International Journal of Clinical Trials
Attre T et al. Int J Clin Trials. 2026 Nov;13(4):xxx-xxx
https://www.ijclinicaltrials.com
pISSN 2349-3240 | eISSN 2349-3259
DOI: https://dx.doi.org/10.18203/2349-3259.ijct20262785

Original Research Article

Comparative evaluation of dimensional changes achieved and osteopontin level in peri-implant crevicular fluid after sinus crestal floor elevation using piezosurgery and concentrated growth factor with or without allograft: a randomized clinical trial

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Received: 15 July 2026
Accepted: 03 August 2026

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ABSTRACT

Background: Limited residual bone height in the posterior maxilla often necessitates sinus floor elevation before implant placement. Piezosurgery-assisted crestal sinus floor elevation offers a minimally invasive approach with reduced membrane-related complications. Concentrated growth factor (CGF) has been proposed to enhance bone regeneration; however, the additional benefit of combining CGF with allograft remains unclear. This randomized clinical trial compared radiographic, clinical, and biochemical outcomes following crestal sinus floor elevation using CGF with or without demineralized freeze-dried bone allograft (DFDBA).

Methods: Twenty posterior maxillary implant sites requiring indirect sinus floor elevation were randomly allocated into two groups (n=10 each): group A, piezosurgery-assisted crestal sinus elevation with CGF + DFDBA; and group B, CGF alone. Simultaneous implant placement was performed in all sites. Vertical bone height (VBH) and bucco-palatal width (BPW) were assessed using cone-beam computed tomography at baseline and 6 months. Implant stability quotient (ISQ) was measured at baseline and 3 months. Osteopontin (OPN) levels in peri-implant crevicular fluid were evaluated at 15, 45, and 90 days using enzyme-linked immunosorbent assay.

Results: Both groups demonstrated significant increases in vertical bone height and implant stability over time ($p<0.05$). Group A showed significantly greater vertical bone gain at 6 months compared with group B ($p<0.05$). Bucco-palatal width remained relatively stable in both groups, although a significant reduction was observed in group B. OPN levels increased progressively in both groups during healing and were significantly higher in group A at all-time intervals ($p<0.05$).

Conclusions: Piezosurgery-assisted crestal sinus floor elevation using CGF, with or without allograft, resulted in favorable clinical and radiographic outcomes. The addition of DFDBA to CGF yielded greater vertical bone gain and higher OPN levels, suggesting enhanced regenerative activity during early healing.

Keywords: Dental implants, Maxillary sinus augmentation, Piezoelectric surgery, Concentrated growth factor, Osteopontin, Peri-implant crevicular fluid

INTRODUCTION

Rehabilitation of the edentulous posterior maxilla with dental implants remains clinically challenging due to reduced residual bone height and compromised bone quality. These limitations primarily result from progressive post-extraction alveolar ridge resorption and maxillary sinus pneumatization, which significantly reduce vertical bone availability and impair primary implant stability.[1] Achieving adequate bone volume in this

region is critical, as primary stability is a prerequisite for predictable osseointegration and long-term implant success.

To overcome these anatomical constraints, sinus floor elevation procedures have been widely adopted. The lateral window technique, originally introduced by Tatum, enables substantial vertical bone augmentation by accessing the sinus through a lateral antrostomy and elevating the Schneiderian membrane prior to graft placement.[2] Although predictable, this approach is relatively invasive and associated with increased surgical morbidity and a higher incidence of membrane perforation.[3]

As a less invasive alternative, Summers described the osteotome-mediated crestal sinus floor elevation technique, which allows indirect elevation of the sinus membrane via the alveolar crest.[4] This technique permits simultaneous implant placement in cases with moderate residual bone height and has gained popularity due to reduced surgical trauma. However, its indication largely depends on residual bone height, with ≥5 mm generally considered necessary to ensure adequate primary stability.[5] Despite its advantages, the use of malleting forces during osteotome sinus elevation may cause patient discomfort and complications such as membrane perforation, vascular injury, and transient vestibular disturbances.[6,7]

