 2003). This type of diabetes mellitus is diagnosed in children from birth up to six months and thereafter it is less common but can present up to 12 months (Lemelman et al 2018). There are over 20 known single gene mutations that cause this diabetes. (Lemelman *et al* 2018).

Epidemiology:

T1DM can be diagnosed in childhood and adolescence however; T1DM can presently be diagnosed at any age. (IDF 2017) Globally 20 million of the 425 million people living with Diabetes Mellitus are diagnosed with T1DM worldwide. (IDF 2017) In South Africa (SA) the incidence rate for children aged 0 - 14 years living with type 1 diabetes mellitus (T1DM) is 0.8/100 000 (Kalweit *et al* 2015)

In a case study done by Nadeau et al 2016 in the United States of America, T2DM was less common in children and adolescents than T1DM and T2DM prevalence in children and adolescents increased with age, tripling from age 10–14 years to 15–18 years. In 2014—2015, the annual incidence of diagnosed diabetes in youth was estimated at 18,200 with type 1 diabetes, and 5,800 with type 2 diabetes. (Nadeau *et al* 2016)

Monogenic diabetes syndromes are even less prevalent among children and adolescents than T2DM, its overall prevalence has been estimated at 2.4 per 100 000 individuals / represents 1.5 -- 2% of diagnosed cases. (Lemelman *et al* 2018)

Diagnostic Criteria:

DM patients present with an increased frequency of dysglycaemia (impaired glucose tolerance and impaired fasting glucose). (Sahay B and Sahay R 2005)

To diagnose DM, certain tests need to be done to indicate whether dysglycaemia exists. (Deja S et al 2013) These tests include the gold standard test, Oral Glucose Tolerance Test (OGTT) for both fasting and 2 hr. post glucose values and the Glycated haemoglobin (HbA1c %) test done at 3month interval. (Deja S *et al* 2013)

Table 1: Glucose tolerance, Fasting plasma glucose (mg/dl) and Glycated haemoglobin (HbA1C %) Tests guidelines. (Chiang et al 2014, ADA 2018)

Test	Normal	IFG	IGT	Diabetes
Fasting plasma glucose (mg/dl)	<100 mg/dl (< 6.1 mmol/l)	100 - 125 mg/dl (6.1- 6.9 mmol/l)	<100 mg/dl (< 6.11 mmol/l)	≥ 126 mg/dl (≥ 7.0 mmol/l)
Glucose (mg/dl) 2hr post glucose plasma	<140 mg/dl < 7.8 mmol/l	<140 mg/dl < 7.8 mmol/l	140-199 mg/dl 7.8-11.1 mmol/l	≥ 200 mg/dl (≥ 11.1 mmol/l)
Glycated haemoglobin (HbA1c %)	<42 mmol/mol < 6.0%%	42-46 mmol/mol 6.0–6.4%	42-46 mmol/mol 6.0–6.4%	> 48 mol/mol > 6.5%

In the diagnosis of DM in children and adolescents a primary screening is done via a random blood glucose test. When test results reveal a blood glucose level of 11.1 millimoles per liter (mmol/L), or 200 milligrams per deciliter (mg/dL), or higher, a diagnosis of diabetes mellitus is made. (American Diabetes Association: ADA 2018) (Anon 2012) Table 2

Table 2: Criteria for the diagnosis of diabetes (Anon 2012)

A1C ≥6.5%. The test should be performed in a laboratory using a method that is NGSP certified and standardized to the DCCT assay.*
OR
FPG ≥126 mg/dl (7.0 mmol/l). Fasting is defined as no caloric intake for at least 8 h.*
OR
2-h plasma glucose ≥200 mg/dl (11.1 mmol/l) during an OGTT. The test should be performed as described by the World Health Organization, using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water.*
OR
In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose ≥200 mg/dl (11.1 mmol/l).

*In the absence of unequivocal hyperglycemia, criteria 1–3 should be confirmed by repeat testing.

T1DM and T2DM may present similarly with hyperglycemic symptoms, however the presentation of T2DM is much less dramatic than in T1DM. (IDF 2017) In neonatal diabetes the hyperglycemia presents in the newborn and persists longer than a week to ten days. (Lemelman *et al* 2018). The diagnostic criteria of Seino *et al* 2010 states that DM in newborns can be diagnosed from birth to under the age of six months. The diagnosis must include hyperglycemia as well gene abnormalities, thus genetic sequencing is essential in diagnosis of neonatal diabetes syndromes due to its specific pathogenesis. (Seino *et al* 2010)

Management

T1DM is characterized with absolute insulin deficiency or insufficient amount of insulin production. The treatment modalities therefore involve methods to keep blood glucose levels as close to normal and to keep the HbA1c% level <7.5%. Treatment modalities include insulin and healthy dietary habits. (Kalweit *et al* 2015)

T2DM is a complex, heterogeneous multisystem disorder and research indicates that treatment is multifaceted and new treatment options have become possible (Onge, E. S *et al* 2015). Though T2DM in children and adolescents is known to be caused by insulin resistance, it can be accompanied with an insufficient amount of insulin production due to pancreatic beta-cell dysfunction. (Gerich 2003) The treatment regimens will include oral agents to help with insulin resistance of body cells, medication to supplement insulin and healthy dietary habits. (Marín-Peñalver *et al* 2016).

Depending on the cause, monogenic diabetes syndromes may be treated with insulin, sulfonylurea or no therapy. (Lemelman *et al* 2018).

Oral therapy

The gold standard oral agent used for T2DM is a Biguanides known as Metformin. (Onge *et al* 2015) (SEMDSA 2017)

Insulin therapy

The management of DM by insulin therapy in children and adolescents is individualized according to the social circumstances of the families of origin, these include factors such as understanding the requirements for treatment as well as lifestyle related factors. Hence there are variations in the types of insulin delivery systems and the frequency thereof. T1DM treatment can begin with 2 injections per day and be increased to three times a day, using two different types of insulin. The control of blood glucose levels with the patients and parent's motivation as well as their lifestyle determines the regime of choice. (Donner *et al* 2019) (SEMDSA 2017)

Types of insulin therapy are as follows according to American Diabetes Association (ADA 2018):

- Rapid or Fast-Acting Insulin: Action starts 5-15min after administration when it reaches the bloodstream, then after 60 minutes, action will peak. This insulin action will last up to 2-4 hours. (Chinnaboina *et al* 2018, Donner *et al* 2019)

- Short or Regular -Acting Insulin: 30 minutes after administration reaches the bloodstream and action will start. Action will peak at 2 to 3 hours and total action duration will be 5 to 8 hours. (Donner *et al* 2019)
- Intermediate Acting Insulin or Neutral Protamine Hagedorn Insulin (NPH) Insulin: In 2-4 hours after administration, insulin will reach the bloodstream and action will start. The action will peak at 4-12 hours later and will be effective for 16 to 18 hours. (Donner *et al* 2019)
- Long-acting insulin: Action will start and reach the bloodstream 1 to 2 hours after administration and will continue to be active, no evident peaks or dips, for about 24 hours, although this can vary from one individual to another. (Donner *et al* 2019)
- Ultra-Long-Acting Insulin: After administration reaches the bloodstream in 6 hours and continues to be active for 36 hours, it does not peak or dip. (Donner *et al* 2019)

Insulin Delivery Methods

There are several methods used to deliver insulin to body which includes: (ADA 2018)

- *Multiple daily injections (MDI)* (Golden *et al* 2012) Some Insulin pens contain a cartridge of Insulin that is inserted into the pen and some are pre-filled with insulin. The Insulin dose is dialed on the pen, and the insulin injected through a needle, much like using a syringe. Cartridges- and pre-filled insulin pens contain only 1 type of insulin, which is discarded after all the insulin has been used. Two injections with 2 different insulin pens must be given if using two types of insulin. (Golden *et al* 2012)

- *Continuous subcutaneous insulin infusion (CSII)* (Golden *et al* 2012, Neupane *et al* 2018) The insulin pump delivers insulin into the body almost on the same principle as a healthy pancreas would. It releases small doses of fast/rapid acting insulin over 24 hours as the body requires. The insulin pump thus replaces frequent injections as required with an insulin pen. It has two types of doses, a Basal Rate and Bolus doses. (Golden *et al* 2012, Peters 2017)

  The Basal rate dose is determined by the physician as a programmed insulin rate made up of small quantities of fast acting insulin which is delivered continuously according to an individual body's need. The basal rate can be adjusted day to day according to an individual's specific needs, you increase, decrease, or even suspend release for a specific period. (Golden *et al* 2012, Peters 2017)

  The Bolus doses can be given on demand at a certain time to match the amount of food intake or to correct blood glucose level. The insulin pump device contains a bolus calculator, which assists to calculate the amount of insulin needed. The

physician predetermines this dosage according to the individual's specific need. (Golden *et al* 2012, Peters 2017)

Periodontal Disease in Children and Adolescents:

The periodontium with primary dentition differs from that of the permanent dentition. (Sjödin and Haubek 2017) The periodontium of primary dentition has a redder clinical appearance due to increased vascularity. (Sjödin and Haubek 2017) The gingival tissues are bulkier, rounder and less stippled, due to teeth that have diastemata to allow eruption of teeth. (Sjödin and Haubek 2017) Radiographically, the periodontal ligament space of primary dentition is a little wider than that of the permanent teeth. (Sjödin and Haubek 2017) The connective tissue is the same, however the junctional epithelium of the primary dentition is thicker and the alveolar bone is less calcified. (Sjödin and Haubek 2017)

Gingivitis is more prevalent than periodontitis in children. (Sjödin and Haubek 2017) The most common form of gingivitis in children is dental biofilm induced gingivitis. (Oh, T-J *et al* 2002) The accumulation of dental biofilm activates the host response and results in inflamed gingiva. (Oh, T-J *et al* 2002). Gingival inflammation with the absence of a significant amount of dental biofilm, may indicate the presence of gingivitis as a result of systemic disorders for example diabetes mellitus. (Madiba and Bhayat 2018) Gingivitis is reversible by improving oral hygiene practices. In severe cases of periodontal diseases, the improvement of oral health practices is not sufficient enough and dental biofilm removal via professional dental cleaning must be done. (Madiba and Bhayat 2018)

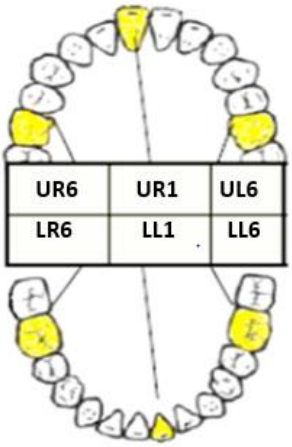
Untreated gingivitis can progress to the early onset of periodontitis, in a susceptible individual, thus including the extension of the inflammatory lesion to the periodontal ligament and alveolar bone. (Oh, T-J *et al* 2002)

Diagnosis

Periodontal diseases are diagnosed according to clinical findings when doing oral examination and using relevant screening indices. One such screening tool is the Basic Periodontal Examination (BPE). (The British Society of Periodontology 2011, 2019). The BPE is an easy and reliable tool to identify if there is disease affecting the gingival structures. (Cole, E. 2014) BPE screening for children involves only six index teeth Upper

Right (UR) 6 &1; Upper Left (UL) 1& 6; Lower Left (LL) 6&1; Lower Right (LR) 1&6. (Cole *et al* 2014)

Figure 1: Diagram showing six index teeth (UR6, UR1, UL6, LL6, LL1 and LR6) (Cole et al 2014)



The periodontal probe used in this screening is the WHO 621 style probe with a 0.5 mm ball /sphere end, black band at 3.5 to 5.5 mm, and additional markings at 8.5 mm and 11.5 mm. (The British Society of Periodontology 2019, Cole *et al* 2014)

BPE for children guidelines: (The British Society of Periodontology 2019)

BPE codes 0-2 are used in the 7- to 11-year-olds, while the full range of codes 0, 1, 2, 3, 4 and * can be used in the 12- to17- year-olds

Table 3: BPE scoring codes (The British Society of Periodontology 2019)

Scoring codes

0	No pockets >3.5 mm, no calculus/overhangs, no bleeding after probing *(black band completely visible)*
1	No pockets >3.5 mm, no calculus/overhangs, but bleeding after probing *(black band completely visible)*
2	No pockets >3.5 mm, but supra- or subgingival calculus/overhangs *(black band completely visible)*
3	Probing depth 3.5-5.5 mm *(black band partially visible, indicating pocket of 4-5 mm)*
4	Probing depth >5.5 mm *(black band entirely within the pocket, indicating pocket of 6 mm or more)*
*	Furcation involvement

Both the number and the * should be recorded if a furcation is detected - e.g. the score for a sextant could be 3* (e.g. indicating probing depth 3.5-5.5 mm PLUS furcation involvement in the sextant).

An example BPE score grid might look like:

4	3	3*
-	2	4*

Stated by Dietrich (2019), in adjunction with the BPE a full diagnostic assessment needs to be performed, to confirm the diagnosis, this include medical and dental history, extra- and intra- oral examination and radiographs. These examinations will allow diagnosis of periodontal disease according to the classification and the various etiologies.

