

IMPACT OF SUGAR-FREE VS CONVENTIONAL TOOTHPASTE OF SALIVARY GLUCOSE & PH IN INDIVIDUALS WITH TYPE-2 DIABETES

Dissertation Submitted to



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in

Pharmaceutical Management

by

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Under the Supervision and Guidance of

Dr. Rahul Sharma

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Mr.Rajendraprasad Bal
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Sub: Completion of summer internship.

Dear Mr.Rajendraprasad Bal,

This is to certify that Mr. Rajendraprasad Bal has successfully completed a 3 month internship at Muller & Phipps (I) Ltd from 10th March 2025 to 10th June 2025. Throughout the duration of the internship, he demonstrated dedication, enthusiasm, and a strong willingness to learn and contribute to our team.

We are confident that he has gained valuable insights and experience during his internship, and we believe he will continue to excel in his future endeavours.

We extend our best wishes for his academic and professional journey ahead.

Regards,

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CERTIFICATE

This is to certify that the dissertation titled “**Impact of Sugar Free Vs Conventional Toothpaste of Salivary Glucose & pH in Individuals with type-2 Diabetes**” is a record of the research work undertaken by **Rajendraprasad Bal** in partial fulfilment of the requirements for the award of the degree of MBA (Pharmaceutical Management) from the IIHMR University, Jaipur under my guidance and supervision and his approach to the research study has been sincere, scientific and analytical.



Faculty guide: **Dr. Rahul Sharma**

IIHMR University, Jaipur

DATE:



School Dean:

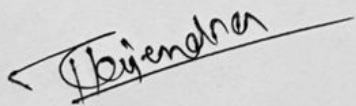
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DECLARATION BY STUDENT

I, **Rajendraprasad Bal** hereby declare that this dissertation titled “**Impact of Sugar-Free vs. Conventional Toothpaste on Salivary Glucose and pH in Individuals with Type-2 Diabetes**” is the Bonafide record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledge in the text



Rajendraprasad Bal

Date:- 16/06/2025

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ABSTRACT

Diabetes mellitus is one of the most prevalent chronic metabolic disorders globally, affecting millions of individuals across all age groups. While its systemic effects are well documented, its oral health implications are often under-recognized but equally significant. Oral manifestations in diabetic patients can range from dry mouth (xerostomia), burning sensation, and altered taste to more severe conditions such as gingivitis, periodontitis, delayed wound healing, and increased susceptibility to oral infections.

One of the key contributors to oral complications in diabetics is the elevated salivary glucose level. Hyperglycaemia in systemic circulation can reflect in the composition of saliva, leading to a higher concentration of glucose in the oral cavity. This excess glucose provides an ideal environment for the proliferation of saccharolytic (sugar-metabolizing) bacteria, which further accelerates the degradation of oral tissues by producing acids and inflammatory mediators. These bacteria disrupt the oral microbiome balance and contribute to the progression of dental caries, plaque formation, and periodontal diseases.

The altered salivary composition, combined with reduced salivary flow and immune dysfunction commonly seen in diabetic individuals, creates a hostile environment for maintaining oral hygiene. Moreover, diabetics tend to experience impaired collagen metabolism, making gum tissues more prone to inflammation, bleeding, and slow healing. If not managed effectively, these oral complications can impact overall health, nutrition, and quality of life.

Given this background, targeted oral care interventions are crucial. A therapeutic toothpaste specifically designed for diabetics, incorporating ingredients that address both microbial overgrowth and tissue repair such as Coenzyme Q10, herbal antimicrobials (Neem, Tulsi, Turmeric), antioxidants (Grape Seed Extract), and regenerative agents (Nano-hydroxyapatite) can provide comprehensive support. Such formulations aim not only to control bacterial load and reduce inflammation but also to enhance gum healing and protect against further oral damage.

In conclusion, the bidirectional relationship between diabetes and oral health necessitates the development of specialized oral care products that consider the unique biochemical and microbial challenges present in diabetic individuals. A well-designed diabetic toothpaste can serve as a preventive and therapeutic tool, supporting both oral hygiene and systemic well-being.

