



Radiographic Impact of Adjunctive Chlorhexidine on Early Peri-Implant Bone Remodeling

A Randomized Controlled Clinical Trial

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Abstract

The present study aimed to determine how chlorhexidine treatment as an additional therapy affects the first radiographic results which include marginal bone level (MBL) changes and grayscale radiographic density proxy values. The research design consisted of a prospective randomized controlled clinical study which studied 48 patients through one dental implant per participant. The investigators used random assignment to place participants into either the chlorhexidine adjunct protocol group or the standard postoperative care group. The examining team took standardized periapical radiographs at both the beginning and six months after the start of the study through a paralleling technique with established exposure settings. The MBL measurement occurred through software calibration which enabled the system to measure the distance both from the mesial and distal sides while using a specific area for grayscale density proxy analysis. The research used paired and independent tests to analyze both within-group and between-group data through repeated-measures analysis which studied time–group interactions at a significance level of $p < 0.05$. The two groups experienced time-dependent changes in their crestal bone structure, yet the chlorhexidine group achieved better results through its lower mean MBL change and higher grayscale density proxy values than the control group ($p < 0.05$). Implant survival was high in both groups, with no statistically significant difference. The measurement reliability proved satisfactory through the results of calibration testing. The using chlorhexidine as an additional treatment resulted in better initial radiographic signs of peri-implant health. The present data shows a possible biological link between treatment responses and patient results, but additional present study needs to confirm these findings by tracking patients for extended periods and measuring biological indicators.

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Introduction

The dental implant therapy method now serves as a standard treatment for restoring dental function in patients who have lost some or all their teeth. The long-term achievement of dental implant therapy depends on the maintenance of stable hard and

soft tissue structures around the implants [1]. The preservation of marginal bone tissue around implants serves as a biological marker which shows the balance between microbial exposure and host inflammatory reactions and mechanical forces. The development of peri-implant mucositis and peri-

implantitis occurs when the equilibrium between the oral environment and implant surface becomes disrupted because of plaque formation and initial biofilm development [2-4]. The pathogenic process of peri-implant disease involves a biofilm-induced inflammatory response which shares

similarities with periodontitis but presents distinct features because of its different tissue structure and immune system response. The peri-implant connective tissue contains a minimal blood vessel network, and its collagen fibers arrange differently than those in the periodontal ligament which could lead to faster inflammatory bone deterioration when disease affects implants [5]. The protection of peri-implant tissues needs preventive methods which block microbial development from the start and control the local inflammatory responses [6]. The antiseptic agent chlorhexidine functions as the first choice because it eliminates various microorganisms while maintaining its presence on oral tissues to deliver prolonged defense [7]. The cationic bis-biguanide structure of this compound allows it to break down bacterial cell membranes and stop bacteria from building biofilms which results in lower microbial numbers during essential healing stages [8,9]. Present study shows that chlorhexidine used as an extra procedure during periodontal and surgical treatments helps patients achieve lower plaque amounts and less gingival inflammation, but results depend on the strength of the solution and method of application and patient compliance with instructions [10].

Research has been conducted to determine if chlorhexidine works as a perioperative implant dentistry tool which helps prevent early microbial contamination during surgical procedures and after implant component placement. Present findings indicate that antiseptic protocols containing chlorhexidine reduce bacterial counts and initial inflammatory markers in implant sites but there is no scientific evidence which demonstrates that these microbiological changes result in measurable bone preservation according to radiographic assessments [11,12]. The study shows that biological reasoning makes sense, but investigators need to verify results through radiographic assessment during controlled clinical tests.

The standard radiographic evaluation of marginal bone level functions as a vital clinical marker which shows peri-implant tissue stability when authors follow standardized imaging protocols and perform their measurements in a consistent manner. The measurement of crestal bone height changes over time serves as an independent evaluation method to assess implant success in research studies and consensus documents. The first year after implant placement or loading serves as the critical period for bone remodeling because it should stay within specific boundaries [13,14]. Biological mechanisms can be linked to measurable treatment results through the connection between

preventive antiseptic methods and radiographic bone responses.

The present investigated whether chlorhexidine treatment during implant healing period would lead to better radiographic signs which show stable peri-implant tissues. The research team analyzed radiographic results through an established antimicrobial and host-response system which previous mechanistic studies had validated. Scientists use present methods to extract findings from their data while following restricted procedures which prevent them from creating false cause-effect relationships.

