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Peri-Implant Reconstruction With Autogenous Bone and Electrolytic Therapy: A Randomized Controlled Clinical Trial

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ABSTRACT

Objectives: To evaluate the efficacy of peri-implant reconstructive therapy using autogenous tuberosity bone grafts, with or without adjunctive electrolytic therapy, as part of surgical treatment for peri-implantitis.

Methods: This randomized controlled clinical trial included 31 patients diagnosed with peri-implantitis. Participants were assigned to either a control group receiving mechanical debridement and bone grafting or a test group undergoing additional electrolytic cleaning (EC). Clinical parameters assessed included probing pocket depth (PPD) at mesial, buccal, distal, and lingual sites, gingival index (GI), and bleeding on probing (BOP), with measurements taken at baseline and at 12 months post-treatment. Radiographic assessments were conducted at baseline and at the 1-year follow-up to evaluate bone defect fill at mesial and distal sites. Intraoperative bone fill was also assessed at mesial, buccal, distal, and lingual sites on the day of surgery and 6 months post-surgery.

Results: Both groups exhibited statistically significant PPD reductions at all sites and improvements in GI and BOP compared to baseline. No statistically significant differences between groups were found for these clinical parameters. Radiographically, the test group demonstrated significantly greater mean bone defect fill at the mesial site compared to the control group, with gains of 4.6 mm (±1.10 mm) versus 2.5 mm (±1.77 mm), respectively ($p = 0.002$). Intraoperatively, the distal site showed a mean gain of 4.7 mm (±1.41 mm) in the test group and 3.8 mm (±1.72 mm) in the control group after 6 months; however, this difference was not statistically significant ($p = 0.069$). Suppuration resolved completely in both groups after 1 year ($p < 0.001$), with no significant differences between groups.

Conclusions: Peri-implant reconstructive therapy using autogenous bone grafts led to statistically significant clinical and radiographic improvements in both groups. The addition of electrolytic cleaning did not result in significant differences. The absence of histological data, which could not be obtained in this human trial, remains a limitation for confirming re-osseointegration.

Algirdas Puisys and Samuel Akhondi contributed equally and should be considered first-authors.

1 | Introduction

Dental implants have become widely used in recent years. In the United States alone, projections suggest that the prevalence of dental implants will increase to 23% by 2026 [1]. Globally, the annual market for dental implants is estimated at around 12–18 million implants sold [2].

As the number of implant procedures increases globally, the incidence of peri-implant diseases, has emerged as a major concern since it affects a notable portion of implant patients. The prevalence of peri-implantitis varies depending on the diagnostic criteria applied, with incidences going from 27.9% to up to 43% over a five-year period [3, 4]. Peri-implantitis is a complex condition primarily caused by bacterial biofilms, with their progression influenced by various local factors that promote biofilm accumulation and trigger an inflammatory response [5].

Various treatments for peri-implantitis have been explored, including mechanical decontamination methods such as titanium brushes and curettes [6], ultrasonic devices [7, 8], as well as more advanced approaches like air polishing and lasers [9–12]. However, none of these methods have consistently achieved predictable long-term results, and there remains a challenge in eliminating bacterial biofilms from implant surfaces without causing damage to the implant itself [13–16]. The goal of such treatments is to reduce the bacterial load below a critical threshold to prevent the recurrence of peri-implant disease [6]. In addition to bacterial biofilm removal, endotoxins must also be cleared, and the implant surface must be prepared in a way that facilitates re-osseointegration [17, 18].

Historically, re-osseointegration following peri-implantitis treatment was considered unpredictable. Despite decontamination efforts, achieving true biological re-osseointegration was often unsuccessful [19]. Early studies have shown that implant surfaces previously contaminated with plaque often fail to fully re-osseointegrate, even after thorough cleaning [20]. Research into implant surface preparation involving bone grafting and re-osseointegration attempts after experimental peri-implantitis in animal models also showed limited success, even with comprehensive decontamination protocols [21, 22]. The success of these efforts largely depended on the characteristics of the implant surface, such as the substantivity of the rough surface in titanium implants. However, no method has consistently proven effective in maintaining previously infected implants in the long-term [23, 24]. Consequently, the risk of re-infection remained significant, with rapid bacterial recolonization often reoccurring after treatment [25].

An emerging alternative to conventional subtractive debridement of contaminated implant surfaces is electrolytic cleaning. Originally developed to clean stainless steel surfaces [26] this method has been adapted for use on titanium implant surfaces. Electrolytic cleaning typically involves the application of a low-voltage current to an electrolyte solution delivered in contact with the implant surface. This process is thought to generate reactive oxygen species (ROS), including tri-iodide and peroxide, while simultaneously producing hydrogen gas. The resulting microbubbles are believed to lift and dislodge biofilm from the implant surface without damaging its microstructure. Some systems incorporate a sponge-like interface to maintain circumferential contact of the solution around the exposed implant, including the apical region [27, 28]. In contrast to traditional methods that may damage implant surfaces or fail to fully eliminate biofilms, electrolytic cleaning preserves the integrity of the implant and supports potential re-osseointegration [29–31]. Although the precise mechanisms remain under investigation, available evidence supports the role of ROS and bubble-mediated disruption in facilitating biofilm removal [32]. Additionally, this approach has been shown to significantly reduce the total bacterial load on previously contaminated implant surfaces. These results support its biological efficacy and reinforce its potential utility in clinical settings, where persistent microbial contamination is a key obstacle to peri-implant tissue regeneration [33].

A large portion of the existing research on implant surface decontamination and re-osseointegration using electrolytic cleaning has been conducted in in vitro settings, evaluating changes in the appearance of titanium discs, such as discoloration after treatment [34–36]. These studies, while insightful, do not necessarily reflect clinical realities.

The objective of this study is to evaluate the effectiveness of a combined treatment approach for managing peri-implantitis using guided bone regeneration (GBR) in conjunction with electrolytic cleaning. The study aims to assess whether electrolytic cleaning can improve clinical and radiographical outcomes, thereby helping in the resolution of the peri-implantitis. Following implant decontamination, GBR using a resorbable membrane and autogenous bone from the tuberosity was performed to fill bone defects around the implant. Clinical outcomes were evaluated through intrasurgical assessments, radiographic analysis, and probing depth measurements. The goal was to determine whether the addition of electrolytic cleaning to a standardized regenerative protocol yields any statistically significant differences in clinical or radiographic outcomes compared to conventional treatment alone.

2 | Materials and Methods

2.1 | Study Design

This randomized controlled clinical trial was conducted at Vilnius Implantology Center (Vilnius, Lithuania). The study received ethical approval from the Vilnius regional biomedical research ethics committee, with the reference number 2020/4-1222-705. It was registered at clinicaltrials.gov under registration number NCT06708247. The study adhered to the principles of the Helsinki Declaration and followed the guidelines outlined in the Consolidated Standards of Reporting Trials 2010 guideline (Consort, www.consort-statement.org). The surgeries were performed between June 2020 and June 2021. Participants were randomly allocated into the control group and the test group and randomization was performed using a computer-generated randomization list, with sealed envelopes ensuring allocation concealment. The null hypothesis was that there is no significant difference in clinical outcomes (e.g., probing pocket depths, bleeding on probing) or bone defect fill between the test group

treated with peri-implant reconstructive therapy using autogenous tuberosity bone grafts combined with adjunctive electrolytic cleaning and the control group treated with the same therapy without electrolytic cleaning.