Table 4: Diagnostic 'look up table' for gingival health or biofilm induced gingivitis in clinical practice. Modified after Chapple et al. 2018 (Dietrich 2019)

Intact periodontium	**Health**	**Gingivitis**
Probing attachment loss	No	No
Probing pocket depths (assuming no pseudo pockets)	≤3 mm	*≤3 mm*
Bleeding on probing	<10%	≥10%
Radiological bone loss	No	No
Reduced periodontium Non-periodontitis patient	**Health**	**Gingivitis**
Probing attachment loss	Yes	Yes
Probing pocket depths (all sites & assuming no pseudo pockets)	≤3 mm	≤3 mm
Bleeding on probing	<10%	≥10%
Radiological bone loss	Possible	Possible
Successfully treated periodontitis patient	**Health (stable)**	**Gingival inflammation in a patient with a history of periodontitis (remission)**
Probing attachment loss	Yes	Yes
Probing pocket depths (all sites & assuming no pseudo pockets)	≤4 mm (no 4 mm site with BOP) *	≤4 mm (no 4 mm site with BOP) *
Bleeding on probing	<10%	≥10%
Radiological bone loss	Yes	Yes
***A successfully treated periodontitis patient in whom sites of gingival bleeding appear remains at high risk of disease recurrence at those sites and of progressive attachment loss. Therefore, gingival inflammation is defined as bleeding at a shallow site of ≤3 mm rather than ≤4 mm, as is the case in gingival health. Where the probing depth is 4 mm with bleeding, or higher, this is no longer a 'closed pocket' and is assumed to be unstable periodontitis It is important to note that a higher probing depth of 5 mm or 6 mm in the absence of bleeding may not necessarily represent active disease, in particular soon after periodontal treatment**		

Management:

In 2016, the Council of the British Society of Periodontology released guidelines on interpretation of BPE scores as a guidance for practitioners.

Table 5: General guidelines below indicate for the BPE scores and for BPE codes 3 or 4 of teeth or sextants need additional radiographs to assess alveolar bone levels.

0	No need for periodontal treatment
1	Oral hygiene instruction (OHI)
2	OHI, removal of plaque retentive factors, including all supra- and subgingival calculus
3	OHI, root surface debridement (RSD)
4	OHI, RSD. Assess the need for more complex treatment; referral to a specialist may be indicated.
*	OHI, RSD. Assess the need for more complex treatment; referral to a specialist may be indicated.

As a general rule, radiographs to assess alveolar bone levels should be obtained for teeth or sextants where BPE codes 3 or 4 are found.

Periodontal Diseases in Children and Adolescents with Diabetes Mellitus

Periodontal diseases are more prone to develop or can be exacerbated in the presence of risk factors. Risk factors for periodontal disease include age, genetics, sex, smoking socioeconomic factors and some systemic disorders. Systemic disorders or diseases that are considered as risk factors, are disorders that have an effect on the efficiency of the body's host defense systems. Therefore, diabetes mellitus is considered as a risk factor for periodontal diseases. (Madiba and Bhayat 2018), however in study done by Polak in 2020 DM is considered a co-morbid condition of periodontal diseases. Studies from Polak (2020) and Nazir, G.; Amin, J. (2021) state that DM and Periodontal disease have similar pathologies. Both cause inflammatory and immune host responses that lead to impaired healing. The modifying factor in both diseases prognosis is the control of HbA1C% (Nazir, G. and Amin, J. (2021)

A case-controlled study by Lalla (2006) showed that children with T1DM have increased gingival inflammation and more plaque accumulation than that of non-diabetic children. The study also found periodontal attachment loss of >2mm in T1DM case participants compared with nondiabetic control participants (1.8 vs.0.8 and 5.8 vs. 1.5, respectively).

According to a review study by Mealey (2006) on T1DM aged between 18 and 50 years, findings state that glycaemic control is an important predictor for periodontal disease in T1DM. T1DM with poor glycaemic control leads to a greater risk for developing

periodontal disease. (Mealey 2006) The inflammatory process of periodontal disease can lead to an insulin resistance and worsen glycaemic control of T1DM. (Mealey 2006) Daković D, 2013 released a review study with a summary table (attach appendix A1) that found strong evidence indicating the parameters for the interaction between T1DM and periodontal disease. The most valuable parameters found was the parameters were hyperglycaemia and elevation of HbA1c%, hyperglycaemia was shown to have a negative impact on the host anti-inflammatory responses and thus perpetuated the pathogenesis of periodontal disease.(Daković D, 2013) In Taiwan, a nationwide population-based cohort study was conducted to determine if there was an association between T1DM individuals and the prevalence of periodontal diseases, their number or emergency room visits and hospitalizations. (Sun et al 2018) The findings showed that there was an association between hyperglycaemia and an increased chance of developing periodontal diseases, such as gingivitis and periodontitis. T1DM had a higher adjusted hazard ratio (aHR) of 13.0 (95% CI = 11.1–15.2). (Sun *et al* 2018)

T2DM was always considered rare in children and adolescents, however with the increase of obesity in children and adolescents, T2DM has become more common in this age group. (Temneanu *et al* 2016).

A descriptive and correlational study conducted by C.Y. Díaz Rosas (2018) on a population of children with diabetes mellitus indicated that there is a relationship between the prevalence of oral diseases and diabetes mellitus in children, with these children showing an increased severity of gingival inflammation (GI mean of 0.50 SD ± 0.56). A case-controlled study by Meenawat (2013) supported these findings and stated that there is a relationship between the glycaemic metabolic control and periodontal disease. In the study DM participants with poor metabolic control were compared with DM participants with moderate or good control, the results of the study revealed a significant difference recorded in the probing pocket depth ($P < 0.001$), bleeding index ($P < 0.001$), and clinical attachment level ($P = 0.001$) Where the mean pocket depth was 6.337 (SD ± 0.650), average bleeding index was 2.708 ± 0.390 and clinical attachment level was greater in the diabetics 4.337(SD ± 0.648.)The mean HbA1c% value was 8.84 (SD ± 1.34) with only 4 of DM participants had value <7 and the rest of participants had HbA1c% values >7%. This indicated that a poorer glycaemic control can result in an increased inflammatory tendency of periodontal disease. In 2007, Lalla did a cohort study that showed that Diabetes Mellitus increased the risk for periodontal destruction at an early age and the prevalence of periodontal disease was directly related to the level of metabolic control (odds ratio =1.56, $p = 0.052$, n = 183). (Lalla *et al* 2007)

Yaakob *et al* 2019 found that children and adolescents who have been diagnosed with Diabetes for more than five years, had shown significantly deeper pocket depths compared to those who were diagnosed less than five years. (mean SD 2.17 ± 0.957 p = 0.03*)
In a systematic review and meta -analysis of studies determining the periodontal health status in diabetic children and adolescents by Zainal Abidin, Z. *et al*. 2021, reviewing only studies done from the year 2000 to 2019 also conclude that diabetic children and adolescents have poorer periodontal health status which is directly associated with their metabolic control of DM. (Zainal Abidin, Z. *et al*. 2021)
A study on periodontal disease and its associations with diabetes in respect of the complications and metabolic glycaemic control in T1DM and T2DM adults' patients by Taylor and Borgnakke in 2008 concluded that the increased occurrence and progression of periodontitis and periodontal infection is directly associated with DM with poorer metabolic control. The review also found strong evidence that indicates that by treating these DM patients with periodontitis and periodontal infections can lead to better management of their metabolic glycaemic control with the possibility of decreasing the burden of diabetic complications. This conclusion is supported by findings in recent review studies done by Chapple, I. L. C. & Genco, R. (2013), Sanz, M. *et al* (2018) Graziani, F. *et al* (2018) and all these studies indicated that glycaemic control plays a definite role in developing periodontal disease in children and adolescents with T1DM. There are a few studies that assessed metabolic control in all types of DM children and adolescents. Most studies relating to this research topic have been done and proven on adult DM patients.
Currently there are no studies regarding the importance of metabolic control on prevalence of periodontal disease in diabetic children in South Africa. This study focused on comparing periodontal status in diabetic children and adolescents with their metabolic control at Tygerberg hospital in the Western Cape, South Africa.

Chapter 3:

Research Question

Is there a difference in the periodontal health status of diabetic patients which include children and adolescents attending Paediatric Diabetic Clinic at Tygerberg Hospital with respect to their metabolic control of Diabetes Mellitus?

Null Hypothesis

There is no difference in the periodontal health status of diabetic patients which include children and adolescents attending Paediatric Diabetic Clinic at Tygerberg Hospital with respect to their metabolic control of Diabetes Mellitus.

Study Objectives:

Aim (General objective):

The aim of this study is to determine the periodontal health status of diabetic patients which include children and adolescents attending the Paediatric Diabetic Clinic at Tygerberg Hospital and compare periodontal status with diabetic control.

Specific Objectives:

i. To determine the absence/presence of periodontal diseases in diabetic patients attending Paediatric Diabetic Clinic at Tygerberg Hospital.

ii. To determine metabolic diabetic control of patients attending Paediatric Diabetic Clinic at Tygerberg Hospital by recording the HbA1c% level.

iii. To determine the associating factors influencing Periodontal status of children and adolescents with Diabetes Mellitus by recording the Type and Duration of Diabetes Mellitus, the Body Mass Index (BMI) percentiles and Puberty.

iv. To compare between the Periodontal status and the HbA1c% levels, age, sex, type and duration of diabetes in years, BMI percentiles, Puberty stage of diabetic mellitus patients attending Paediatric Diabetic Clinic at Tygerberg Hospital on different Diabetic treatment Regimens.

Chapter 4: Research Methodology

Study Design

A descriptive cross-sectional study design was conducted. Descriptive cross-sectional studies provide information for describing, assessing and estimating the prevalence or relationship or association of one or more variables of interest in a population. These studies can be seen as taking a snapshot of the prevalence and features of a condition at a single point in time of a particular population to analyze data in respect of one or more variables to determine prevalence or relationships or associations between these variables. (Aggarwal & Ranganathan, 2019) (Ihudiebube-Splendor and Chikeme 2020)

A major potential down side of cross-sectional studies compare to cohort studies or clinical trials is that cross-sectional studies can be affected by antecedent-consequent bias, due to the potential challenge to determine the association between exposure (risk factor) and outcome (disease) in respect of whether the exposure precede the outcome as both is ascertained at the same time and therefore the investigator cannot assume that the exposure caused the outcome. (Aggarwal & Ranganathan, 2019) (Ihudiebube-Splendor and Chikeme 2020).

Study Population

Diabetic patients attending the Paediatric Diabetic Clinic at Tygerberg Hospital

Inclusion Criteria:

Diabetes Mellitus participants at the Tygerberg Paediatric Diabetic Clinic between the ages of 5 and 19

Exclusion Criteria:

Participants with additional disabilities or conditions influencing oral health and oral health care practices.

Sampling

Based on a 5% level of significance and a power of 80% and an estimated odds ratio of 1.6 when assessing whether there was an association between periodontal disease diagnosis (gingivitis and periodontitis) versus (VS) healthy subjects in participants who were not metabolically controlled, the required sample size is 180. Stratified sampling was employed to enroll study participants.

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Data Collection

A data collection sheet with close- ended questions was used to obtain and record the medical diabetic history in respect of the HbA1c%, age, sex, type of diabetes, and treatment of the DM disease from patient or patients' parents. Also, the investigator was given access to the medical records to patients at Paediatric Diabetic Clinic in Tygerberg Hospital to obtain additional medical history done by a qualified physician at the clinic to record puberty, duration of disease and BMI percentile.

Puberty was recorded yes or no according the onset of secondary sexual characteristics, usually at 11 yrs. in girls, 12 yrs. in boys.

The BMI was calculated in STATA 17 using the CDC BMI-for-age growth charts. The z score was then transformed into a percentile and the percentiles were categorized into weight status categories as described below.

BMI CAT	Weight Status Category	Percentile Range
1	Underweight	Less than the 5th percentile
2	Healthy Weight	5th percentile to less than the 85th percentile
3	Overweight	85th to less than the 95th percentile
4	Obesity	Equal to or greater than the 95th percentile

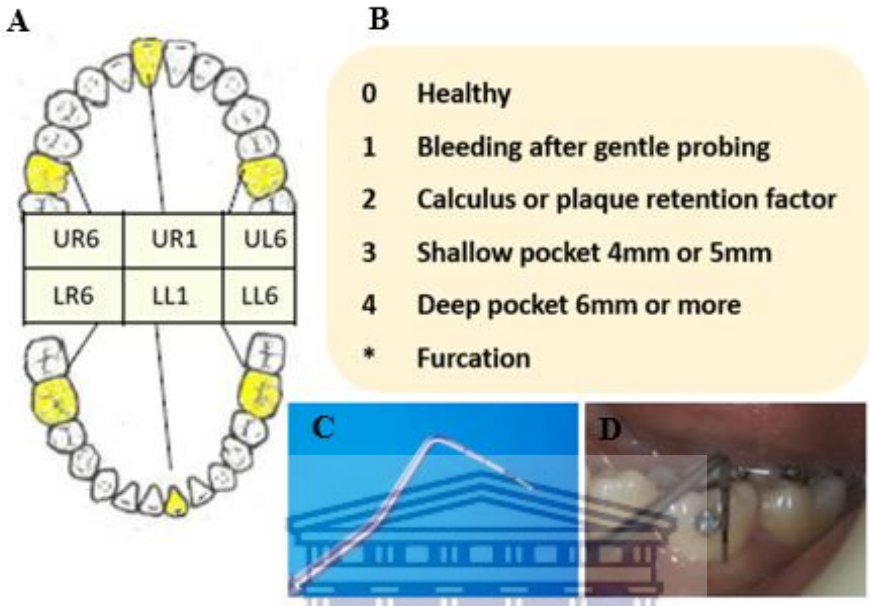
This data collection assisted to determine objectives 2,3, and 4 of the study. Example referenced as Appendix B: Questionnaire: Medical Diabetic History.