Subjects and Methods

Study Design and Ethical Approval

The research followed a prospective parallel-group randomized controlled clinical study design to assess how chlorhexidine addition affects peri-implant tissue changes through radiographic evaluation during the initial healing period.

Participant Selection

The Department of oral surgery conducted consecutive screenings of patients who wanted single-tooth implant treatment for their posterior jaw area. The authors established their eligibility criteria in advance to minimize the differences between participants.

The research participants needed to fulfill specific requirements

- (1) adults aged ≥ 18 years,
- The (2) requirement exists to ensure a single endosseous dental implant can be used.
- (3) The bone tissue present in this area provides enough support for implant placement so additional grafting procedures at the same time are not required.
- (4) acceptable general health status compatible with routine implant surgery.

Exclusion criteria included:

- (1) uncontrolled systemic disease (e.g., uncontrolled diabetes mellitus),
- (2) current smoking or heavy tobacco use,
- (3) pregnancy or lactation,
- (4) ongoing immunosuppressive or long-term corticosteroid therapy,
- (5) active untreated periodontal disease, and
- (6) recent use of systemic antibiotics or antiseptic mouthrinses within the preceding four weeks.

A total of 48 eligible participants met the selection criteria and were enrolled in the study.

Due to the nature of the postoperative antiseptic intervention, participant and operator blinding was not feasible. However, outcome assessment was performed under assessor blinding conditions. The radiographic examiner maintained no knowledge about which groups the subjects belonged to while performing the evaluation of all images which

received anonymous coding for measurement purposes. The research team performed statistical analysis through group-coded datasets which helped them achieve analytical objectivity. The same experienced operator conducted all surgical procedures through a standardized protocol which minimized performance differences between procedures.

Randomization and Allocation Concealment

The investigators used a 1:1 random assignment to place participants into either the chlorhexidine adjunct group or the control group through a computer-generated randomization sequence which an independent researcher created without participating in clinical care or outcome evaluation. Allocation concealment was implemented using sequentially numbered, opaque, sealed envelopes opened only at the time of intervention assignment. The examining team used this method to reduce selection bias while maintaining the random process of participant allocation.

Interventions and Clinical Procedures

All implant surgeries were performed by the same experienced implant surgeon to reduce operator-related variability. The surgical team performed all procedures according to a standardized protocol which involved local anesthesia and crestal incision and full-thickness flap elevation when needed and sequential osteotomy preparation according to the manufacturer's drilling instructions. The surgical team performed all procedures with implants from one commercial brand which had a surface finish classified as moderately rough (sandblasted, large-grit, acid-etched — SLA or equivalent) and an internal conical connection. The design needed platform-switching geometry to function as its fundamental requirement. The dental implant sizes included diameters between 3.5 mm and 5.0 mm and lengths between 8 mm and 12 mm which were chosen based on bone availability at each site while maintaining uniform macro-design throughout all cases.

The chlorhexidine group patients received a standardized antiseptic treatment which included chlorhexidine gluconate 0.12% mouthrinse for twice daily use during 14 days beginning right after their surgical procedure. In addition, a 0.2% chlorhexidine gel was applied to the peri-implant sulcus at the surgical visit and at the first postoperative review (7 ± 2 days). The research team established both concentration levels and delivery methods before beginning to reduce participant variations which would result in more reliable findings. The patient received verbal and written instructions about the postoperative rinsing protocol which they

needed to follow. The research team asked participants to monitor their drug adherence and medication side effects during both the 1-week and 1-month duration. Patients needed to follow their scheduled medication schedule for the first 14 days of treatment unless their doctor gave them alternative instructions.

The control group patients followed the same surgical and postoperative guidelines but they skipped chlorhexidine usage and used sterile isotonic saline for twice daily rinsing during the 14-day period to create equal chemical rinsing conditions without any antiseptic properties. The study employed the same mechanical oral hygiene procedures and identical systemic medications with analgesics to evaluate the antiseptic protocol as the main treatment for both groups.

The study did not use systemic antibiotics as standard treatment but doctors documented all antibiotic prescriptions along with their medical reasons which they treated all patients equally to prevent any bias from occurring.

