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An in Vivo Clinical Evaluation of the Primary Stability of Osseointegrated Implants in Type II Diabetes Patients Using Novel Radio Frequency Analysis (RFA)– A Cone Beam Computed Tomography Based Original Research Study

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KEYWORDS

Radiofrequency Analysis (RFA), Cone Beam Computer Tomography (CBCT), Diabetes mellitus (DM), Stability, Implantology, Implant Stability Quotient

ABSTRACT:

Aim: This study aims to evaluate the primary stability of osseointegrated implants in patients with type II diabetes using novel radiofrequency analysis (RFA).

Materials and Methods: The study involved 40 participants aged .20 healthy individuals and 20 with type II diabetes mellitus, who were all missing a mandibular first premolar. Implant primary stability was assessed using Resonance Frequency Analysis (RFA). After placing 20 implants in each group and evaluated stability using the Implant Stability Quotient (ISQ).

Statistical Analysis and Results: This study examined 40 patients with missing mandibular first premolars, split into two groups, 20 healthy individuals (Group 1) and 20 with type II diabetes mellitus (Group 2). Participants, aged 35 to 60, included 25 males and 15 females. The research evaluated dental implant stability using the Implant Stability Quotient (ISQ) via the Osstell device. Group 1 showed higher ISQ values (buccal 80.1 ± 6 Ncm, lingual 72.4 ± 6 Ncm, mesial 69.5 ± 5 Ncm, distal 65.3 ± 3 Ncm) compared to Group 2 (buccal 47.1 ± 3 Ncm, lingual 43.4 ± 5 Ncm, mesial 37.5 ± 3 Ncm, distal 35.3 ± 2 Ncm).

Conclusion: This study concluded thathealthy individuals show better primary stability after dental implants compared to type II diabetes patients. The findings suggest that RFA is a more reliable measure for assessing primary stability, impacting treatment planning and outcomes in dental implantology.

Introduction

Diabetes mellitus (DM) is a chronic condition marked by high blood sugar levels, resulting from insufficient insulin production or improper usage of insulin.[1,2] Effective management is crucial to prevent complications, which include microvascular issues (like retinopathy, nephropathy, and neuropathy) and macrovascular problems that increase heart disease risk. There are three main types of diabetes type 1 (5-10% of cases), where the immune system attacks insulin-producing cells type 2 (about 90% of cases), where the body cannot use insulin effectively, and gestational diabetes, which occurs during pregnancy.[3,4] Diabetes

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and prediabetes pose significant public health challenges and affect various health aspects, including dental health. One of the critical areas affected is the complexity of dental procedures, particularly the placement of dental implants.[5,6] For patients with diabetes, these procedures can present unique challenges, but advancements in technology have paved the way for safer and more effective implant placements.[7,8] The success of dental implants hinges on their ability to achieve stability within the jawbone. This stability involves two essential components: primary stability, which refers to the immediate fit of the implant at the moment of insertion, and secondary stability, which develops gradually as the jawbone heals and integrates with the implant over time.[9,10] Several factors influence the stability of dental implants, including the quality and density of the surrounding bone, the design and material of the implant itself, and the surgical techniques employed during the procedure.[11,12] To thoroughly assess the stability of a dental implant following surgical placement, dental professionals frequently utilize a sophisticated method known as resonant frequency analysis (RFA). Osstell Starting in 2001, the first commercially available RFA device was released for clinical use. This cutting-edge, non-invasive technique provides crucial insights by measuring the response of the implant to applied pressures, effectively capturing the intricate vibrational patterns that occur during the healing process. By meticulously analyzing these vibrations, dentists are able to gather valuable data that informs their clinical decisions, ultimately enhancing patient care and improving overall treatment outcomes. The Implant Stability Test (IST) values range from 1 to 99, indicating stability levels. Values below 60 indicate low stability, 60-65 indicate medium stability, and above 65 indicate high stability.[13-15] Successful dental implant procedures rely on the quality and quantity of bone at the implant site, which affects stability. Utilizing cone-beam computed tomography (CBCT) scans and primary stability parameters before placement can help assess initial stability and the potential for early loading.[16] This study focuses on evaluating the primary stability of osseointegrated implants in Type II diabetic patients, in all the four surfaces to gain insights into their unique healing responses.