Follow-up assessments were made 6 months post-operatively when the second-stage surgery was performed, as well as 12 months after prosthetic loading (Figures 1 and 2).

2.2 | Sample Size Calculation

A sample size calculation was performed prior to patient enrollment using G*Power (version 3.1). At the time of conceptualization of this trial, only minimal clinical data were available on the use of electrolytic cleaning in peri-implantitis treatment. Consequently, the anticipated effect size (Cohen's $d = 1.0$) was estimated based on the clinician's experience with the treatment

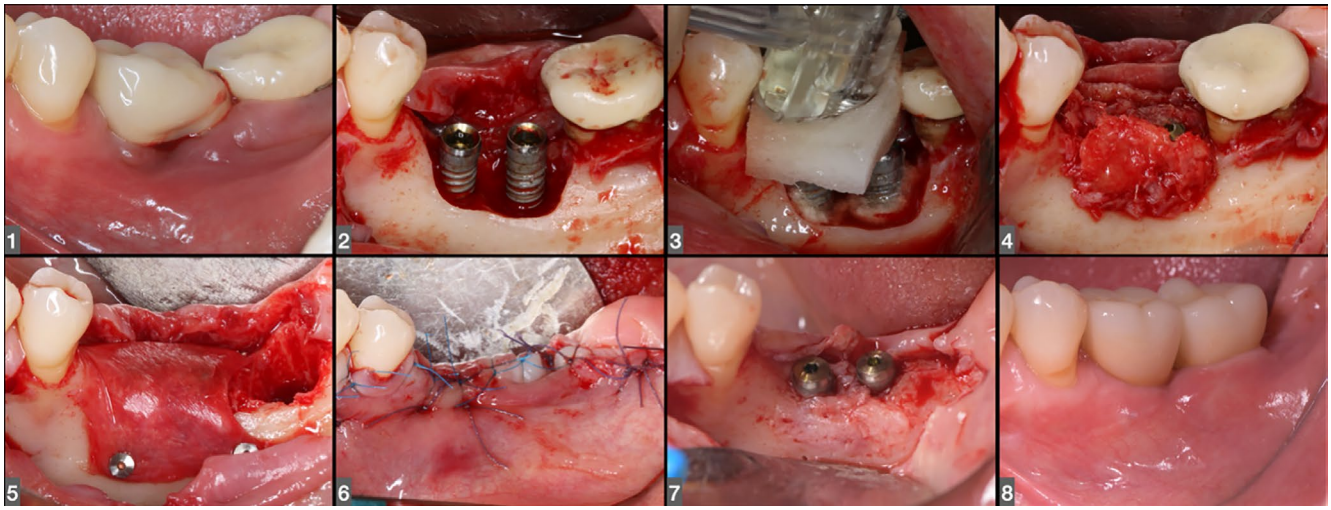

FIGURE 1 | (1) Clinical presentation after 3 months of conservative peri-implantitis treatment, enabling surgical intervention. (2) Surgical site after granulation tissue removal and implant surface debridement. (3) Supplementary cleaning of the implant surface using an electrolytic cleaning device. (4) Defect filled with autologous bone chips harvested from the maxillary tuberosity; additional autologous bone chips from the mandible layered to augment the defect. (5) Collagen membrane secured with titanium pins. (6) Primary, tension-free flap closure achieved. (7) Second-stage surgery at 6 months post-treatment showing bone defect fill of the peri-implant defect. (8) One-year follow-up with new prosthesis and re-established soft tissue dimensions.

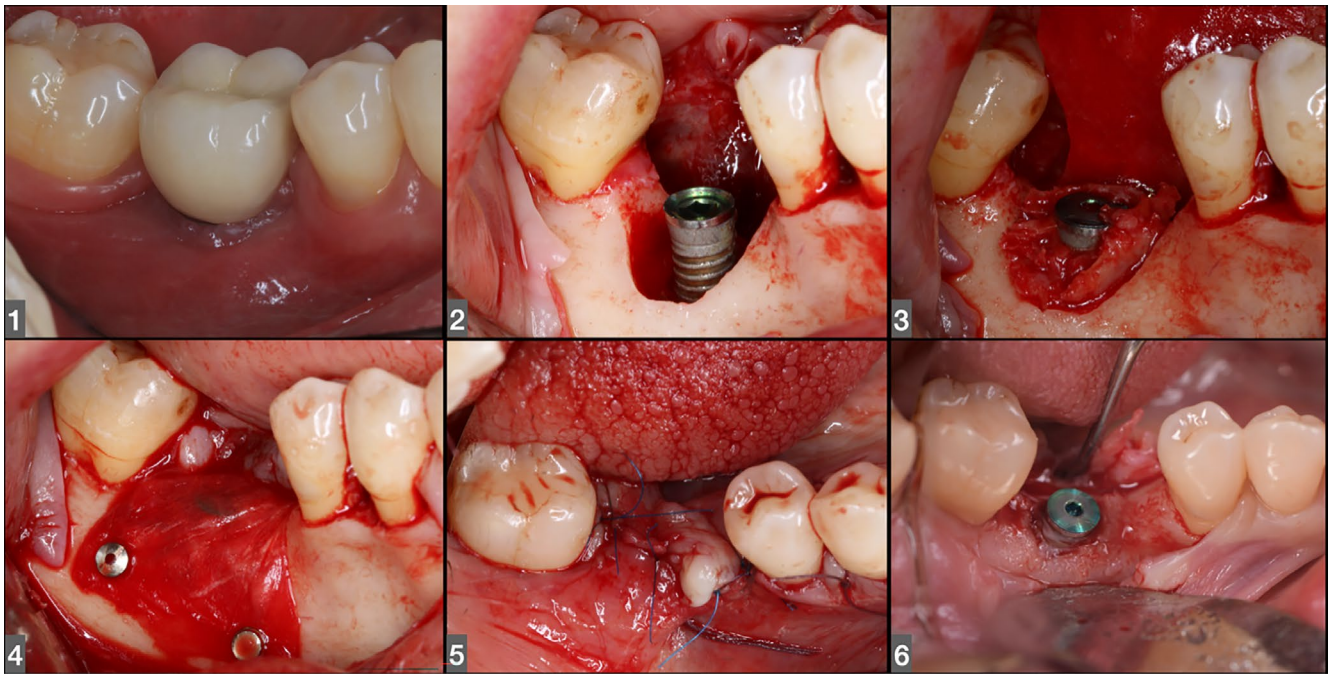

FIGURE 2 | (1) Clinical presentation after 3 months of conservative peri-implantitis treatment, enabling surgical intervention. (2) Surgical site after granulation tissue removal and implant surface debridement. (3) Defect filled with autologous bone chips harvested from the maxillary tuberosity. (4) Collagen membrane secured with titanium pins. (5) Primary, tension-free flap closure achieved. (6) Second-stage surgery at 6 months post-treatment showing bone defect fill of the peri-implant defect.

protocol and the expected magnitude of clinical improvement. Assuming a significance level of $\alpha = 0.05$ and a power (1–β) of 0.80, the calculation indicated a minimum of 34 patients (17 per group) would be required. Ultimately, 31 patients were enrolled, closely approximating this target. While the reliance on clinical experience to define the effect size is acknowledged as a limitation, it reflects the evidence gap at the time of study design and provides a pragmatic framework for trial planning.