Technological advancements have aimed to enhance the safety and precision of crestal sinus lift procedures. Piezoelectric surgery, introduced by Vercellotti, utilizes ultrasonic microvibrations to selectively cut mineralized tissues while preserving adjacent soft tissues, including the Schneiderian membrane.[8] The cavitation effect improves intraoperative visibility and reduces bleeding, thereby enhancing surgical control. Clinical evidence suggests that piezoelectric devices significantly reduce membrane perforation rates compared with conventional rotary instruments.[9,10] These advantages have facilitated the broader adoption of minimally invasive sinus augmentation techniques.

With improved surgical precision, interest has grown in graftless sinus augmentation approaches. The Schneiderian membrane exhibits inherent osteogenic potential, containing mesenchymal progenitor cells capable of contributing to new bone formation.[11] In appropriately selected cases, the stabilization of the elevated membrane and blood clot alone may permit bone regeneration without exogenous grafting materials.

Concurrently, autologous platelet concentrates have gained prominence in regenerative procedures. Concentrated growth factor (CGF), developed by Sacco, represents an advanced generation platelet derivative obtained through a variable-speed centrifugation protocol, producing a dense fibrin matrix enriched with growth factors.[12,13] CGF has demonstrated favorable effects on angiogenesis, collagen synthesis, and osteoblastic differentiation, thereby enhancing bone regeneration in sinus augmentation procedures.[14] However, whether CGF alone can provide comparable outcomes to conventional graft-assisted techniques remains insufficiently clarified.

Among graft materials used in sinus augmentation, demineralized freeze-dried bone allograft (DFDBA) has been widely utilized due to its osteoconductive properties and the presence of bone morphogenetic proteins that may promote osteoinduction.[15,16] The potential synergistic effect of combining DFDBA with CGF warrants further clinical investigation.

Beyond radiographic evaluation of bone gain, biochemical assessment provides insight into the biological events underlying osseointegration. Peri-implant crevicular fluid (PICF) analysis represents a minimally invasive method for monitoring molecular markers associated with bone remodeling.[17] Among these, osteopontin (OPN) is a non-collagenous phosphoprotein secreted by osteoblasts and osteoclasts that plays a critical role in cell adhesion, mineralization, and bone turnover.[18] OPN expression has been shown to increase during early phases of osseointegration, correlating with active bone remodeling.[19] Therefore, longitudinal assessment of OPN levels in PICF may provide valuable information regarding peri-implant healing dynamics following sinus augmentation.

Given the evolving paradigm toward minimally invasive, biologically driven regenerative approaches, the comparative efficacy of crestal sinus floor elevation using piezoelectric surgery with CGF alone versus CGF combined with DFDBA remains to be fully elucidated. Furthermore, limited clinical data exist correlating radiographic bone gain with biochemical markers of early osseointegration in this context.

Accordingly, the present randomized clinical trial aimed to evaluate dimensional bone changes, implant stability, and OPN levels in peri-implant crevicular fluid following piezoelectric crestal sinus floor elevation using CGF with or without allograft.

Objectives

The primary objective of this randomized clinical trial was to compare vertical bone gain following crestal sinus floor elevation using piezoelectric surgery with CGF with or without allograft in the posterior maxilla.

Secondary objectives were: to compare bucco-palatal width changes and vertical bone gain between groups using cone-beam computed tomography at baseline and 6 months, to evaluate implant stability quotient (ISQ) values at baseline and 3 months, to assess peri-implant soft tissue parameters, including plaque index (PI) and gingival index (GI), at baseline and 3 months, and to quantify OPN levels

in PICF at 15, 45, and 90 days following implant placement.

Null hypothesis

The null hypothesis states that there would be no significant differences between crestal sinus floor elevation using CGF with allograft and CGF alone in terms of: vertical bone gain, bucco-palatal dimensional changes, implant stability and OPN levels in peri-implant crevicular fluid.

