ISSN 0973-2063 (online) 0973-8894 (print)
Bioinformation 22(10): 7633-7637 (2026)
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BIOINFORMATION
Discovery at the interface of physical and biological sciences
BIOMEDICAL INFORMATICS
www.bioinformation.net
Volume 22(10)
Research Article

Received October 1, 2026; Revised October 31, 2026; Accepted October 31, 2026, Published October 31, 2026
DOI: 10.6026/973206300227633

SJIF 2026 (Scientific Journal Impact Factor for 2026) = 8.478
2022 Impact Factor (2023 Clarivate Inc. release) is 1.9

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Citation: Singh *et al*. Bioinformation 22(10): 7633-7637 (2026)

Efficacy of platelet rich fibrin in Osseo densification mediated indirect sinus lift: A CBCT - based randomized controlled trial

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ISSN 0973-2063 (online) 0973-8894 (print)
Bioinformation 22(10): 7633-7637 (2026)
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Abstract:
Limited evidence exists regarding the effectiveness of platelet-rich fibrin (PRF) in enhancing bone formation following indirect sinus lift procedures using osseodensification. Therefore, it is of interest to evaluate the platelet-rich fibrin (PRF) in indirect sinus lift procedures using Osseodensification and CBCT assessment. Hence, twenty patients were randomly allocated to graftless control and PRF-assisted groups, with simultaneous implant placement and CBCT evaluation at baseline and six months. Both groups showed significant bone formation, with greater bone height gain in the PRF group than controls (3.06 ± 0.56 vs. 2.28 ± 0.43 mm; p = 0.003). Bone density increased significantly more with PRF than without PRF (47.20 ± 11.14 vs. 28.90 ± 14.32 HU; p = 0.005). Thus, PRF-assisted osseodensification may enhance bone gain and density, supporting posterior maxillary implant rehabilitation.

Keywords: Platelet-Rich Fibrin (PRF), osseo densification, sinus floor elevation, cone beam computed tomography (CBCT), dental implants and bone regeneration

Background:
Edentulous patients in the posterior maxilla frequently present with reduced alveolar bone height and density because of post-extraction ridge resorption and maxillary sinus pneumatization, complicating predictable implant placement **[1]**. Maxillary sinus floor elevation is an established method for increasing vertical bone volume, while the crestal approach offers a less invasive alternative to the traditional lateral window technique **[2]**. Osseo densification uses non-extractive burs to compact and autograft bone, thereby increasing bone density and facilitating controlled Schneiderian membrane elevation during indirect sinus augmentation **[3]**. This approach may improve primary implant stability and permit simultaneous implant placement in sites with limited residual bone height **[4].** Platelet-rich fibrin (PRF) is an autologous platelet concentrate prepared without anticoagulants and contains a fibrin matrix enriched with platelets, leukocytes and growth factors **[5]**. Its biological properties may promote angiogenesis, cellular proliferation and tissue healing and bone regeneration while providing a scaffold beneath the elevated sinus membrane **[6]**. Cone beam computed tomography (CBCT) provides three-dimensional assessment of residual bone height and density and is valuable for preoperative planning and postoperative evaluation of sinus augmentation procedures **[7]**. Therefore, it is of interest to evaluate the effectiveness of PRF as a regenerative biomaterial in osseodensification-assisted indirect sinus lift procedures using three-dimensional CBCT to assess postoperative changes in bone height and density.

Materials and Methods:
Study design and ethical considerations:
This prospective, single-blinded comparative clinical study was conducted at the Department of Prosthodontics, Crown and Bridge and Implantology at Geetanjali Dental and Research Institute, Udaipur, Rajasthan, India. The primary objective was to assess hard tissue changes following the placement of platelet-rich fibrin (PRF) during indirect sinus lift procedures using cone beam computed tomography (CBCT). The study protocol adhered to the principles of the Declaration of Helsinki and received approval from the Institutional Ethics Committee of Geetanjali University (Approval No. GU/HREC/2024/2390; dated April 29, 2024). Written informed consent was obtained from all participants prior to enrolment.