2.3 | Participants

2.3.1 | Inclusion Criteria

Panoramic radiographs, cone-beam computed tomography (CBCT) as well as clinical diagnosis were used for initial participants screening. Participants were included if they met the following criteria: (1) Age > 18 years; (2) At least one titanium implant diagnosed with peri-implantitis defined as bleeding and/or suppuration on gentle probing, an increase in probing depth compared to previous measurements (PPD > 6 mm), and radiographic evidence of bone loss [37]; (3) Implants in function for over 1 year with progressive bone loss > 3 mm detected radiographically.

Only one implant per participant was included in the final analysis to avoid within-subject clustering bias; in cases with multiple affected implants, the site with the most severe baseline condition was selected.

2.3.2 | Exclusion Criteria

Exclusion criteria were as follows: (1) Uncontrolled medical conditions or systemic diseases (2) Pregnant women (3) Smokers consuming more than 10 cigarettes/day (4) Implant mobility (5) Cases where it was not possible to remove the supra-structure (e.g., cemented implant supported restoration).

2.4 | Randomization and Blinding

Patients were randomized 1:1 to adjunctive electrolytic cleaning (EC) or control (C) using a computer-generated sequence (randomizer.org). Allocation was concealed with sequentially numbered, opaque, sealed envelopes prepared by a coordinator not involved in treatment or assessments. Baseline intraoperative defect measurements at mesial, buccal, distal, and lingual sites were recorded before randomization. The surgeon remained blinded until completion of flap elevation, initial mechanical debridement of the implant surface, and defect measurement (surgical step 4). The envelope was then opened in the operatory immediately before any adjunctive decontamination to reveal EC or C; masking of the surgeon thereafter was not feasible. Participants were not informed of allocation. All follow-up clinical examinations at 6 and 12 months were performed by a calibrated examiner blinded to allocation and not involved in surgery. Radiographic measurements were performed on anonymized, time-coded images by an independent assessor blinded to allocation and time point. Primary analyses were conducted by a statistician on a dataset with groups coded A/B and unblinded only after database lock.

2.5 | Pre-Surgical Treatment

A two-step conservative treatment protocol was administered to reduce inflammation prior to surgical intervention, with all procedures performed in the private practice. In the first step, the old restoration was removed, and patients were scheduled for weekly visits for 3 weeks. At each visit, the affected area was cleaned by local rinsing with chlorhexidine delivered by a syringe, and local antibiotics (metronidazole and piperacillin/tazobactam [Gelcide, Implantprotect, Italy]) were applied to reduce the bacterial load [38]. In the second step, non-surgical mechanical debridement was performed using curettes and erythritol powders (Perioflow, EMS, Germany). During these sessions, the area was again rinsed locally with CHX (chlorhexidine gluconate), and local antibiotics were applied. This debridement procedure was repeated at two-week intervals, up to three times, under professional supervision in the clinic.

After completion of the non-surgical phase, all participants were re-evaluated at 3 months. Clinical parameters including probing depths, bleeding on probing, and suppuration were reassessed at that time. None of the participants met the criteria to remain in non-surgical maintenance and were enrolled to proceed with surgical intervention [39].

2.6 | Surgical Treatment

All surgeries were performed by a single surgeon (A.P.) under local anesthesia with articaine hydrochloride 4% with epinephrine (1:100.000). A sample case for the treatment protocol in the test group is presented in Figure 1.

2.6.1 | Test Group (Electrolytic Cleaning + Bone Grafting)

1. A mid-crestal incision with a mesial vertical releasing incision was made using a #15c blade. Intrasulcular incisions were extended around adjacent teeth or, if the edentulous area was distal, a vertical incision was made distal to the site.
2. A full-thickness mucoperiosteal flap was elevated to expose the implant surface and surrounding bone defect.
3. Granulation tissue was removed using hand curettes (Hu-Friedy, Chicago, IL, USA), followed by refinement with a Gracey curette.
4. Erythritol air-powder (Perioflow, EMS, Switzerland) was used to remove biofilm and decontaminate the surface [40], followed by thorough rinsing with chlorhexidine gluconate 0.12% (CHX) [41], metronidazole, and saline solution to ensure a sterile environment (Figures 1 and 2).
5. Electrolytic cleaning was performed immediately after degranulation. A sponge-based applicator containing a conductive interface was positioned circumferentially around the exposed implant body. A low-voltage direct current—typically around 15 VDC at a current of up to 0.6 A—was applied to an electrolyte solution composed of sodium formate and hydroxycarboxylic acid, which was continuously delivered at a flow rate of approximately 100 mL/min. The system is

designed to generate reactive oxygen species (ROS) and hydrogen gas (GalvoSurge Dental AG, Widnau, Switzerland). The resulting bubble formation facilitated detachment of biofilm. Stable fluid contact was ensured across all exposed implant threads, including the apical region. Cleaning was carried out for 2 min, during which visible foaming was observed. To avoid interference, metallic instruments were kept at a distance of over 20 mm. The site was thoroughly rinsed with sterile saline following the procedure.

6. The bone defect was grafted using cortico-spongious autogenous bone harvested from the maxillary tuberosity with a trephine drill (TRE060M, Hufriedy, Chicago, IL, USA). If additional graft volume was required, autologous bone chips and allograft material (Maxgraft, Germany) were blended with the tuberosity graft.
7. The graft was covered with a resorbable collagen membrane (Membrane Flex, Straumann, Switzerland), which was stabilized using titanium membrane pins (Metapin, Meta, Italy).
8. The flap was released by periosteal scoring and closed tension-free using a double-layer suture technique, consisting of horizontal mattress sutures (4–0 PGA) and interrupted sutures (6–0 polypropylene). Implants were left submerged during healing.
9. After 6 months, a second-stage surgery was performed. Healing abutments were placed, and autogenous soft tissue grafting was performed in cases requiring enhanced keratinized mucosa or soft tissue volume around the implant.

2.6.2 | Control Group (Bone Grafting Only)

The control group followed the same surgical protocol as the test group with the exception of step 5. All other steps, including incision design, grafting, membrane placement, flap closure, and second-stage procedures, were identical to those described in the test group (Figure 2).

2.7 | Postoperative Instructions and Medications

All patients in both groups received postoperative care, which included antibiotics (875 mg amoxicillin plus 125 mg clavulanic acid, twice daily for 7 days) and pain management with ibuprofen (400 mg, three times daily for 5 days). Chlorhexidine rinses were prescribed for use after surgery. Patients were also given oral hygiene instructions, which instructed the patients to avoid cleaning the surgical area and to clean the surrounding tissues gently with a soft toothbrush post-surgery. Normal oral hygiene practices were resumed after 2 months, once the suprastructure was attached.

2.8 | Outcome Measurements

2.8.1 | Primary Outcome Measurements

To assess the extent of bone defect fill, linear measurements were performed from the implant shoulder to the first bone-to-implant contact at four sites (mesial, buccal, distal, and lingual) using a calibrated periodontal probe (UNC-15, Hu-Friedy). The initial measurements were taken during the initial surgery, after debridement and implant surface cleaning, but prior to group allocation. At 6 months, during implant uncovery, the same measurements were repeated at the same four sites. All measurements were conducted by the same operator (A.P.), who remained blinded to group allocation at the time of initial defect assessment. Bone defect fill was defined as the reduction in distance from the implant shoulder to the bone crest between the two time points, reflecting the amount of vertical bone regeneration achieved.