METHODS

Study design and ethical approval

This randomized controlled clinical trial was conducted in the Department of Periodontology and Oral Implantology, I.T.S Centre for Dental Studies and Research, Ghaziabad, India. The study protocol was reviewed and approved by the Institutional Ethics Committee (Protocol No. ITSCDSR/IIEC/2023-26/PERIO/04) and performed in accordance with the Declaration of Helsinki. Written informed consent was obtained from all participants before enrollment.

Study population

Patients requiring implant-supported rehabilitation in the posterior maxilla and presenting with reduced residual bone height suitable for crestal sinus floor elevation were screened for eligibility. A total of 20 posterior maxillary implant sites were included. A maximum of two sites per patient was permitted when clinically indicated.

Inclusion criteria

Patients of age 18–60 years, residual bone height ≥5 mm, healed extraction site (≥3 months post-extraction), adequate inter-occlusal space, good oral hygiene, and systemically healthy individuals were included.

Exclusion criteria

Patients with uncontrolled diabetes, maxillary sinus pathology, autoimmune diseases or osteoporosis, history of head and neck radiotherapy/chemotherapy within 12 months, heavy smokers, alcohol or drug abuse, pregnant or lactating women, and poor oral hygiene were excluded.

Sample size calculation

Sample size was calculated using G*Power software (version 3.1.9.7) based on previously reported mean vertical bone gain values (11.96±0.81 mm versus 10.69±0.67 mm). With an effect size of 1.25, α=0.05, and power=80%, the required sample size was 10 sites per group (total=20 sites). The calculated post hoc power was 95.05%.

Randomization and allocation

Eligible sites were randomly allocated into the following.

Eligible implant sites were randomly assigned in a 1:1 ratio into two treatment groups using a computer-generated randomization sequence. Allocation was concealed using sequentially numbered opaque sealed envelopes opened at the time of surgery.

Group A

Piezosurgery-assisted crestal sinus floor elevation using CGF + DFDBA with simultaneous implant placement.

Group B

Piezosurgery-assisted crestal sinus floor elevation using CGF alone with simultaneous implant placement.

Clinical parameters

The following parameters were recorded.

Plaque index

Assessed on the mesial surface of the adjacent tooth according to Silness and Löe (1964) at baseline and 3 months.

Gingival index

Evaluated using Löe and Silness (1963) criteria at baseline and 3 months.

Implant stability quotient

Measured using resonance frequency analysis (Penguin® RF device) immediately after implant placement and at 3 months. Measurements were recorded in mesiodistal and buccopalatal directions, and the mean value was used for analysis.

Radiographic assessment

Cone-beam computed tomography (CBCT) was performed at baseline and 6 months using NewTom GiANO (0.150 mm voxel size; 90 kVp; FOV 5×5 or 8×8 cm).

A customized radiographic stent with gutta-percha marker was fabricated to standardize measurements.

Radiographic measurements

Residual bone height

Distance from alveolar crest to sinus floor at the planned implant site.

Vertical bone height

Bone height at baseline and 6 months.

Bucco-palatal width

Measured at 0 mm, 2 mm, and 4 mm apical to the alveolar crest.

Measurements were obtained using multiplanar reconstruction (MPR) views.

Biochemical measurement

To evaluate the OPN level in PICF at 15th, 45th and 90th day.

Surgical procedure

All surgical procedures were performed by a single experienced periodontist under local anesthesia (2% lidocaine with 1:100,000 epinephrine). Patients were instructed to rinse with 0.2% chlorhexidine gluconate for 30 seconds prior to surgery.

A mid-crestal incision was made using a no. 15 blade, followed by full-thickness mucoperiosteal flap reflection to expose the alveolar crest.

Osteotomy preparation and crestal sinus elevation

Initial osteotomy preparation was performed using the manufacturer's standard implant drilling protocol up to 1 mm short of the radiographically determined sinus floor.