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Introduction

Diabetes Mellitus (DM) is one of the most widespread endocrine disorders, marked by insufficient insulin production or the body's reduced sensitivity to insulin's effects. A key consequence of DM is hyperglycemia, which can lead to significant damage across various organs, causing both microvascular and macrovascular complications over time.

India, with its rapidly aging population, is expected to witness a sharp rise in diabetes prevalence. Globally, around 8.3% of the adult population is affected by diabetes, and by 2030, this number is projected to rise to approximately 551.9 million people, representing nearly 10% of the global adult population. Among these, Type 2 DM ranks as the fifth most common chronic disease and is a leading cause of death in older adults. Indian populations, particularly Asian Indians, are genetically and lifestyle-wise more prone to developing Type 2 DM. Currently, India ranks second in terms of the number of diabetic individuals, with estimates suggesting that by 2025 and 2030, the diabetic population could reach 57.2 million and 101.2 million respectively, making India the potential diabetes capital of the world.

Chronic diabetes has profound effects on oral health, often manifesting as periodontal disease, gingival inflammation, tooth loss, altered taste sensation, increased risk of oral infections, and salivary gland dysfunction. These oral complications are largely a result of poorly managed blood glucose levels, which directly influence the oral environment.

Scientific studies have shown that elevated blood glucose levels in diabetics also lead to increased salivary glucose. Saliva serves as a key diagnostic fluid, reflecting the individual's overall metabolic, nutritional, and immune status. Glucose, being a small molecule, can pass through the blood vessels and gingival fluid into the saliva. The high glucose content in saliva

supports the growth of sugar-metabolizing bacteria, which in turn produce acids that lower salivary pH and contribute to the breakdown of oral tissues. A more acidic salivary environment is commonly observed in diabetic patients and favors the proliferation of pathogenic microorganisms, worsening oral health outcomes.

Toothpaste and toothbrushes are the most accessible tools for maintaining daily oral hygiene. Beyond mechanical cleaning, toothpaste also influences salivary chemistry, including pH levels.

Material and Method

This investigation followed a randomized, controlled crossover design and was carried out in two separate phases. Prior to inclusion, all participants provided written informed consent. The study received ethical clearance from the Institutional Ethics Committee of ACPM Dental College, Dhule.

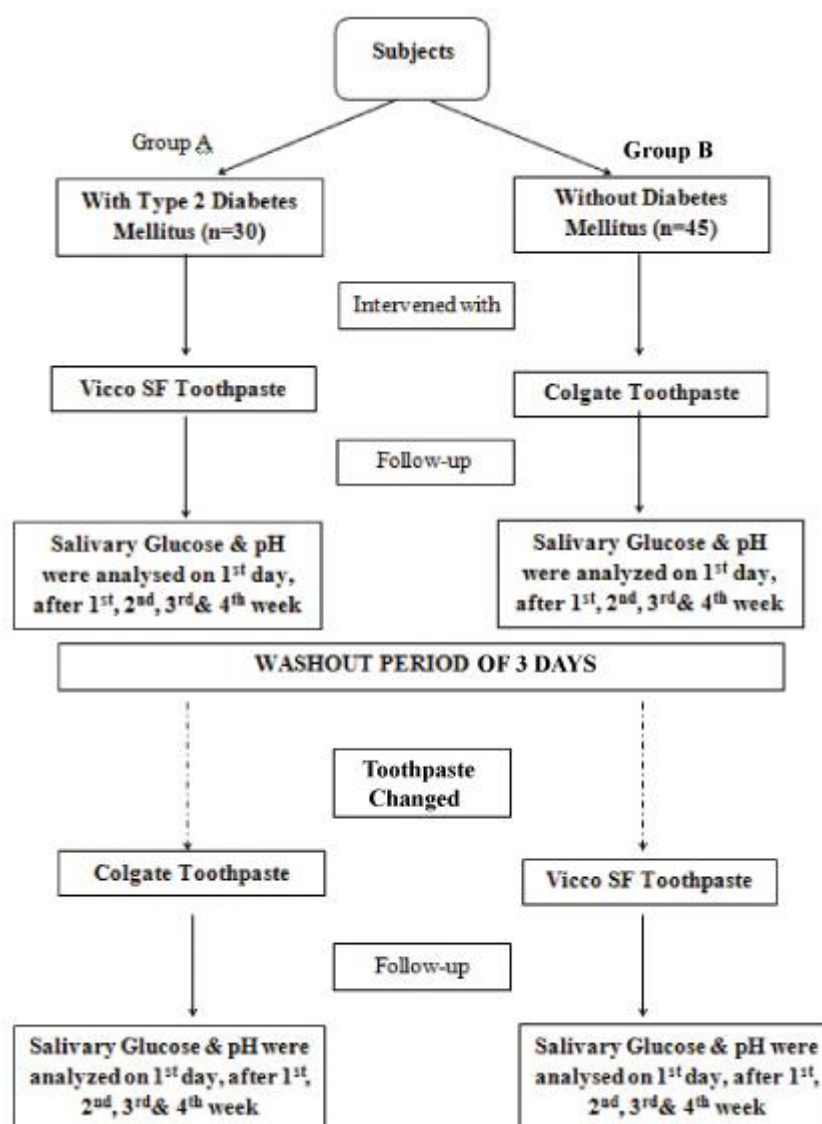
A preliminary pilot study was conducted to determine the appropriate sample size for the main trial. The calculation was based on the formula: $N = 2T^2 \times S^2 / D^2$, where T (2.13) corresponds to a 95% confidence interval, D represents the minimum anticipated difference in salivary glucose levels between diabetic and non-diabetic individuals, and S is the pooled standard deviation. From this, a minimum of 20 participants per group was required. A participant ratio of 1:1.5 was adopted for the main study.