A Basic Periodontal Examination (BPE) examination was conducted to determine the prevalence of periodontal disease as recommended by the British Society of Periodontology 2019. The diabetic children and adolescents were not seen in an ideal dental setting. Periodontal screening (BPE) was conducted at the diabetic outpatients' clinic at Tygerberg hospital with the examiner using a headlamp and patients on a medical examination bed. The limitation of access to an ideal dental setting made it difficult to do an accurate bleeding on probing analysis. (Banakar, M. *et al* 2020) (Dietrich *et al* 2019)

The BPE was conducted by probing the periodontal tissue around a fully erupted permanent tooth (Fig 2D) to determine and assess the bleeding on probing, plaque and calculus deposits and the depth of periodontal pockets. This was done by dividing the mouth into 6 sextants (Fig 2A) and using the WHO/BPE probe (Fig 2C) with a light force to probe around each permanent tooth. Periodontal tissues of all permanent teeth were examined to ensure that the highest score in the sextant was recorded before examining the next sextant. The BPE scores

(Fig 2B) of 0 - 2 were used in 7 to 11-year-olds (during the mixed dentition phase and only around permanent teeth) and the full range of codes 0, 1, 2, 3, 4 and * was used in 12 to 17-year-olds (when most permanent teeth erupt). (British Society of Periodontology 2016)

***Fig. 2 Simplified BPE codes for under 18 years* (BSP 2016)**



The BPE is an easy and reliable tool in identifying if there is disease affecting the free gingival structures to determine periodontal disease in patients, hence assisted to determine objective 1. (Cole, E. 2014) Appendix B: Patient Examination.

The treatment protocol and instrument used was the WHO probe that is specifically designed for BPE screening. The principal researcher is familiar with this screening protocol as it is used daily in the examination of patients. All examinations were carried out by a single operator, the principal researcher (Dentist).

Statistical Analysis

The STATA (Stata Corp. 2017. *Stata Statistical Software: Release 15*. College Station, TX: Stata Corp LLC) was used to analyze the data. The data were presented via statistical diagrams such as histograms, bar charts, number (percentage), mean (standard deviation) or median [Interquartile Range] or 95% CI [confidence interval] depending on the distribution of data. For categorical data, a Chi square test was used. For continuous data, a t-test was used to demonstrate any differences between two groups; an ANOVA was used for group sizes greater than 2. In the event that the data did not fulfill the assumptions for the above stated tests, a non-parametric equivalent was used. All data was significant at a *p* level of less than 0.05.

Ethical Considerations

Approval was obtained from the University of the Western Cape's Research and Ethics Committee and the Stellenbosch University's Ethics Committee following the protocol presentation of the study. Ethics Reference Number: BM19/9/5: Letter Appendix C

Study participants were provided with an information sheet indicating what the study was about and according to the Declaration of Helsinki of the World Medical Association, informed consent was obtained from all participants and their parents or legal guardians (BMJ, 1996) with explicit details of the benefits and reasons for participating in the study. Example Appendix D

The investigator explained both these to the Patients/Participants and Parents/Guardians. Patients/ Participants and rights in terms of privacy, confidentiality and total anonymity were fully respected and specified in the information sheet that was given to Parents/Guardians who chose, for whatever reason, not to disclose their child's personal information. The Patients/Participants and Parents/Guardians choice to participate in the study was fully respected and voluntary, with no penalty for deciding not to participate (for whatever reason) and no consequence, prejudicial or preferential treatment resulted for participation or non-participation in this study. All patients requiring dental treatment were referred to the dental faculty for management.

CHAPTER 5:

Results

A total of 180 diabetic children and adolescents that attended the Paediatric Diabetic Clinic at Tygerberg hospital participated in this study.

Participant Demographics

The sample population had a fair proportion of males (n 93) to females (n 87). Ninety-six (53%) of the participants were in puberty compared to 84 not in puberty (47%). An unfavorable sample proportion of the type of diabetes mellitus was found. T2DM encompassed only 10 participants and T1DM was found in 170 participants. The mean (SD) age of the participants was 11.5 (3.73) years. The median number of years since diagnosis was 4 years. The average HbA1c was 9.8 (SD 2.13).

The majority of the 180 participants had a BPE score of 1 and 2, which is a differential diagnosis of dental biofilm induced gingivitis 72% (n130) compared to 28% (n50) participants with a differential diagnosis of periodontitis.

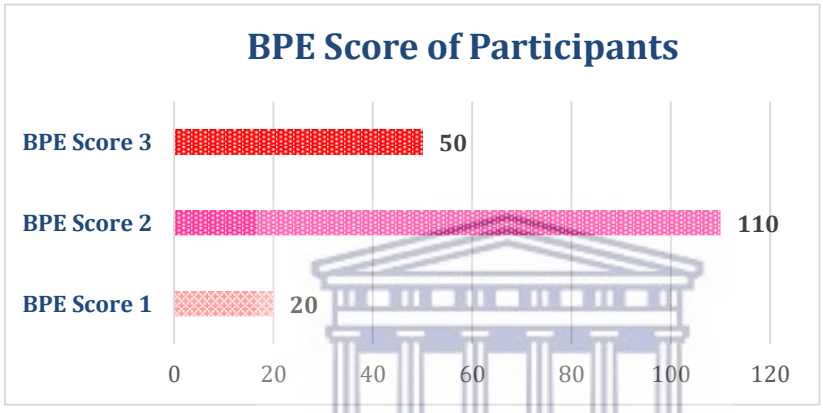
Table 6: Baseline Demographics		n (%)	Mean (SD)	Median [IQR]
Age			11.5 (3.73)	
Sex	Male	93 (51.67)		
	Female	87 (48.33)		
Puberty	Yes	96 (53.33)		
	No	84 (46.67)		
BMI (Categories - CAT)	Underweight	8 (4.44)		
	Healthy	109 (60.56)		
	Overweight	22 (12.22)		
	Obesity	41 (22.78)		
Type of DM	I	170 (94.44)		
	II	10 (5.71)		
Number of years since Diagnosis				4 [IQR: 2 to 6]
HbA1C			9.756 (2.13)	
Periodontal Status	Gingivitis	130 (72.22)		
	Periodontitis	50 (27.78)		

Periodontal health status:

BPE Results:

The 180 participants were screened with BPE and 130 participants had a BPE score of 1 (11%, n 20) or 2 (61%, n 110) meaning they had bleeding on probing and plaque retaining factors with probing depths below 3.5mm. The remaining 50 (28%) had probing depths of above 3.5mm up to 5.5mm, bleeding on probing and plaque retaining factors.

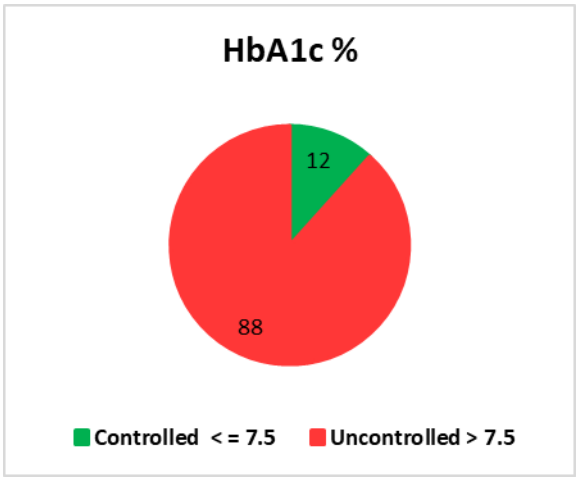
. *Figure 3: BPE score of participants*



Metabolic control of DM:

The mean (SD) HbA1c% level of the sample participants was 9.8(2.13). Where 21 of the participants HbA1c levels were below or equal to 7.5% and 159 of the sample participants HbA1c levels were above 7.5%.

Figure 4: HbA1c levels



Metabolic control (HbA1c%) in comparison to periodontal status:

The HbA1c% level in subjects with a differential diagnosis of periodontitis was 11.7 (2.11); 95% CI [11.09, 12.29] compared to those with a differential diagnosis of dental biofilm induced gingivitis, 9.0 (1.62); 95% CI [8.76, 9.32]. This difference was statistically significant, $p < 0.001$, (table 7) and clinically significant (95% CI).

The participants with gingivitis had a 2.7-unit HbA1c lower compare to participants with periodontitis, this was statistically significant, $p < 0.001$, (table 7.1)

Table 7: Table of HBA1C levels amongst different associated factors		HBA1C levels mean (SD)	95% Confidence Intervals [CI]	p-value
Sex	Male	9.684 (2.17)	[9.235201,10.13254	
	Female	9.877 (2.08)	[9.433023, 10.321]	0.5446
Puberty	Yes	9.486 (1.93)	[9.572091, 10.4924	
	No	10.032 (2.27)	[9.067613, 9.90381	0.0858
Type of DM	I	9.837 (2.08)	[9.522748, 10.1525	
	II	8.75 (2.78)	[6.764607, 10.7353	0.1167
BMI CAT	Underweight	11.813 (2.34)	[9.851125, 13.7738	
	Healthy	9.99 (1.99)	[9.618051, 10.3746	
	Overweight	9.464 (2.05)	[8.553696, 10.3735	
	Obesity	8.966 (2.17)	[8.281033, 9.65067	0.0016*
Periodontal Status	Gingivitis	9.040(1.62)	[8.75995, 9.321588	
	Periodontitis	11.692 (2.11)	[11.08998, 12.2940	<0.001*

Table 7.1 HbA1c% levels amongst Periodontal disease status.

HbA1c	Simple regression	P>|t|	Model 1: multiple Regression	P>|t|	Model 2: multiple Regression	P>|t|	Model 3: multiple Regression	P>|t|	Model 4: multiple Regression	P>|t|	Model 5: multiple Regression	P>|t|
periostat_1												
Periodontitis												
Gingivitis	-2.642(-3.25 to -2.04)	<0.001*	-2.604(-3.19 to -2.02)	<0.001*	-2.6(-3.18 to -2.02)	<0.001*	-2.6(-3.18 to -2.02)	<0.001*	-2.638(-3.21 to -2.06)	<0.001*	-2.68(-3.26 to -2.1)	<0.001*
_cons	12.763(10.98 to 14.55)	0	12.499(11.06 to 13.93)	<0.001*	12.715(11.43 to 14.)	<0.001*	12.715(11.43 to 14.)	<0.001*	12.92(11.69 to 14.15)	<0.001*	13.153(11.94 to 14.37)	<0.001*

Associating factors Age, Sex, Puberty, Type of Diabetes, Duration of Diabetes and BMI percentile influencing Periodontal status and HbA1c% levels:

Age, Sex, Puberty and Duration Diabetes:

Table 6 indicates that the HbA1c% levels in males was 9.7 (2.17) and in females it was 9.9 (2.08) $p = 0.5446$. There was no statistically significant difference in HbA1c% levels between those who were undergoing puberty, 9.5 (1.93), compared to those who were not undergoing puberty, 10.0 (2.27), $p = 0.0858$.

Type of DM:

There was no statistically significant difference between HbA1c% values in T1DM and T2DM p =0.1167 (Table 6), however the T2DM participants showed a 1.4-unit HbA1c% lower compared to T1DM, this was statistically significant, $p < 0.016$, (table 7.2)

Table 7.2: Table of HbA1c% levels amongst Associating factors.