Materials and Methods

This study involved a total of 40 patients, comprising both healthy individuals and those diagnosed with type II diabetes mellitus. Initially, 60 patients indicated that they had lost their mandibular first premolar; however, only 40 of these expressed a willingness to proceed with the placement of dental implants along with implant-supported prostheses. Prior to starting the implant procedures, thorough screening was conducted for these 40 participants, and informed consent was obtained to ensure their understanding and agreement to proceed. The selected patients were categorized into two distinct groups for the purpose of the study. Group I consisted of 20 healthy individuals who received implants in their mandibular first premolar sites. To evaluate the primary stability of the implants, effective techniques such as Resonance Frequency Analysis (RFA) was used. Group II was comprised of 20 patients with type II diabetes mellitus, who likewise had implants placed in their mandibular first premolar. This group was assessed for primary stability using the same advanced methods employed in Group I, ensuring a consistent approach to data collection and analysis.The study included participants aged 35 to 60 years and encompassed both males and females. The inclusion criteria required participants to have a missing mandibular first premolar, while the exclusion criteria disqualified patients suffering from hypertension. To standardize the study, all surgical procedures were conducted by the same experienced operator. All implants were placed using the same implant kit. CBCT scans were performed to assess the size of the implants to be placed and evaluate bone density. Before starting the procedure, patients were rinsed with chlorhexidine, and local anesthesia was administered. The mucosal flap was then reflected, and drills were used for implant placement. A total of 20 implants were placed in healthy individuals with missing mandibular first premolars, and 20 implants were placed in patients with type II diabetes mellitus under the same circumstances. After the implants were placed, cover screws were fitted, and the flap was repositioned (RFA) Primary implant stability was measured using a resonance frequency analysis (RFA) instrument (Ostell). RFA values are recorded in a quantitative unit called the Implant Stability Quotient (ISQ), which ranges from 1 to 100. The assessment of primary stability was conducted in Group I, which consisted of 20 healthy individuals, and

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Group II, which included patients with type II diabetes. All four surfaces buccal, lingual, mesial, and distal were evaluated for primary stability using radiofrequency analysis.

Statistical Analysis and Results

This study utilized SPSS software for thorough data evaluation, uncovering various patient characteristics and treatment variables. The findings included means and standard deviations to summarize data and numerical values to illustrate proportions. To assess statistical significance, the chi-square test was employed, allowing for meaningful comparisons of categorical data across groups.

Results

This study involved 40 patients with missing mandibular first premolars, divided into two groups. Group 1 had 20 healthy individuals, while Group 2 included 20 patients with type II diabetes mellitus. Participants were between 35 and 60 years old, with a demographic of 25 males and 15 females. Table 1 details the age and gender distribution, while Graph 1 visually represents the study group's composition..The study also focused on assessing primary stability in the dental implants of the two groups. Table 2 outlines the stability evaluation for Group 1 (n=20) across four surfaces buccal, lingual, mesial, and distal. This evaluation was carried out using radiofrequency analysis via the Osstell device, which enabled the calculation of the Implant Stability Quotient (ISQ) in the cohort of healthy individuals. The findings revealed that the buccal surface exhibited an impressive mean ISQ value of 80.1 ± 6 Ncm, recorded in 8 healthy participants. The lingual surface showed an ISQ value of 72.4 ± 6 Ncm from 5 individuals, while the mesial surface recorded an ISQ of 69.5 ± 5 Ncm in 4 individuals. Finally, the distal surface exhibited an ISQ value of 65.3 ± 3 Ncm, noted in 3 healthy individuals. Statistical analysis of these results was conducted using the Pearson Chi-Square test to highlight significant differences. Similarly, Table 3 presents the primary stability evaluation for Group 2 (n=20) concerning the same four surfaces among patients with type II diabetes mellitus. The statistical assessment was again performed using the Pearson Chi-Square test, with results indicating a marked difference. For this group, the buccal surface recorded a mean ISQ value of 47.1 ± 3 Ncm among 7 patients, while the lingual surface yielded an ISQ of 43.4 ± 5 Ncm in 5 participants. The mesial surface reflected a lower ISQ value of 37.5 ± 3 Ncm in 4 patients, and the distal surface, after comparable evaluation, presented an ISQ value of 35.3 ± 2 Ncm in 4 patients.A comparison of Tables 2 and 3 reveals that primary stability is significantly higher in healthy individuals compared to those with type II diabetes mellitus, as assessed by the Implant Stability Quotient (ISQ) using the Osstell device. This suggests that type II diabetes may adversely affect early implant stability. Additionally, Table 4 summarizes estimated values across all groups, analyzed via one-way ANOVA, to shed light on variations in implant stability based on health status.