Following the pilot, the diabetic group (Group A) consisted of 30 participants aged 38 to 66 years, with a mean age of 53. All were previously diagnosed with Type 2 Diabetes Mellitus.

Subjects were selected randomly using a lottery method facilitated by the administrative officer of Archana Diabetologic Hospital. The control group (Group B) included 45 non-diabetic individuals aged between 34 and 64 years, with an average age of 51.

Participant Eligibility Criteria

Eligible participants included individuals diagnosed with either controlled or uncontrolled Type 2 Diabetes, as well as first-, second-, or third-degree relatives of diabetic patients. A minimum of 20 functional teeth was required for inclusion. Individuals were excluded if they had systemic illnesses unrelated to diabetes or if they had habits such as chewing tobacco or betel nut.



Study Design and Flow of Intervention

The study was conducted in two distinct phases using a randomized crossover design. In Phase

1, participants from Group A (diabetic individuals) were instructed to use a sugar-free toothpaste (Vicco SF), while those in Group B (non-diabetic controls) were given a regular toothpaste (Colgate). Both groups were advised to maintain a brushing routine of twice daily for a period of four weeks.

Following the completion of Phase 1, a washout period of approximately 2.5 to 3 days was implemented. During this time, all participants were asked to brush using only water, to help eliminate any residual effects of the previous toothpaste and ensure no carryover effect influenced the next phase. Importantly, participants were instructed not to make any changes to their brushing habits apart from the temporary switch to water.

In Phase 2, the toothpaste types were switched between the groups. Thus, Group A participants began using the regular toothpaste (Colgate), and Group B participants started using the sugar-free toothpaste (Vicco SF), again for a duration of four weeks with continued instruction to brush twice daily.

Saliva Sample Collection and Blinding

During both phases of the study, unstimulated saliva samples were collected from all subjects at five time points: day 1, and then at the end of each week (week 1, 2, 3, and 4). For consistency and reliability, samples were collected once daily at each time point. These samples were gathered before and after brushing, using sterile containers for analysis.

To maintain objectivity and eliminate bias, both the study participants and the laboratory personnel analyzing the saliva samples were blinded to the type of toothpaste being used. To facilitate blinding, all toothpaste tubes were wrapped in brown-colored sellotape, concealing the brand. Saliva samples were labeled systematically—"bb" for samples collected *before brushing* (e.g., bb1, bb2) and "ab" for samples collected *after brushing* (e.g., ab1, ab2)—to ensure proper identification without revealing group allocation.

