

# Clinical Efficacy and Safety of Local Bone Grafting Combined with Implant Restoration in Patients with Diabetes Mellitus and Partial Edentulism

Xin Wang<sup>1</sup>, Quan-hua Shi<sup>2</sup>

<sup>1</sup>Department of Stomatology, Nanjing Pukou People's Hospital (Liangjiang Hospital, Southeast University), Nanjing, Jiangsu, 211800, People's Republic of China; <sup>2</sup>Department of Stomatology, Nanjing Pukou District Hospital of Traditional Chinese Medicine, Nanjing, Jiangsu, 211800, People's Republic of China

Correspondence: Quan-hua Shi, Department of Stomatology, Nanjing Pukou District Hospital of Traditional Chinese Medicine, Nanjing, Jiangsu, 211800, People's Republic of China, Email moonrive\_r@yeah.net

**Background:** Patients with diabetes mellitus are at increased risk of partial edentulism, which may lead to tooth loss, compromised masticatory function, and dietary restrictions. Delayed or inadequate treatment can cause complications and sequelae that severely reduce quality of life. This study aimed to explore the clinical efficacy of local bone grafting combined with implant restoration in diabetic patients with partial edentulism, to provide evidence for clinical treatment strategies.

**Objective:** To assess the clinical efficacy and safety of local bone grafting combined with implant restoration in diabetic patients with partial edentulism.

**Methods:** A total of 122 eligible patients were randomly divided into control and observation groups (n=61 each). The control group received conventional implant restoration, while the observation group underwent local autogenous bone grafting combined with implant restoration. Outcomes included peri-implant bone mineral density, new bone formation, bone-to-implant contact, inflammatory cytokines in peri-implant crevicular fluid, periodontal indicators, serum bone metabolic markers, and postoperative soft tissue complications.

**Results:** Preoperative baseline values were comparable between groups ( $P > 0.05$ ). At 6 months postoperatively, the observation group exhibited significantly higher bone mineral density, new bone area percentage, and bone-to-implant contact, along with lower levels of TNF- $\alpha$ , IL-8, and IFN- $\gamma$ . Periodontal status, implant stability, and bone metabolism markers were also improved, and the overall complication rate was significantly lower ( $P < 0.05$ ).

**Conclusion:** Local bone grafting combined with implant restoration effectively improves early implant stability and osseointegration, reduces inflammatory responses, and lowers the incidence of postoperative complications in diabetic patients with partial edentulism. The method is safe and effective and holds high clinical application value.

**Keywords:** diabetes mellitus, partial edentulism, local bone grafting, implant restoration

## Introduction

Partial edentulism is a common oral condition, typically resulting from trauma, dental caries, or congenital tooth malformations. Beyond their aesthetic impact, such defects can compromise masticatory function and reduce speech clarity.<sup>1-3</sup> In recent years, with population aging and changes in dietary habits, the incidence of type 2 diabetes mellitus has been steadily increasing. Patients with diabetes mellitus often experience chronic disturbances in glucose metabolism, which can lead to microvascular damage and immune dysfunction, disrupting alveolar bone metabolism and accelerating bone resorption, thereby increasing the risk of partial edentulism.<sup>4,5</sup> If left untreated, partial edentulism may give rise to various complications and sequelae, potentially impairing the health of the oral and maxillofacial system and severely affecting patients' daily work, learning, and quality of life.<sup>6,7</sup>

Dental implant restoration is currently the preferred treatment for partial edentulism. However, in diabetic patients with partial edentulism, factors such as insufficient bone volume, impaired bone healing capacity, dysregulated glucose metabolism, and compromised immune function often result in suboptimal implant survival and bone integration, with a relatively high incidence of postoperative complications.<sup>8,9</sup> Previous studies have demonstrated that local bone grafting can augment bone volume and optimize the quality of the implant bed, providing stable mechanical support for the implant, and in recent years, this technique has been widely applied in the implant restoration of patients with partial edentulism.<sup>10,11</sup> Nevertheless, clinical research on the efficacy and long-term outcomes of combining local bone grafting with implant restoration specifically in diabetic patients with partial edentulism remains relatively limited.

Therefore, the present study conducted a retrospective analysis of clinical data from diabetic patients with partial edentulism. By comparing the clinical efficacy of conventional implant placement with that of local autologous bone grafting combined with implant restoration, this study aimed to explore the optimal treatment strategy for this condition and to provide additional evidence for the comprehensive management of diabetic patients with partial edentulism.