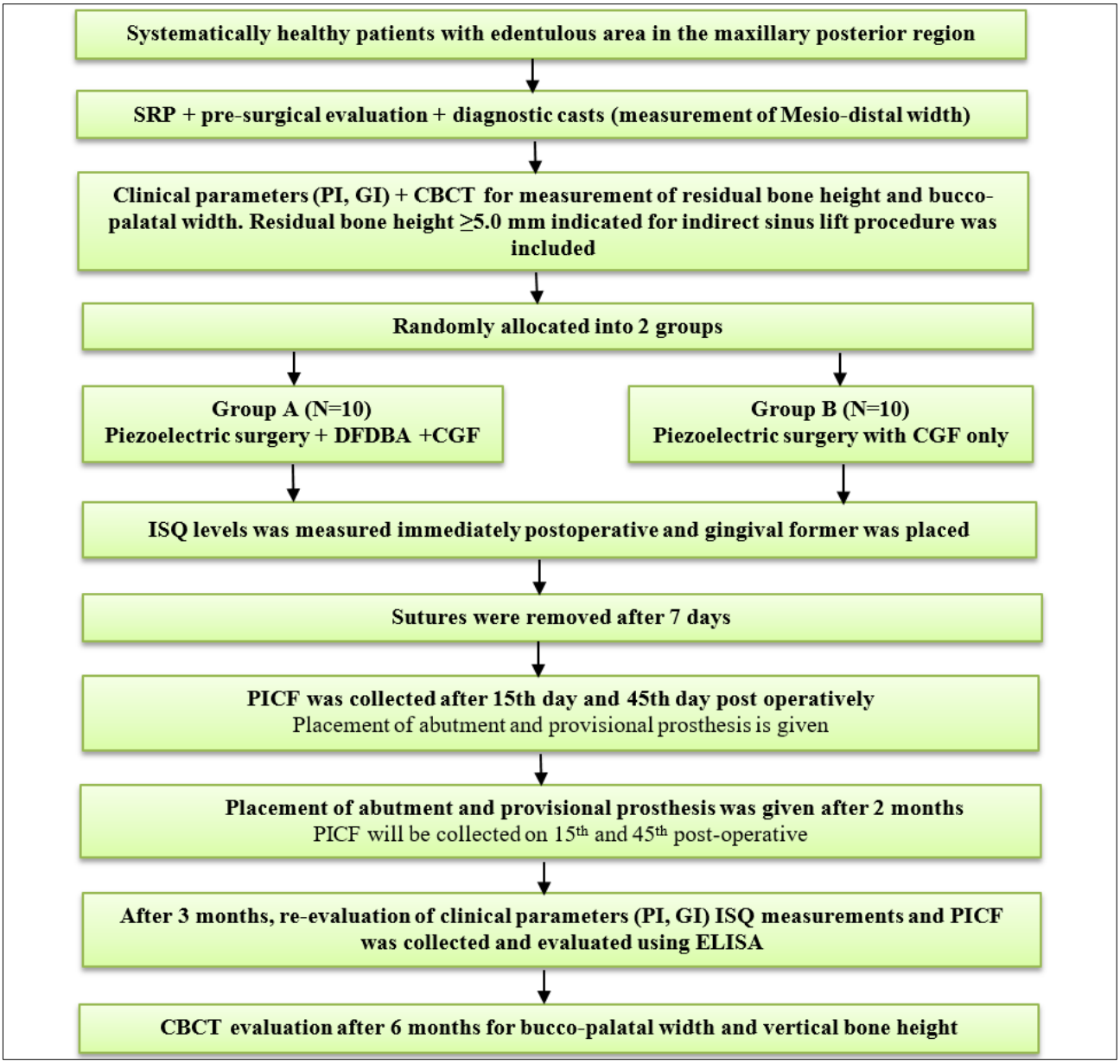

Figure 1: Study design.