2.8.2 | Secondary Outcome Measurements

Clinical and radiological assessments were carried out at baseline and after a 1-year follow-up to measure treatment efficacy: Gingival Index (GI) as described by Löe [42], suppuration, bleeding on probing (BOP), and probing pocket depths (PPD) were measured at four sites: mesial (M), distal (D), lingual (L), and buccal (B). Radiographs were used to evaluate bone levels, and both clinical and radiological stability were assessed. Standardized digital periapical radiographs were obtained at baseline and 12 months using a long-cone paralleling technique. All images were acquired on the same x-ray unit with fixed exposure parameters, exported without compression, and archived in TIFF. Calibration was performed in the measurement software using a known linear reference (implant body length or thread pitch) to determine the pixel-to-millimeter ratio. Mesial and distal crestal bone levels were measured along the implant axis from the implant shoulder to the most coronal bone-to-implant contact, to 0.01 mm precision; negative values indicate bone loss and positive values indicate bone gain versus baseline. All secondary outcome parameters were recorded by the same experienced examiner following a standardized protocol to reduce measurement variability. While formal inter- or intra-examiner reliability testing was not conducted, the examiner was blinded to group allocation throughout the study.

This clinical trial was initiated in 2020, prior to the publication of the Implant Dentistry Core Outcome Set and Measurement (ID-COSM) framework in 2023 [43]. While full adherence was not possible, we acknowledge the importance of this initiative. Several recommended outcome domains—such as peri-implant soft tissue health and radiographic assessments—were already included in our protocol. However, patient-reported outcomes were not incorporated.

2.9 | Statistical Analysis

Descriptive statistics, including mean and standard deviation for normally distributed variables, and median with Q1 and Q3 for non-normally distributed variables, were calculated for each quantitative parameter. Frequency counts and percentages were computed for categorical data. A repeated measures analysis of variance (ANOVA) was performed to evaluate the effects of time, group, and their interaction for normally distributed quantitative variables. For non-normally distributed and ranked data, Fisher's exact test was used for time and group comparisons, while the Cochran–Mantel–Haenszel test assessed the interaction between time and group. A two-tailed

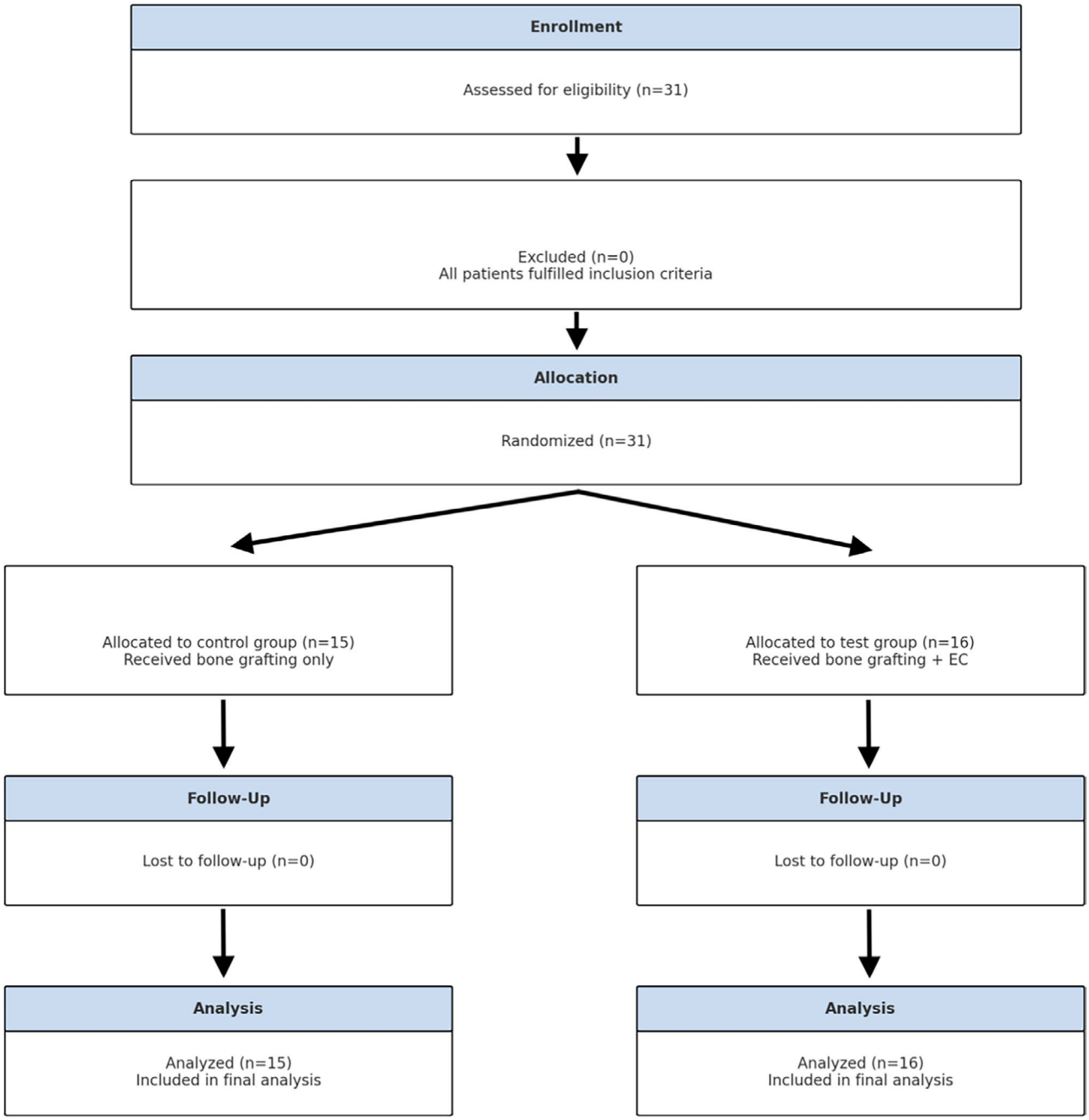

FIGURE 3 | CONSORT flow diagram of patient allocation and follow-up.

p-value of less than 0.05 was considered statistically significant. Statistical analyses were conducted using R version 4.3.1 and RStudio version 2024.09.0 + 375.

3 | Results

3.1 | Patient Demographics and Baseline Characteristics

A total of 31 patients participated in the study, with the control group comprising 15 patients and the test group (Electrolytic Cleaning) including 16. However, some participants presented with multiple affected implants; only the implant with the most severe baseline condition was selected for analysis (Figure 3).

