FLAPLESS PERI-IMPLANTITIS TREATMENT WITH OR WITHOUT ADJUNCTIVE RECONSTRUCTIVE THERAPY: A 12 MONTHS RANDOMIZED CONTROLLED TRIAL

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Abstract:

Introduction: Limited evidence exists on the effectiveness of flapless peri-implantitis treatment compared to reconstructive therapy. The aim of this study is to evaluate the outcomes of the flapless treatment of peri-implantitis with adjunctive reconstructive surgery compared to the same flapless treatment with tailored supportive peri-implant care (SPIC).

Material and methods: A randomized clinical trial included patients diagnosed with peri-implantitis exhibiting intraosseous defects (≥ 3mm). All patients received a standardized peri-implant flapless therapy. Patients who did not achieve disease resolution were randomized in two different groups and undergone reconstructive therapy (RG) or a 3-month interval supportive peri-implant care (NRG). Clinical and radiographic parameters were recorded at the initial examination, 12 weeks, 6 months, and 12 months. Patient-reported outcomes were assessed. A composite disease resolution criterion was predefined.

Results: Overall, 34 patients (implants = 34) completed the study. Both therapies showed significant improvement after 1 year. No significant differences were found in clinical variables (PPD, BOP), but radiographic bone fill was significantly greater in RG after 12 months (1.2 mm vs 0.5 mm). Disease resolution rates were similar (33.3% FG vs 43.7% RG).

Conclusions: Despite radiographic benefits, reconstructive therapy may not offer superior clinical outcomes compared to flapless therapy with tailored SPIC every 3 months.

1. Introduction

Peri-implantitis is defined as a plaque-associated pathological condition, characterized by inflammation of the peri-implant mucosa and the subsequent progressive loss of bone (1). Despite the generally high success rate of implant therapy (2), peri-implantitis remains a relatively common issue, impacting one in every five loaded implants (3).

The primary goal of peri-implantitis treatment is the resolution of the peri-implant soft tissue inflammation and the maintenance/stability of the supporting bone (1). Traditionally, non-surgical therapy has demonstrated restricted effectiveness in disease resolution, often leading to the requirement for surgical intervention to access implant surfaces (4). Indeed, reconstructive approaches have been recommended for addressing intra-bony defects associated with peri-implantitis (5, 6).

In recent years, several research groups have documented promising results employing a novel non-surgical treatment approach conducted according to a specific protocol, and associated with the administration of systemic antibiotics (7-9). The proposed approach, also called flapless peri-implantitis therapy, includes the

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removal of the prostheses to gain access to perform an extensive peri-implant mucosa curettage to remove granulation tissue. This closed approach favors the space maintenance effects of the soft tissue architecture and is believed to improve the stability of the blood clot (9,10). This flapless approach could lead to a radiographic peri-implant defect fill comparable to that achieved with a reconstructive approach (8). Indeed, in a recent randomized controlled trial (RCT) conducted by Blanco et al., this flapless protocol resulted in a 1 year radiographic bone gain (RBG) of 2.33 (1.58–30.9) mm when systemic antibiotics were used, and a bone gain of 1.13 (0.31–1.95) mm when antibiotic was not administer (8). These promising findings can be compared with those from a large multicenter RCT, where surgical reconstructive therapy led to an RBG of 1.1 (± 1.4) mm (11).

The objective of this randomized clinical trial is to evaluate the outcomes of the flapless treatment of peri-implantitis with adjunctive reconstructive surgery compared to the same flapless treatment with a tailored supportive peri-implant therapy.

2. Material and Methods

The present investigation was designed as a randomized, single-center, clinical trial (RCT) with two parallel groups and a follow-up of 12 months.

The study was conducted at the Department of Periodontology of Universitat Internacional de Catalunya. The protocol of the trial was registered in advance at *ClinicalTrials.gov* (NCT05168891) and approved by the *Comité de Ética de Investigación con medicamentos* (CEIm) (PER-ECL-2019-05). All participants were informed in detail about the study protocol and provided written informed consent prior to inclusion. This manuscript is reported following the Consolidated Standards of Reporting Trials (CONSORT) 2010 guidelines (12).

2.1 Study population

Subjects eligible for the study were identified from patients referred to the Department of Periodontology of Universitat Internacional de Catalunya between January 2020 and October 2022. The study included subjects with (I) ≥ 18 years of age, (II) the presence of at least one implant diagnosed with peri-implantitis (1) , (III) intraosseous ≥ 3mm defects, (IV) presence of screw-retained single-unit crowns and partial dental prosthesis that allowed correct access for brushing; and, if not, prostheses that could be modified, and (V) presence of at least 2 mm of keratinized mucosa. Subjects were excluded from the study if they (I) had received previous non-surgical peri-implantitis treatment during the last 6 months or surgical treatment, (II) were pregnant or breast-feeding, (III) had received antibiotic treatment in the previous 3 months, (IV) had systemic conditions that contraindicated treatment, (V) smoking more than 10 cigarettes/day or (VI) presents a poor plaque control (full-mouth plaque score ≥25%), (VII) implant mobility, and (VIII) allergy or intolerance to metronidazole.