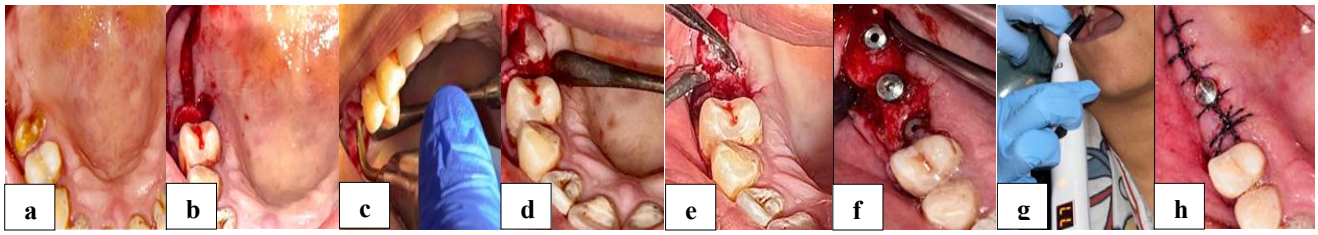

Figure 2: (a) Pre-operative intraoral view showing edentulous posterior maxillary site, (b) crestal incision and full-thickness mucoperiosteal flap reflection exposing the alveolar crest, (c) osteotomy preparation using piezoelectric surgical inserts for controlled thinning of the sinus floor, (d) placement of CGF membrane, (e) placement of allograft, (f) placement of implants following sinus, (g) intraoperative implant stability assessment using resonance frequency analysis (Penguin® RF device), and (h) flap repositioning and primary closure achieved with interrupted sutures.

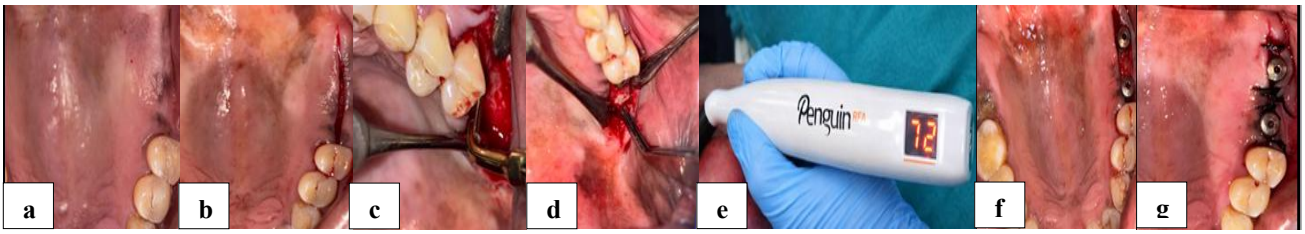

Figure 3: (a) Pre-operative intraoral view showing edentulous posterior maxillary site, (b) crestal incision and full-thickness mucoperiosteal flap reflection exposing the alveolar crest, (c) osteotomy preparation using piezoelectric surgical inserts for controlled thinning of the sinus floor, (d) placement of CGF membrane, (e) intraoperative implant stability assessment using resonance frequency analysis (Penguin® RF device), (f) placement former, and (g) flap repositioning and primary closure achieved with interrupted sutures.

Crestal sinus membrane elevation was then performed using a piezoelectric surgical device (Implant mode) with dedicated sinus lift inserts in the following sequence - UI2 insert: used for controlled penetration and thinning of the sinus floor, UI8 and UI9 inserts: used sequentially to perform atraumatic micro-fracture of the sinus floor and gradual elevation of the Schneiderian membrane with copious irrigation, and UI7 insert: used for smoothing and finishing the osteotomy walls to achieve the final diameter.

The integrity of the Schneiderian membrane was verified clinically. Intraoperative radiographic confirmation was obtained to ensure appropriate elevation and absence of perforation.

Group allocation–specific procedures

Group A (piezoelectric surgery + DFDBA + CGF)

After membrane elevation, DFDBA was placed into the elevated sinus cavity along with CGF. The implant was then inserted at crestal level according to the manufacturer's protocol.

Group B (piezoelectric surgery + CGF only)

Following sinus membrane elevation, CGF alone was placed into the elevated space without the addition of bone graft material. Implant placement was subsequently performed at crestal level.