Table 1: Age & gender based statistical description of contributing patients

Age Group (Yrs)	Male	Female	Total	P value
35-40	5	3	8	0.01*
41-45	7	5	12	0.20
46-50	6	3	9	0.60
51-55	3	2	5	0.90
56-60	4	2	6	0.50
Total	25	15	40	*Significant
				*p<0.05 significant

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Graph 1: Patients demographic distribution and associated details

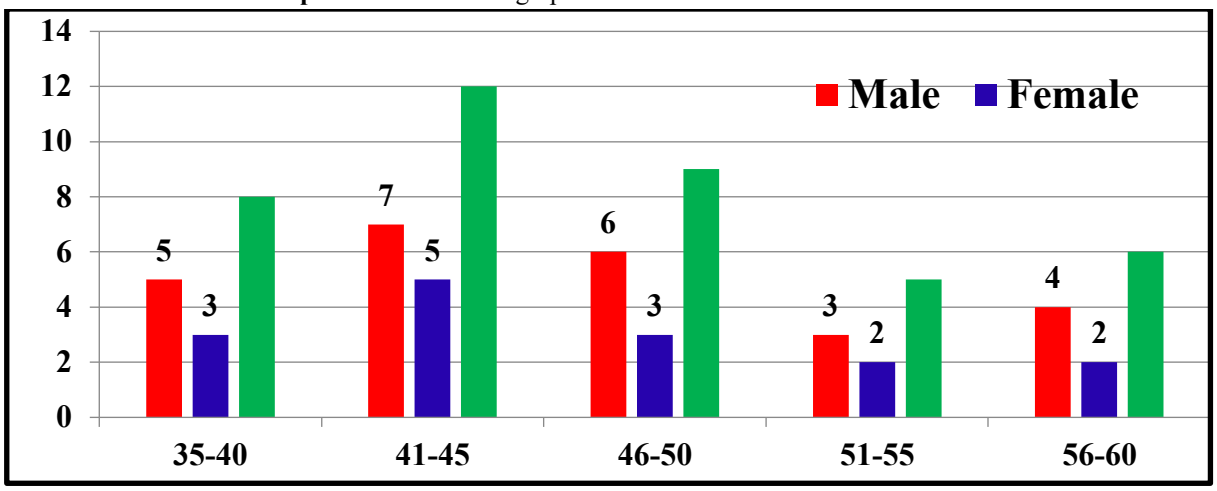

Table 2: Group I (n=20) primary stability was evaluated in all four surfaces, buccal, lingual, mesial, and distal, using radiofrequency analysis (Osstell) using implant stability quotient (ISQ) in healthy individuals. Statistical assessment was performed using the Pearson Chi-Square test

Tooth surfaces	ISQ value	n	Stat. Mean	Std. Dev.	Std. Error	95% CI	Pearson Chi-Square Value	df	p value
Buccal	80.1±6Ncm	8	2.23	2.094	2.055	2.36	2.356	1.0	0.02*
Lingual	72.4±6Ncm	5	2.14	1.086	1.240	2.26	2.082	1.0	0.80
Mesial	69.5±5Ncm	4	1.09	0.289	0.049	1.48	1.078	1.0	0.56
Distal	65.3±3Ncm	3	1.02	0.078	0.035	1.11	1.056	1.0	0.45
*p<0.05 significant									

Table 3: Group II (n=20) primary stability was evaluated in all four surfaces, buccal, lingual, mesial, and distal using radiofrequency analysis (Osstell) using implant stability quotient (ISQ) in type II diabetes mellitus patients. Statistical assessment was performed using the Pearson Chi-Square test