2.2 Interventions

All patients received professional supragingival teeth/implant therapy, oral hygiene instructions, and

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corrections to implant-supported prostheses if needed (13).

After one-week, all the patients received a standardized peri-implant flapless therapy (*Figure 1*): after local anesthesia (articaine 4% and adrenaline 1:100,000), the implant surfaces was treated with ultrasonic devices (Newtron P5, Satelec Acteon; Olliergues, France) with the H3 dental ultrasonic scaler (H3, Satelec Acteon; Olliergues, France). Curettage (SyG 7/89 Everdge, Hu-Friedy; Chicago, IL, USA) of the bone defect was performed and glycine air powder was applied submucosally (Air-flow® powder sub + supragingival PERIO, EMS; Nyon, France) with an air-flow piezon device (Air-flow master piezon®, EMS, Nyon; France) (9). In addition, adjunctive systemic metronidazole (500 mg every 8 hours for 7 days) was administered (7). Following flapless therapy treatment, patients were advised to use a 0.12% chlorhexidine (CHX) mouth rinse twice daily for two weeks. If necessary, anti-inflammatory therapy, specifically ibuprofen 600 mg, was prescribed, with a maximum dosage of three times daily.

At twelve weeks post-flapless therapy, a clinical and radiographic evaluation was performed and patients not achieving disease resolution were randomized into two different groups (14):

- **Reconstructive group (RG):** following local anesthesia, intrasulcular incisions were made and mucoperiosteal flaps were raised. The surgical approach was customized to the specific scenario: granulation tissue was removed using curettes and an ultrasonic device, and implantoplasty was conducted when supracrestal defect components were present, using a tungsten carbide bur. Subsequently, the intra-bony component of the defect was filled with xenograft biomaterial (Straumann® XenoGraft, Straumann Group, Basel, Switzerland) and covered with a collagen membrane (Straumann® Flex Membrane, Straumann Group, Basel, Switzerland). Then, flaps were repositioned and sutured using polypropylene 5/0 interrupted sutures (Aragó®, Barcelona, Spain), facilitating non-submerged healing (6) (*Figure 2*). Patients were advised to use a 0.12% chlorhexidine (CHX) mouth rinse twice daily for two weeks. Additionally, 7-days antibiotic regimen (Amoxicillin 2 × 750 mg daily) was initiated and anti-inflammatory therapy with ibuprofen 600 mg was prescribed, with a maximum dosage of three times daily. Patients were enrolled in a 3-month interval supportive peri-implant care (SPIC) where supragingival debridement was performed (14).
- **Non-reconstructive group (NRG):** patients were enrolled in a 3-month interval SPIC. During each treatment session, patients with residual PPD >5mm with >1 point of BOP or SOP underwent repeated instrumentation by ultrasonic submucosal debridement (*Figure 3*). (8,14).

Those patients demonstrating bone-destructive activity in any of the evaluations were immediately excluded from the study, and individualized peri-implantitis treatment was provided.

2.3 Outcomes

The primary outcome at 12 months was mean radiographic bone change (MBL). Secondary outcomes included (i) changes (i.e., from baseline to 12 months) of PPD, (ii) changes of BOP%, (iii) SOP%, (iv) plaque, (v) buccal

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REC (vi) buccal keratinized mucosa (KM) and (vii) patient-reported outcomes. A composite variable, disease resolution, was evaluated based on the latest consensus during the 12-month follow-up period. The evaluation criteria included: having ≤1 point of BOP, the absence of SOP, PPD ≤ 5 mm, and no progressive bone loss compared to pre-treatment bone levels (14).

2.4 Clinical examination

Clinical assessments were conducted at several time points:

- Initial examination: before flapless therapy.
- Baseline: at 12 weeks, when flapless therapy was reevaluated, and patients were randomized.
- Follow-up: at 6 and 12 months from the baseline.

Information regarding age, race, gender (female/male), medical history, medication, and health behaviour (smoking habits and smoking exposure) were obtained. Additionally, implant position and implant system were recorded, as well as the type of prosthesis (cemented/screw-retained).

All clinical examinations were performed using a UNC-15 periodontal probe, with six sites per implant, by a calibrated examiner (M.C.S). The clinical examination included assessments of the following variables:

- **Full-mouth plaque score (FMPS):** was calculated by assigning a binary score to each surface (1 for plaque present, 0 for absent) and calculating the percentage of total tooth/implant surfaces that revealed the presence of plaque detected by a periodontal probe **(15).**
- **Bleeding on probing (BOP):** was assessed dichotomously as the presence or absence of bleeding within 30 seconds after probing **(16).**
- **Suppuration on probing (SOP):** was assessed dichotomously as the presence or absence of suppuration within 30 seconds after probing **(16).**
- **Peri-implant probing depth (PPD):** was calculated as the distance from the mucosal peri-implant margin to the bottom of the peri-implant pocket **(16).**
- **Recession (REC):** was measured as the distance (in mm) from the free marginal mucosa to the most apical portion of the crown**.**
- **Keratinized mucosa width (KMW**): was measured as the distance (in mm) from the mucosal margin to the mucogingival junction.