Implant stability assessment

Primary implant stability was measured immediately after placement using resonance frequency analysis (Penguin® RF device). A compatible MulTipeg™ was hand-tightened onto the implant, and ISQ values were recorded in mesiodistal and buccopalatal directions. The mean value was used for analysis.

Healing abutments were placed, and flaps were repositioned and sutured using interrupted sutures.

Biochemical analysis

Peri-implant crevicular fluid (PICF) was collected at 15, 45, and 90 days' post-implant placement using calibrated microcapillary pipettes (5 µl). Samples were stored at −20°C.

OPN levels were quantified using enzyme-linked immunosorbent assay (ELISA) kits according to manufacturer instructions.

Postoperative care and follow-up

Patients received antibiotics for 5 days and analgesics as required. Sutures were removed after 1 week. At 2 months, provisional prosthesis delivered; at 3 months, clinical parameters and ISQ reassessed, PICF collected; and at 6 months: CBCT evaluation performed.

RESULTS

A total of 20 posterior maxillary implant sites were enrolled and randomly allocated equally to group A (CGF + DFDBA) and group B (CGF alone), with 10 sites in each group. All participants completed the scheduled follow-up period, and no implant failures or major intraoperative or postoperative complications were observed.

Demographic characteristics

The mean age was 40.7±3.8 years in group A and 40.9±4.0 years in group B, with no statistically significant difference between groups (p>0.05).

Gender distribution was identical in both groups (60% males, 40% females).

Table 1: Age distribution of study subjects in group A and group B.

Group	Sample size (N)	Mean age±SD (years)
Group A	10	40.7±3.8
Group B	10	40.9±4.0
Total	20	40.8±3.9

Table 2: Gender distribution of study subjects in group A and group B.

Gender	Group A (n=10), N (%)	Group B (n=10), N (%)	Total (n=20), N (%)
Male	6 (60.0)	6 (60.0)	12 (60.0)
Female	4 (40.0)	4 (40.0)	8 (40.0)
Total	10 (100)	10 (100)	20 (100)

Clinical parameters

Plaque index and gingival index

Baseline PI and GI scores were comparable between groups (p>0.05). At 3 months, both groups demonstrated a statistically significant reduction in PI and GI compared to baseline (p<0.05).

However, intergroup comparisons at baseline and 3 months showed no statistically significant differences (p>0.05).

Implant stability quotient

Baseline ISQ values were similar between groups (p>0.05). At 3 months, both groups exhibited a significant increase in ISQ values compared to baseline (p<0.05).

No statistically significant intergroup difference was observed at either time point (p>0.05).

Radiographic parameters

Buccopalatal width

Mean BPW was comparable between groups at baseline and at 6 months (p>0.05). Intragroup analysis revealed a reduction in BPW from baseline to 6 months in both groups; this reduction reached statistical significance in group B (p<0.05) but not in group A (p>0.05). No significant intergroup differences were detected at any time interval.

Vertical bone height

Baseline VBH was similar between groups (p>0.05). At 6 months, both groups demonstrated a statistically significant increase in VBH compared to baseline (p<0.05). Intergroup comparison at 6 months revealed significantly greater vertical bone gain in group A compared to group B (p<0.05).

Biochemical parameter (osteopontin levels)

OPN levels in peri-implant crevicular fluid increased progressively from 15 to 90 days in both groups, with statistically significant intragroup increases across all time intervals (p<0.05).

Intergroup comparisons demonstrated significantly higher OPN levels in group A compared to group B at 15, 45, and 90 days post-implant placement (p<0.05).

Table 3: Clinical parameters: intergroup and intragroup comparison.

Parameter	Time	Group A (mean±SD)	Group B (mean±SD)	Intergroup p value	Intragroup p value (A)	Intragroup p value (B)
Plaque index	Baseline	0.84±0.25	0.76±0.23	>0.05	—	—
	3 months	0.38±0.13	0.40±0.16	>0.05	<0.05*	<0.05*
Gingival index	Baseline	0.99±0.20	0.83±0.26	>0.05	—	—
	3 months	0.40±0.14	0.35±0.12	>0.05	<0.05*	<0.05*
ISQ	Baseline	71.20±5.51	73.20±8.68	>0.05	—	—
	3 months	78.80±6.11	75.30±6.95	>0.05	<0.05*	<0.05*

*P value statistically significant

Table 4: Radiographic parameters: intergroup and intragroup comparison.