Saliva Collection Procedure

Saliva samples were obtained during the early morning hours to reduce the influence of food intake and daily activities on the sample composition. Participants were instructed to avoid eating, drinking, or performing any oral hygiene routines for at least one hour before sample collection. They were then asked to allow saliva to naturally pool in the mouth and gently expel it into a sterile container pre-filled with sodium fluoride, which acted as a preservative. Approximately 1.5 ml of unstimulated saliva was collected from each subject.

Following collection, the samples were promptly stored in a refrigerated environment at 4°C to maintain their biochemical stability. Samples were transported to the laboratory at the earliest opportunity to ensure their quality for further testing.

Assessment of Salivary pH and Glucose Concentration

The pH of each saliva sample was determined using a digital pH meter (Hanna Instruments – Hanna pH Tester Checker), allowing for precise and repeatable measurements.

To analyze salivary glucose levels, the collected samples were first centrifuged using a Remi Centrifuge (Mumbai). One milliliter of each unstimulated saliva sample was spun at 3000 revolutions per minute for 20 minutes to obtain a clear supernatant. This supernatant was used for glucose analysis.

The glucose concentration was measured using the Glucose Oxidase-Peroxidase (GOD-POD) enzymatic method with a commercial diagnostic kit (ERBA, Germany). For each test, 1000 µl of the glucose reagent was dispensed into a test tube, followed by the addition of 10 µl of the saliva sample. The mixture was thoroughly mixed and incubated for 15 minutes to allow for the reaction to occur. Glucose levels were then measured using an ERBA CHEM-5 Plus semi-automated biochemical analyzer.

Statistical Analysis

The data collected throughout the study was dichotomous in nature, meaning it involved categorical outcomes that required the use of suitable statistical tools to extract valid and interpretable conclusions. To comprehensively assess the effectiveness of the toothpaste interventions both within the same group over time and between different groups—a combination of intragroup and intergroup statistical XVI, which is widely accepted for clinical

research due to its robustness and reliability.

Intragroup Analysis

To measure the impact of each intervention within the same group over the course of the study, paired t-tests were employed. This test is specifically designed for repeated measurements or related samples, such as observations made on the same subjects at different time points. In this study, the paired t-test was used to compare each group's baseline measurements (i.e., values recorded before brushing on Day 1) with the values recorded after brushing at the end of the fourth week. This allowed the researchers to evaluate whether the interventions (use of sugar-free or regular toothpaste) led to statistically significant changes in the selected salivary parameters—namely salivary glucose levels and salivary pH—within each group over time.

Intergroup Analysis

For comparisons between different groups, where the observations are independent of each other, an unpaired t-test (also known as an independent samples t-test) was used. This test is suitable for evaluating whether there is a significant difference in mean values between two unrelated groups. The intergroup comparisons were carefully structured to ensure a thorough understanding of how the interventions performed relative to each other across both study phases.

This multi-layered analytical framework provided a detailed view of the treatment effects, capturing both within-group trends and between-group contrasts. By comparing different group and phase combinations, the study aimed to uncover any meaningful variations in the outcomes that could be directly attributed to the type of toothpaste used and the diabetic status of the participants.

All statistical analyses were carried out using SPSS software version XVI, ensuring that data processing, calculations, and hypothesis testing were conducted in a systematic and standardized manner. A predefined level of statistical significance was applied in interpreting the results of the t-tests, guiding the conclusions regarding the efficacy and comparative performance of the toothpaste formulations. The use of both paired and unpaired t-tests allowed the study to not only detect significant internal improvements but also to highlight differential treatment responses across diabetic and non-diabetic groups.

Discussion

Hyperglycemia is the primary and immediate metabolic effect of diabetes mellitus (DM). Over time, the metabolic disruptions associated with DM lead to widespread secondary changes affecting various organ systems, imposing a significant health burden on individuals. As blood glucose levels rise in diabetic individuals, there is a corresponding increase in salivary glucose levels.

It has been found that salivary pH is generally lower in people with diabetes than in healthy individuals, indicating an altered oral environment.