The overall median age was 60.0 years (Q1: 49.0; Q3: 70.0), with no significant difference between the control (median: 60.0 years, Q1: 51.0; Q3: 70.0) and test groups (median: 59.5 years, Q1: 49.0; Q3: 74.5) ($p = 0.766$). Gender distribution was 74.2% female (13 in the control group, 10 in the test group) and 25.8% male (2 in the control group, 6 in the test group), showing no significant difference between the two groups ($p = 0.220$). All implants included in this study were titanium-based and featured either additively anodized or subtractively roughened surfaces. The test group included 7 anodized implants (NobelActive and NobelReplace, Nobel Biocare, Zurich, Switzerland) and 9 subtractively roughened implants: 5

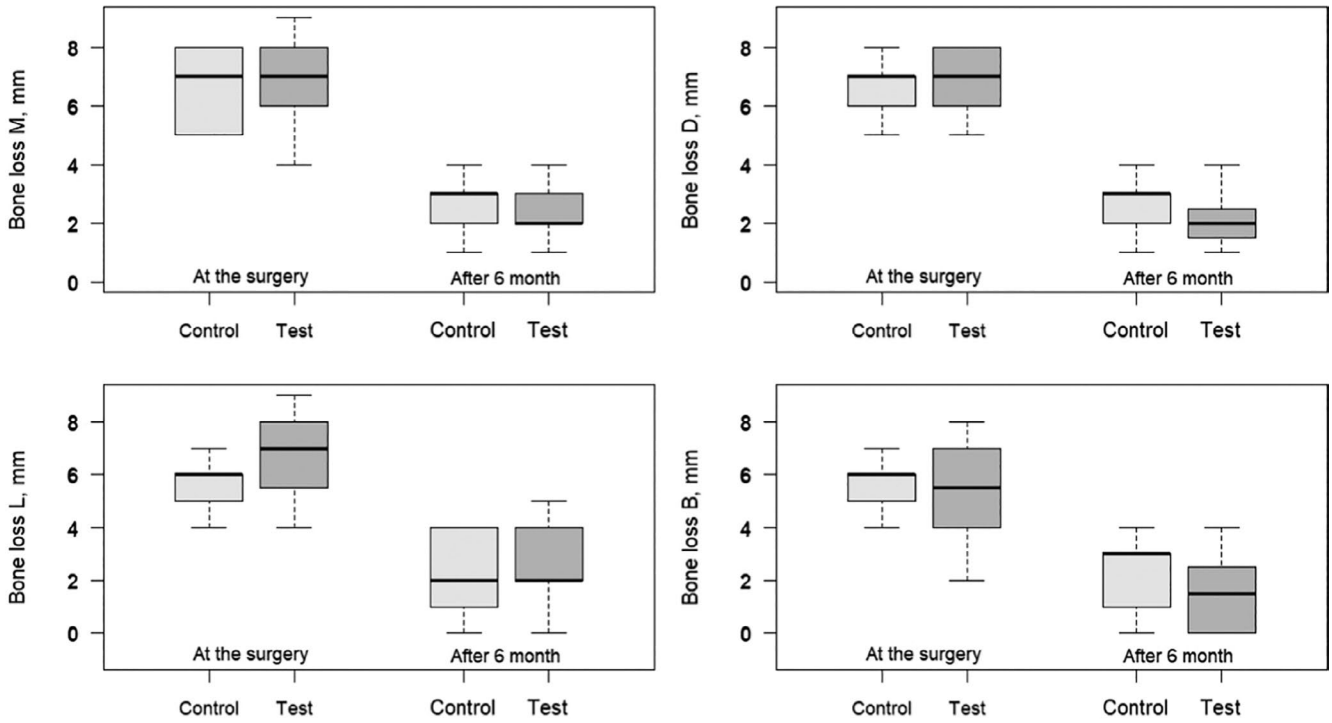

FIGURE 4 | Comparison of bone loss (mm) at mesial (M), distal (D), lingual (L), and buccal (B) implant positions in the Control and Test groups. Measurements were taken at two time points: At the time of surgery and after 6 months. The central line in each box represents the median, while the edges indicate the interquartile range (IQR). Whiskers extend to the minimum and maximum values within 1.5 times the IQR.

BioHorizons, Birmingham, AL, USA; 1 Straumann Bone Level, Institut Straumann AG, Basel, Switzerland; 3 Megagen, Daegu, South Korea. The control group included 2 anodized implants (Nobel Biocare), and 15 subtractively roughened implants: 5 BioHorizons, 5 Straumann, 2 Friadent Xive (Dentsply Sirona, Mannheim, Germany), 1 Ankylos (Dentsply Sirona, Mannheim, Germany). No implants with machined surfaces were included.

3.2 | Primary Outcome—Bone Defect Fill (Intraoperative Measurements)

The results of the primary outcome are summarized in Figure 4.

Bone defect fill around the implant was assessed at mesial, distal, buccal, and lingual sites at surgery and after 6 months. Higher baseline values indicate greater bone loss; reduced values at 6 months reflect bone defect fill. At baseline, the measured amount of bone loss mean (±SD) for the control group was 6.6 mm (±1.22), 6.6 mm (±1.45), 6.0 mm (±1.47), and 5.8 mm (±0.89) at the mesial, distal, lingual, and buccal sites, respectively. For the test group, the baseline distances were 6.6 mm (±1.45), 6.8 mm (±1.11), 6.8 mm (±1.44), and 5.6 mm (±1.75) at the corresponding sites.

After 6 months, these distances reduced substantially, reflecting successful bone defect fill. For the control group, the postoperative measurements were 2.6 mm (±1.34), 2.8 mm (±0.89), 2.4 mm (±1.34), and 2.2 mm (±1.25) at the mesial, distal, lingual, and buccal sites, respectively. In the test group, the corresponding values were 2.3 mm (±0.70), 2.1 mm (±0.85), 2.4 mm (±1.36), and 1.5 mm (±1.32).

At the mesial site this translates to mean bone gains of 4.0 mm (±1.84 mm) in the control group and 4.3 mm (±1.42 mm) in the test group ($p = 0.587$). At the distal site, gains were 3.8 mm (±1.72 mm) in the control group and 4.7 mm (±1.41 mm) in the test group, but this was not statistically significant ($p = 0.069$). At the buccal site, mean bone gains were 3.6 mm (±1.53 mm) for the control group and 4.1 mm (±2.18 mm) for the test group ($p = 0.347$). At the lingual site, bone gains were 3.6 mm (±1.98 mm) and 4.4 mm (±1.97 mm) for the control and test groups, respectively ($p = 0.872$). While trends favored the test group at most sites, only the distal site approached statistical significance.

3.3 | Secondary Outcomes

The results of the secondary outcomes are summarized in form of a radar plot in Figure 5a,b with a visual representation of a healthy implant summarized in Figure 6a,b.

