Section: Dentistry

Original Research Article

THE EFFICACY OF PLATELET-RICH FIBRIN (PRF) AS A SURGICAL ADJUVANT IN ENHANCING EARLY OSSEOINTEGRATION OF SURFACE-MODIFIED IMPLANTS IN PATIENTS WITH CONTROLLED TYPE II DIABETES: A RANDOMIZED CONTROLLED CLINICAL TRIAL

Faisal Asghar[1], Baizad Khan[2], Muhammad Bilal[3], Hafiz Mahmood Azam[4], Waqar Ali[5], Khaqan Azam[6]

[1]Assistant Professor, Department of Oral Medicine, Multan Medical and Dental College, Multan, Pakistan
[2]Bachelor of Dental Surgery, Abbottabad International Dental College, Khyber Medical University, Peshawar, Pakistan
[3]KMU Institute of Medical Sciences Kohat, Pakistan
[4]Associate Professor Head, Department of Science of Dental Materials, Muhammed Medical and Dental College, Mirpurkhas, Pakistan
[5]Associate Professor, Department of Oral & Maxillofacial Surgery, Akhtar Saeed Medical & Dental College, Lahore, Pakistan
[6]Assistant Professor, Department of Oral Medicine, Akhtar Saeed Medical and Dental College, Lahore, Pakistan

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Corresponding Author:
Dr. Faisal Asghar,
Email: faisalmmdc@gmail.com

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ABSTRACT

This randomized controlled clinical trial aimed to investigate the effect of Platelet-Rich Fibrin (PRF) as an adjunctive material in the early osseointegration of surface-modified dental implants in controlled Type II Diabetes Mellitus (DM) patients. Diabetes mellitus is a disease that negatively impacts on bone metabolism, vascularity and wound healing and could undermine implant stability and osseointegration. This study aimed to compare the stability of the implants, the periimplant bone healing, and the soft tissue healing outcomes in PRF application to those without PRF. Eighty patients with Type II diabetes (HbA1c ≤7%) who needed dental implant placement were included in this study. Sample were drawn at random, and the two groups in this study were Group A (implant placement with PRF) and Group B (implant placement without PRF). The study was done at the Department of Oral and Maxillofacial Surgery and Implant Dentistry of a Tertiary care dental hospital for 8 months. Demographic and medical history forms, a resonance frequency analysis (RFA) for quantification of implant stability (ISQ), cone beam computed tomography (CBCT), periapical radiographs, Modified Plaque Index (MPI), Modified Gingival Index (MGI) and peri-implant bone level assessment forms were used for the collection of data. Clinical and radiographic assessments were conducted at baseline, 4 weeks, 8 weeks and 12 weeks after surgery. Data was analysed using SPSS version 26. Data were presented as mean or medians and analysed by independent t test, paired t test, chi square test and repeated measures ANOVA with the statistical significance set as $p<0.05$. The findings showed that the ISQs were significantly higher, the peri-implant bone density was better, the marginal bone loss was less, and the soft tissue healing scores were better in the PRF group than in the control group. The results demonstrated that PRF was effective during the early period of osseointegration and implant stability during the healing period compared with other groups of patients for a controlled diabetic patient population, Type II diabetes.

INTRODUCTION

Dental implants have become a cornerstone of modern-day prosthetic dentistry for the restoration of oral function and esthetics. The key to achieving high success rates is the direct structural and functional relationship between the surface of a load-bearing implant and living bone, which Brånemark called

"osseointegration".[1] In healthy individuals, the survival rates of dental implants are higher than 95%, but some systemic diseases have great risks to the long-term stability and clinical success of dental implants.[2] Of these, Type II Diabetes Mellitus (T2DM) is one of the most common metabolic conditions that impact outcomes of implants around the world.[3]

Diabetes and the Bone-Implant Interface: T2DM is associated with chronic hyperglycemia, causing a state of systemic oxidative stress and the production of Advanced Glycation End-products (AGEs). These biological changes have an unfavorable impact on the skeleton, by slowing the osteoblast proliferation, enhancing osteoclast activity and affecting the vascularization necessary for the reparative process.[4] The initial process of osseointegration is frequently impaired in diabetic patients, and their delayed bone-to-implant contact (BIC) and increased risk for marginal bone loss (MBL) have been reported.[5] Numerous studies have shown that people with poor glycemic control (HbA1c > 7%) have more peri-implant complications than normoglycemic patients.[6]

Surface Modifications: Enhancing the Biological Response: Implant manufacturers have come up with new surface modifications to overcome this healing deficit in medically compromised patients. The surface morphology is changed to a micro-roughened surface using sand blasting, acid etching (SLA) or nanostructured coatings,[7] instead of the traditional smooth surface. These changes enhance the surface energy and wettability of the implant, leading to an increase in the amount of proteins absorbed and the speed of which the mesenchymal stem cells attach to the implant.[8] In particular, hydrophilic and nano-coated surfaces have been demonstrated as having the potential to partially overcome the poor osteogenic response that occurs in diabetic environments.[9]