## Materials and Methods

### General Information

A total of 122 diabetic patients with partial edentulism who were treated at our hospital between March 2022 and March 2025 were included in this study. Using a random number table, the patients were assigned to a control group (n =61) and an observation group (n =61). The control group comprised 31 males and 30 females, with a mean age of  $53.85 \pm 5.51$  years, while the observation group included 29 males and 32 females, with a mean age of  $56.71 \pm 4.68$  years. All patients in both groups underwent delayed implant placement (at least 3 months after tooth extraction), and no immediate extraction or immediate implant cases were included in this study to ensure homogeneity of the study population. All participants voluntarily agreed to participate in the study; those who did not consent were excluded. Informed consent was obtained from all included patients, and the study protocol was approved by the Medical Ethics Committee of the hospital. This study was performed in line with the principles of the Declaration of Helsinki. Comparison of baseline characteristics between the two groups revealed no statistically significant differences ( $P > 0.05$ ), indicating comparability (see Table 1).

### Inclusion and Exclusion Criteria

#### Inclusion Criteria

1. Patients diagnosed with type 2 diabetes mellitus (in accordance with the 2020 ADA diagnostic criteria), with stable glycemic control. (HbA1c  $< 7.5\%$  for at least 3 months prior to surgery).

Additionally, we have added details in the Material and Methods that fasting blood sugar (FBS) and glycated hemoglobin (HbA1c) levels were measured at baseline (preoperatively), 3 months, and 6 months postoperatively to monitor glycemic status throughout the study period.

2. Individuals diagnosed with partial edentulism.
3. Those willing to undergo dental implant surgery.

**Table 1** Comparison of Baseline Characteristics Between the Two Groups of Patients (n, %) ( $X \pm s$ )

Group	Age (Years)	Male	Female	Diabetes Duration	Reasons for Attrition (Cases)		
					Trauma	Periodontal Disease	Tooth Defects
Control Group (n=61)	53.85±5.51	31 (51.00)	29 (48.00)	7.02±2.21	16 (26.23)	27 (44.26)	18 (29.51)
Observation Group (n=61)	54.71±5.68	30 (49.00)	32 (52.00)	7.14±2.32	19 (31.15)	23 (37.70)	19 (31.15)
$T/\chi^2$	0.86	0.131		0.293	0.604		
P-value	0.391	0.717		0.77	0.74		

4. Participants who have been fully informed about the procedure and voluntarily consented.
5. Patients exhibiting normal immune and coagulation functions.
6. Individuals capable of normal communication.
7. Cases approved by the Ethics Committee for inclusion in the study.

### Exclusion Criteria

1. Individuals with partial edentulism in multiple locations.
2. Patients with systemic diseases affecting the heart, liver, kidneys, or other organs.
3. Those with hematological disorders.
4. Patients with a history of hypertension with inadequate blood pressure control.
5. Individuals with a history of infectious diseases such as viral hepatitis or pulmonary tuberculosis.
6. Women who are currently menstruating.

Fasting blood sugar (FBS) and glycated hemoglobin (HbA1c) levels were measured at baseline (preoperatively), 3 months, and 6 months postoperatively to monitor glycemic status throughout the study period.

### Treatment Procedures

**Control group:** Patients received conventional implant placement and restoration. Preoperatively, cone beam computed tomography (CBCT) was used to locate the implant site. After local infiltration anesthesia, a gingival incision was made and a mucoperiosteal flap was elevated. The implant osteotomy was prepared, and a titanium alloy implant (Weike Testing Group Co., Ltd., Zhongshan, Guangdong Province, China) of appropriate size was placed into the prepared site. A healing abutment was then screwed in, and the wound was sutured. After the surgery, amoxicillin capsules were administered for anti-infective treatment for 3 days. Patients were instructed to maintain oral hygiene. Sutures were removed 2 weeks after surgery, and definitive crown restoration was performed 6 months postoperatively.