2.5 Radiographic examination

Radiographic examinations were conducted at several time points:

- Initial examination: before flapless therapy.
- Baseline: at 12 weeks, when flapless therapy was reevaluated and patients were randomized.
- Follow-up: at 6 and 12 months from baseline.

All periapical radiographs were taken with an intra-oral phosphor plate using a long-cone parallel technique. Additionally, radiographs were captured with the aid of a custom-made holder's silicone index (17) to evaluate peri-implant marginal radiographic bone levels. Marginal bone levels at the mesial and distal aspects of each

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implant were assessed using image analysis software (ImageJ64; National Institutes of Health, Bethesda, MD, USA) by one previously calibrated examiner (R.P). The examiner reached an inter-examiner Cohen kappa index >85% after analyzing 10% of the sample calculated a priori in the power analysis. Radiographs were calibrated using the known implant dimensions as reference values. The following variables were assessed on the radiographs:

- **Mean bone level (MBL):** The mean distance (mm) between the implant shoulder and the base of the defect.
- **Intra-bony defect angle (AW):** The angle resulting from a vertical line along the outer implant surface and a line extending along the peri-implant bone defect.

2.6 Patient-reported outcome measures (PROMs)

Patients from both groups underwent assessment using the 14-item Spanish version of the Oral Health-Related Quality of Life (OHIP-14sp) questionnaire at the initial examination, as well as at 1 week after the flapless therapy and 12 months after the reconstructive therapy (only RG patients) (18). Additionally, patients were required to self-report their frequency and consumption of pain medication during the first week using a table provided by the investigator. Pain levels were evaluated at baseline, 1 week after both therapies using a visual analog scale (VAS score; VAS 0-100, with 100 indicating the highest morbidity). Furthermore, spontaneous bleeding, pain, and swelling during the week following the different therapy were assessed using a visual analog scale (VAS score; VAS 0-100). Additionally, patients were asked about the cost associated with the different treatment and their willingness to undergo the treatment again.

2.7 Data Analysis:

Sample size calculation was made on the primary outcome variable, mean radiographic bone change (MBL). Thirty-six patients (18 patients in each group) were necessary to detect a difference ≥ 0.5 mm in bone fill, assuming a common standard deviation of 0.41 (19).

The randomization sequence was generated using a computer-generated list with a 1:1 allocation ratio based on a block randomization procedure (block size of four).

In this investigation, only one implant per patient was included in the analysis. In case patients had more than one implant, all the implants were treated but the implant with the most severe condition was included (i.e., the implant with the deepest PPD at baseline). The unit of analysis for clinical and radiographic evaluations was the implant.

To describe the qualitative variables, absolute frequencies, and percentages were used. The description of quantitative variables was performed using the mean, standard deviation (SD), median, and quartiles. Mann – Whitney two-sample tests were performed for inter-group comparisons of numerical variables. Chi-squared and Fisher tests were used for categorical variables. All tests were performed at a significance level of $\alpha = 0.05$.

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3. Results:

3.1. Study population

Out of the initially included 36 participants and implants, 2 subjects (2 implants) were lost to follow-up before the 12-month evaluation (*Figure 4*). Disease resolution (14) was achieved in one implant after the revaluation of the flapless therapy, so this patient was excluded from the study. Another implant was removed before the final examination due to continuous loss of MBL. One patient from the non-reconstructive group (NRG) did not attend the 6 months follow-up because of reasons unrelated to the study.

In this study, an intention-to-treat approach (ITT) was followed.

3.2. Characteristics of the patients and implants at baseline

Table 1 presents the characteristics of the 36 patients and implants at the initial examination. The mean age of the participants was 60.1 (12.3) for the NRG and 56.4 (11.6) for the RG. All patients in both groups had history of periodontitis, with 4% of patients in the NRG and 3% in the RG having systemic diseases such as cardiovascular disease and controlled diabetes. None of these parameters exhibited statistically significant differences between groups (*p-value> .05*).

In the initial examination, the majority of the implants replaced molar teeth, and supported either single restorations (38.9%) or bridges (55.6%). Most of the restorations were screw-retained (97.2%), and almost all implants had a modified surface (91.7%).

3.3. Clinical variables

Clinical outcomes at the initial examination, at baseline (i.e., 12-week follow-up of flapless therapy), and 6, and 12-month follow-up were displayed in Table 2.

Overall, no differences were observed between the clinical parameters at the initial therapy between groups. Following a single session of flapless therapy, significant improvements were observed across all the variables with no remarkable difference between the groups.