Outcome Measures

Primary Radiographic Outcome — Marginal Bone Level (MBL)

The study measured its main outcome through changes in marginal bone levels which occurred relative to the implanted devices. The authors took standardized digital periapical radiographs right after implant placement (T0) and again during the six-month follow-up period (T1). The investigators used paralleling technique with an individualized positioning device to achieve standardized positioning through a system which maintained equal angulation between different time points. The maintained constant exposure parameters which included kVp and mA and exposure time for all patients.

The measurements took place through the use of calibrated image analysis software which had been properly calibrated. The vertical distance from the implant platform reference point to the first bone-to-implant contact was measured on both mesial and distal aspects, and the mean value was recorded for analysis. The examining team used known implant thread pitch and implant length as internal references to normalize their measurements for radiographic magnification effects (Figure 1).

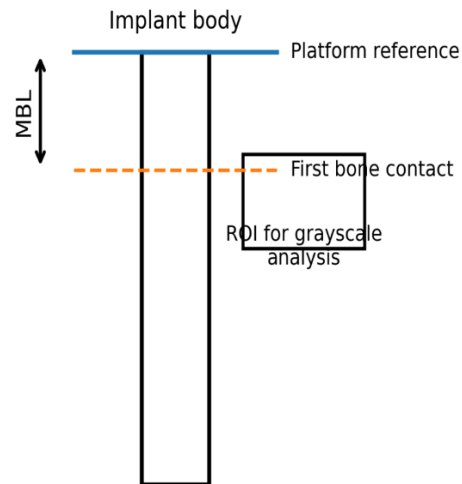


Figure 1. Standardized radiographic measurement protocol showing the implant platform reference line, marginal bone level (MBL) measurement axis, and the predefined grayscale region of interest (ROI).

Secondary Radiographic Outcome — Grayscale Density Proxy

The assessment of peri-implant radiographic density used grayscale values to show the density of the surrounding tissue which covered the implant surface inside a specified ROI. The ROI size and position followed established definitions which researchers used to analyze both baseline and follow-up images. The two-dimensional radiograph grayscale values depend on exposure and processing variables so this parameter functioned as a relative radiographic density indicator instead of a direct bone mineral density measurement. The acquisition of all images occurred through the same device settings which minimized technical differences between images.

Examiner Calibration and Measurement Reliability

A blinded examiner who did not know which group the participants belonged to performed all radiographic measurements. The examiner needed to complete a calibration process which involved using a limited set of images that he measured twice during a two-week period. The intraclass correlation coefficient (ICC) measured the degree of observer agreement between their multiple observations. The investigators started their measurements after they reached acceptable results for repeatability which had an ICC value of 0.85 or higher. The present study team conducted a review of all discrepant readings which they then combined to generate an average value.

Follow-Up and Clinical Monitoring

The medical team performed scheduled follow-up evaluations of patients at 1 week, 1 month, 3 months and 6 months after surgery. The team conducted clinical evaluations of

implant stability together with peri-implant soft tissue health assessments at all scheduled appointments while recording all treatment-related issues. The survival of implants depended on their continued presence in the body while showing no signs of mobility or pain or infection or bone deterioration that exceeded typical early bone remodeling boundaries.

Sample Size Sample size was calculated based on the primary outcome (change in marginal bone level, Δ MBL) using a two-group comparison of mean differences. An expected standardized effect size of approximately 0.7 was derived from previously reported variability and between-group differences in early peri-implant marginal bone level changes in controlled implant studies. The study required 22 participants for each group to achieve statistical power of 80% while maintaining a 0.05 significance level. The authors determined 24 participants for each group to account for possible participant dropout which they predicted [13,14].

Statistical Analysis

Data analysis was conducted using SPSS software. Continuous variables were tested for normal distribution using the Shapiro-Wilk test. Descriptive statistics were expressed as mean \pm standard deviation.

The research team performed paired t-tests to evaluate the changes which occurred between baseline data and six-month assessment results for all groups. The present study team performed independent-samples t-tests to determine if groups showed different changes through their Δ scores which equal T1 minus T0. In addition, a two-way repeated-measures ANOVA was applied to examine the interaction effect between time and treatment group for the principal radiographic outcomes. The examining team performed Fisher's exact test to evaluate categorical data between implant survival rates and all other measured outcomes. The present finding established $p < 0.05$ as its statistical significance threshold. Homogeneity of variance between groups was evaluated using Levene's test before applying independent-samples comparisons. In addition to p-values, 95% confidence intervals (95% CI) for mean differences and change scores were calculated to support effect size interpretation.