**Observation group:** Patients underwent implant restoration combined with local autologous bone grafting. The preparation of the implant site was identical to that of the control group. According to the extent of alveolar bone defects (Bone defect refers to a circumferential or circumoral osseous gap  $\geq 2$  mm around the implant site, resulting from alveolar ridge resorption, trauma, or periodontal disease, which requires bone grafting to achieve sufficient implant stability and osseointegration), an appropriate amount of autologous bone was harvested from the anterior superior iliac spine of the patient, trimmed into particulate form, and packed into the bone defect area surrounding the implant site with gentle compaction. Subsequently, an implant of the same specification as that used in the control group was placed to ensure primary stability. A healing abutment was then installed, and the surgical site was sutured. All patients in the observation group received a resorbable collagen membrane after grafting. Postoperatively, amoxicillin capsules were administered for 3 days for infection prophylaxis, and patients were instructed to maintain proper oral hygiene. Sutures were removed 2 weeks after surgery, and definitive prosthetic crown restoration was performed 6 months postoperatively.

All bone harvesting procedures in the observation group were performed under local anesthesia with intravenous sedation to ensure patient comfort. Autologous bone was harvested from the anterior iliac crest for all patients in the observation group, regardless of the volume of bone defect, to maintain consistency in the surgical protocol.

### Outcome Measures

#### Radiographic Assessment

Cone-beam computed tomography (CBCT) was performed to scan the implant sites preoperatively and at 1 and 6 months postoperatively, with a slice thickness of 0.2 mm. Imaging analysis software was used to obtain the following measurements:

- 1) Peri-implant alveolar bone mineral density (BMD): measurements were taken at three locations around the implant (cervical, middle, and apical regions), and the mean value was calculated;

- 2) Percentage of newly formed bone area: based on sagittal reconstructed images of the implant, the area of newly formed bone was calculated as a percentage of the total bone defect area;
- 3) Bone-to-implant contact rate (BIC): at 6 months postoperatively, peri-implant bone tissue specimens were harvested, processed into histological sections, and examined under microscopy to determine the proportion of the implant surface in direct contact with bone tissue relative to the total implant surface length.

### Collection of Peri-Implant Crevicular Fluid (PICF) and Measurement of Inflammatory Factors

PICF samples were collected from both groups preoperatively and at 6 months postoperatively. The gingiva and tooth surfaces were gently cleaned with sterile cotton pellets, and the area was isolated to avoid contamination. A sterile filter paper strip was then inserted into the peri-implant sulcus and left in place for 60s. The strip was subsequently removed and placed into an Eppendorf microtest tube containing 2 mL of phosphate-buffered saline, and the samples were stored at  $-80^{\circ}\text{C}$  until analysis. After thawing, the samples were centrifuged, and the concentrations of tumor necrosis factor-alpha (TNF- $\alpha$ ), interleukin-8 (IL-8), and interferon-gamma (IFN- $\gamma$ ) were determined using enzyme-linked immunosorbent assay (ELISA). In addition, the incidence of peri-implantitis within 6 months after surgery was recorded for both groups.

### Periodontal Parameter Assessment

1. At 6 months postoperatively, the implant stability of both groups was measured using the Osstell Mentor device to determine the Implant Stability Quotient (ISQ), which ranges from 1 to 100, with higher values indicating greater stability.
2. At 6 months postoperatively, the sulcus bleeding index (SBI) was evaluated. Scoring was as follows: 0 = no bleeding; 1 = punctate bleeding; 2 = linear bleeding without overflow from the sulcus; 3 = bleeding overflowing the sulcus or spontaneous bleeding.
3. Probing depth (PD) was measured using a periodontal probe to assess the distance from the gingival margin to the base of the sulcus.
4. Plaque Index (PLI) was assessed as follows: 0 = no plaque; 1 = plaque detectable by gentle probing of the implant surface; 2 = plaque visible to the naked eye; 3 = abundant soft deposits.
5. Depth of socket bone loss (DSB) was measured using CT scans of the implant site by determining the distance from the midpoints of the buccal, lingual, mesial, and distal implant shoulder to the alveolar bone base.

### Assessment of Osseointegration

Approximately 5 mL of venous blood was collected from the antecubital fossa (elbow vein) of each patient. Serum levels of Bone Gla Protein (BGP) and Alkaline Phosphatase (AKP) were measured in both groups using the AU-480 fully automated biochemical analyzer (Shenzhen Genrui Biotechnology Co., Ltd). In addition, fasting blood glucose (FBG) and glycated hemoglobin (HbA1c) levels were monitored at 3 and 6 months postoperatively to ensure adequate glycemic control.

### Comparison of Postoperative Soft Tissue Complications

The incidence of soft tissue complications, including gingival swelling, bleeding, fistula formation, and peri-implantitis, was recorded for both groups before treatment and at 6 months postoperatively. The overall incidence of adverse events was then calculated.