Parameter	Time	Group A (mean±SD)	Group B (mean±SD)	Intergroup p value	Intragroup p value (A)	Intragroup p value (B)
Buccopalatal width (mm)	Baseline	7.38±0.84	8.08±1.83	>0.05	—	—
	6 months	7.16±1.28	7.56±1.82	>0.05	>0.05	<0.05*
Vertical bone height (mm)	Baseline	8.06±1.45	7.57±1.73	>0.05	—	—
	6 months	10.24±0.94	8.69±2.13	<0.05*	<0.05*	<0.05*

*P value statistically significant

Table 5: Osteopontin levels (ng/ml): intergroup and intragroup comparison.

Time interval (days)	Group A (mean±SD)	Group B (mean±SD)	Intergroup p value	Intragroup p value
15	1.61±0.19	1.12±0.07	<0.05*	<0.05*
45	3.27±0.48	1.97±0.14	<0.05*	<0.05*
90	5.68±0.81	3.14±0.24	<0.05*	<0.05*

*P value statistically significant

DISCUSSION

The present randomized clinical study evaluated clinical, radiographic, and biochemical outcomes following crestal sinus floor elevation using piezoelectric surgery with CGF alone or in combination with DFDBA. The primary finding was that although both treatment modalities resulted in significant vertical bone gain and implant stability, the addition of DFDBA to CGF produced significantly greater vertical bone height and higher OPN levels during early healing.

Crestal sinus floor elevation is considered a predictable and minimally invasive approach for implant placement in the posterior maxilla with limited residual bone height. In the present study, both groups demonstrated significant vertical bone gain at 6 months. These findings are consistent with Summers, who introduced the osteotome-mediated sinus elevation technique and demonstrated reliable bone formation beneath the elevated sinus membrane.[4] Similarly, Toffler reported favorable bone gain and high implant survival rates with indirect sinus floor elevation combined with simultaneous implant placement.[20] The vertical bone formation observed in the present study supports the biological concept that membrane elevation and clot stabilization create a secluded environment conducive to osteogenesis.

However, significantly greater vertical bone height was observed in the DFDBA + CGF group compared with CGF alone. This finding suggests that the addition of an osteoconductive scaffold enhances regenerative potential. Sohn et al demonstrated that concentrated growth factors combined with graft materials promote enhanced angiogenesis and osteoblastic differentiation during sinus augmentation.[21] In the present study, DFDBA likely provided structural support and space maintenance, while CGF contributed sustained release of growth factors such as PDGF and TGF-β. The synergistic interaction between scaffold and biologically active matrix may explain the superior dimensional outcomes observed.

Implant stability, assessed using resonance frequency analysis, increased significantly from baseline to 3 months in both groups, reflecting progressive osseointegration. These results are consistent with Rodrigo et al who reported improvement in implant stability during early healing following sinus augmentation procedures.[22] Although intergroup differences were not statistically significant, the numerically higher increase in ISQ values in the combined graft group may reflect improved bone density and maturation around the implant surface.

Peri-implant soft tissue parameters demonstrated significant reductions in PI and GI scores at 3 months in both groups, indicating favorable tissue health and adequate plaque control. These findings are in accordance with Mombelli et al who emphasized the importance of plaque control in maintaining peri-implant tissue stability.[23] The absence of significant intergroup differences suggests that the grafting modality did not influence peri-implant mucosal healing.

Buccopalatal ridge width showed a mild reduction over 6 months, which reached statistical significance in the CGF-alone group. Ridge remodeling following implant placement is a well-documented phenomenon. Araújo and Lindhe demonstrated that dimensional changes occur even in augmented sites due to physiologic bone remodeling.[24] The relatively stable ridge width in the combined graft group may be attributed to the space-maintaining properties of DFDBA, which potentially reduced transverse collapse during healing.