All study patients (NRG and RG) demonstrated an overall improvement in clinical variables at both the 6-month and 12-month follow-ups. However, no statistically significant differences were detected between the two groups (p-value > 0.05).

From the initial examination to the end of the study, probing pocket depth (PPD) decreased by 2.4 (1.4) mm in NRG and 2.1 (0.9) mm in RG. Both therapies following the initial flapless treatment led to a notable additional decrease in PPD. Specifically, the NRG group achieved an additional reduction of 1.3 (1.2) mm after re-instrumentation, whereas the RG group achieved an additional reduction of 1.0 (0.6) mm following reconstructive therapy. Intra-group analysis revealed no significant differences between groups. When considering only the deepest probing pocket depth (maxPPD) a reduction of 2.2 (1.6) mm and 1.6 (1.0) mm was observed. Suppuration (SOP) decreased by 7.4% and 9.3% in the NRG and RG groups, while BOP decreased by 45.4% and 23.1% (p-value < .05), respectively. Disease resolution was achieved in 6 (33.3%)

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NRG patients and in 7 (43.8%) RG patients with no statistically significant differences (Table 4.).

3.4. Radiographic variables

Peri-implant radiographic variables at the initial examination, at baseline (12-week follow-up of flapless therapy), and 6, and 12-month follow-up after reconstructive therapy or repeated subgingival instrumentation were displayed in Table 3. Overall, no differences were found between the clinical parameters at the initial therapy between the two groups. Statistically significant differences were observed thereafter between groups: the reconstructive therapy achieved a radiographic MBL gain of 0.9 (1.1) mm and 1.2 (0.9) mm after 6 and 12 months from the treatment. On the contrary, after the repetitive instrumentation, the radiographic MBL gain was 0.3 (0.5) mm and 0.4 (0.6) mm after 6 and 12 months.

However, in both groups an overall improvement in radiographic MBL was observed, and only 4 (22.2%) NRG patients and 3 (18.8%) RG patients showed no radiographic MBL gain (Table 4.).

Similarly, the intra-bony defect angle (AW) exhibited significant differences were noted during the 6- and 12-month follow-ups, where a marked increase in AW was observed in the reconstructive groups due to radiographic bone fill of the intra-bony defect.

3.5. Patient related outcomes

Patients related outcomes at the different follow-up were described in Table 5. At 12 months, most of the patients were satisfied with the therapy with no differences between groups.

After one week, the Visual Analog Scale (VAS) score for pain was significantly lower in the NRG compared to the RG [1.5 (1.8) vs. 3.1 (1.4)]. Similarly, NRG patients reported experiencing less pain while brushing, as well as reduced swelling and bleeding. Furthermore, medication consumption during the first week was notably lower in NRG patients [1.7 (1.6)] pills compared to RG patients [7.2 (4.0)] pills *(p-value < .05).*

4. Discussion

To date, this was the first RCT designed to evaluate the efficacy of the flapless treatment of peri-implantitis with adjunctive reconstructive surgery compared to the same flapless treatment with a tailored supportive peri-implant therapy.

At 12 months most implants presented with shallow PPD (≤5 mm): 77.8% in the NRG and 75% in the RG *(p-value > .05*). These results are very similar to those obtained in a recent study where reconstructive therapy was compared to open flap debridement (11), thus suggested that flapless therapy may be effective in reducing deep PPD. From the initial examination, the non-reconstructive group reduced PPD by 2.4 (1.4), while the repeated instrumentation accounted for 1.1 (0.8) mm of this reduction. These results are consistent to those obtain in other studies where a similar non-surgical /flapless approach was used (8,9).

Similarly, BOP decreased substantially in the non-reconstructive group, dropping from 86.11% of sites at the initial examination to 40.7% after flapless therapy, reaching 22.2% at the 12-month follow-up. Once again, the results seem to be in line with previous studies, where at the one-year follow-up, BOP had been reduced

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to 21.2% (9) and 31.4% (8).

The reconstructive group also underwent a significant improvement in the number of sites with BOP throughout the study, decreasing from 78.7% at the beginning to 36.5% at the one-year follow-up. However, these findings should be interpreted with caution, as the literature suggests that it is more likely to stop bleeding at a single site than to achieve overall peri-implant health in all aspects of the affected implant (5). Indeed, only 27.8% of NRG implants and 18.8% of RG implants did not present any bleeding site at the 12 months follow-up.

While no statistically significant differences were noted between groups regarding disease resolution and clinical variables, reconstructive therapy notably favored radiographic bone fill at any time point.

From the initial examination, a mean radiographic bone gain of 0.7 mm was found in the non-reconstructive group, this is something lower than that observed in previous studies, where it ranged from 0.9 mm (20) to 2.3 mm (9). This could partially be explained by the configuration of the peri-implant defect which plays an important role in clinical and radiographic outcomes (21).