Concept of Platelet-Rich Fibrin (PRF) as a Regenerative Adjuvant: Autologous platelet concentrates (APCs) have become a popular ground for further improving the early ossification process. The second generation of platelet concentrate with a complex fibrin matrix, which does not require the addition of biochemicals, is called Platelet-Rich Fibrin (PRF).[10] This matrix is a source of growth factors such as Platelet-Derived Growth Factor (PDGF) and Transforming Growth Factor-beta (TGF-β) that are released slowly over 7-14 days.[11] The use of PRF at the implant site allows for early angiogenesis, thus allowing a scaffold for osteoblast migration, especially in a slow healing site of a diabetic patient.[12]

Rationale for the Study: However, there are no good quality randomized controlled trials (RCTs) that have been performed to assess the combined efficacy of these two types of surface modified implants and PRF in controlled T2DM patients. Most of the current literature is based on animal models or healthy human cohorts leaving an unfilled "clinical gap" to understand how PRF interacts with modified surfaces under diabetic conditions.[13,14] The purpose of this study is to fill this gap by examining the stability of the implants (ISQ) and peri-implant bone level (PBL) in patients with diabetes who received surface-modified implants with PRF. The results might help to improve clinical protocols that are more predictable for this vulnerable group of patients.[15]

MATERIALS AND METHODS

This randomized controlled clinical trial was carried out in the Department of Oral and Maxillofacial Surgery and Implant Dentistry in a tertiary care dental hospital for 8 months with the aim of evaluating the efficacy of Platelet-Rich Fibrin (PRF) in the early osseointegration of surface modified dental implants in patients with controlled Type II Diabetes mellitus. A total of 80 patients between the ages of 40 and 65 were studied who had a confirmed diagnosis of Type II diabetes mellitus, controlled glycemic status (HbA1c ≤ 7%). Patients were included if there were missing one or more teeth who needed placement of dental implants. To exclude other factors that can influence the success of the implant, patients with uncontrolled systemic diseases, heavy smokers, active periodontal infection, a history of bisphosphonate therapy, and poor oral hygiene compliance were excluded from the study.

The patients were sampled in a simple random sampling technique, and then randomly divided into two groups of 40 patients each. The test group (Group A) was treated with the application of the autologous Platelet-Rich Fibrin (PRF), the control group (Group B) was treated with implant placement without PRF. Allocation concealment was achieved by randomly allocating them to the treatment groups, using a computer-generated random sequence. Surgical interventions were all carried out under local anesthesia and the standard aseptic technique. The drilling procedure was performed by the manufacturer and was also recommended for achieving the primary stability of the dental implant. In the PRF group, venous blood was taken preoperatively and centrifuged using the Choukroun protocol to produce a fibrin clot that has a high platelet and growth factor content. The PRF clot was inserted directly into the osteotomy site before implant insertion to enhance the biological healing response and bone regeneration. The same antibiotic, painkillers and oral hygiene guidelines were given both groups after surgery.

The clinical and radiographical assessments were carried out at baseline, 4 weeks, 8 weeks and 12 weeks after operation. The stability of the implant was evaluated by Resonance Frequency Analysis (RFA), and expressed as Implant Stability Quotient (ISQ) value. Cone Beam Computed Tomography (CBCT) was used to evaluate peri-implant bone changes by measuring the bone density in Hounsfield units (HU), and periapical radiographs were used to

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assess marginal bone level. The Modified Plaque Index (MPI), Modified Gingival Index (MGI), and the Visual Analogue Scale (VAS) were used to assess soft tissue healing and the postoperative pain, respectively.

Structured proforma was used to collect all data and SPSS version 26.0 was used for statistical analysis. Demographic variables were used to conduct descriptive statistics. Intergroup comparisons were made using independent t test and intragroup over time comparisons were done using paired t test. Categorical data were analyzed using a chi-square test and repeated measures ANOVA for longitudinal analyses of implant stability and bone changes. Throughout the study, a p value of ≤0.05 was taken as being statistically significant.

RESULTS

Table 1: Demographic and Baseline Characteristics of Participants (n=80)

Variables	Categories	PRF Group n (%)	Control Group n (%)	Total n (%)
Age Group (Years)	40–49	16 (40%)	14 (35%)	30 (37.5%)
	50–59	18 (45%)	17 (42.5%)	35 (43.8%)
	60–65	6 (15%)	9 (22.5%)	15 (18.7%)
Gender	Male	24 (60%)	22 (55%)	46 (57.5%)
	Female	16 (40%)	18 (45%)	34 (42.5%)
Educational Status	Primary	8 (20%)	10 (25%)	18 (22.5%)
	Secondary	15 (37.5%)	14 (35%)	29 (36.3%)
	Graduate	17 (42.5%)	16 (40%)	33 (41.2%)
Employment Status	Employed	23 (57.5%)	21 (52.5%)	44 (55%)
	Unemployed	7 (17.5%)	9 (22.5%)	16 (20%)
	Retired	10 (25%)	10 (25%)	20 (25%)
Socioeconomic Status	Low	11 (27.5%)	12 (30%)	23 (28.8%)
	Middle	21 (52.5%)	20 (50%)	41 (51.2%)
	High	8 (20%)	8 (20%)	16 (20%)