HbA1c	Simple regression	P>|t|	Model 1: multiple Regression	P>|t|	Model 2: multiple Regression	P>|t|	Model 3: multiple Regression	P>|t|	Model 4: multiple Regression	P>|t|	Model 5: multiple Regression	P>|t|
Age	-0.024(-0.12 to .07)	0.621										
Nr Years	0.081(-0.01 to 0.17)	0.082	0.07(-0.01 to 0.15)	0.087	0.069(-0.01 to 0.15)	0.092	0.069(-0.01 to 0.15)	0.092	0.077(0.00 to 0.16)	0.056		
Gender_												
F												
M	0.083(-0.43 to 0.6)	0.75	0.071(-0.44 to 0.58)	0.785	0.076(-0.43 to 0.58)	0.766	0.076(-0.43 to 0.58)	0.766				
In puberty YN												
N												
Y	0.547(-0.04 to 1.13)	0.067	0.485(-0.04 to 1.01)	0.072	0.453(-0.06 to 0.97)	0.085	0.453(-0.06 to 0.97)	0.085				
Type DM												
I												
II	-1.189(-2.48 to .1)	0.071	-1.24(-2.51 to .03)	0.056	-1.398(-2.53 to -.26)	0.016*	-1.398(-2.53 to -.26)	0.016*	-1.304(-2.43 to -.18)	0.023*	-1.392(-2.52 to -.27)	0.016*
BMICAT												
1												
2	-1.545(-2.79 to -.3)	0.015	-1.524(-2.76 to -.28)	0.016*	-1.541(-2.77 to -.31)	0.015*	-1.541(-2.77 to -.31)	0.015*	-1.47(-2.7 to -.24)	0.02*	-1.298(-2.53 to -.07)	0.039*
3	-1.09(-2.5 to .32)	0.128	-1.078(-2.48 to .33)	0.132	-1.123(-2.52 to .27)	0.114	-1.123(-2.52 to .27)	0.114	-1.145(-2.54 to .25)	0.108	-1.067(-2.47 to .34)	0.136
4	-2.188(-3.52 to -.86)	0.001	-2.161(-3.48 to -.84)	0.002*	-2.197(-3.51 to -.88)	0.001*	-2.197(-3.51 to -.88)	0.001*	-2.114(-3.43 to -.8)	0.002*	-1.956(-3.27 to -.64)	0.004*
_cons	12.763(10.98 to 14.55)	0	12.499(11.06 to 13.93)	<0.001*	12.715(11.43 to 14.)	<0.001*	12.715(11.43 to 14.)	<0.001*	12.92(11.69 to 14.15)	<0.001*	13.153(11.94 to 14.37)	<0.001*

BMI percentile:

The HbA1c% levels in participants with obesity was 9.0 (2.17), which was lower compared to the other BMI percentiles. This difference was statistically significant, $p < 0.001$, (Table 6) In table 7.2 - 61% participants in the healthy BMI percentile had a 1.6-unit HbA1c lower compared to 4% underweight BMI percentile, this was statistically significant, $p < 0.039$. Also, the 23% participants in the obesity BMI percentile had a 2.0-unit HbA1c% lower compared to 4% underweight BMI percentile, this was statistically significant, $p < 0.004$.

Figure 5: BMI Percentile CAT for DM

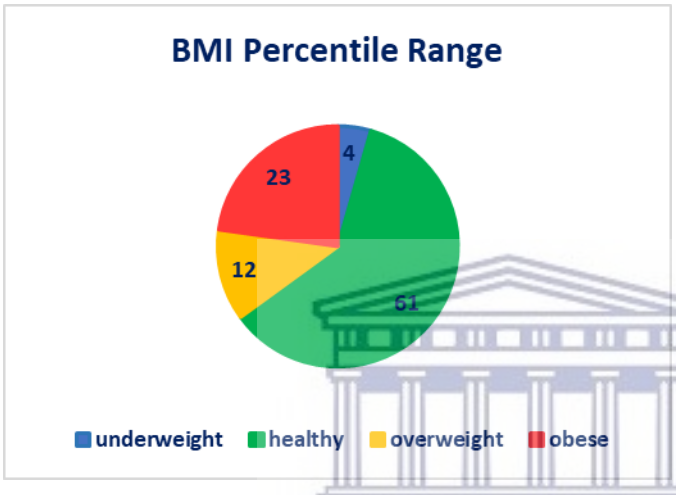


Figure 6: BMI percentile for T1DM

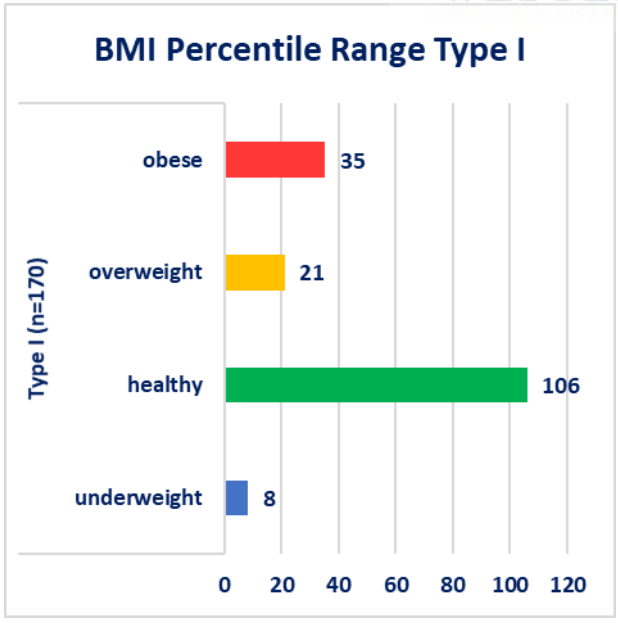
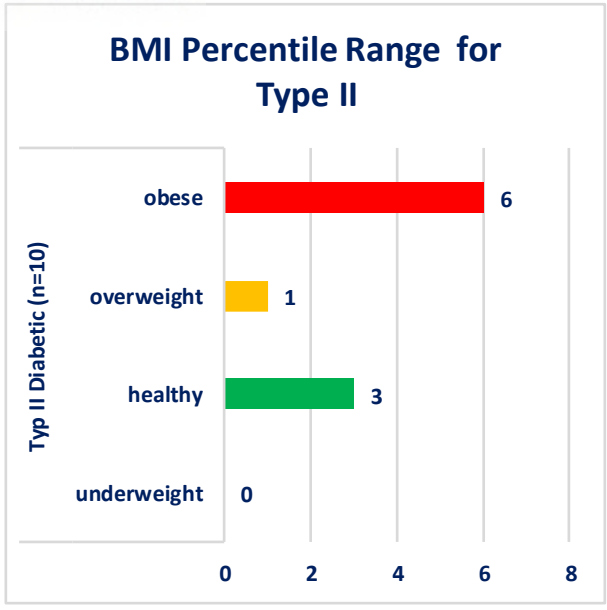


Figure 7: BMI percentile for T2DM



Management of DM Results:

The most prevalent treatment for T2DM children and adolescents in present study was oral therapy via Metformin 500mg tablet in mornings and evenings in figure 8.

The management for T1DM children and adolescents attending the Paediatric clinic that was most commonly used was the multiple daily injections (MDI) three times a day via an Insulin pen or syringe delivery system (figure 8). The most common type of insulin treatment therapy was a combination of a fast-acting – (Actrapid / Novorapid) and long-acting- (Protophane) insulin (table 8). Most participants used fast acting insulin in the morning and late afternoons between 5-6pm and long acting insulin in the mornings and evenings at 9h00pm. Results indicated that there was no association between medication and periodontal status, p =0.321and no association between medication regime and HbA1c% levels as shown (tables 6 and 7.3).

Figure 8: Diabetes Mellitus Management

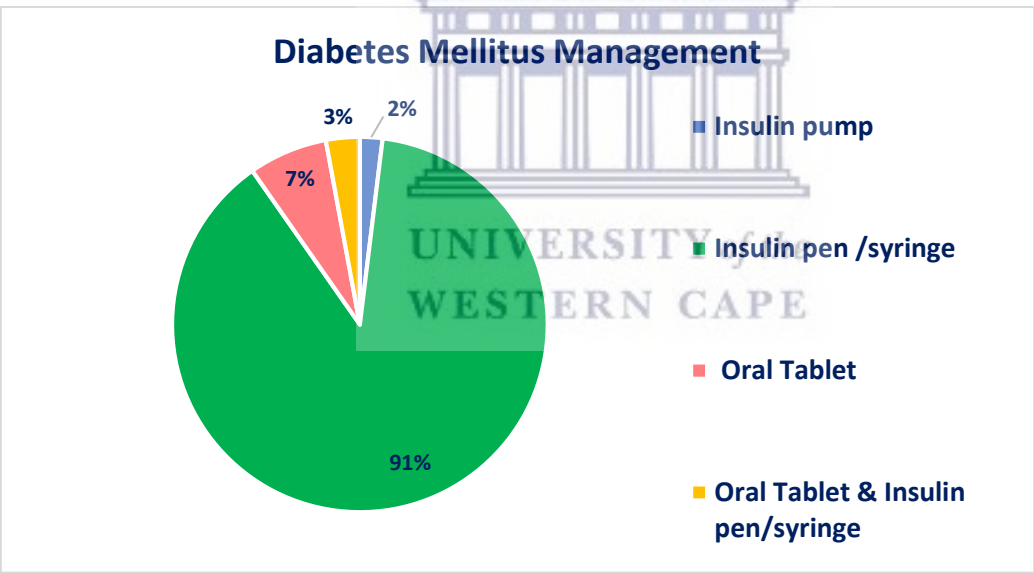
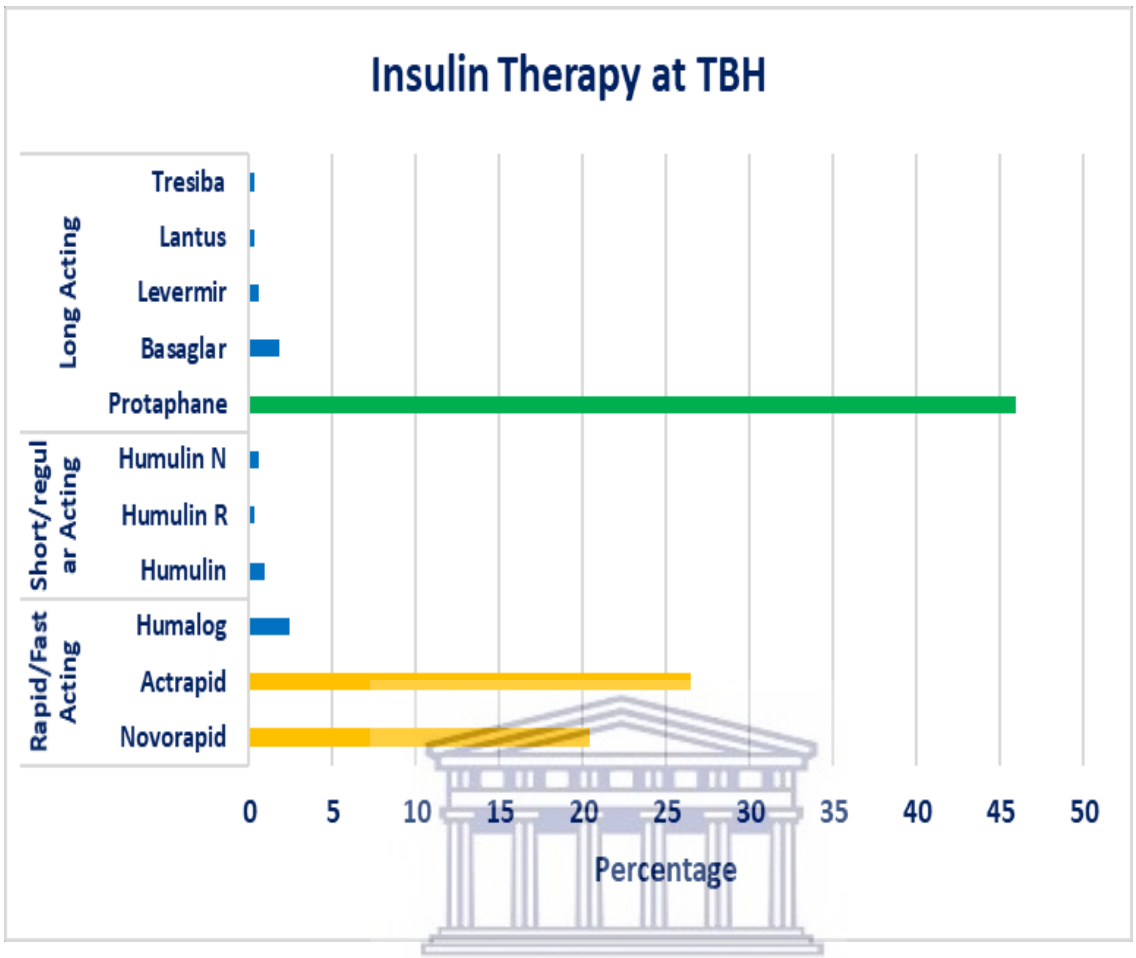


Table 7.3: Table of HbA1c% levels amongst Management of DM.

HbA1c	Simple regression	P>|t|	Model 1: multiple Regression	P>|t|	Model 2: multiple Regression	P>|t|	Model 3: multiple Regression	P>|t|	Model 4: multiple Regression	P>|t|	Model 5: multiple Regression	P>|t|
Medication												
Other												
Actrapid, Protaphane	0.132(-0.61 to 0.87)	0.726	0.142(-0.59 to 0.88)	0.704								
Novorapid, protaphane	0.24(-0.57 to 1.05)	0.558	0.304(-0.46 to 1.07)	0.434								
_cons	12.763(10.98 to 14.55)	0	12.499(11.06 to 13.93)	<0.001*	12.715(11.43 to 14.)	<0.001*	12.715(11.43 to 14.)	<0.001*	12.92(11.69 to 14.15)	<0.001*	13.153(11.94 to 14.37)	<0.001*

Table 8: Table of Insulin treatment therapy at Tygerberg Pediatric Clinic.



CHAPTER 6:

Discussion

Participant Demographics

DM has a high prevalence globally and in South Africa 6% of the overall population suffers from DM (IDF, 2017) and the estimated prevalence of T1DM for the age group 0-14yrs is 8.27%. (Kalweit et al 2015). Studies also report that the prevalence of T2DM among children and youth are increasing as obesity in these age groups increase. (Nadeau et al 2016) (Khan et al 2018).