From the other hand, the adjunctive reconstructive therapy resulted in a radiographic bone fill of 1.2 (0.9) mm at the one-year follow-up. This observation aligns with findings in the literature, where the use of collagen membrane and allograft yielded a radiographic bone fill of 1.7 (0.7) mm, while xenograft alone resulted in a bone fill of 1.1 mm (6,11).

In this study, disease resolution was observed in 33.3% of the implants in the NRG and in 43.7% of the implants in the RG. While these results are comparatively lower than those reported in other studies, our findings align closely regarding the percentage of PPD ≤ 5mm and the reduction in the bleeding score. (6, 8, 11). Although the disparity between the RG and NRG disease resolution lacked statistical significance in this study, exceeded 10%, suggesting its potential significance with a larger sample size. Moreover, an accurate identification of the type of peri-implant defect (21), in terms of morphology and severity, on the implant surface could lead to a higher disease resolution in the RG patients, as observed in previous studies (22, 23). It's important to note that this study, conducted in a university setting with students of different experience levels, may have also affected the results, as seen in prior studies on periodontal (24) and bone regeneration (25).

The management of patients who do not achieve disease resolution after the peri-implant therapy remains uncertain. A recent long-term retrospective study found that, on average, one out of every four implants required surgical retreatment approximately 4.5 years after the initial procedure (26). In our study, it is evident that the patient's adherence to a strict regimen of peri-implant maintenance therapy every 3 months improves the prognosis of the implant over time by enhancing clinical parameters. These results could be compared with classic studies focused on the treatment of periodontitis and maintenance therapy (27) given the similarities between periodontitis and peri-implantitis from an etiological perspective (28).

This study presents some limitations: while recent evidence supports the use of metronidazole as systemic antibiotic in flapless therapy (29) due to its lower levels of bacterial resistance compared to other antibiotics

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(30), the use of systemic antibiotics remains a concern. Moreover, the incorporation of microbiological analysis could have enhanced the characterization of results between groups. Another issue is represented by the difficulty in accurately determining radiographic bone change, because distinguishing between graft material and newly formed bone on radiographs can be challenging.

Conclusion

Findings from the present randomized controlled trial study are promising in the therapy of peri-implantitis. As has been observed, despite the potential benefit observed in the radiological appearance, reconstructive therapy provided no benefit in terms of reducing PPD and BOP when compared to flapless therapy followed by a tailored supportive peri-implant care (SPIC) every 3 months. While historical practice dictated surgical intervention to treat peri-implantitis, our study revealed progressive improvements in clinical and radiographic parameters among the flapless group over time. Furthermore, this protocol holds the potential for advantages in terms of patient satisfaction, post-treatment morbidity, and economic cost-effectiveness. However, the evidence available to date on this topic is scarce and thus, prospective controlled studies with long follow-up should be performed to validate the effectiveness of this approach.

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Table 1: Description of the studied patients and implants at initial examination

Description of the studied patients				
	Overall (N=36)	**NRG** (N=18)	**RG** (N=18)	*p-value*
Age (years), mean (SD)	58.2 (11.9)	60.1 (12.3)	56.4 (11.6)	*0.401**
Gender, N (%)				
Male	15 (41.6)	8 (44.4)	7 (38.9)	*0.735†*
Female	21 (58.3)	10 (55.6)	11 (61.1)	
Smoking Status, N (%)				
Non-smokers	22 (61.1)	13 (72.2)	9 (50.0)	*0.098†*
Former smokers	10 (27.8)	2 (11.1)	8 (44.4)	
Current smokers	4 (11.1)	3 (16.7)	1 (5.9)	
Smoking exposure, mean (SD)	9.2 (7.1)	13.5 (10.5)	6.8 (2.8)	*0.254**
HTA, N (%)				
No	32 (88.9)	15 (83.3)	17 (94.4)	*0.603†*
Yes	4 (11.1)	3 (16.7)	1 (5.5)	
Diabetes, N (%)				
No	34 (94.4)	17 (94.4)	17 (94.4)	*1.000†*
Yes	2 (5.6)	1 (5.6)	1 (5.6)	
History of Periodontal Disease, N (%)				
No	0 (0.0)	0 (0.0)	0 (0.0)	*0.603†*
Yes	36 (100.0)	18 (100.0)	18 (100.0)	
Extension of Periodontal Disease, N (%)				
Generalized	34 (94.4)	17 (94.4)	17 (94.4)	*1.000†*