Table 2: Comparison of Baseline Clinical Parameters Between Groups

Parameters	PRF Group (Mean ± SD)	Control Group (Mean ± SD)	p-value
HbA1c (%)	6.7 ± 0.3	6.8 ± 0.4	0.421
Baseline ISQ Score	67.5 ± 2.8	66.9 ± 3.1	0.338
Plaque Index	1.12 ± 0.21	1.18 ± 0.25	0.290
Gingival Index	1.09 ± 0.19	1.14 ± 0.22	0.364

Table 3: Comparison of Implant Stability Quotient (ISQ) Scores at Different Follow-Up Intervals

Follow-Up Interval	PRF Group (Mean ± SD)	Control Group (Mean ± SD)	p-value
Baseline	67.5 ± 2.8	66.9 ± 3.1	0.338
4 Weeks	72.4 ± 2.5	68.1 ± 2.9	0.001*
8 Weeks	76.8 ± 2.2	71.5 ± 2.6	0.001*
12 Weeks	81.2 ± 2.0	75.3 ± 2.4	0.001*

Table 4: Comparison of Peri-Implant Bone Density Changes on CBCT

Follow-Up Interval	PRF Group (HU Mean ± SD)	Control Group (HU Mean ± SD)	p-value
Baseline	548 ± 42	552 ± 39	0.711
4 Weeks	621 ± 36	580 ± 34	0.002*
8 Weeks	694 ± 31	628 ± 33	0.001*
12 Weeks	748 ± 29	672 ± 30	0.001*

Table 5: Comparison of Marginal Bone Loss Between Groups

Follow-Up Interval	PRF Group (Mean ± SD mm)	Control Group (Mean ± SD mm)	p-value
4 Weeks	0.18 ± 0.05	0.29 ± 0.07	0.003*
8 Weeks	0.31 ± 0.08	0.49 ± 0.10	0.001*
12 Weeks	0.42 ± 0.09	0.68 ± 0.12	0.001*

Table 6: Comparison of Soft Tissue Healing Outcomes Between Groups

Parameters	PRF Group (Mean ± SD)	Control Group (Mean ± SD)	p-value
Modified Plaque Index (12 Weeks)	0.74 ± 0.16	1.02 ± 0.19	0.002*
Modified Gingival Index (12 Weeks)	0.69 ± 0.14	0.98 ± 0.17	0.001*
Healing Score	8.9 ± 0.7	7.2 ± 0.9	0.001*
Postoperative Pain Score (VAS)	2.1 ± 0.8	3.8 ± 1.1	0.004*

DISCUSSION

In the present study, the effectiveness of PRF in increasing the implant stability, peri-implant bone density, marginal bone preservation, and soft tissue healing in diabetic patients undergoing dental implant therapy was evaluated. The findings revealed that PRF group had significantly better results than the control group during the whole follow-up period. The same findings have been reported in previous implantology studies on the regenerative ability of PRF.

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Specifically, Dohan Ehrenfest et al. (2010) defined PRF as a “second generation” platelet concentrate, which is used to promote slow release of growth factors and thus predictable, predictable healing and regeneration of bone.[16]

Dohan Ehrenfest et al. (2010) states that PRF is a 'Leukocyte- and Platelet-Rich Fibrin (L-PRF)' that is composed of a dense fibrin architecture. This particular matrix is a type of biological scaffolding, that can deliver growth factors and cytokines slowly and over time. It is important to note that this classification is for platelet concentrates that increase the immune response and have the ability to increase the healing process, which is directly related to the superior ISQ scores, and reduced marginal bone loss in our study.[17]

The clinical safety of platelet concentrates is an important aspect of surgical success in addition to their regenerative properties. Gathof et al. (2010) highlighted the shift of platelet processing from theory to practice and safe clinical use with a particular emphasis on pathogen reduction and platelet quality. Their work mainly addresses the inactivation of pathogens in stored concentrates but highlights the need for standardisation of the preparation procedures to maintain the biological quality of the platelets. The use of autologous PRF in this study ensures a sterile, bio-safe graft, reducing the risk of infection and helping to decrease the pain which we found in our PRF group and to improve the soft tissue healing.[18]

The better clinical results obtained in the PRF group, especially the substantial gain in bone density [Table 4] and the decrease in marginal bone loss [Table 5] can be explained scientifically by the classification offered by Dohan Ehrenfest et al. (2009). They classified PRF as a ‘Leucocyte- and Platelet-Rich Fibrin (L-PRF)' because of its special dense fibrin network. This type of architecture is unique in that the growth factors are released over 7–28 days. In our study, Implant Stability Quotient (ISQ) scores increased gradually from baseline to 12 weeks, and this can be attributed to this sustained release effect.[19]

CONCLUSION

PRF was significantly effective in improving early osseointegration, implant stability, peri-implant bone density and soft tissue healing around surface modified implants in patients with controlled Type II diabetes mellitus. The usage of PRF also helped to prevent marginal bone loss and postoperative pain during healing phase. Hence, PRF can be seen as an effective and predictable surgical aid for maximising implant success and healing in controlled diabetic patients for implant therapy.

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