Numerous studies support a positive correlation between blood glucose and salivary glucose levels, although some studies—particularly in pediatric diabetic populations—have reported a less pronounced association.

In this randomized crossover trial, participants were divided into two groups: Group A, consisting of 30 subjects with Type 2 DM, and Group B, comprising 45 non-diabetic individuals. In Phase 1, Group A used sugar-free toothpaste (Vicco SF), while Group B used regular toothpaste (Colgate) for a period of four weeks. After a washout period, toothpastes were switched in Phase 2, and the new intervention continued for another four weeks.

To evaluate the study parameters, unstimulated whole saliva was collected at multiple intervals, potentially affecting diagnostic accuracy.

The saliva collection was done using the spitting method into sterile containers containing sodium fluoride, which acts to stabilize glucose levels by preventing enzymatic breakdown. For salivary pH estimation, a digital pH meter (Hanna Instruments) was used, as it offers precise numerical readings, making it more suitable for comparative studies than the commonly used strip-based method.

Salivary glucose levels were measured using the glucose oxidase-peroxidase (GOD-POD) method, a technique widely supported and validated in scientific literature for its reliability in detecting glucose concentrations.

The results demonstrated that the use of sugar-free toothpaste resulted in a notable decrease in salivary glucose levels and a significant increase in salivary pH in both diabetic and non-diabetic groups. These effects were significantly more pronounced in comparison to the groups using regular toothpaste. Interestingly, the intergroup comparison between Phase 1 Group A

and Phase 2 Group B revealed no statistically significant difference. This is likely because both groups were using the same sugar-free toothpaste (Vicco SF) during their respective phases, which aligns with the expectation of similar outcomes.

The increase in salivary pH among users of sugar-free toothpaste may also be explained by the reduction in salivary glucose, as high glucose levels can foster an acidic oral environment.

On the other hand, sorbitol, commonly used as a humectant and sugar substitute in many commercial toothpastes, has not been shown to significantly affect oral microorganisms or glucose clearance in the oral cavity. However, an increase in salivary pH was also observed in individuals using regular toothpaste. This could be attributed to the mechanical action of tooth brushing, which can reduce microbial load, thereby indirectly influencing salivary pH and glucose levels.

Salivary pH is naturally regulated, or buffered, by components such as salivary proteins and phosphate ions. However, the most substantial buffering comes from bicarbonate ions, which are metabolic by-products found in saliva. These ions help neutralize acids produced by oral bacteria during carbohydrate fermentation. As metabolic activity increases, so does the bicarbonate concentration, leading to a rise in salivary pH, making it more alkaline.

Recommendations

The evaluation of sugar-free toothpaste demands a thorough and multidimensional approach that encompasses its acceptability, clinical efficacy, and potential adverse effects over an extended period of use. This holistic assessment is particularly vital for high-risk populations such as individuals with diabetes, where oral health is closely linked to systemic health. The influence of sugar-free toothpaste extends beyond immediate oral cleanliness, potentially impacting long-term oral tissue integrity and salivary biochemistry. Therefore, systematic observation of changes in both hard and soft tissues of the oral cavity during and after regular use is essential to determine the product's overall safety and therapeutic value.

User acceptability is a cornerstone in the continued use of any toothpaste. Factors such as flavor, texture, foaming capacity, and aftertaste play a critical role in determining whether

individuals will adhere to a routine oral hygiene regimen. For sugar-free toothpastes to gain widespread usage, they must meet user expectations in these sensory domains. Collecting feedback at regular intervals regarding the sensory experience ensures an objective measure of acceptance and helps in making necessary formulation improvements to promote long-term compliance.

In terms of efficacy, the focus lies on the toothpaste's ability to support or enhance oral hygiene, prevent dental decay, reduce plaque formation, and promote periodontal health. Sugar-free toothpastes often utilize non-fermentable sweeteners such as xylitol or sorbitol, which are not metabolized by oral bacteria, thus minimizing acid production that can damage tooth enamel. Assessment tools like plaque indices, gingival bleeding scores, and periodontal evaluations before and after intervention provide concrete evidence of clinical benefits. Additionally, evaluating the toothpaste's role in preventing enamel demineralization and encouraging remineralization is essential to comprehensively gauge its effectiveness.