Due to similarities in study population demographics, the following studies are used as comparison to this study;

A case-controlled study done by Lalla *et al* 2006 (New York) with 170 DM and 160 Non-DM children and adolescents between ages 6-18. The DM children and adolescents had a mean age of 11.9 (SD ± 3.3 years), 80 (50%) participants were females and the duration of diagnosis was 4.5 (SD ± 8.0 years). The case participants had an average BMI (kg/m2) of 22.2 and BMI for age (percentile) 74.4 (24.4%). The BMI- for age percentile categories were as follows; 38 (20.9%) participants were at risk of being overweight (85th-94th percentile), 46 (25.3%) were classified as overweight (95th percentile). The DM children and adolescents were managed with multiple daily injections (MDI) 130 (74.7%) and 44 (25.3%) used continuous subcutaneous insulin infusion (CSI).

Two studies by Lalla *et al* 2007 (USA) one cohort study and one case-controlled study used the same sample of DM children. 350 DM consisted of 325 (93%) type 1 DM and 25 (7%) type 2 DM between the ages 6–18. The mean age of participants was 11.33 (SD ± 3.41. 153 (44%) were females, with an average BMI, kg/m2 21.50 (6.43%) and BMI-for-age, percentile 70.84 (26.20%) BMI-for-age percentile at risk of being overweight (85th to 94th percentile) 74 (21%) overweight (95th percentile) 69 (20%) with DM treatment regime MDI 223 (64%), CSI 103 (29%) and Oral 8 (2%).

A cross sectional study by Merchat *et al* 2011(USA) with 155 participants which included 126 T1DM and 29 T2DM. The two types of DM were categorized as T1DM / T2DM with no periodontal damage and T1DM/ T2DM with periodontal damage. These categories where further subdivided according to average mean age, sex, duration of diagnosis in years. A case control study by Yaacob *et al* 2019 (Malaysia) had 32 DM participants where 22 (68.8%) participants were T1DM; 17 (53.17%) were males and 15 (46.9%) females.

Ten (31.2%) were T2DM, with 16 (50%) Males and Females between ages 10-19 years with average age 13.72 (SD ± 2.77). The duration of diagnosis with DM was divided according to >5 years 16 (50%); 5-10 years 15 (46.95) and >10 years 1 (3.1%).

Though study populations are comparable, these above studies do differ from the present study with regards to their sample population (Lalla 2006, only Type1 children and adolescents studied), or in study design (Lalla 2007, Yaacob *et al* 2019*)*, which were both case controlled studies. The mean duration of diagnosis of DM was more than 4 years in all the above studies, which was the same as the present study and none of the above studies considered the role of puberty in their participants. Despite the differences of demographic variables these studies were valuable in creating a baseline to interpret the present study findings as no previous literature regarding the association between the prevalence of periodontal health status and the metabolic control in diabetic children were conducted in South Africa.

Periodontal Health Status:

<u>BPE Results:</u>

Periodontal diseases are characterized with clinical symptoms such as gingival inflammation, bleeding and clinical attachment loss/ pockets formation of 3.5mm and more. (Zainal Abidin, Z. et al 2021) In this study the BPE was used to determine these clinical symptoms of periodontal diseases and findings confirm that there was prevalence of periodontal disease in diabetic children and adolescents attending the Tygerberg Paediatric Diabetic Clinic, as 72% of the participants had a differential diagnosis of dental biofilm induced gingivitis and 28% had a differential diagnosis of periodontitis. Our findings were similar to the previous research done by Lalla (2007, 2006) where the results showed that the presence of diabetes clearly conferred a significant risk for periodontal destruction, as the regression analysis revealed that diabetes was statistically significantly correlated to periodontitis in 6- to 11-year old children with T1DM and this association became more pronounced after the age of 12. (5.79 SD ± 5.34 vs.1.53 SD ± 3.05, unadjusted $P > 0.001$).

Yaacob *et al* (2019) also reported on the prevalence of periodontal diseases in DM children and adolescents. In their study, 1 with periodontal health, 19 with mild gingivitis, 10 with moderate gingivitis, 1 with mild chronic periodontitis and 1 with severe chronic periodontitis. The results in respect of periodontal status outcomes showed significance

(p=0.01) with deeper probing pocket depths (PPD) found in cases (DM) compared to controls (Non- DM) with 95% CI [1.55,2.08] and [1.53, 1.76] respectively.
Even though the majority of these researchers used the old American Academy of Periodontology (AAP) 1999 Classification of Periodontal Diseases and Conditions with different diagnostic indices such as gingival index and pocket depth recordings to determine the prevalence of periodontal disease, (Zainal Abidin, Z. *et al* 2021), the findings of these studies corresponded with this study's findings.

Metabolic control of DM:

DM metabolic control is considered under controlled when the HbA1c% level is or below 7.5% (Kalweit *et al* 2015) and the HbA1c% is also the method by which a clinician can monitor the treatment modality of diabetic patients (Donner *et al* 2019).
At the Paediatric Diabetic Clinic at Tygerberg hospital the children and adolescents' metabolic control are assessed every 3 months. In this study only one measurement of HbA1c % level was recorded and it was done on the same day as the BPE screening. The HbA1c% level results (table 6) of the participants had an average of 9.7%, which is above 7.5 % and indicated that the majority of the participants attending the Paediatric Diabetic clinic at Tygerberg hospital, on the day that the BPE screening were conducted, were poorly controlled diabetics.

Similarly, Yaacob *et al* 2019 also reported that the majority of their participants were uncontrolled with an HbA1c% level above 9.5%. The protocols of testing also differed as in their setting the HbA1c% level was measured every 6 months, whereas it is done at 3 monthly intervals at Tygerberg Hospital. However, the differences in monitoring of DM the present study results and literature both indicate that most of the DM children and adolescents when attending DM clinics their metabolic control are uncontrolled as they present with HbA1c% above 9,5% (Yaacob *et al* 2019).
This could be contributed to the fact that when participants visit Tygerberg Paediatric Diabetic Clinic it is around the time the majority needs a renewal on script for their medication, thus their compliance and availability to medications is low or their blood sugar reading have been high and need an adjustment to their medications or it's a newly diagnosis patient. (Kalweit et al 2015).

Metabolic control (HbA1c%) in comparison to periodontal health status:

Literature has shown that there is a bidirectional relationship between DM and periodontal diseases (Madiba and Bhayat 2018) (Stöhr, et al 2021) and that diabetic children and adolescents periodontal health status are directly related to their metabolic control of DM. (Z. et al. 2021).

In this study the average HbA1c% levels in participants with a differential diagnosis of periodontitis was 11.692 (2.11) 95% Confidence Intervals [CI] [11.08998, 12.29402] compared to those with gingivitis, at 9.040(1.62) 95% Confidence Intervals [CI] [8.75995, 9.321588] $p < 0.001$ this difference was statistically and clinically significant. (table 7). These results were in line with the findings reported by Yaacob *et al* 2019 where the uncontrolled group of children and adolescents had deeper pocket depths, which shows that there was an association between the prevalence of periodontal disease and uncontrolled metabolic glycaemic control of DM (higher HbA1c% level) and this correlates with the systematic review and meta-analysis by Zainal Abidin, Z. *et al* 2021. The present study results also reveal that the diabetic participants with gingivitis and BPE scores of two had an HbA1c% level that was a 2.7-unit level lower compare to participants with periodontitis and BPE score of 3, this was statistically significant, $p < 0.001$, (table 7.1), which indicates a controlled metabolic glycaemia (HbA1c% level) increased the probability that the participant will present with a more favourable or healthier periodontal status This association or relationship between metabolic control and periodontal disease corresponded with other studies. (Meeawat, 2013 and Diaz rosa, 2018) (Stöhr, et al 2021) (Yaacob *et al* 2019) (Zainal Abidin, Z. *et al* 2021).

Associating factors Age, Sex, Puberty, Type of Diabetes, Duration of Diabetes and BMI percentiles influencing Periodontal status and HbA1c% levels:

Age, Sex, Puberty and Duration Diabetes

Yaakob et al 2019 found in DM children and adolescents with a duration of diagnosis of DM of five years and more had an association with deeper probing pocket depth mean (SD) 2.17 ± 0.957 p = 0.03, thus the possibility of periodontitis increases. In the systematic review and meta-analysis by Zainal Abidin, Z. et al (2021) found that a duration of DM of one year will have an impact on the periodontal health status of DM children and adolescents in comparison to non-diabetic children and adolescents.

However, the present study failed to obtain a statistically significant association between age, sex, puberty and duration of disease with prevalence of periodontal diseases and HbA1c%.

Type of DM

In the study no association was made between T1DM and T2DM with prevalence of periodontal diseases and HbA1c%. However, results did show that T2DM metabolic control of DM was better than T1DM and T2DM participants HbA1c% level was a 1.4-unit HbA1c% lower and was statistically significant, $p < 0.016$. This could be due to the treatment regime of T2DM, the preferable medication in the public health sector and private sector, does not differ greatly as it does for T1DM in South Africa and globally. (Kalweit et al 2015) (Donner *et al* 2019).

BMI percentile:

In the current study the BMI was determined by the BMI- based CDC weight percentile as done by Yaacob (2019). Findings reveal an association between the BMI obesity percentile and the HbA1c% unit level. As participants in the obesity BMI percentile had lower HbA1c% level compared to the other BMI percentiles. This difference was statistically significant, $p < 0.001$. Meaning their DM metabolic control is better than participants in other BMI percentiles. It is important to note even though the group presented with a lower HbA1c% their average HbA1c % level of 9 % is still high and indicates that their DM metabolic control is still uncontrolled. This group also has the majority of participants in the sample that has T2DM. As obesity in children and adolescents increased with the increased chance of T2DM. The current study indicated that in participants with T2DM the majority were obese. This corresponds with research by (Khan et al 2018).

In this study the majority of 170 T1DM children and adolescents (figure 5 indicate that 106) had a healthy BMI percentile which corresponded with majority of diabetic children and adolescents in the Yaacob study, which also had normal / healthy BMI percentile and the same as this study no association was made between the BMI percentiles with prevalence of periodontal diseases and HbA1c%. However, in study by Lalla 2006 evidence revealed a positive and statistically significant association between the number of affected teeth by periodontal destruction and BMI percentile ($p = 0.006$), which this study failed to do.

Management of DM:

Effective management for DM is greatly influenced by the patients and parent's motivation and their lifestyle. (Donner et al 2019) (SEMDSA 2017). According to Kalweit et al 2015 the management strategies in South Africa are linked to poor glycaemic control as the public health sector treatment medication methods and availability are significantly less effective than in the private sector. As the public health sector treatment management is mainly controlled by government tender, access to regular appointments is limited in this sector. It was also found that social economic factors play an important role in the effectiveness of treatment especially the family dynamic such as single-parent households. (Kalweit et al 2015).

At Tygerberg Paediatric clinic the preferable treatment for children with T2DM was oral therapy and few of the participants had combination treatment of oral therapy with insulin therapy. The drug prescribed for T2DM participants was Metformin 500mg, which is supported by literature (Temneanu *et al* 2016) (Yaakob *et al* 2019), however in Lalla study (2007) the majority of T2DM used oral hypoglycaemic medication and MDI with insulin. For T1DM diabetic children and adolescents the most common treatment delivery system was the Multiple daily injections (MDI) and common treatment regime was the combination use of fast-acting and long-acting insulin as the literature stated. (Golden *et al* 2012). These findings are similar to medication history of Yaakob study were of the 32 Diabetic patients 18 used Insulin, 5 used oral hypoglycaemic agent (OHA), 1 used Insulin and/or OHA combined with antibiotics and 4 used Insulin and/or OHA combined with other drugs. In Lalla study 2006 and 2007 with 350 DM participants, of the 325 T1DM 223 used MDI and 103 CSI and of the 25 T2DM 8 used oral hypoglycaemic medication and 11 used both oral hypoglycaemic medication and MDI. In the present study no association was made between the various treatment regimens and the prevalence of periodontal disease and HbA1c% level.

Limitations:

- As the study was based on a cross-sectional study design there is the potential that the researcher can be affected by antecedent-consequent bias.

- The periodontal health status was determined by the BPE screening only, due to the COVID pandemic and the examination done at the outpatient Paediatric Diabetic Clinic at Tygerberg hospital, the setting for periodontal diagnosis was not as ideal as it would've been in a well-ventilated and fully equipped dental clinic. The periodontal health status was based on a differential diagnosis as bleeding on probing percentage was not obtained to give definitive diagnosis, also the preferred radiographs were not obtainable, thus the staging and grading for periodontitis could not be determined.

- There was no statistically significant association between HbA1c% levels, periodontal status and the associating factors of age, puberty, duration of DM disease and management of DM. The sample size determination at the protocol development stage was for an outcome of periodontal status compared with metabolic control, thus the current sample size may have been too limited to attain significance between these outcomes and other variables listed above.

- Working with a study population consisting of children can have many challenges as they have a mixed dentition and can be complicated to diagnose periodontitis accurately.

- Puberty was not directly assessed, but only inferred from the age of the child.

- A proper comparison between a basal bolus regimen (insulin therapy) and the modified conventional regimen could have identified a difference between periodontal health status and HbA1c% levels.

- The present study matchup between the 2 DM groups was less favourable due to the participant sample size including only a small sample of T2DM children and adolescents and this difference between T1DM and T2DM can be why no statistically significant association between periodontal status was made.