### Statistical Analysis

All data were analyzed using SPSS version 25.0 (SPSS Inc., Chicago, IL, USA). The Shapiro–Wilk test was used to examine the normality of continuous data. Continuous variables were expressed as mean  $\pm$  standard deviation ( $X \pm SD$ ), and categorical variables were presented as percentages (%). Chi-square ( $\chi^2$ ) tests were used for univariate analysis of categorical data, while comparisons between the two groups were performed using independent samples *t*-tests. A *p*-value  $< 0.05$  was considered statistically significant.

## Results

### Comparison of Radiographic Parameters

Preoperatively, there were no statistically significant differences between the two groups in peri-implant BMD or the percentage of newly formed bone ( $P > 0.05$ ). At 1 month postoperatively, both BMD and the percentage of newly formed bone showed slight increases in both groups, but the intergroup differences remained not statistically significant ( $P > 0.05$ ). At 6 months postoperatively, the observation group exhibited significantly higher BMD, percentage of newly formed bone, and bone-to-implant contact rate (BIC) compared with the control group, with differences reaching statistical significance ( $P < 0.05$ ) (Figure 1).

### Comparison of Inflammatory Cytokine Levels in PICF

Preoperatively, there were no statistically significant differences between the two groups in the levels of TNF- $\alpha$ , IL-8, and IFN- $\gamma$  in PICF ( $P > 0.05$ ). Postoperatively, the levels of TNF- $\alpha$ , IL-8, and IFN- $\gamma$  in the PICF of the control group (implant-only restoration) increased significantly compared with their preoperative values ( $P < 0.05$ ). In contrast, the observation group (local autologous bone graft combined with implant restoration) exhibited significantly lower postoperative levels of TNF- $\alpha$ , IL-8, and IFN- $\gamma$  compared with the control group, with all differences reaching statistical significance ( $P < 0.05$ ) (Figure 2).

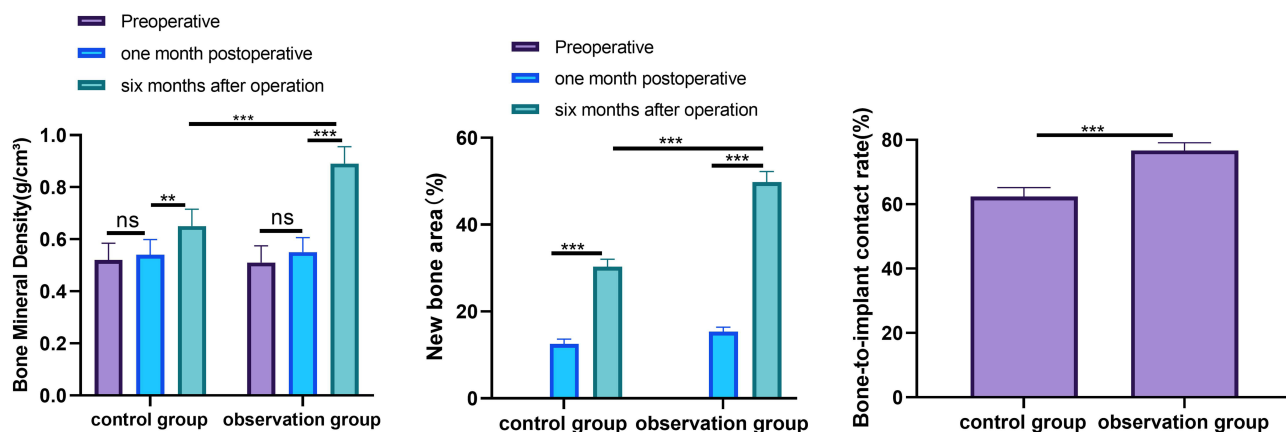


Figure 1 Comparison of Radiographic Parameters Between the Two Groups. ns  $P > 0.05$ , \*\* $P < 0.01$ , \*\*\* $P < 0.001$ .