3.3.1 | Probing Pocket Depth (PPD) Reduction

Probing pocket depths (PPD) were significantly reduced over time in both groups ($p < 0.001$). However, differences between the control group and the test (EC) group were not statistically significant for any site ($p > 0.05$). At the mesial site, mean PPD reductions were 4.5 mm (±1.82 mm) in the control group and 3.7 mm (±1.43 mm) in the test group ($p = 0.531$). At the buccal site, the control group exhibited a mean reduction of 3.6 mm (±2.71 mm), compared to 4.3 mm (±1.51 mm) in the test group ($p = 0.269$). At the distal site, the control group showed a reduction of 4.3 mm (±2.28 mm), while the test group achieved a reduction of 3.5 mm

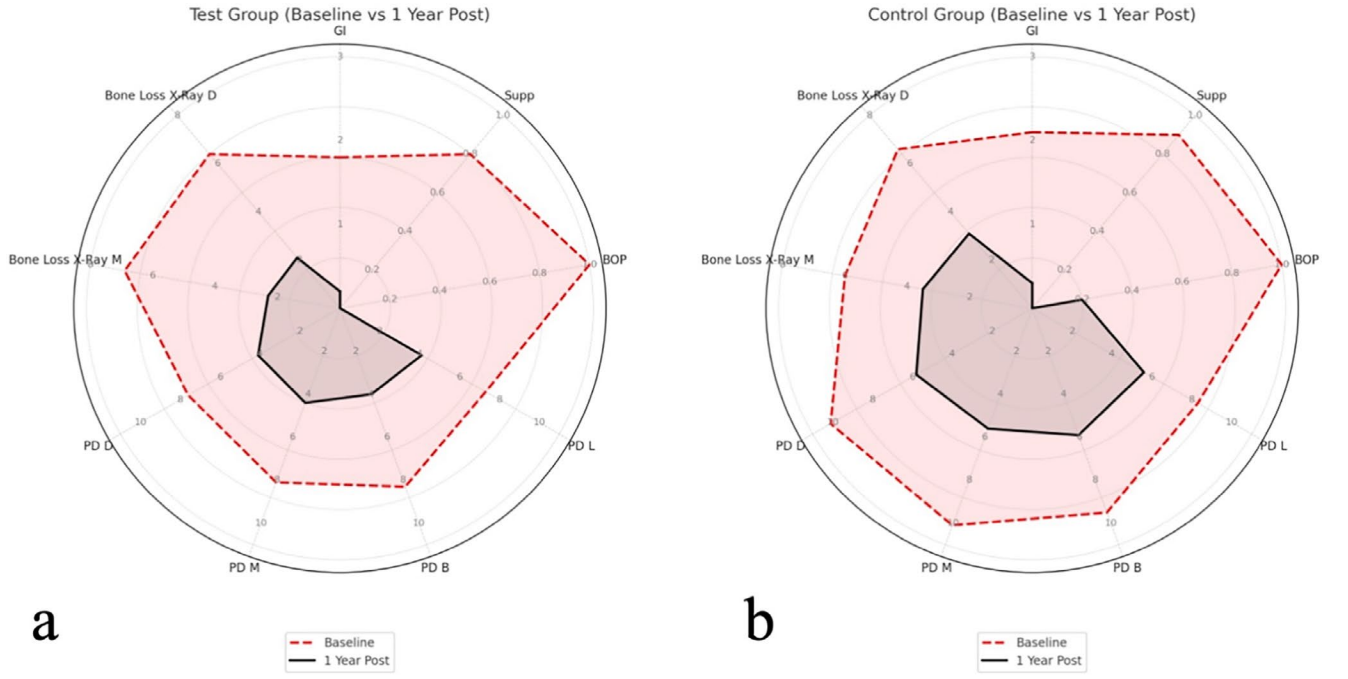

FIGURE 5 | Clinical and radiographic changes from baseline to 1-year post-treatment. (a) Test group (electrolytic cleaning + bone grafting); (b) Control group (bone grafting only). Radar plots display the actual measured values for gingival index (GI), suppuration (Supp), bleeding on probing (BOP), probing depth at mesial, buccal, distal, and lingual sites (PD M, B, D, L), and radiographic bone levels at mesial and distal implant sites. Both groups demonstrated clinical improvement after 1 year.

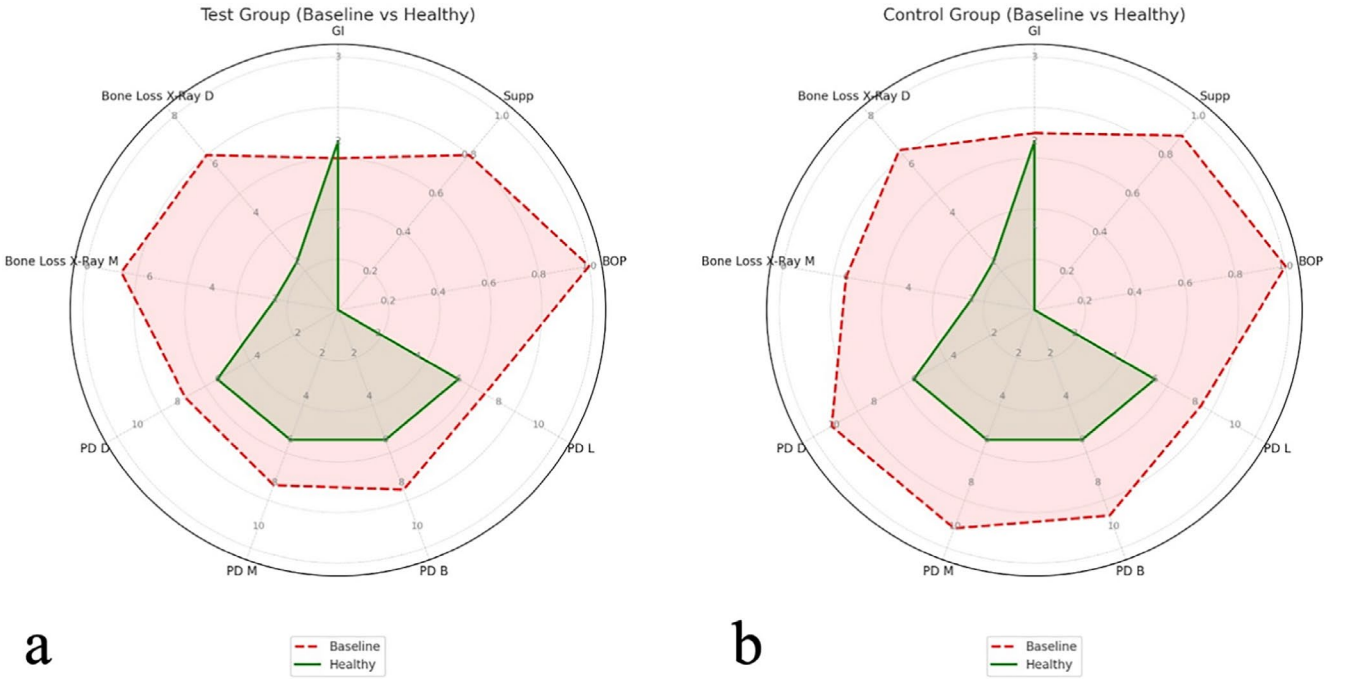

FIGURE 6 | Baseline disease profile compared to a healthy reference profile. (a) Test group; (b) Control group. Radar plots compare baseline clinical and radiographic parameters to values obtained from healthy implants in a cross-sectional reference cohort. Despite treatment, certain parameters—particularly probing depth—remained elevated compared to healthy controls.

(±1.79 mm) ($p = 0.583$). At the lingual site, reductions were 2.7 mm (±2.39 mm) and 3.2 mm (±1.75 mm) for the control and test groups, respectively ($p = 0.520$). The control group started with higher baseline values and showed greater absolute reduction. However, at 1 year, mean PPDs remained higher in the control group (5.6–5.9 mm) than in the test group (4.0–4.4 mm) at all sites.