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Localized	2 (5.6)	1 (5.6)	1 (5.6)	
Periodontal Stage N (%)				
1	0 (0.0)	0 (0.0)	0 (0.0)	*0.342†*
2	10 (27.8)	7 (38.9)	3 (16.7)	
3	21 (58.3)	9 (50.0)	12 (66.7)	
4	5 (13.9)	2 (11.1)	3 (16.7)	
Periodontal Grade N (%)				
A	9 (25.0)	6 (33.3)	3 (16.7)	*0.511†*
B	20 (55.6)	9 (50.0)	11 (61.1)	
C	7 (19.4)	3 (16.7)	4 (22.2)	
Description of the studied implants				
	Overall (N=36)	**NRG** (N=18)	**RG** (N=18)	*p-value*
Jaw, N (%)				
Maxilla	11 (30.i6)	6 (33.3)	5 (27.8)	*0.717†*
Mandible	25 (69.4)	12 (66.7)	13 (72.2)	
Position, N (%)				
Incisor	2 (5.6)	1 (5.6)	1 (5.6)	*1.000†*
Canine	3 (8.3)	2 (11.1)	1 (5.6)	
Premolar	8 (22.2)	4 (22.2)	4 (22.2)	
Molar	23 (63.9)	11 (61.11)	12 (66.67)	
Type of Restoration, N (%)				
Single crown	14 (38.9)	4 (22.2)	10 (55.6)	*0.082†*
Bridge	20 (55.5)	13 (72.2)	7 (38.9)	

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Overdenture	1 (2.8)	1 (5.6)	0 (0.0)	
Full-arch fixed restoration	1 (2.8)	0 (0.0)	1 (5.6)	
Retention, N (%)				
Screwed	35 (97.2)	17 (94.5)	18 (100.0)	*1.000≠*
Cemented	1 (2.7)	1 (5.5)	0 (0.0)	
Implants design				
Tissue level	11 (30.6)	6 (33.3)	5 (27.8)	*0.310†*
Bone level	25 (69.4)	12 (66.7)	13 (72.2)	
Implants surface				
Modified	33 (91.7)	17 (94.4)	16 (88.9)	*0.603≠*
No modified	3 (8.3)	1 (5.6)	2 (11.1)	
Implant diameter				
<4mm	6 (16.7)	3 (16.7)	3 (16.7)	*1.000≠*
>=4 mm <5mm	29 (80.6)	14 (77.8)	15 (83.3)	
>=5mm	1 (2.8)	1 (5.6)	0 (0.0)	
Implant length				
<8mm	0 (0.0)	0 (0.0)	0 (0.0)	*0.502≠*
>=8 mm <=10mm	20 (55.6)	9 (50.0)	11 (61.1)	
>10mm	16 (44.4)	9 (50.0)	7 (38.9)	

** Mann –Whitney two-sample test*
† Chi2 test
≠ Fisher exact test

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Table 2. Description of peri-implant clinical variables at initial therapy, baseline, 6 months and 12 months.

	Initial examination				Baseline (Revaluation of NRG therapy)			Changes Baseline-Initial examination *			6 months follow up			Changes Baseline-6 months			12 months follow up			Changes Baseline-12 months		
	Overall n=36	NRG *n=18*	RG *n=18*	*p-value **	NRG *n=18*	RG *n=18*	*p-value **	NRG	RG	*p-value **	NRG *n=17*	RG *n=16*	*p-value **	NRG	RG	*p-value **	NRG *n=18*	RG *n=16*	*p-value **	NRG	RG	*p-value **
PPD (mm)	5.9 (0.9)	5.9 (1.1)	5.8 (0.7)	*0.898*	4.7 (0.5)	4.8 (0.87)	*0.408*	-1.2 (1.1)	-0.9 (0.6)	*0.775*	4.1 (0.7)	4.1 (0.8)	*0.942*	-0.5 (0.7)	-0.8 (0.9)	*0.613*	3.6 (0.8)	3.7 (0.9)	*0.640*	-1.1 (0.7)	-1.1 (0.9)	*0.795*
maxPPD (mm)	7.5 (1.2)	7.66 (1.2)	7.3 (1.1)	*0.400*	5.4 (1.0)	5.7 (1.0)	*0.261*	-2.2 (1.6)	-1.5 (1.0)	*0.240*	4.6 (0.9)	4.1 (1.2)	*0.312*	-0.7 (0.6)	-1.7 (1.2)	***0.011***	4.1 (1.2)	3.8 (1.4)	*0.655*	-1.4 (1.1)	-2.0 (1.4)	*0.195*
BOP (%)	82.4 (87.7)	86.1 (18.3)	78.7 (16.9)	*0.166*	40.7 (24.0)	55.5 (30.2)	***0.041***	-45.3 (27.9)	-23.1 (33.4)	***0.031***	25.5 (16.8)	27.1 (25.0)	*0.736*	-11.7 (29.3)	-28.1 (29.6)	*0.098*	22.2 (21.4)	36.4 (29.9)	*0.146*	-18.5 (31.2)	-18.7 (38.4)	*0.754*
SOP (%)	12.5 (19.6)	9.2 (15.3)	15.7 (23.2)	*0.436*	1.8 (7.8)	6.5 (23.6)	*0.552*	-7.4 (18.2)	-9.2 (29.8)	*0.899*	2.9 (8.8)	4.16 (16.6)	*0.638*	1.0 (4.0)	-3.1 (31.2)	*0.340*	2.7 (8.6)	0.0 (0.0)	*0.175*	0.92 (3.92)	-7.3 (25.1)	*0.079*
PL (%)	31.48 (28.1)	31.4 (26.1)	31.4 (30.7)	*0.871*	21.2 (33.2)	19.9 (22.7)	*0.496*	-10.1 (40.1)	-11.57 (40.9)	0.632	14.7 (16.5)	17.7 (17.7)	0.620	-2.9 (31.8)	-2.4 (26.5)	*0.479*	20.4 (31.1)	20.8 (24.7)	*0.460*	-0.92 (34.5)	3.1 (30.5)	0.803