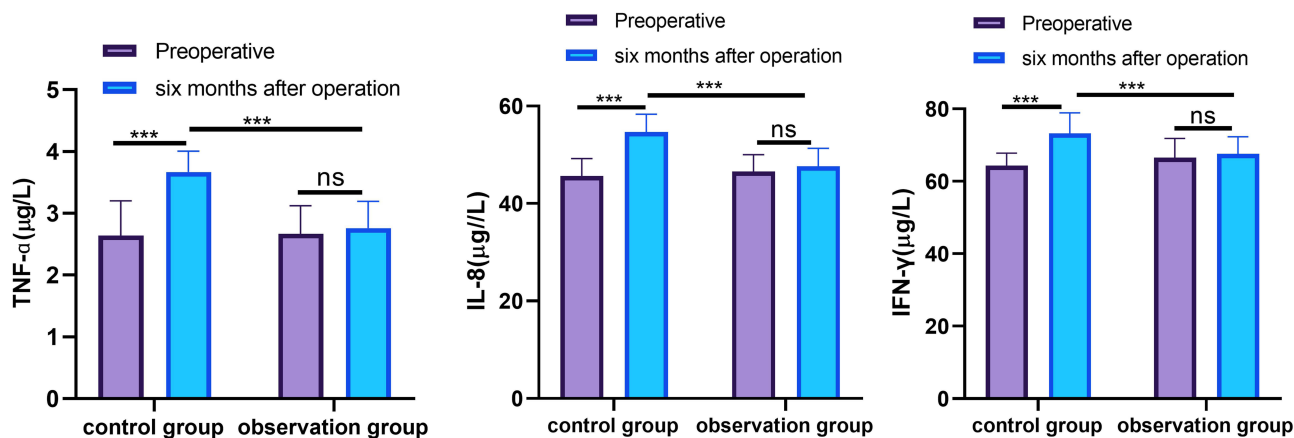


Figure 2 Comparison of PICF Inflammatory Cytokine Levels Between the Two Implant Treatment Groups. ns  $P > 0.05$ , \*\*\* $P < 0.001$ .

## Comparison of Periodontal Parameters

First, we measured the ISQ values for primary stability (assessed immediately after implantation) in both groups, and no significant difference was found between the two groups ( $P > 0.05$ ). This finding supports the consistency of our surgical technique. In our study, the results showed that the observation group (local autologous bone graft combined with implant restoration) exhibited significantly higher Implant Stability Quotient (ISQ) values compared with the control group (implant-only restoration). Conversely, the sulcus bleeding index (SBI), probing depth (PD), plaque index (PLI), and depth of socket bone loss (DSB) were significantly lower in the observation group than in the control group. All differences were statistically significant ( $P < 0.05$ ) (Figure 3).

## Comparison of Osseointegration

The results indicated that the observation group (local autologous bone graft combined with implant restoration) exhibited significantly lower levels of Bone Gla Protein (BGP) and Alkaline Phosphatase (AKP) compared with the control group (implant-only restoration), with all differences reaching statistical significance ( $P < 0.05$ ). No significant fluctuations in fasting blood glucose (FBG) and glycated hemoglobin (HbA1c) levels were observed in either group at 3 and 6 months postoperatively ( $P > 0.05$ ) (Figure 4).

## Comparison of Postoperative Soft Tissue Complications

Within 6 months postoperatively, the control group (implant-only restoration) experienced 3 cases of gingival swelling, 2 cases of bleeding, 3 cases of fistula formation, and 2 cases of peri-implantitis, with an overall complication rate of 16.39%. In the observation group (local autologous bone graft combined with implant restoration), there was 1 case of gingival swelling, 0 cases of bleeding, 1 case of fistula formation, and 1 case of peri-implantitis, resulting in an overall complication rate of 4.92%. The incidence of complications in the observation group was significantly lower than that in the control group, with the difference reaching statistical significance ( $P < 0.05$ ) (Table 2).

The results demonstrate that local bone grafting combined with implant restoration achieves favorable clinical efficacy and safety in diabetic patients with partial edentulism, which extends previous findings by focusing on this specific patient population and providing evidence for clinical decision-making.

## Discussion

Implant rehabilitation in patients with diabetes mellitus complicated by partial edentulism has long represented a major challenge in clinical dentistry, with the core issue being hyperglycemia-induced disruption of the osteogenic microenvironment.<sup>12,13</sup> In diabetic patients, chronic hyperglycemia suppresses osteoblast proliferation and differentiation