3.3.2 | Radiographic Analysis

Bone levels were evaluated radiographically at mesial and distal sites. At the mesial site, mean bone gains were 2.5 mm (±1.77 mm) in the control group and 4.6 mm (±1.10 mm) in the test group. The Time*Group interaction was statistically

significant ($p = 0.002$). At the distal site, bone gains were 3.5 mm (±1.77 mm) in the control group and 4.3 mm (±1.10 mm) in the test group, but the difference was not statistically significant ($p = 0.144$). These findings suggest significantly greater bone defect fill at the mesial site for the test group compared to the control group, while differences at the distal site did not reach statistical significance.

3.3.3 | Gingival Index (GI)

The Gingival Index (GI) improved significantly over time in both groups, but differences between groups were not statistically significant. Mean reductions were 1.8 (±0.51) in the control group and 1.6 (±0.48) in the test group ($p = 0.498$).

3.3.4 | Bleeding on Probing (BOP)

BOP decreased from baseline to 1 year in both groups. The control group had a mean reduction of 0.8 (±0.41), while BOP was entirely absent in the test group. The difference between groups was not statistically significant although a trend favoring the test group (EC) was noticed ($p = 0.061$).

3.3.5 | Suppuration

Suppuration was completely resolved in both groups at 1 year ($p < 0.001$ for time effect). There were no significant differences between the groups ($p > 0.05$).

4 | Discussion

This randomized controlled trial demonstrated that a comprehensive surgical approach—combining autogenous tuberosity bone grafting with or without electrolytic cleaning (EC)—can lead to substantial clinical and radiographic improvements in patients with peri-implantitis. Both groups achieved meaningful reductions in probing pocket depth (PPD), with mean improvements of 4.5 mm (±1.82 mm) in the control group and 4.3 mm (±1.79 mm) in the EC group. Radiographically, the EC group showed notable bone regeneration, including mesial gains of 4.6 mm (±1.10 mm) and distal gains of 4.3 mm (±1.10 mm). While differences between groups were modest, the overall outcomes are clinically relevant, adding to the limited pool of controlled prospective studies reporting successful regenerative outcomes in peri-implantitis treatment.

The management of peri-implantitis requires a comprehensive approach, as no single device, treatment, or protocol can be solely credited with the success observed in this study. A rigorous initial conservative phase is essential to reduce the bacterial load and create the biological conditions necessary for successful surgical intervention [39, 44, 45]. A minimum three-month healing phase was implemented following non-surgical therapy, as this was considered critical to allow for immune-mediated bacterial reduction, even in cases where surface decontamination may have been incomplete. Long-term peri-implant health is also heavily dependent on patient compliance and at-home oral hygiene [46]. The removal of prosthetic restorations to allow submerged healing and use of adjunctive antibacterial therapies likely contributed to the favorable healing environment observed in both groups [47–50]. Prosthesis removal allowed for direct assessment of the implant shoulder to rule out fractures, as this would preclude any regenerative attempt and necessitate implant removal. The prosthetic design itself can contribute to peri-implant complications, particularly in cases of overcontoured crowns, cement-retained restorations, or incompatible subgingival materials [51–55].

Autogenous bone was selected as the grafting material, despite reports of potential resorption when used in surgical treatment of peri-implantitis [56]. In this study, the graft was placed into an infection-free environment, which may have helped mitigate the risk of resorption. Tuberosity bone, rather than other autogenous sources, was specifically selected for its favorable structural and biological properties. It offers regenerative potential, serving as a source of osteoprogenitor cells and growth factors, supporting bone healing and defect fill [57], while its structural role in protecting vital maxillary anatomy—such as the posterior superior alveolar nerve and the pterygoid venous plexus—may hint at a relative resistance to resorption [58].

The soft tissue harvested from the tuberosity provides regenerative potential, owing to its rich lamina propria content, which supports peri-implant tissue integration around avascular titanium surfaces [59, 60]. This approach addresses key soft tissue parameters required for a stable and functional implant, including adequate vertical and horizontal thickness and sufficient keratinized tissue [61].

Surface decontamination remains a central challenge in peri-implantitis treatment [13, 62, 63]. The use of electrolytic cleaning in the test group provided a non-invasive method to decontaminate the implant surface while preserving its structural and biochemical integrity [29], in contrast to traditional mechanical or chemical decontamination methods, which may compromise the implant's ability to support re-osseointegration [63] although—like conventional osseointegration—it cannot be definitively confirmed without histological analysis, which is not feasible in clinical studies. However, even in the control group, where EC was not employed, outcomes were significantly improved, highlighting the importance of other key factors in the protocol, including pre-surgical treatment, defect-specific grafting, and the removal of the implant-supported restoration.

While the only statistically significant differences between the control group and the test group were observed at the mesial site, some other differences, such as intraoperative bone gains and BOP that did not achieve statistical significance, can still be debated as clinically significant. A noteworthy distinction between the two groups is the radiographic appearance of the bone defect fill. As illustrated in Figure 7, the EC group demonstrated a more homogenous radiographic appearance of the bone defect fill after 1 year of loading and appeared indistinguishable from the surrounding native bone. In contrast, the control group consistently showed the appearance of grafted bone, appearing more radiolucent around the implant threads, which could hint at incomplete integration (Figure 7).

While electrolytic cleaning has demonstrated effectiveness in removing biofilms from contaminated titanium surfaces in vitro, most available data pertain to subtractively roughened surfaces, such as sandblasted, acid-etched (SLA) titanium [64]. However, no comparative studies have directly assessed differences in electrolytic cleaning efficacy between various surface types, such as anodized versus sandblasted and acid-etched titanium surfaces. All implants included in the present study were composed of commercially available titanium-based materials, with roughened surface treatments using either subtractive or additive modifications. The distribution of implant types varied slightly between groups, with the test group including a greater number of anodized implants. While this distribution was not stratified for analysis, it may warrant consideration in interpreting outcomes. Emerging clinical evidence suggests that implant surface characteristics may influence the peri-implant microbiome. In particular, Sinjab et al. reported that anodized implants affected by peri-implantitis exhibited a more diverse and abundant microbial community than their SLA counterparts [65]. While the present study did not evaluate microbial profiles, this finding raises the possibility that anodized implants, once diseased, may present with more complex or mature biofilm structures that are more difficult to eliminate. If true, this could represent a potential bias against the test group, which had a higher proportion of anodized implants requiring decontamination. It is further acknowledged that not all peri-implant defects lend themselves to successful augmentation. Favorable defect configurations, such as three-wall defects, allow for better containment of the graft material and promote predictable outcomes [66].