Results

Participant Flow and Baseline Characteristics

A total of 48 patients were enrolled and randomized equally into two arms (chlorhexidine adjunct group, $n=24$; control group, $n=24$). All participants completed the six-month radiographic follow-up and were

included in the final analysis. The documented no deviations from the protocol which impacted the assessment of results. The investigators assessed initial demographic and clinical data through which they measured age distribution and sex breakdown and implant locations and first radiographic measurements, but they did not detect any meaningful differences between groups ($p > 0.05$). (Table 1) and (Figure 1).

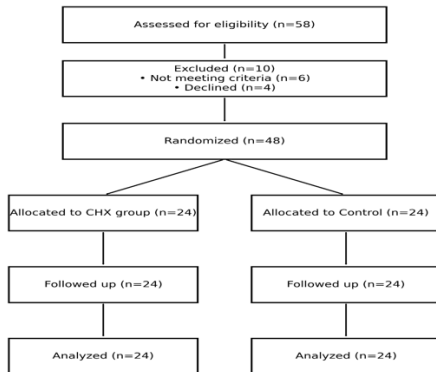


Figure 1. CONSORT flow diagram of patient screening, exclusion, randomization, allocation, follow-up, and final analysis.

Marginal Bone Level Changes

The researchers calculated marginal bone level changes through Δ MBL measurements which compared each patient's present condition to their baseline measurement. Both groups demonstrated time-related crestal remodeling over six months; however, the magnitude of Δ MBL differed between the intervention arms.

The within-group analysis showed that both study groups experienced a statistically significant increase in their mean marginal bone loss when compared to their baseline measurements (paired t-test, $p < 0.05$). Nevertheless, the chlorhexidine adjunct group exhibited a smaller mean MBL change compared with the control group at six months. The analysis of change scores (Δ MBL) between groups showed that the between-group difference in Δ MBL was statistically significant because the chlorhexidine group achieved a 0.29 mm better result (95% CI: 0.16 to 0.42 mm, $p < 0.01$), indicating a more favorable radiographic bone preservation pattern in the antiseptic-supported protocol. The Two-way repeated-measures ANOVA results showed that MBL demonstrated a significant time \times group interaction effect ($p < 0.05$) which proved that treatment approaches produced different bone level changes throughout time instead of showing typical physiological bone remodeling patterns. (Table 2, Figure 2).

The study used T0 measurements as internal references to evaluate implant marginal bone level changes throughout the study

period. The investigators used T0 measurements as their reference point to measure bone level changes instead of establishing zero as an errorless value.

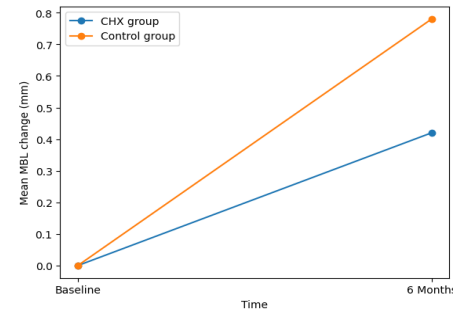


Figure 3. Mean marginal bone level (MBL) change from baseline to six months in the chlorhexidine and control groups.

Radiographic Grayscale Density Proxy

The quantitative grayscale analysis of the defined peri-implant region of interest showed that chlorhexidine group mean grayscale values rose in a specific pattern during the study period, but the control group showed either no change or a smaller increase in values. The grayscale measurements function as a relative radiographic density proxy which makes direct mineral density measurement impossible, so we used them for comparative pattern analysis under controlled exposure conditions.

The present study results from within-group analysis demonstrated that the chlorhexidine group showed a significant increase from T0 to T1 ($p < 0.05$) but the control group did not achieve statistical significance in their changes. The analysis of grayscale changes scores between groups showed that the chlorhexidine protocol produced better results than the other protocol ($p < 0.05$). The repeated-measures ANOVA interaction term for grayscale values showed statistical significance ($p < 0.05$) which proved that the two groups demonstrated different time-dependent patterns (Table 3).