Although rare in high-quality formulations, adverse effects must be systematically investigated, particularly with long-term use. Potential reactions may include oral mucosal irritation, hypersensitivity reactions, allergic responses, or enamel erosion due to abrasive ingredients. Extended use might also result in changes to taste perception or contribute to xerostomia (dry mouth). Continuous monitoring of these parameters ensures that any negative outcomes are promptly identified, allowing for a robust safety profile of the toothpaste.

An important component of evaluating sugar-free toothpaste involves observing clinical changes in the oral tissues. Initial baseline examinations should comprehensively document the condition of teeth (including caries, enamel wear, and sensitivity) and soft tissues (such as gingival health, mucosal lesions, or signs of inflammation). Follow-up assessments at specified intervals enable the comparison of oral health status over time, revealing whether the toothpaste contributes to improvement or deterioration in oral tissue condition.

A significant indicator of the biochemical effectiveness of sugar-free toothpaste is its effect on salivary parameters, particularly glucose concentration and pH. Elevated salivary glucose levels, commonly found in diabetic individuals, can promote the growth of pathogenic microbes and increase acid production, thereby elevating the risk of caries and periodontal disease. Sugar-free toothpaste formulations, by incorporating non-cariogenic sweeteners, may reduce salivary glucose levels, which in turn can elevate salivary pH. A shift toward a more alkaline environment fosters remineralization and reduces bacterial acid damage. Tracking these changes through serial salivary analysis offers objective data on the biochemical contributions of the toothpaste to **oral homeostasis**.

Microbial modulation is another vital aspect of assessment. The oral cavity harbors a dynamic microbiome, and maintaining a healthy balance between beneficial and harmful microorganisms is crucial for oral health. Traditional toothpastes that contain fermentable sugars may encourage the growth of acidogenic bacteria such as *Streptococcus mutans*, which are closely associated with dental caries. In contrast, sugar-free toothpastes—especially those containing xylitol—have been shown to suppress cariogenic bacteria and reduce overall plaque accumulation. Conducting microbial evaluations using saliva or plaque samples to analyze bacterial counts and species diversity before and after long-term use can reveal how these toothpastes influence the oral microbial ecosystem, particularly in vulnerable populations such as diabetic individuals.

Conclusion

Study Summary: The Benefits of Sugar-Free Toothpaste for Diabetic Patients

Our study investigated the effects of sugar-free toothpaste on oral health parameters in subjects with diabetes mellitus, focusing particularly on salivary glucose levels, salivary pH, and overall oral health status. The findings demonstrate that regular use of sugar-free toothpaste positively influences these critical factors, making it a valuable recommendation for diabetic individuals. Diabetes mellitus often leads to elevated salivary glucose, creating an environment conducive to the growth of harmful oral bacteria. This imbalance contributes to increased risk of dental caries, periodontal disease, and other oral infections. Managing salivary glucose and maintaining an optimal pH level are therefore essential for preventing these complications. The sugar-free toothpaste evaluated in this study contains non-cariogenic sweeteners, which do not elevate salivary glucose and help maintain a neutral to alkaline pH in the oral cavity.

Our results show a significant reduction in salivary glucose levels after prolonged use of the sugar-free toothpaste, accompanied by a corresponding increase in salivary pH. This shift creates a less acidic environment, which is less favorable for the proliferation of acidogenic and cariogenic bacteria. Consequently, users experienced improvements in plaque control, reduced gingival inflammation, and enhanced overall oral tissue health.

Furthermore, the toothpaste was well accepted by the study participants, with no adverse effects reported on the oral mucosa or tooth enamel. The positive changes observed in both hard and soft tissues of the oral cavity underscore the toothpaste's safety and efficacy.

In conclusion, this study supports the recommendation of sugar-free toothpaste for individuals with diabetes mellitus as an effective oral care product. By helping regulate salivary glucose and pH, sugar-free toothpaste plays a vital role in maintaining oral health and preventing disease progression in this high-risk group. Continued use as part of a comprehensive oral hygiene regimen can contribute significantly to improved quality of life for diabetic patients.

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