Abbreviations: NRG: non-reconstructive group, RG: reconstructive group, PPD, probing pocket depth; maxPPD, deepest probing pocket depth; BOP, bleeding on probing; SOP, suppuration on probing; PL, plaque
** Mann –Whitney two-sample test*

Table 3. Description of peri-implant radiographic variables at initial therapy, baseline, 6 months and 12 months.

	Initial examination				Baseline			Changes Baseline- Initial examination *			6 months follow up			Changes Baseline-6 months			12 months follow up			Changes Baseline-12 months		
	Overall n=36	NRG *n=18*	RG *n=18*	*p-value **	NRG *n=18*	RG *n=18*	*p-value **	NRG	RG	*p-value **	NRG *n=17*	RG *n=16*	*p-value **	NRG	RG	*p-value **	NRG *n=18*	RG *n=16*	*p-value **	NRG	RG	*p-value **
MBL (mm)	4.46(1.1)	4.61 (1.2)	4.3 (0.9)	*0.751*	4.3 (1.2)	3.9 (0.9)	0.447	-0.3 (0.4)	-0.4 (0.40)	0.669	3.9 (1.25)	3.1 (1.0)	0.125	-0.3 (0.5)	-0.9 (1.0)	***0.002***	3.9 (1.0)	2.8 (0.9)	***0.003***	-0.3 (0.6)	-1.2 (0.9)	***0.005***
maxMBL (mm)	4.6 (1.1)	4.81 (1.13)	4.7 (1.1)	*0.704*	4.52 (1.2)	4.3 (1.1)	*0.375*	-0.3 (0.4)	-0.4 (0.6)	*0.775*	4.1 (1.2)	3.6 (1.2)	***0.047***	-0.3 (0.5)	-1.1 (1.2)	***0.002***	4.1 (0.9)	3.5 (1.2)	***0.002***	-0.4 (0.7)	-1.4 (1.1)	***0.004***
AW (°)	34.4 (7.4)	35.5(7.7)	33.4 (6.9)	*0.590*	40.2 (8.9)	38.6 (10.7)	*0.824*	4.6 (5.5)	5.2 (6.7)	*0.974*	42.9 (7.5)	46.8 (11.2)	*0.367*	2.2 (2.8)	10.3 (11.6)	***0.010***	43.7 (7.8)	50.3 (10.6)	***0.045***	3.6 (5.1)	13.8 (10.5)	***0.002***

Abbreviations: NRG; non-reconstructive group; RG;reconstructive group; MBL, mean bone level ; maxMBL, worst mean bone level; AW, angle width
** Mann –Whitney two-sample test*

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Table 4. Threshold and composite outcomes at 12 months by group.

	NRG *n= 18*	**RG** *n= 16*	***p*-value**
PPD			
≤5 mm, N (%)	14 (77.8)	12 (75.0)	*0.583†*
>5 mm, N (%)	4 (22.2)	4 (25.0)	
BOP			
No, N (%)	5 (27.8)	3 (18.5)	*0.536†*
Yes, N (%)	13 (72.2)	13 (81.5)	
BOP			
≤1 site N (%)	11 (61.1)	7 (43.5)	*0.311†*
>1 site, N (%)	7 (38.9)	9 (56.5)	
SUP			
No, N (%)	16 (88.9)	16 (100.0)	*0.487‡*
Yes, N (%)	2 (11.1)	0.00 (0.0)	
Buccal REC <1 mm >=1 mm			
<1 mm, N (%)	13 (72.2)	12 (80.0)	*0.604†*
>=1 mm, N (%)	5 (27.8)	3 (20.0)	
MBL Change ≥1 mm			
≥1mm, N (%)	2 (11.1)	11 (68.5)	*0.001‡*
<1 mm, N (%)	16 (88.8)	5 (31.5)	
MBL Change ≥ 0.5mm			
< 0.5 mm, N (%)	11 (61.11)	3 (18.7)	
MBL Change ≥0 mm			
≥0mm, N (%)	14 (77.8)	13 (81.2)	*0.803 †*
< 0 mm, N (%)	4 (22.2)	3 (18.8)	
Disease resolution*			
No, N (%)	12 (66.7)	9 (56.2)	*0.533 †*
Yes, N (%)	6 (33.3)	7 (43.7)	

† Chi2 test
‡ Fisher exact test
Abbreviations: NRG, non-reconstructive group; RG, reconstructive group; PPD, probing pocket depth; BOP, bleeding on probing; SOP, suppuration on probing
***Disease resolution:** Herrera et al. 2023: ≤1point of BOP, absence of SOP, PD ≤ 5 mm and absence of progressive bone loss compared to pre-treatment bone levels to verify disease

Table 5. Patient-reported outcomes at baseline, 2 weeks, and 12 months by group.