- Oral health practices can be impeded which means that the prevalence of periodontal disease is not only diagnosed in diabetic children and by adding a control group to study can add valuable to study to confirm the association between the prevalence of periodontal diseases and their metabolic control of DM.

CHAPTER 7:

Conclusion

This study was conducted to find if there is an association between periodontal health status and the metabolic control in Diabetic children and adolescents at Tygerberg Hospital in the Western Cape, South Africa.

The results indicated an association between periodontal health status, as determined by BPE, and the metabolic control, as determined by HbA1c %. As the BPE value increased, so did the HbA1c% value, indicating poor metabolic control with the presence of a differential diagnosis of periodontitis. These findings are supported by previous studies as seen in Appendix A and literature review.

Findings in the study also revealed that if the HbA1c % level decreased by 2.7 units the prevalence of a lower BPE code (0-2) increases. A 1.4 unit decrease in HbA1c% for subjects with T2DM showed an increased prevalence of a lower BPE code (0-2).

Recommendations

- Further research is required relating to periodontal health status of Diabetic children and adolescents in the Western Cape, South Africa with larger sample sizes to support the results obtained in this study and studies should include non-diabetic children in the sample This study only use the BPE screening tool, if more diagnostic tools were including in a study such as bleeding on probing percentage and plaque percentage and radiographs a definitive diagnosis can be made to support findings.

- Oral health educational programs specifically tailored for children and adolescents with diabetes must be designed and implemented to promote periodontal disease prevention with an emphasis on the benefits of good oral hygiene practices such as the use of dental floss, fluoridated toothpastes and regular dental visits where treatment can be provided.

- In consideration of the present findings, oral health care workers and clinicians must consider oral screenings as a standard of care for children and adolescents with diabetes.

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Addendum A1: Findings of clinical studies

Correlaton beetwen type 1 diabetes mellitus (DM)and periodontal disease Daković, D. et al. (2015)

Author/ year	Study population	Duration of diabetes mellitus Type 1 (years)	Glycated haemoglobin level – HbA1c (%)	Gingival parameters	Periodontal parameters	Main findings
Rylander et al. 1987. [56]	46 patients with DM1 mean age 22.1 ± 4.7 41 healthy individuals mean age 22.3 ± 2.1	10–14 years – 24 children 15–19 years – 20 children > 20 years – 2 children	< 7.0 – 2 children 7.0–8.9 – 13 children 9.0–11.9 – 17 children 12.0–13.9 – 12 children > 14.0 – 2 children	PI GI	PPD (mm) only probing depths of > 3 mm CAL (mm) measured at 4 sites around each tooth GR (mm)	Higher frequency with clinical attachment loss on buccal sites, and GR in diabetic group than in the control group. The presence of dental biofilm on these tooth surfaces was equally low in the 2 groups; in interproximal regions very low frequency of periodontal tissue breakdown
Rosenthal et al. 1988. [57]	52 patients with DM1 mean 14.5 years	NR	Patients with DM1 without periodontitis HbA1c – 12.56% DM1 patients with periodontitis HbA1c – 9.17%	PI GI SBI	PPD (mm) measured at 4 sites around each tooth	GI and SBI were significantly higher in the periodontitis group. PI was not significantly different between the groups. Diabetics with periodontitis had a significantly lower glycosylated hemoglobin than diabetics without periodontitis
Sandholm et al. 1989. [58]	85 patients with DM1 mean 15.1 ± 1.5 SV years 85 healthy adolescents mean 15.1 ± 1.6 years	mean 5.2 ± 3.5 years	mean 10.9 ± 2.2 (SD)	PI GI RC	CPITN (registrated using 16, 21, 26, 36, 41 and 46 as index teeth) PPD (mm) measured at 4 sites around each tooth	Finnish adolescents with DM1 had more gingivitis than their age- and sex-matched healthy controls. There were no differences in periodontal destruction as measured in number of pockets > 4 mm. All gingivitis does not lead to periodontitis, but periodontitis preceeded by gingivitis
Pinson et al. 1995. [14]	26 patients with DM1 mean 13.50 ± 3.36 years included one set of identical twins 24 control subjects mean 13.54 ± 3.08 years	mean 6.58 ± 3.66 years, with 24 of the patients having had DM1 for at least 5 years	3.4–6.1 – 6 children 6.2–9.0 – 9 children > 9.0 – 11 children	PI GI gingival bleeding on probing	PPD (mm) measured at 4 sites of each tooth CAL (mm) measured at 4 sites around each tooth GR (mm)	Significant association of age with pocket probing depth, clinical attachment levels, and bleeding in the diabetic group. Duration of diabetics and metabolic control level were not related to periodontal parameters. DM1 had a significant association with severity of periodontitis when tooth sites in patients groups were statistically compared
Karjalainen et Knuuttila 1996. [59]	12 patients with DM1 mean 10.6 ± 2.4 years 80 healthy subjects mean 14.5 ± 1.6 years	NR	on the 3rd day in hospital 14.9 ± 3.8% on the 12rd day in hospital 13.1 ± 2.9% on the 1st outpatient visit at the hospital 1 month later 8.4 ± 1.5%	PI % of visible plaque gingival bleeding on probing % of bleeding surfaces	NR	Hyperglycaemia and poor metabolic control of diabetes increased gingival bleeding. Not all gingivitis proceeds into a destructive periodontal disease. Lower resistance toward dental plaque in poorly-controled patients indicates that biological alterations could take place during glucose balance deterioration
Firatli 1997. [16]	77 patients with DM1 mean age 12.47 years 77 healthy volunteers mean age 12.59 years	mean 48.34 ± 23.69 months	children with DM1 9.34 ± 3.99% control group 5.96 ± 1.02%	PI GI gingival bleeding on probing	PPD (mm) measured at 4 sites of each tooth CAL (mm) measured at 4 sites around each tooth	A positive correlation between the duration of DM1 and CAL. Relationship between the duration of DM1 and severity of periodontal alterations
Aren et al. 2003. [18]	Group 1: 16 newly diagnosed children; mean age 12.8 ± 5.8 Group 2: 16 children with diabetes of long duration; mean age 12.7 ± 3.8 Group 3: 16 healthy subjects; mean age 12.4 ± 1.9	Children in Group 1 with newly diagnosed DM1 and Group 2 with diabetes of long duration;	Group 1 8.01 ± 1.79 % Group 2 8.43 ± 1.36 % Group 3 5.05 ± 0.36 %	PI GI gingival bleeding on probing	PPD (mm)	Glycaemic status of the diabetic subjects affects the periodontal probing depths, salivary pH, buffering capacity, and peroxidase activity.

Lalla etal. 2006. [11]	182 patients with DM1 mean 11.9 ± 3.3 years 160 healthy children mean 10.9 ± 2.6 years	mean 4.5 ± 8.0 years Age of diagno-sis DM1 mean 7.8 ± 4.0 years	< 7.5% – 55 children 7.5–9.5% – 80 children > 9.5% – 36 children	PI % of sitesPI GI % of bleeding sites GI score of2 or 3 de- notes a bleeding site	PPD (mm) measured at4 sites of each tooth CAL (mm) measured at 4 sites around each tooth Number of affected teeth(at least one site with at-tachment los > 2 mm on at least two teeth)	Periodontal destruction was increased in children and adolescents with DM1. Diabetes started earlier in lifethan formerly recognized. Duration of DM1, and especially mean A1c, were not significantly correlated with the number of affected teeth.
Lalla etal. 2007. [17]	350 patients with DM1 mean 11.33 ± 3.41 years	mean 3.96 ± 3.39 years Age of diagno-sis DM1 mean 7.54 ± 4.0 years	< 7.5% – 97 children 7.5–9.5% – 170 chil-dren > 9.5% – 73 chil-dren	PI % of sitesPI GI % of bleeding sites GI GI score of2 or 3 de- notes a bleeding site	PPD (mm) measured at4 sites of each tooth CAL (mm) measured at 4 sites around each tooth Number of affected teeth(at least one site with at-techment loss > 2 mm on at least two teeth)	Increased periodontal destruction in children and ado-lescents with DM1 was connected with increased meta-bolic control. If gingival bleeding and attachment loss measurements were both used, the present study revealed that hemo-globin A1c significantly correlated with periodontitis
Dakovićand Pavlović 2008. [12]	187 patients with DM1 mean 12.4 ± 4.2 years 178 healthy children mean 11.4 ± 4.3 years	mean 4.9 ± 3.5 years Age of diagno-sis DM1 mean 7.9 ± 4.2 years	< 7.5% – 20 children 7.5–9.5% – 95 children > 9.5% – 65 children	PI % of sitesPI GI % of bleeding sites GI GBI bleed-ing/plaque ratio	PPD (mm) measured at4 sites of each tooth CAL (mm) measured at4 sites around eachtooth Number (%)of patients with perio- dontitis and any level of CAL, and CAL > 1,5 mm	Periodontal disease was more prevalent in children with DM1 and was in function of metabolic control and dis-ease duration. The gingival inflammation in the evolu- tion of periodontal destruction was more important in children with DM1 than in subjects without the disease

Addendum A2: Findings of clinical studies

Table of findings of cross-sectional studies from 2000-2019 by Zainal Abidin, Z. *et al* . (2021)

Table 1. Summary of characteristic for the included in the systematic review

Author/year	Country	Type of study	Type of diabetic (*n*)	Age range of diabetic (mean ± SD) range	No of controls	Age range of control (mean ± SD) range	Periodontal parameters assessed
Al Khabbaz [33] et al. (2013)	Kuwait	Comparative Cross-sectional	T1DM (95)	(9.1 ± 3.9) 4–14	61	(8.9 ± 2.2) 4–14	Plaque Index Gingival Index Bleeding on Probing Clinical Attachment Loss
Lalla et al. (2006)[34]	New York	Case control	T1DM (170) Unspecified (12)	(10.9 ± 2.6) 6–18	160	(11.9 ± 3.3) 6–18	Plaque Index Gingival Index Clinical Attachment Loss
Babu et al. (2018)[37]	India	Comparative, Cross-sectional	T1DM (80)	6–18	80	6–18	Percentage of bleeding sites Gingival Index
Aren et al. (2003)[40]	Turkey	Comparative, Cross-sectional	T1DM (16)	(12.7 ± 3.8)	16	(12.4 ± 1.9)	Plaque Index Gingival Index Bleeding on Probing Probing Depth
Ismail et al. (2017)[42]	Hong Kong	Comparative, Cross-sectional	T1DM (32)	(12 ± 4) 4–17	32	(12 ± 4) 4–17	Plaque index Gingival index Bleeding on Probing Calculus index
Yaakob et al. (2019)[41]	Malaysia	Comparative, Cross-sectional	T1DM (22) T2DM (10)	(13.72 ± 2.77) 8–19	32	(13.53 ± 2.5) 8–19	Plaque index Gingival index Percentage of Bleeding Probing Depth
Dakovic and Pavlovic. (2008)[43]	Serbia	Comparative, Cross-sectional	T1DM (187)	(11.4 ± 4.3) 6–18	178	(12.4 ± 4.2) 6–18	Plaque Index Gingival Index Clinical Attachment Loss Probing Depth Percentage of Bleeding sites
Sadeghi et al. (2017)[38]	Iran	Comparative, Cross-sectional	T1DM (50)	6–18	50	6–18	Plaque Index Gingival Index Calculus index Probing Depth
Orbak et al. (2004)[39]	Turkey	Comparative, Cross-sectional	T1DM (50)	(9 ± 0.14) 6–14	50	(9 ± 0.11) 6–14	Plaque Index Gingival Index Calculus index
Siudikiene_ et al. (2005)[36]	Lithuania	Comparative, Cross-sectional	T1DM (70)	(13.6 ± 1.61) 10–15	70	(13.6 ± 1.61) 10–15	Plaque index Gingival index Calculus index
Tagelsir et al. (2011)[35]	Belgium	Comparative, Cross-sectional	T1DM (52)	(9.84 ± 3.52) 3–16	50	2–16	Plaque index

Addendum B: Questionnaire: Medical Diabetic History:

Patient Record No.:

Date of Birth:____/____/____ Age:_____ Sex:

F	M

Parents/Guardians Name: _____

Diagnosis with Diabetes:

TYPE I	**TYPE II**

Duration of Disease: _____

Other Medical Conditions and Allergies:_____

Treatment Regimen:
Insulin Pen (I/M) or multiple injection:

Short Acting:_____ Units(am) _____

Units 6h00pm _____

Sliding scale _____

Long acting:_____ Units(am) _____

Units 9h00pm _____

Sliding scale _____

Intermediate:_____ Units(am) _____

Other medication:_____...