Sample size and randomization:
The required sample size was initially determined using G*Power version 3.1 software. Based on a significance level of 5%, a statistical power of 80% and an anticipated effect size of 1.32, a baseline requirement of 20 participants were calculated. To account for a potential 10% attrition rate over the 6-month follow-up period, the final sample size was adjusted to 22 participants (yielding 11 participants per group, with one implant placed per participant). Patients were recruited using purposive sampling and randomly allocated into two equal groups (n=11) via a lottery method utilizing pre-prepared coded envelopes:

[1] **Group I (Control Group):** Underwent indirect sinus lift with simultaneous implant placement without PRF or any grafting material (n=11).
[2] **Group II (Test Group):** Underwent indirect sinus lift with simultaneous implant placement supplemented by PRF placement beneath the elevated membrane (n=11).

Participant selection:
Patients were screened through detailed medical and dental histories, clinical examinations, radiographic evaluations and routine blood investigations. Diagnostic casts and CBCT scans were utilized to assess residual alveolar bone height, bone quality and adjacent anatomical structures.

Inclusion criteria:

[1] Age above 18 years.
[2] Minimum residual bone height of 6 mm below the maxillary sinus floor.
[3] Single or multiple missing teeth in the maxillary premolar or molar region.
[4] Healthy periodontium adjacent to the edentulous site.
[5] Willingness to participate maintains good oral hygiene and complies with follow-up visits.

Exclusion criteria:
[1] Presence of sinus pathologies (*e.g.*, sinusitis).
[2] Heavy smoking habits or poor oral hygiene.
[3] Untreated periodontal disease or acute infections at the proposed implant site.
[4] Parafunctional habits, such as bruxism.
[5] Uncontrolled systemic diseases, history of chemotherapy, or medications affecting bone metabolism/soft tissue healing.
[6] Pregnant or lactating women.

Surgical procedure:
Preoperative preparation:
All procedures were performed under strict aseptic conditions. Patients were administered prophylactic amoxicillin (1 g) one hour before surgery and instructed to rinse with 0.2% chlorhexidine gluconate for one minute. Regional anesthesia was achieved using posterior superior alveolar and greater palatine nerve blocks, supplemented with local infiltration of 2% lidocaine containing 1:80,000 epinephrine.

Osteotomy and sinus elevation:
A mid-crestal incision with releasing incisions was utilized to elevate a full-thickness mucoperiosteal flap. Following pilot drill initiation, osteotomy preparation was performed sequentially using osseodensification burs according to the manufacturer's recommendations, extending to approximately 1–2 mm short of the sinus floor. Indirect sinus membrane elevation was achieved through the crestal approach by carefully fracturing the sinus floor and elevating the Schneiderian membrane.

Group-specific interventions:
Group I (control):
No grafting material or PRF was placed. To enhance primary stability and engage available native bone, implants were placed with a slight mesial or distal inclination. This tilted placement engaged the cortical bone of the sinus wall, supported the elevated membrane and minimized intrusion into the sinus cavity. Implants were placed until an insertion torque of approximately 40 Ncm was achieved.

Group II (Test):
Autologous PRF was prepared following the protocol by Choukroun *et al.* Approximately 20 mL of venous blood was collected in sterile, anticoagulant-free tubes and centrifuged at 3000 rpm for 10 minutes. The resulting middle-layer PRF clot was separated from red blood cells, gently compressed into a membrane and inserted beneath the elevated Schneiderian membrane. Implants were then placed to achieve adequate primary stability.