No external radiographic density calibration phantom or step wedge was used; therefore, grayscale values were not interpreted as absolute bone mineral density measurements. The mean between-group difference in grayscale proxy change was 13.6 units (95% CI: 2.1 to 25.0 units, $p = 0.03$) which showed a more radiopaque peri-implant pattern under controlled imaging conditions.

Implant Survival and Clinical Events

The six-month evaluation showed that all implants in the chlorhexidine group survived but the control group reached 95.8% survival because one implant failed to meet stability requirements thus being considered unsuccessful. The results from Fisher's exact test showed no statistically significant differences between groups because the p value

exceeded 0.05 despite the small number of actual events. The antiseptic protocol proved safe because it did not lead to any major postoperative infections or tissue reactions during the present study period. The results for implant survival and clinical events appear in Table 4.

Measurement Reliability

The calibration process required multiple measurements which showed that the radiographic linear measurements and grayscale ROI assessment between different examiners produced similar results. The intraclass correlation coefficient exceeded the established acceptability threshold (ICC ≥ 0.85) which showed that the measurements demonstrated sufficient consistency.

Discussion

The study used randomization to show that chlorhexidine treatment during the first stage of implant healing produced better radiographic results and produced higher grayscale values which indicated a more radiopaque implant environment under controlled imaging protocols.

The method requires precise control of exposure geometry and detector behavior because two-dimensional grayscale analysis produces relative radiographic patterns which should not be used as actual densitometric measurements.

The present work data shows that local antiseptic control methods help maintain peri-implant tissue stability during the first period when authors depend on radiographic assessment instead of biological tests.

The mechanistic view of early marginal bone remodeling in implants shows that this process results from multiple factors which include surgical damage to tissues and the body's inflammatory reaction and the way the body responds to mechanical forces and the growth of microorganisms on implant surfaces. The consensus reports demonstrate that plaque-induced inflammation becomes the main cause of peri-implant tissue deterioration after biofilm reaches its mature stage [2,3].

The reduction of initial microbial growth through any intervention will create a negative impact on the inflammatory processes which activate osteoclasts to cause bone loss in the alveolar crest. The wide antimicrobial spectrum and ability to bond with surfaces of chlorhexidine makes it the main oral antiseptic for chemical plaque control [8,9].

The chlorhexidine group showed a smaller MBL change which can be explained through its antimicrobial-inflammatory mechanism. present work findings from laboratory studies and medical facilities show that biofilm formation near implant collar edges creates a new environment which leads to changes

in cytokine levels that result in higher IL-1 β and TNF- α production which causes bone destruction. The early inflammatory response becomes less severe because chlorhexidine protocols decrease bacterial numbers and extend the period needed for biofilm formation to begin. Studies about periodontal and peri-implant areas demonstrate that chlorhexidine mouthrinses and gels decrease plaque formation and gingival inflammation, but the level of success depends on how long and how the products are applied [10].

The radiographic results we obtained match the preventive pattern, but they also show how bone tissue near implants reacts to the situation.

The results need to be evaluated against the established biological boundaries which control bone transformation during the initial period of implant integration. The first year following implant placement or loading needs significant crestal bone changes to achieve successful implant results based on traditional success criteria.

The present study detected between-group differences which indicate remodeling occurs at different levels of intensity rather than complete elimination of the process. The antiseptic adjunct seems to influence the bone remodeling process instead of stopping bone transformation from occurring.

The antiseptic group showed higher grayscale radiographic density proxy values which indicate better peri-implant bone response, but investigators need to exercise caution when analyzing this parameter. The grayscale values from standardized periapical radiographs function as relative density indicators which do not represent actual bone mineral density measurements. Studies about imaging have shown that grayscale values remain affected by exposure settings and device specifications when examining team perform their studies under controlled environments. The main advantage of their method stems from their ability to evaluate different data points across each study rather than their ability to measure density precisely. The researchers use this data as a longitudinal proxy under fixed acquisition conditions to identify important biological changes which impact mineralization and trabecular organization patterns between groups.

The implant survival results showed higher numbers in the chlorhexidine group but no significant difference between groups because of the small number of events and small sample. The current consensus reports show that implant survival rates stay high during short implantation times when surgeons execute procedures with correct control methods, but investigators need to study

large numbers of patients to demonstrate survival rate variations [3]. The lack of statistical separation between survival results does not oppose the observed radiographic benefits because it demonstrates how small groups with infrequent events will behave statistically.