Tooth surfaces	ISQ value	n	Stat. Mean	Std. Dev.	Std. Error	95% CI	Pearson Chi-Square Value	df	p value
Buccal	47.1±3Ncm	7	2.19	2.086	2.046	2.32	2.246	1.0	0.02*
Lingual	43.4±5Ncm	5	2.14	1.086	1.240	2.26	2.082	1.0	0.80
Mesial	37.5±3Ncm	4	1.09	0.289	0.049	1.48	1.078	1.0	0.56
Distal	35.3±2Ncm	4	1.09	0.289	0.049	1.48	1.078	1.0	0.56
*p<0.05 significant									

Table 4: Estimation amongst all studied groups using one-way ANOVA

Variables	Degree of Freedom	Sum of Squares ∑	Mean Sum of Squares m∑	F	Level of Sig. (p)
Between Groups	2	1.119	1.025	1.2	0.001*

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Within Groups	14	2.200	0.425	–
Cumulative	104.13	6.035	*p<0.05 significant	

Discussion

Cohen, A et al reviewed that type 2 diabetes is the most common type of diabetes, representing about 90 to 95 percent of all diagnosed instances. As of 2021, it was estimated that around 537 million adults across the globe were living with this condition. This highlights the seriousness of the condition. Blood sugar levels are important for managing diabetes, as research shows a strong link between controlling blood sugar and preventing complications. Strict management of blood sugar can delay many diabetes-related issues, but the benefits decrease once complications already exist.[17,18,19] Al Ansari, Y et al reviewed that diabetes has a detrimental impact on bone health, raising significant concerns regarding the long-term viability of dental implants in affected individuals. The condition can lead to subtle movements between the implant and the surrounding bone, which can cause damage to the bone tissue itself and hinder the healing process.[20] Huang YC et al included in their study that when excessive stress occurs at the junction where the implant connects to the bone, it can result in the formation of fibrous tissue instead of encouraging direct contact with the bone. This fibrous tissue presence can impede the successful integration of the implant, ultimately jeopardizing its stability and effectiveness over time. As more people seek dental implants for comfort and aesthetics, improvements in implant materials, design, and stabilization methods can lead to better results.[21] Sennerby et al showed in their study that the success of the implant depends on several factors, such as stability during placement, surgical techniques, the quality and amount of bone, biting forces, and the design of the implant. The way an implant is treated can help it bond better with bone. Achieving strong initial stability is key to successful integration of the implant. However, many factors affect this stability, including the implant's design, the surgical method, and the surrounding bone quality and quantity. Increasing contact between the implant and bone improves stability.[22] In practice, various techniques can check implant stability, including measuring torque during placement, resonance frequency analysis, and X-ray microtomography. Firm primary implant stability is regarded as a determinant of success in implant dentistry. The concept stems from observations that implant failures are more common with unfavourable biomechanical factors like low bone density, short implants, grafted bone, early loading, and excessive loading. Inadequate implant stability can cause micro-movements at the bone-implant interface during healing, potentially leading to fibrous tissue instead of bone. Andersson P et al reviewed in their study that Resonance frequency analysis (RFA) tools assess implant stability by measuring the stiffness of the interface. This technique uses a transducer attached to the implant, and combining RFA with torque measurement is beneficial for evaluating stability immediately after placement. Resonance Frequency Analysis (RFA) is the measurement of the frequency with which a device vibrates.[23] Nienkemper M et al reviewed in their study that RFA measurements reflect the micro-mobility of dental implants, which in turn is determined by the bone density at the implant site. This method provides a clear, objective way to track the implant's success and integration, with results shown as an Implant Stability Quotient (ISQ) on a scale from 1 to 100 a higher score indicates a more stable implant.[24] Wada M et al in their study found correlations between cortical bone thickness and voxel values from CBCT scans with implant stability. It was also established that cortical bone thickness, voxel value, and implant length positively correlated with ITV and ISQ values.[25]

Conclusion

Within the limitations of this study, which clearly demonstrated that healthy individuals possess significantly greater primary stability after dental implant placement compared to those with type II diabetes. This primary stability is crucial for the successful integration of implants, and the evidence was overwhelmingly in favour of the healthy group. Radiofrequency analysis (RFA), a reliable method for measuring implant stability, underscored this distinction with compelling results.

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