A distinctive component of this study was the evaluation of OPN levels in peri-implant crevicular fluid at 15, 45, and 90 days. OPN plays a critical role in bone remodeling, mineralization, and cell–matrix interactions. Both groups demonstrated a progressive and statistically significant increase in OPN levels over time, indicating active bone remodeling during early osseointegration. However, significantly higher OPN levels were observed in the DFDBA + CGF group at all-time intervals.

These findings are consistent with Giannobile et al, who reported that peri-implant crevicular fluid biomarkers reflect dynamic bone remodeling events.[25] The temporal increase in OPN levels parallels the biological healing sequence described by Davies, in which early inflammatory events are followed by osteoblastic differentiation and matrix mineralization.[26] The enhanced OPN expression observed in the combined graft group may therefore indicate more active osteogenesis and accelerated bone maturation.

Although some studies have suggested that platelet concentrates alone may be sufficient for sinus augmentation, Mazor et al reported favorable outcomes using platelet-rich fibrin as the sole grafting material.[27] In the present investigation, both groups achieved satisfactory clinical and radiographic outcomes; however, the combined use of DFDBA and CGF resulted in superior vertical bone gain and greater biochemical activity. These findings suggest that while CGF alone supports bone regeneration, the adjunctive use of an osteoconductive graft may enhance the magnitude of regeneration in cases requiring substantial augmentation.

Future perspectives of this treatment approach include validating the present findings through multicenter randomized controlled trials with larger sample sizes and longer follow-up periods to assess the long-term survival, stability, and clinical success of implants placed after piezosurgery-assisted crestal sinus floor elevation using CGF, with or without allograft.

Extended follow-up would help determine whether the early benefits observed with the DFDBA + CGF combination translate into sustained regenerative and functional advantages over time.

Future perspectives also involve incorporating histologic and histomorphometric evaluation to assess the quality, maturation, and quantity of newly formed bone within the augmented sinus. In addition, peri-implant crevicular fluid biomarker analysis should be expanded beyond OPN to include markers of bone remodeling and inflammation such as alkaline phosphatase, osteocalcin, RANKL, OPG, IL-1β, and TNF-α, which may provide a more comprehensive understanding of peri-implant healing and osseointegration.

Another important future perspective is the comparison of CGF with other grafting materials such as xenografts, alloplasts, or autogenous bone to identify the most effective regenerative approach for different clinical scenarios.

Integration of digital technologies such as CBCT-based volumetric analysis, computer-guided implant placement, and artificial intelligence-assisted imaging may further improve treatment precision and outcome assessment, ultimately supporting personalized treatment planning in sinus augmentation procedures.

Limitations

Within the study limitations, the combined approach appears to provide superior regenerative outcomes while maintaining clinical predictability and safety.

CONCLUSION

Piezosurgery-assisted crestal sinus floor elevation using CGF, with or without allograft, resulted in significant vertical bone gain and improved implant stability in the posterior maxilla. Both groups demonstrated comparable peri-implant soft tissue health and implant stability over the 3-month healing period. However, the addition of DFDBA to CGF yielded significantly greater vertical bone height and higher OPN levels, indicating enhanced bone remodeling.

ACKNOWLEDGEMENTS

Authors wound like to acknowledge the support of the Department of Periodontology and Oral Implantology, I.T.S Centre for Dental Studies and Research, Ghaziabad, for providing clinical and institutional facilities for this study. They also thank all patients who participated in the trial.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Attre T, Malhotra S, Chowdhry R, Gupta D, Pandey A, Chopra R. Comparative evaluation of dimensional changes achieved and osteopontin level in peri-implant crevicular fluid after sinus crestal floor elevation using piezosurgery and concentrated growth factor with or without allograft: a randomized clinical trial. Int J Clin Trials 2026;13(4):xxx-xx.