The results from this study follow the same pattern as previous interventional studies which demonstrate that infection-control protocols during implant healing bring benefits through antiseptic rinses and local antimicrobial measures [11,12]. The previous reviews showed that authors employed distinct methods and antiseptic concentrations which they delivered through different systems to record their effects by using multiple assessment parameters. This work adds new controlled radiographic information to the field but fails to address the existing differences between studies because it lacks standardized antiseptic methods and common radiographic assessment criteria.

The evaluation needs to identify various elements which might result in wrong assessments about cause-and-effect relationships. The used radiographic results as its main data but it did not measure biological markers including peri-implant crevicular fluid cytokines or microbiological profiles so the study cannot prove the biological process directly. Second, grayscale density analysis follows standardized internal procedures, but it does not match the precision of calibrated densitometry. The follow-up period shows the initial stages of tissue recovery and reconstruction instead of demonstrating how the body responds to extended functional stress. The present work included enough participants to analyze radiographic changes through statistical methods although the limited number of participants made it difficult to identify rare implant failure occurrences.

The study data shows a methodical yet restricted understanding which demonstrates that chlorhexidine treatment as an adjunct therapy produces superior first radiographic assessments of peri-implant tissues because of its antimicrobial and anti-inflammatory properties. The present work requires additional studies which will link biomarkers to longer observation periods to validate the obtained results. The following stage for biological-radiographic correlation development needs scientists to combine their radiographic measurement data with their molecular inflammatory data analysis results.

Limitations

The current study contains multiple methodological restrictions which need to be recognized. The results focused on radiographic data because scientists did not measure any biological or molecular indicators which

would show peri-implant inflammation or microbial load so the results cannot be used to prove any mechanisms. Second the grayscale radiographic density values function as a relative measurement which does not correspond to standardized bone mineral density values. The duration study was six months allowed investigators to observe initial tissue recovery, but it did not show how the treatments would affect patients' long-term functional abilities. The used an appropriate number of participants to identify radiographic changes but the small participant count restricted from achieving sufficient power to measure rare clinical events which include implant failures and complications. The study evaluated one antiseptic treatment method with its specific concentration which could limit the application of results to different chlorhexidine protocols and application techniques. Operator and participant blinding were not possible due to the nature of the antiseptic intervention, which may introduce performance-related bias despite assessor blinding. The failure to register trials in advance before their start constitutes a problem with reporting..

Conclusion

The current study data from this randomized clinical study showed that chlorhexidine treatment during the first stage of peri-implant healing produced better results than standard treatment because it led to small bone level changes and better radiographic density results. The current findings align with biological principles because scientists have established that interrupting biofilm development at its beginning stage minimizes implant site inflammation while protecting tissue health. The current results depend on radiographic markers instead of direct molecular or microbiological evidence so the observed benefit should be viewed as an association between results rather than as proof of biological processes. Research studies need to validate their findings through the connection of X-ray data to medical documents and biomarker assessment which should continue throughout the entire period [2,3].

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Table 1. Baseline demographic and clinical characteristics of the study groups.

Parameter	Group A (CHX)	Group B (Control)	p-value
Number of patients	24	24	—
Mean age (years)	41.3 ± 7.2	42.1 ± 6.8	0.68
Gender (M/F)	13 / 11	12 / 12	0.77
Implant site (Maxilla/Mandible)	10 / 14	11 / 13	0.79

Table 2. Marginal bone level change relative to baseline reference (mm).

Time Point	Group A (CHX)	Group B (Control)	p-value
Baseline (reference)	—	—	—
6 months (Δ MBL)	0.62 ± 0.18	0.91 ± 0.24	< 0.01

Table 3. Peri-implant grayscale density proxy values at baseline and six months.

Time Point	Group A (CHX)	Group B (Control)	p-value
Baseline	112.4 ± 14.6	110.9 ± 15.1	0.74
6 months	138.2 ± 16.3	124.6 ± 18.7	0.03

Table 4. Implant survival and clinical events at 6-month follow-up.

Outcome	CHX group (n=24)	Control group (n=24)	p-value
Surviving implants	24 (100%)	23 (95.8%)	0.31*
Failed implants	0 (0%)	1 (4.2%)	
Post-operative infection	0	0	—
Adverse tissue reaction	0	0	—

* Fisher's exact test