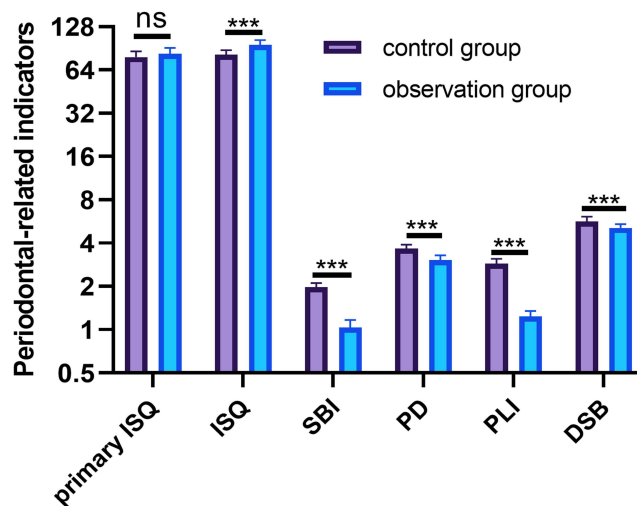
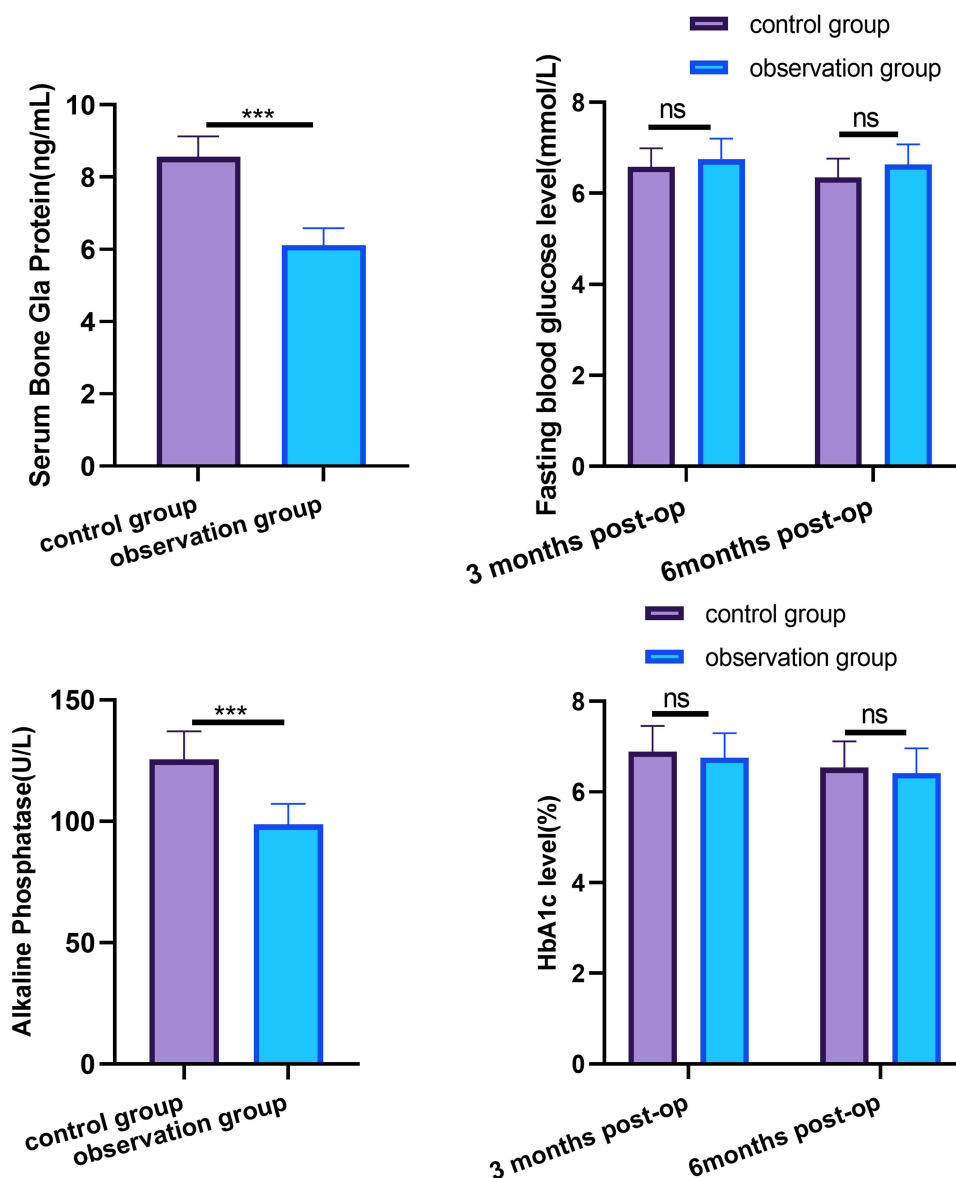


Figure 3 Comparison of Periodontal Parameters Between the Two Groups. ns  $P > 0.05$ , \*\*\* $P < 0.001$ .