Insulin Pump (I/M):

GLYSOSYLATE HEMOGLOBIN (Hb-A_{1C}):
DATE OF LAST READING:_____

NORMAL :(3-6%)	**CONTROLED (6-10%)**	**POORLY CONTROLED (8-15%)**

Addendum B: Patient Examination:

Patient Record No.:

Date of Birth:_____/_____/_____ **Age:_____.** **Sex:**

F	M

Parents/ Guardians Name: _____

Contact number:_____

BMI (Body Mass Index):

In puberty:

Yes	No

Social History:

Yes	No

Smoker Smokes ___ per day Smokes for ___ years

Intra-Oral Examination:

Excellent	Good	Fair	Bad	Poor

Oral health

Periodontal Status evaluation:

0	No pockets <3.5 mm, no calculus/overhangs, no bleeding after probing (black band completely visible)
1	No pockets <3.5 mm, no calculus/overhangs, but bleeding after probing (black band completely visible)
2	No pockets <3.5 mm, but supra- or sub gingival calculus/overhangs (black band completely visible)
3	Probing depth 3.5-5.5 mm (black band partially visible, indicating pocket of 4-5 mm)
4	Probing depth >5.5 mm (black band entirely within the pocket, indicating pocket of 6 mm or more
*	Furcation involvement

BPE Index Scoring codes
BPE codes 0 - 2 are used in 7 to 11-year-olds (during the mixed dentition phase)
Full range of codes 0, 1, 2, 3, 4 and * can be used in 12 to 17-year-olds (when the permanent teeth erupt)

Bleeding on probing			
supra- or sub gingival calculus/overhangs (black band completely visible)			
No pockets <3.5 mm,			
Pockets:3.5-5.5 mm (black band partially visible)			
Pockets:>5.5 mm (black band entirely within the pocket)			
Furcation involvement			
Score/Code:	**16/55**	**11/51**	**26/65**
Score/Code:	**31/71**	**36/76**	**46/85**
Bleeding on probing			
supra- or sub gingival calculus/overhangs (black band completely visible)			
No pockets <3.5 mm,			
Pockets:3.5-5.5 mm (black band partially visible)			
Pockets:>5.5 mm (black band entirely within the pocket,)			
Furcation involvement			

General Hard Tissue

Edentulous	
Partially edentulous	
Fully dentate	

Description:

Addendum C: Research study: Ethics approval letter:

UNIVERSITY of the WESTERN CAPE

OFFICE OF THE DIRECTOR: RESEARCH
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13 October 2020

Dr L Scholtz-Evans
Faculty of Dentistry

Ethics Reference Number: BM19/9/5

Project Title: The comparison of the Periodontal health status and metabolic control in diabetic children and adolescents at Tygerberg Hospital

Approval Period: 17 April 2020 - 17 April 2023

I hereby certify that the Biomedical Science Research Ethics Committee of the University of the Western Cape approved the scientific methodology and ethics of the above mentioned research project.

Any amendments, extension or other modifications to the protocol must be submitted to the Ethics Committee for approval.

The permission to conduct the study must be submitted to BMREC for record keeping.

Please remember to submit a progress report in good time for annual renewal.

The Committee must be informed of any serious adverse event and/or termination of the study.

Ms Patricia Josias
Research Ethics Committee Officer
University of the Western Cape

Addendum D: Research study: patient information and consent document

Parental Informed Consent Document

PROJECT TITLE
The Comparison of Periodontal Health Status and Metabolic Control in Diabetic Children and Adolescents at Tygerberg Hospital.

INTRODUCTION
Your child has been invited to join a research study to look at the relationship between the health of their gums and their diabetic control.
Please take whatever time you need to discuss the study with your family and friends, or anyone else you wish to. The decision to let you child join, or not to join, is up to you.
In this research study, we are evaluating if there is a relationship between gum health and control of diabetes mellitus. We know that the inflammation of gum disease can make it difficult to control the disease of diabetes. This information is not known for younger diabetic patients in South Africa.

WHAT IS INVOLVED IN THE STUDY?
Your child will be asked to have an examination of their teeth and gums. The dentist will look and take measurements around each tooth. If Radiographs are needed, they will also be taken. The findings will be recorded and your child will be referred for any treatment needs diagnosed at this visit. The examination will take about 1 hour and the treatment will differ according to the needs of each child and will be conducted at a second and subsequent visit/s.
The investigators may stop the study or take your child out of the study at any time they judge it is in your child's best interest. They may also remove your child from the study for various other reasons. They can do this without your consent.
Your child can stop participating at any time. If your child stops he/she will not lose any benefits of access to dental treatment needs.

RISKS
This study involves the following risks.
If your child already suffers from bleeding gums, the examination may cause minor bleeding at the margin of the gum line.
The examination may be sensitive in children who have severe forms of gum disease.
There may also be other risks that we cannot predict.

BENEFITS TO TAKING PART IN THE STUDY?
It is reasonable to expect the following benefits from this research:
The diagnosis of unknown gum and other dental diseases and facilitated access to treatment is the greatest benefit of participating in this study. However, we can't guarantee that your child will personally experience benefits from participating in this study if they are uncooperative in the dental chair or do not keep set appointments.
Others may benefit in the future from the information we find in this study as we will discover the role that gum disease plays in the ability to affect diabetic control.

CONFIDENTIALITY
Your child's name will not be used when data from this study are published. Every effort will be made to keep clinical records, research records, and other personal information confidential.
We will take the following steps to keep information confidential, and to protect it from unauthorized disclosure, tampering, or damage: A code will be placed on the survey and other

collected data and through the use of an identification key the researcher will be able to link your survey to your identity. All information collected will be locked in cabinets and password protected computers. No one has the right to access this information except the researcher. He has only access for the purpose of research.

INCENTIVES
There are no incentives to participate in this study.

YOUR RIGHTS AS A RESEARCH PARTICIPANT?
Participation in this study is voluntary. Your child has the right not to participate at all or to leave the study at any time. Deciding not to participate or choosing to leave the study will not result in any penalty or loss of benefits to which your child is entitled, and it will not harm his/her relationship with the dentist or the diabetic clinic.
If your child decides to leave the study, the procedure is: to contact the researcher, whose name and number is at the bottom of this page.

CONTACTS FOR QUESTIONS OR PROBLEMS?
Call Dr. Scholtz-Evans at 021937 3154/3167/3168/ 0727194942 or email ldscholtz@uwc.ac.za, if you have questions about the study, any problems, if your child experiences any unexpected physical or psychological discomforts, any injuries, or think that something unusual or unexpected is happening.

BMREC UWC Private Bag x17 Bellville 7535 Tel: + 27 21 959 4111 Email: research-ethics@uwc.ac.za	The Dean Prof. N. Myburgh Faculty of Dentistry Tygerberg Campus 0219373001 Email: nmyburgh@uwc.ac.za	The Head of Department Dr A Jeftha Faculty of Dentistry Tygerberg Campus 021 9373158/ 3186 Email: ajeftha@uwc.ac.za

Parental Consent Document

Title of Research Project:

The Comparison of Periodontal Health Status and Metabolic Control in Diabetic Children and Adolescents at Tygerberg Hospital.

Permission for a Child to Participate in Research

As parent or legal guardian, I authorize _____ (child's name) to become a participant in the research study described in the information form.

Child's Date of Birth _____

Parent or Legal Guardian's Signature Date

_____

_____

Upon signing, the parent or legal guardian will receive a copy of this form, and the original will be held in the subject's research record.

BMREC UWC Private Bag x17 Bellville 7535 Tel: + 27 21 959 4111 Email: research-ethics@uwc.ac.za	The Dean Prof. N. Myburgh Faculty of Dentistry Tygerberg Campus 0219373001 Email: nmyburgh@uwc.ac.za	The Head of Department Dr A Jeftha Faculty of Dentistry Tygerberg Campus 021 9373158/ 3186 Email: ajeftha@uwc.ac.za

Inligting en toestemmingsvorm vir Ouers

NAVORSINGS TITEL:
The Comparison of Periodontal Health Status and Metabolic Control in Diabetic Children and Adolescents at Tygerberg Hospital.

INLEIDING:
Ons vra hiermee toestemming dat jou kind mag deelneem aan n navorsingsprojek wat die verhouding van jou kind se vermoe om diabetes te beheer met die gesondheid van jou kind se tandvleis vergelyk.
Neem asseblief tyd om hierdie inligling te lees en jou besluit hieroor, met jou familie en of vriende te deel. Die besluit om jou kind by hierdie navorsing te betrek, of nie te betrek nie, is in jou beheer en jou keuse.
Vorige navorsing het getoon dat siektes van die tandvleis wel pasiente met Diabetes laat sukkel om hul diabetes te beheer. Hierdie navorsing op kinders in Suid Afrika is nog nie beskikbaar nie, en dus wil ons graag hierdie navorsing doen.

VERDERE INLIGTING OOR DIE NAVORSINGSPROJEK.
Ons gaan jou kind se tandvleis en tande ondersoek.
Die tandaarts gaan ook die spasie tussen die tand en die tandvleis meet, dus die manier is waarop ons die gesondheid van die tandvleis bepaal.
As daar x-strale van die tande nodig is, sal ons dit ook laat doen. Alle informasie wat ons van jou kind se mond kry sal op dieselfde manier gedokumenteer word as waneer hy/sy vir n normale tandheelkundige ondersoek gaan.
Indien jou kind tandheelkundige behandeling nodig sou hê, sal ons reelings tref om jou kind na ‘n tandaarts by ons Fakulteit te stuur vir hierdie behandeling.
Die ondersoek sal omtrent 1uur duur en enige behandeling sal op ‘n opvolg afsprake gedoen word.
Die navorsers mag jou kind se betrokkenheid by die projek stop as dit nie in die welbehae van jou kind is. Dit kan sonder jou bemagtiging gebeur.
Jou kind mag ook sy/haar betrokkenheid by hierdie projek enige tyd stop. Dit sal sy/haar verdere tandheelkundige behandeling nie negatief beinvloed nie.

RISIKOS
Hierdie navorsing behels die volgende risikos:
Jou kind se tandvleis mag gedurende die ondersoek bloei, dit sal definitief bloei as hy/sy al klaar by die huis bloeding ervaar waneer hulle hul tande borsel. Hierdie bloeding sal nie jou kind op enige manier siek maak of benadeel nie.
Kinders met erge inflammatoriese tandvleissiektes mag miskien ongerief gedurende die ondersoek ondervind. Ander risikos kan op hierdie tydperk nie voorspel word nie.

VOORDELE VAN BETROKKENHEID BY HIERDIE PROJEK
Die volgende voordele kan verwag word:
Onbekende mond of tand siektes sal gediagnoseer en behandel word. Hierdie voordeel is alleenlik moontlik, as jou kind wel samewerking tot behandeling sal gee en as hy of sy hul afprake nakom.
Ander jong volwassenes wat ook Tipe 1 diabetes het sal voordeel uit die resultate van hierdie navorsing hê.

VERTROULIKHEID
Alle besonderhede van jou kind, hul name en kliniese inligting sal vertroulik hanteer word. Jou kind se naam en identiteit sal nie saam met sy kliniese inligting bekend gemaak word waneer ons die uitslae van hierdie navorsing publiseer nie.

A kode sal aan die document van jou kind se kliniese inligting wees en nie hul name nie. Die navorser sal alleenlik die lys van name en kodes op sy persoonlike rekenaar bere. Dit sal deur mate van a wagwoord beskerm word.

AANSPORINGS
Daar is geen aansporings vir die deelname by hierdie navorsing nie.

DIE REGTE VAN DEELNAMERS
Betrokkenheid by hierdie navorsing is vrywillig. Jou kind het op enige tydperk die reg om te onttrek. Jou kind sal sy/haar toegang tot tandheelkundige en diabetes behandeling nie negatief afekteer nie, al besluit hul om te ontrek.
Indien jou kind besluit om te onttrek, moet u asseblief die navorser in kennis stel. Sy besonderhede is hieronder aangeheg.

KONTAKTE
Dr. Scholtz-Evans 021 937 3154/3167/3168/0727194942 of e-pos ldscholtz@uwc.ac.za

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Inligting en toestemmingsvorm vir Ouers

NAVORSINGS TITEL:
The Comparison of Periodontal Health Status and Metabolic Control in Diabetic Children and Adolescents at Tygerberg Hospital.

Toestemming vir my kind om aan die narvorsing deel te neem:

As ouer of wettige voog, gee ek hiermee toestemming dat _____

_____ (volle naam van kind) by hierdie navorsingsprojek betrokke mag wees.

Geboortedatum van kind _____

Ouer of Wettige Voog se handtekening_____ _____ Datum _____

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Iphepha-mvume lomzali

ISIHLOKO
The Comparison of Periodontal Health Status and Metabolic Control in Diabetic Children and Adolescents at Tygerberg Hospital.

INTSHAYELELO
Umntwana wakho uyamenywa abeyinxalenye yophando, phado elo elijonga ubudlelwane kwimpilo yentsini kunye nendlela abalawula ngayo idiabethi.
Thatha ixesha elaneleyo ukuthetha nezihlobo, izizalwane malunga nesisifundo. Isigqibo sokuvumela umntwana wakho abeyinxalenye yesisifundo sixhomekeke kuwe.
Koluphando sijonga ubudlelwane kwimpilo yentsini kunye nendlela abalawula ngayo idiabethi, siyayazi ukuvutha kwesigulo sentsini kwenza kubenzima ukulawula idiabethi. Olu lwazi alaziwa kubantu abaselula eMzantsi Afrika.