Postoperative
Healing abutments were connected and the flaps were repositioned and sutured using 3-0 non-resorbable sutures. The postoperative pharmacological regimen included Amoxicillin Clavulanate 625 mg (every 8 hours for five days), diclofenac sodium 50 mg (twice daily for three days) and a 0.2% chlorhexidine mouth rinse (twice daily for one week). Patients were instructed to maintain a soft diet, avoid smoking and refrain from nose blowing, sneezing with a closed mouth and strenuous physical activity. Sutures were removed one week postoperatively.

Radiographic evaluation:
Radiographic assessments were conducted using CBCT scans obtained preoperatively and six months postoperatively, utilizing standardized imaging parameters and Carestream 3D Imaging Software.
[1] Bone height: Measured on cross-sectional images as the vertical distance from the alveolar crest to the maxillary sinus floor preoperatively. Postoperatively, it was measured along the implant's long axis from the alveolar crest to the most coronal aspect of newly formed bone above the implant apex. Bone gain (mm) was calculated as the difference between these measurements.
[2] Bone density: Evaluated using grayscale values expressed as Hounsfield Unit (HU) equivalents. Preoperative density was recorded in the residual alveolar bone, while postoperative density was measured in the augmented sinus floor region surrounding the implant apex. A standardized, consistent region of interest (ROI) was utilized across all scans to ensure reproducibility.

Statistical analysis:
Data analysis was performed using the Statistical Package for the Social Sciences (SPSS) software. Descriptive statistics were generated for all study variables. Data were evaluated for normal distribution using the Shapiro-Wilk test. Intragroup comparisons were conducted using paired t-tests and intergroup comparisons were analyzed using independent t-tests, with the significance level set at $p \leq 0.05$.

Results:
A total of 20 patients were included in the study, with 10 patients each in the platelet-rich fibrin (PRF) and non-PRF groups. Intragroup analysis demonstrated a statistically significant increase in bone height in both groups at the six-month follow-up **(Table 1)**. In the PRF group, mean bone height increased from 6.70 ± 0.64 mm preoperatively to 9.76 ± 0.88 mm post-operatively, with a mean gain of 3.06 mm ($t = -17.275$, $p < 0.001$). Similarly, the non-PRF group showed an increase from 6.61 ± 0.59 mm to 8.89 ± 0.81 mm, corresponding to a mean gain of 2.28 mm ($t = -16.808$, $p < 0.001$). Bone density also increased significantly in both groups after six months **(Table 2)**. In the

PRF group, mean bone density increased from 303.50 ± 14.86 HU to 350.70 ± 12.44 HU, yielding a mean increase of 47.20 HU (t = −13.394, p < 0.001). In the non-PRF group, bone density increased from 298.90 ± 15.21 HU to 327.80 ± 18.09 HU, with a mean increase of 28.90 HU (t = −6.383, p < 0.001). Intergroup comparisons revealed no statistically significant difference in baseline bone height between the groups (p = 0.748), indicating comparable initial measurements. At six months, bone height was significantly greater in the PRF group than in the non-PRF group (9.76 ± 0.88 mm vs. 8.89 ± 0.81 mm; p = 0.034). The mean bone height gain was also significantly greater in the PRF group (3.06 ± 0.56 mm) than in the non-PRF group (2.28 ± 0.43 mm), with a between-group difference of 0.78 mm (t = 3.496, p = 0.003; **Table 3**). Similarly, baseline bone density did not differ significantly between the groups (p = 0.593). At the six-month follow-up, the PRF group exhibited significantly greater bone density than the non-PRF group (350.70 ± 12.44 HU vs. 327.80 ± 18.09 HU; p = 0.004). The mean increase in bone density was also significantly greater in the PRF group (47.20 ± 11.14 HU) than in the non-PRF group (28.90 ± 14.32 HU), representing a between-group difference of 18.30 HU (t = 3.19, p = 0.005; **Table 4**). Overall, both treatment approaches were associated with significant improvements in bone height and density over six months. However, the PRF-assisted approach demonstrated significantly greater gains in both outcomes compared with the non-PRF approach.