**Figure 4** Comparison of Osseointegration Outcomes Between the Two Groups. ns  $P > 0.05$ , \*\*\* $P < 0.001$ .

while enhancing osteoclast activity, leading to imbalanced peri-implant bone metabolism and impaired osseointegration, thereby increasing the risk of implant failure.<sup>14,15</sup> Implant-only restoration is insufficient to address inadequate bone volume and fails to effectively improve the local osteogenic microenvironment, resulting in limited clinical efficacy. In contrast, local bone grafting techniques can augment bone volume, improve the quality of the implant bed, and provide adequate mechanical support for the implant, ultimately enhancing implant stability.<sup>16</sup>

**Table 2** Comparison of Postoperative Complications and Adverse Reactions Between the Two Groups (n, %)

Group	Gingival Redness/Swelling	Bleeding	Fistula	Peri-Implantitis	Overall Incidence
Control Group (n=61)	3 (4.92)	2 (3.28)	3 (4.92)	2 (3.28)	10 (16.39)
Observation Group (n=61)	1 (1.64)	0 (0.00)	1 (1.64)	1 (1.64)	3 (4.92)
$\chi^2$	-	-	-	-	4.219
P-value	-	-	-	-	0.04

BMD refers to the mineral content of the alveolar bone within a defined region surrounding the implant. This parameter reflects the degree of mineralization and mechanical strength of peri-implant bone tissue. Higher BMD indicates stronger support for the implant, which can reduce the likelihood of long-term bone resorption and improve the long-term success rate of implant restoration.<sup>17,18</sup> The percentage of newly formed bone directly reflects the osteoinductive potential of the graft material and the regenerative capacity of host bone tissue; higher values indicate more effective repair of bone defects and better long-term implant stability.<sup>19</sup> Bone-to-implant contact rate (BIC) is a key indicator for evaluating the quality of osseointegration, with higher values representing closer contact between the implant and bone tissue, more effective distribution of occlusal forces, and a reduced risk of implant loosening or failure.<sup>20,21</sup> In the present study, at 6 months postoperatively, peri-implant BMD, the percentage of newly formed bone, and BIC in the observation group were all significantly higher than those in the control group, suggesting that implant restoration combined with local bone grafting can effectively promote peri-implant osteogenesis in patients with diabetes mellitus. Mechanistically, on the one hand, allogeneic bone powder, as a bone substitute material, can directly fill alveolar bone defects while releasing minerals such as calcium and phosphorus, thereby enhancing local mineralization and promoting new bone formation.<sup>22,23</sup> On the other hand, the application of a resorbable collagen membrane effectively isolates soft tissue, prevents the loss of osteogenic cells, and creates favorable conditions for bone regeneration.<sup>24</sup>

The main components of PICF are derived from serum, surrounding periodontal tissues, and microbial sources. Measurement of these components can provide an indication of the presence and severity of oral diseases.<sup>25,26</sup> In this study, postoperative levels of TNF- $\alpha$ , IL-8, and IFN- $\gamma$  in the PICF of the observation group (local autologous bone graft combined with implant restoration) were significantly lower than those in the control group (implant-only restoration), consistent with previous findings of da Silva MR et al.<sup>27</sup> This suggests that the inflammatory response in the peri-implant GCF is reduced following local autologous bone grafting combined with implant restoration. The underlying mechanism may be attributed to the favorable biocompatibility and osteoconductive and osteoinductive properties of autologous bone, which accelerate the repair of peri-implant bone defects and promote rapid formation of a stable bone-implant interface. This process reduces bacterial colonization and the accumulation of inflammatory mediators caused by unfilled bone defects. Furthermore, autologous bone grafting can optimize the morphology of the surrounding soft and hard tissues, improve soft tissue attachment, and form a more compact crevicular barrier, thereby limiting bacterial invasion into peri-implant tissues and decreasing levels of inflammatory cytokines in the GCF, such as TNF- $\alpha$ , IL-8, and IFN- $\gamma$ .<sup>28,29</sup>

Primary stability is achieved through three key mechanisms: (1) Implants of the same specification (diameter and length) as the control group were used to ensure a precise fit with the osteotomy site, minimizing gaps between the implant and bone; (2) The implant was inserted with controlled torque (35–40 Ncm) to achieve sufficient cortical bone engagement; (3) Autologous bone graft was gently compacted around the implant to fill residual defects, enhancing mechanical anchorage. These measures collectively ensure primary stability and lay the foundation for subsequent osseointegration.