YINTONI ECHAPHAZELEKAYO KWESISIFUNDO?
Umntwana wakho uzakucelwa ukuhlolwa intsini kunye namazinyo. Ugqirha wamazinyo uzakuhlola, athathe umlinganiselo kwizinyo ngalinye. Ukubangaba imifanekiso iyadingeka nayo izakuthathwa. Iziphumo zizokushicilelwa umntwana wakho uzokusiwa okanye anikwe amachiza awadingayo koluphando. Olu hlolo lizokuthatha iyure enye kwaye amachiza azakohluka kumntwana ngamnye kuxhomekeke kwizidingo zomntwana ngamnye.
Umphandi angasimisa esisifundo okanye akhuphe umntwana wakho koluphando nangaliphi na ixesha ebona kufanelekile. Bangamkhupha umntwana koluphando nangezinye izizathu, bangayenza lonto ngaphandle kwemvume yakho.
Umntwana wakho angarhoxa ukuthatha inxaxheba nangaliphi na ixesha. Nokuba umntwana wakho utrhe wayeka ukuba kwesisifundo akuzukuphulukana nokufumana amachiza kugqirha wamazinyo.

MNGCIPHEKO
Oluphando luquka imingcipheko elandelayo:
Ukubangaba umntwana wakho uhlutshwa zintsini ezophayo, uhlolo lungenza kubekhona ukopha kwentsini. Uhlolo lungangabalungeli abantu abophelwa zintsini ngokumandla. Ingakhona neminye imingcipheko esingenoyibona okwangoku.

INZUZO YOKUBAYINXALENYE YESISIFUNDO
Ukuhlolwa kwentsini nezinye izifo ezinxulumana namazinyo, ukufumana amachiza zinzuzo azakuthi azifumane umntwana, kodwa asinokutsho ngokuphelelyo ukuba umntwana wakho akazukwazi ukusebenzisana nogqirha wamazinyo. Abanye bangafumana inzuzo ngolwazi oluzakufumaneka koluphando, lwazi olo luzakujonga indima edlalwa sisifo sentsini ekulawuleni idiabethi.

IMFIHLO
Igama lomntwana lizokuba yimfihlo, xakukhutshwa iziphumo zophando. Sizakuqinisekisa lonke ulwazi olushicilelweyo luyimfihlo.
Sizakuthatha lamanyathelo alangelayo ukuqinisekisa uphando luyimfihlo nokulikhusela kumonakalo. Ikhowudi izakusetyenziswa njenngendlela umphandi azakuthi abonengayo inkcukhaca zomntwana ngamnye. Lonke uphando oluqokelelweyo lizakugcina kwikhabhathi kunye nekhompuyitha ezitixiweyo. Akukho bani onelungelo lokufumana olu lwazi ngaphandle komphandi.

INKUTHAZO
Akukho nkuthazo yokuyinxalenye yoluphando.

ILUNGELO LAKHO NJENGOMNTU OTHATHA INXAXHEBA
Ukubayinxalenye yoluphando ayisosinyanzeliso. Umntwana wakho unelungelo lokurhoxa koluphando kwaye angayeka nangaliphi na ixesha. Ukuyeka kwakhe akuzukwenza umntwana aphulukane nenzuzo azifaneleyo, akuzubanafuthe libi kubudlelwane bakhe nogqirha wamazinyo. Ukubangaba umntwana uthatha isigqibo sokurhoxa koluphando anagatsalela umxeba umphandi igama lakhe nenombolo yomxeba yakhe iyafumaneka ezantsi kweliphepha.

INOMBOLO MALUNGA NEMIBUZO OKANYE INGCACISO
Fowunela Dr Scholtz-Evans kulenombolo 021 937 3154/3167/3168/0727194942 okanye ldscholtz@uwc.ac.za. Ukubangaba unemibuzo ngoluphando, okanye ingxaki athi umntwana abenayo nezinye izinto ofuna ukuziqonda.

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Iphepha-mvume lomzali

ISIHLOKO
The Comparison of Periodontal Health Status and Metabolic Control in Diabetic Children and Adolescents at Tygerberg Hospital.

Imvume yokuba umntwana abeyinxalenye yoluphando

Mna mzali, ndinikka imvume _____(igama lomntwana) athathe inxaxheba kwesisifundo sichaziweyo ngasentla.

Usuku lokuzalwa komntwana _____

Isistyikityo somzali _____ umhla _____

Ngokusayina, umzali uzakufumana ikopi yeliphepha, eyokwenene ikopi igcinwe.

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PARTICIPANT INFORMATION LEAFLET AND ASSENT FORM

TITLE OF THE RESEARCH PROJECT:
The Comparison of Periodontal Health Status and Metabolic Control in Diabetic Children and Adolescents at Tygerberg Hospital.

RESEARCHERS NAME(S): Dr Lèzaan Scholtz-Evans
ADDRESS: Dept of Oral Medicine and Periodontology, D Floor, UWC Faculty of Dentistry, Tygerberg Hospital. Francie Van Zyl Road. Cape Town.
CONTACT NUMBER: 021 937 3154/3167/3168 or 0727194942

What is RESEARCH?
Research is something we do to find new knowledge about the way things (and people) work. We use research projects or studies to help us find out more about disease or illness. Research also helps us to find better ways of helping, or treating children who are sick.

What is this research project all about?
This project is about the relationship between gum disease and how your diabetes is controlled.

Why have I been invited to take part in this research project?
You have been invited because you have been diagnosed and treated for diabetes.

Who is doing the research?
I am Lèzaan Scholtz-Evans a student at the University of the Western Cape and I am studying further about how to diagnose and treat adults and children with gum diseases.

What will happen to me in this study?
I will look, feel and measure around your gums in your mouth. If I find any diseases, I will give you follow up appointments for treatment in either my clinic or other clinics within our dental hospital.

Can anything bad happen to me?
If you suffer from bleeding gums, your gums may bleed during the examination. You may have some pain if your gum disease is very bad. If you have any problems with what I do, you are allowed to tell your parents and they can tell me if you experience any problems while I examine your mouth.

Can anything good happen to me?
Yes. You may have some diseases in your mouth that you are not aware of. We will then find them, send you for the proper treatment, and teach you how to prevent them from happening again.

Will anyone know I am in the study?
Only your parents and I will know that you are in the study. I will not use your name on any documents that I have to share with others, who help me to analyze what I find in your mouth. I will keep your name separate and save it on a computer that only I will have access to because it will require a password, that only I will know.

Who can I talk to about the study?
Me, Dr. Scholtz-Evans or
My supervisor, Dr. Jeftha
021 937 3158 or
BMREC

UWC
Private Bag x17
Bellville
7535
Tel: + 27 21 959 4111
Email: research-ethics@uwc.ac.za

What if I do not want to do this?
You are free to refuse to be included in this study. You can stop your participation in this study at any time. Even if you choose to stop, we will still see that you get your dental treatment if you need it.

Do you understand this research study and are you willing to take part in it?
YES NO

Has the researcher answered all your questions?

YES NO

Do you understand that you can pull out of the study at any time?

YES NO

_____ _____
Signature of Child **Date**

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DEELNAME INLIGTINGS EN INSTEMMINGSVORM

NAVORSINGS TITEL:
The Comparison of Periodontal Health Status and Metabolic Control in Diabetic Children and Adolescents at Tygerberg Hospital.

NAME VAN NAVORSER: Dr Lèzaan Scholtz-Evans
ADRES: Dept of Oral Medicine and Periodontology, D Floor, UWC Faculty of Dentistry, Tygerberg Hospital. Francie Van Zyl Road. Cape Town.
KONTAK NOMMERS: 021 937 3154/3167/3168 of 0727194942

WAT IS NAVORSING?
Navorsing is die manier vir navorsers om nuwe inligting bekom. Navorsingsprojekte word gebruik om ons te help om nuwe inligting oor siektes te bekom. Navorsing help ook om uit te vind wat is die beste maniere vir die behandeling van siektes in kinders en volwassesnes.

INLIGTING OOR HIERDIE NAVORSINGSPROJEK?
Hierdie projek sal die verhouding tussen die beheer van Tipe 1 Diabetes en tandvleis siektes ondersoek.

HOEKOM IS EK GEVRA OM HIERMEE BETROKKE TE RAAK?
Jy is betrokke omdat jy met Tipe 1 Diabetes gediagnoseer en behandel word.

WIE DOEN HIERDIE NAVORSING?
My naam is Dr. Lèzaan Scholtz-Evans, ek is n student by die Universiteit van Wes Kaapland en ek studeer hoe om kinders met tandvleis siektes te diagnoseer en te behandel.

WAT GAAN MET MY IN HIERDIE PROJEK GEBEUR?
Ek gaan in jou mond kyk, voel en by jou tandvleis meet. As ek wel mondsiektes diagnoseer, sale ek jou vir verdere behandeling verwys.

KAN ENIG IETS SLEG MET MY GEBEUR?
As jou tandvleis bloei wanneer jy jou tande by die huis borsel, mag dit ook bloei wanneer ek jou tandvleis meet. As jy tandvleis siektes wel het, mag die ondersoek n bietjie seer wees. Jy moet jou ouers vertel as enigiets jou pla terwyl jy jou ondersoek ondergaan.

WAT SAL VIR MY HIERMEE GOED WEES?
Dit sal goed wees om uit te vind of jy enige siektes in jou mond het, en daarvoor behandeling te kan kry.

WIE SAL WEET DAT EK BY HIERDIE NAVORSING BETROKKE IS?
Jou ouers en die navorser sal alleenlik van jou betrokkenheid bewus wees. Jou naam sal nie met ander gedeel word nie, behalwe as jy wel verdere behandel nodig het.

MET KAN EK HIERDIE NAVORSING BESPREEK ?
Ek, Dr Scholtz-Evans of
My Oorsiener, Dr Jeftha
021 937 3158 of
BMREC

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MAG EK NEE SE?
Jy mag beslis nie hiermee betrokke word as jy nie wil nie. Jy mag ook jou betrokkenheid op enige tyd onttrek. Jy sal nog steeds behandeling vir enige mondsiektes en jou diabetes ontvang.

Verstaan jy hierdie inligting, en is jy beried om deel te neem?
Ja Nee

Het ons al jou vrae beantwoord?
Ja Nee

Verstaan jy dat jy enige tyd mag onttrek?
Ja Nee

_____ _____
Handtekening van Kind Datum

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Ulwazi nesiqinisekiso sokubayinxalenye yoluphando

Isihloko sesifundo: The Comparison of Periodontal Health Status and Metabolic Control in Diabetic Children and Adolescents at Tygerberg Hospital

Amagama abaphandi: Dr Lèzaan Scholtz-Evans
Idilesi: Dept of Oral Medicine and Periodontology, D Floor, UWC Faculty of Dentistry, Tygerberg Hospital. Francie Van Zyl Road. Cape Town
.
Inombolo yomxeba: 021 937 3154/3167/3168 or 0727194942

Yintoni uphando?
Uphando yinto esiyenzayo ukufumana ulwazi olutsha ngendlela izinto ezisebenza ngayo. Sisebenzisa uphando ukufumana ulwazi oluphangaleleyo ngezifo okanye izigulo. Uphando lusinceda sifumane indlela ezingcono zokunceda nokunyanga abantwana abagulayo.

Lungantoni oluphando?
Koluphando sijonga ubudlelwane kwimpilo yentsini kunye nendlela abalawula ngayo idiabethi.

Kutheni ndiyinxalenye yoluphando?
Uyinxalenye yoluphando kuba ungumntu ophila nediabethi.

Ngubani owenza oluphando?
Ndingu Lèzaan Scholtz-Evans, umfundi kwiDyunivesithi yseNtshona-koloni.Ndenza izifundo eziqwalasela indlela zokubona nokunceda abantu abadala kunye nabantwana abanesifo sentsini.

Kuzokwenzeka ntoni kum koluphando?
Ndizokujonga, ndive kwaye ndithathe umlinganiselo kwintsini ezisemlonyeni wakho. Ukubangaba ndifumana isigulo okanye isifo ndizakunika amachiza okanye ndikuthumele kugqirha wamazinyo.

Ingakhona into embi enokwenzeka kum?
Ukuba usokoliswa zintsini ezophayo, intsini zakho zingopha xa ndikuhlola. Ungava ubuhlungu ukuba isifo sakho sentsini sigqithisile. Nayiphi ingxaki engathi ivele ngexesha ndikuhlola, ungaxelela umzali wakho anditsalele umxeba.

Ingakhona into entle enokwenzeka?
Ewe. Kungakho isifo emlonyeni wakho ongasaziyo singasifumana sikuthumele kumachiza afanekileyo singaphindi sibekho kwakho.

Ukhona umntu ongayzi ndiyinxalenye yoluphando?
Mna kunye nabazali bakho kuphela. Andiyikulisebenzisa igama lakho kumaphepha endiwanika abantu endisebenza nabo. Ndizokuligcina liyimfihlo igama lakho.
Ndingathetha nabani ngoluphando?
mna, Me, Dr Scholtz-Evans
okanye Dr Jeftha
021 937 3158
Okanye BMREC
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Ukubangaba andifuni kubayinxalenye yoluphando?
Unelungelo lokungathathi nxaxheba koluphando. Ungarhoxa nangaliphi ixesha ufuna. Nokuba uthe warhoxa sizokuqhubeka sikunika amachiza owadingayo.

Uyaluqonda oluphando, kwaye uyafuna ukubayinxalenye?
EWE HAYI
Ingaba umphandi uphendule yonke imibuzo onayo?
EWE HAYI
Uyayiqonda ungarhoxa koluphando nangaliphi ixesha?
EWE HAYI

_____ _____
Isityikityo somntwana Umhla

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