Table 1: Intra-group comparison of bone height (mm)

Group	Pre	Post	Difference	t-value	p-value
With PRF	6.70 ± 0.64	9.76 ± 0.88	3.06	-17.275	<0.001*
Without PRF	6.61 ± 0.59	8.89 ± 0.81	2.28	-16.808	<0.001*

*Paired t test; * indicates a significant difference at p≤0.05*

Table 2: Intra-group comparison of bone density (hu)

Group	Pre		Post		Difference	t-value	p-value
With PRF	303.50 14.86	±	350.70 12.44	±	47.2	-13.394	<0.001*
Without PRF	298.90 15.21	±	327.80 18.09	±	28.9	-6.383	<0.001*

*Paired t test; * indicates a significant difference at p≤0.05*

Table 3: Intra-group comparison of bone height (mm)

Interval	Pre	Post	Difference	t-value	p-value
With PRF	6.70 ± 0.64	6.61 ± 0.59	0.09	0.326	0.748
Without PRF	9.76 ± 0.88	8.89 ± 0.81	0.87	2.292	0.034*
Change	3.06 ± 0.56	2.28 ± 0.43	0.78	3.496	0.003*

*Paired t test; * indicates a significant difference at p≤0.05*

Table 4: Inter-group comparison of bone density (hu)

Interval	Pre		Post		Difference	t-value	p-value
With PRF	303.50 14.86	±	298.90 15.21	±	4.6	0.684	0.593
Without PRF	350.70 12.44	±	327.80 18.09	±	22.9	3.299	0.004*
Change	47.20 ± 11.14		28.90 ± 14.32		18.3	3.19	0.005*

*Paired t test; * indicates a significant difference at p≤0.05*

Discussion:

The rehabilitation of the atrophic posterior maxilla remains a surgical challenge. This study demonstrated that indirect sinus floor elevation combined with simultaneous implant placement effectively increases vertical bone height and density, both with and without the utilization of PRF. The concept of graftless sinus augmentation relies on the "tent pole" effect, where the implant itself supports the elevated Schneiderian membrane, allowing the isolated space to fill with a blood clot **[8]**. The native osteogenic potential of the Schneiderian membrane, combined with a stable blood clot, provides a natural scaffold for bone regeneration **[9]**. This was corroborated by our control group, which achieved a significant mean bone height gain of 2.28 mm relying solely on the native blood clot and a mechanical tilting technique to support the membrane. However, the addition of PRF yielded statistically superior outcomes. The PRF group demonstrated a net bone gain of 3.06 mm, surpassing the control group by 0.78 mm. Furthermore, the PRF group showed a marked enhancement in bone density (47.20 HU increase vs 28.90 HU in the control group). These findings align with the biological rationale that PRF acts as an optimized, sustained-release biological scaffold. The high concentration of growth factors trapped within the dense fibrin matrix stimulates osteoblastic activity, promotes angiogenesis and accelerates bone maturation **[10]**. A critical methodological consideration in this study was the variation in implant trajectory. The control group utilized a tilted placement to maximize engagement with native cortical bone and ensure primary stability in the absence of a graft **[11].** In contrast, the PRF group received vertically aligned implants, relying on the PRF matrix for initial biological stabilization. Despite the mechanical advantages of the tilting technique used in the control group, the PRF cohort achieved superior vertical bone gain and density **[12]**. This highlights that the intrinsic regenerative capacity of PRF surpasses the mechanical benefits of implant tilting alone in indirect sinus lift procedures.

Conclusion:

Indirect sinus augmentation using osseodensification burs effectively increased bone volume in the posterior maxilla. The addition of platelet-rich fibrin (PRF) resulted in significantly greater vertical bone gain and bone density than graftless treatment alone. PRF-assisted Osseodensification may offer a biologically favourable and cost-effective approach for improving outcomes in posterior maxillary implant rehabilitation.

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