The surgical techniques used in both groups are analogous to those of vertical augmentation procedures, involving proper flap design, buccal flap release in the maxilla, lingual flap release in the mandible, preparation of the recipient bed, and tension-free closure achieved through double-layer suturing using both horizontal mattress sutures and simple interrupted sutures [67–69]. The proper execution of these highly technique-sensitive steps was essential in achieving the reported outcomes. Given that all surgeries were performed by an experienced clinician specialized in these surgical techniques, this may limit the generalizability of the findings. Additionally, the relatively small sample size restricts the ability to perform detailed subgroup analyses, which could provide further insights into defect-specific outcomes. At the time of study conceptualization, no robust clinical data were available to guide power analysis for electrolytic cleaning in peri-implantitis. The reliance on clinical experience to define the effect size is acknowledged as a limitation. However, it reflects the evidence gap present at the time and provided a pragmatic framework to initiate the trial. The one-year follow-up, while sufficient to demonstrate clinical and radiographic

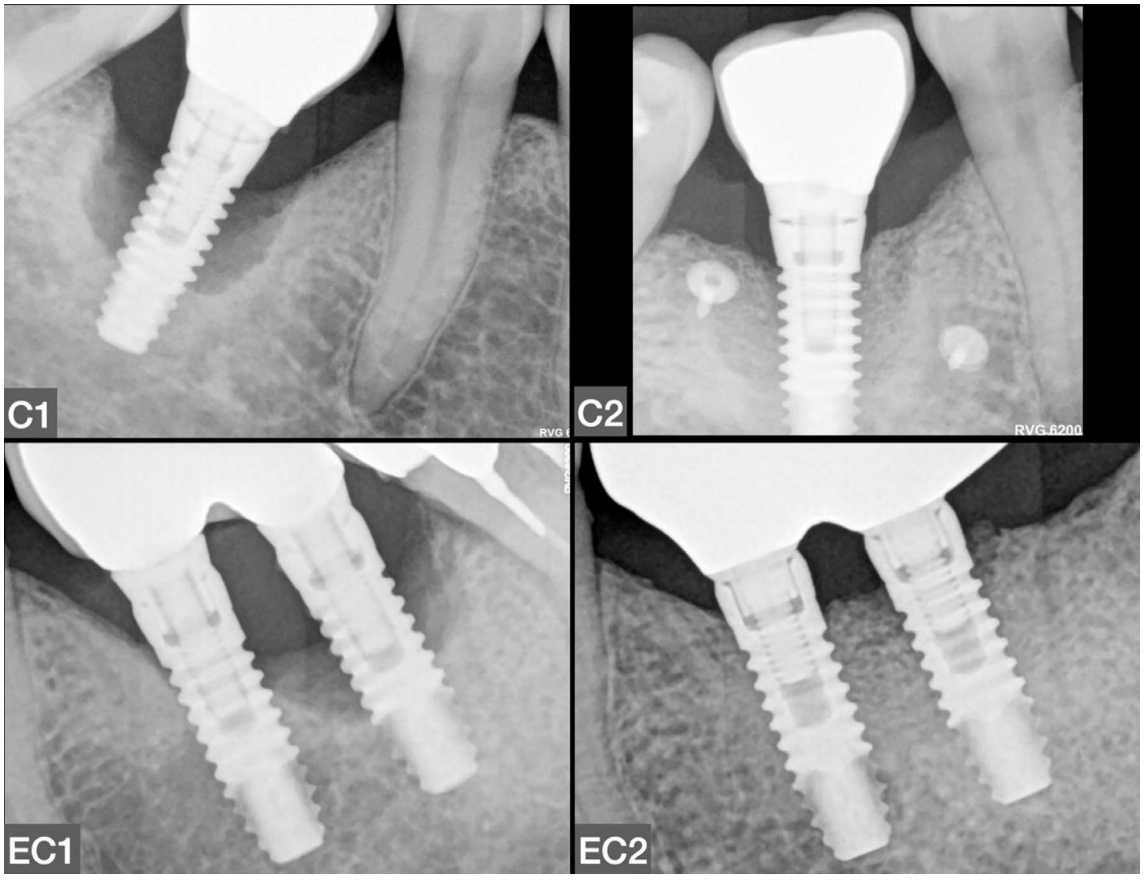

FIGURE 7 | C1: Periapical radiograph of the control group case (Figure 1), showing extensive bone loss indicative of peri-implantitis. C2: Final periapical radiograph of the control group case taken 1 year after prosthesis loading. EC1: Periapical radiograph of the electrolytic cleaning group case (Figure 2), showing extensive bone loss indicative of peri-implantitis. EC2: Final periapical radiograph of the electrolytic cleaning group case taken 1 year after prosthesis loading.

improvements, does not capture the long-term stability of these outcomes. Future studies should aim to validate these findings in larger, more diverse populations and assess the durability of the results over an extended period. Additionally, a potential limitation is that probing depths were measured both with and without the prosthesis in place at different time points, which, however, is consistent with the existing literature, as according to Derks et al. only 6% of studies explicitly remove the prosthesis for probing peri-implant pockets [70].

At the time of study initiation in 2020, current EFP S3 guidelines had not yet been published [39]. While the use of chlorhexidine and air polishing is currently not recommended, there is currently no data suggesting that air polishing negatively impacts surgical outcomes. Chlorhexidine was included in the decontamination protocol due to its well-established antimicrobial efficacy [41], although later studies raised concerns about its effect on titanium surfaces and osteoblastic response, potentially compromising re-osseointegration [71]. Chlorhexidine may absorb to titanium [72] and shows dose- and time-dependent cytotoxicity to peri-implant cell types [73]; moreover, randomized trials did not demonstrate additional clinical benefit from chlorhexidine applied to implant surfaces [74]. Accordingly, routine use of chlorhexidine to 'detoxify' titanium is not recommended [71]. In this study chlorhexidine was limited to soft-tissue rinsing and was not allowed to remain on the implant surface. For air-polishing, intra-operative use under an open flap is off-label and rare cases of subcutaneous emphysema have been described [75]. We therefore used brief, low-pressure application with coronal nozzle orientation and continuous high-volume suction to minimize risk.

Beyond study design considerations, electrolytic cleaning itself presents limitations that should be acknowledged. First, proper application requires complete prosthesis removal, as direct access to the implant surface is essential for the electrochemical reaction to occur. This limits its use in clinical scenarios where the restoration cannot be removed without creating damage or excessive risk. While in vitro evidence supports its safety across rough titanium surfaces, comparative data on different surface types has not been evaluated systematically. The use of EC also requires specific equipment, including a dedicated generator and electrodes, as well as trained personnel. These requirements may limit availability in some clinical settings and introduce additional cost and logistical considerations not present with conventional mechanical debridement.

The clinical relevance of these findings lies in the consistent improvements observed across complex and advanced peri-implantitis cases, which are typically considered unlikely to respond predictably to regenerative surgery. In this study, a structured protocol combining comprehensive non-surgical therapy, prosthesis removal, thorough surface decontamination, and site-specific grafting yielded outcomes that are still uncommon in clinical trials. These results suggest that when each of these key components is addressed in a coordinated and individualized manner, even severely compromised implants can benefit from regenerative treatment approaches. This highlights the potential for translating these steps into predictable clinical protocols for managing challenging peri-implant defects.

5 | Conclusion

Within the limitations of this study, peri-implant reconstructive therapy using autogenous tuberosity bone grafts demonstrated favorable clinical and radiographic outcomes. The adjunctive use of electrolytic cleaning did not result in statistically significant differences. Further studies with larger sample sizes and extended follow-up are needed to confirm these findings and further define the role of electrolytic cleaning in peri-implant defect management.

Author Contributions

A.P. and E.V.-N. conceived and designed the idea. T.Z. contributed to data acquisition and analysis. S.A. and I.P. led the writing. G.O.G. critically revised the manuscript and gave final approval. All authors agreed to be accountable for all aspects of the scientific work.

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Ethics Statement

2020/4-1222-705—Vilnius regional biomedical research ethics committee.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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