Moreover, this study revealed that the observation group, which underwent local autologous bone grafting combined with implant restoration, exhibited significantly higher ISQ values and notably lower SBI, PD, PLI, and DSB compared with the control group. The underlying mechanism is primarily attributed to the intrinsic osteoconductive and osteoinductive properties of autologous bone, which can rapidly guide proliferation and differentiation of host osteoblasts, accelerating the osseointegration process at the bone-implant interface and enhancing early implant stability, as directly reflected by elevated ISQ values. Additionally, a stable bone-implant interface reduces mechanical stimulation-induced bone resorption, thereby lowering SBI levels.<sup>30–32</sup> Furthermore, autologous bone grafting replenishes the bone volume in the implant region, optimizes the anatomical morphology of the surrounding soft and hard tissues, and promotes the attachment and healing of keratinized gingiva. These effects limit bacterial and toxin invasion, leading to reduced PD, PLI, and DSB values, reflecting improved periodontal health around the implant.<sup>33–35</sup>

BGP and AKP are important biomarkers reflecting systemic bone metabolism. Our study demonstrated that the levels of BGP and AKP in the observation group, which underwent local autologous bone grafting combined with implant restoration, were significantly lower than those in the control group receiving implant-only restoration. This suggests that the combined approach can more effectively enhance osseointegration compared to implant-only treatment. The

underlying mechanism is primarily attributed to the formation of a stable bone-implant interface following autologous bone grafting, which efficiently distributes occlusal forces and prevents continuous mechanical stimulation of the bone tissue due to implant micromotion.<sup>36,37</sup> The elimination of micromotion reduces stress-induced activation of osteoblasts, thereby decreasing their synthesis and secretion of BGP and AKP. In contrast, insufficient bone support in the implant-only group can lead to micromotion, maintaining osteoblasts in a hyperactive state. Concurrently, the chronic inflammatory environment may induce compensatory secretion of BGP and AKP by osteoblasts to counteract the negative effects of inflammation on bone-implant integration, ultimately resulting in elevated levels of these markers.<sup>38,39</sup>

Regarding postoperative complications, the incidence of soft tissue complications, including gingival swelling, bleeding, and peri-implantitis, was significantly lower in the observation group compared with the control group. The underlying mechanism is primarily attributed to the ability of autologous bone grafts to accelerate wound healing and reduce inflammatory responses. Additionally, the application of a bioresorbable membrane effectively isolates the surgical site from oral bacteria, thereby lowering the risk of infection.<sup>40</sup>

In summary, local autologous bone grafting combined with implant restoration in patients with diabetes mellitus and partial edentulism can significantly enhance the initial stability of implants, improve osseointegration, attenuate inflammatory responses, and reduce the incidence of soft tissue complications such as gingival swelling, bleeding, and peri-implantitis. This approach represents a safe and effective treatment strategy and may be widely applicable in clinical practice. Our results are consistent with the findings of Do JH, who reported that bone grafting combined with implant restoration is effective in diabetic patients.<sup>41</sup> However, our study further emphasizes the safety profile in this population, which adds to the existing literature. Our results are consistent with the study objectives. The significantly improved secondary stability in the observation group demonstrates the effectiveness of autologous bone grafting for implant therapy in diabetic patients, providing valuable evidence for this high-risk population.

Nevertheless, this study has some limitations. The follow-up period was limited to 6 months, which is insufficient to assess long-term implant stability and late complications. Future studies with extended follow-up to 12–24 months are warranted to further evaluate long-term and delayed outcomes, thereby providing more comprehensive evidence for clinical practice.

## Conclusion

In conclusion, local bone grafting combined with implant restoration is effective and safe for diabetic patients with partial edentulism. These findings provide clinical evidence for the management of this patient population and warrant further large-scale studies.

## Data Sharing Statement

The datasets generated during and analysed during the current study are available from the corresponding author on reasonable request.

## Ethics Approval and Informed Consent

This study was conducted in accordance with the principles of the Declaration of Helsinki and was approved by the Medical Ethics Committee of Nanjing Pukou People's Hospital (Approval No. NJPCPH-EC-2022-003).

## Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

## Disclosure

The authors report no conflicts of interest in this work.

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