		NRG			RG			*p-value*
		n	*Med (IQR)*	*Mean (SD)*	*n*	*Med (IQR)*	*Mean (SD)*	
Initial examination	**Pain (VAS)**	18	0 (2)	1.2 (1.9)	18	1 (3)	1.9 (2.4)	*0.257*
	OHIP-14	18	0.3 (0.3)	0.3 (0.31)	18	0.3 (0.5)	0.5 (0.7)	*0.513*
1 week		*n*	*Med (IQR)*	*Mean (SD)*	*n*	*Med (IQR)*	*Mean (SD)*	
	Pain (VAS)	18	1 (2)	1.5 (1.8)	15	3 (2)	3.1 (1.4)	***0.003***
	OHIP-14	18	0.17 (0.4)	0.25 (0.3)	16	0.1 (0.2)	0.2 (0.3)	*0.751*
	Pain on brushing	18	1 (3)	1.5 (1.6)	15	0 (4)	1.8 (2.1)	*0.528*
	Swelling	18	0 (0)	0.3 (1.0)	15	2 (4)	2.3 (2.3)	***0.002***
	Bleeding	18	0 (1)	0.7 (1.3)	15	0 (1)	0.4 (0.8)	*0.818*
	Medication consumption	18	2 (3)	1.7 (1.6)	17	6 (3)	7.2 (3.9)	***0.000***
		n	*Med (IQR)*	*Mean (SD)*	*n*	*Med (IQR)*	*Mean (SD)*	
12 months	**OHIP-14**	18	0.18 (0.2)	0.21 (0.3)	16	0.1 (0.3)	0.2 (0.3)	0.490
	Expensive (1-10)	18	3 (3)	3.5 (2.3)	16	2 (2.5)	1.9 (1.6)	0.042
			No	Yes		No	Yes	
	Satisfaction N (%)	18 (100)	4 (22.2)	14 (77.7)	16 (100)	3 (18.8)	13 (81.2)	1.000*

Abbreviations: NRG: non-reconstructive group, RG: reconstructive group, VAS: visual analogue scale, OHIP-14: Oral Health Impact Profile-14

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Figure 1. Prosthesis removal (A) for standardized flapless therapy with intensive bone curettage (B and C).

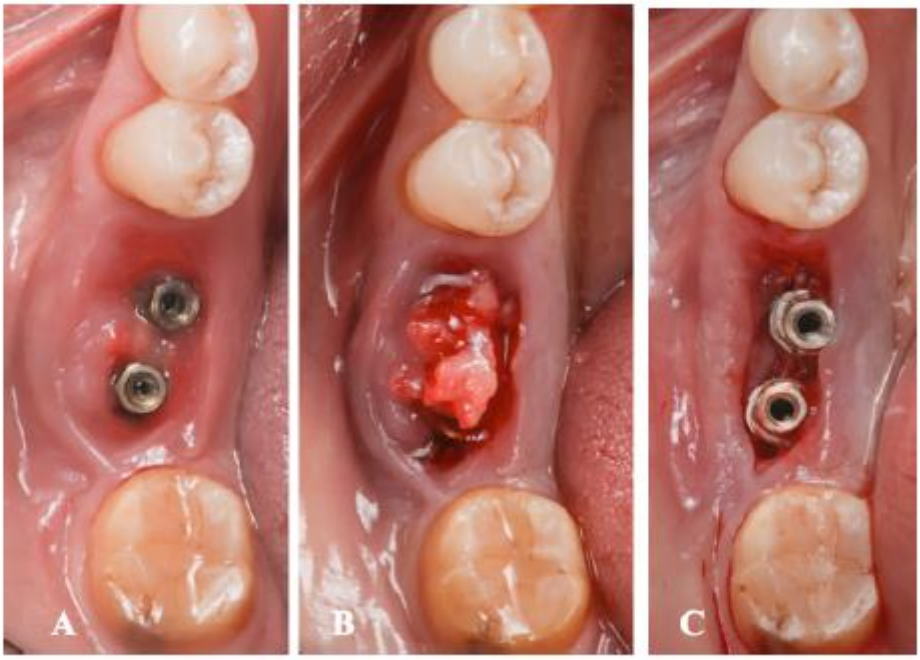

Figure 2. Non-reconstructive group (NRG): Initial examination (A and B), baseline 12 weeks after flapless therapy (C and D), and 12 months examination (F and G).

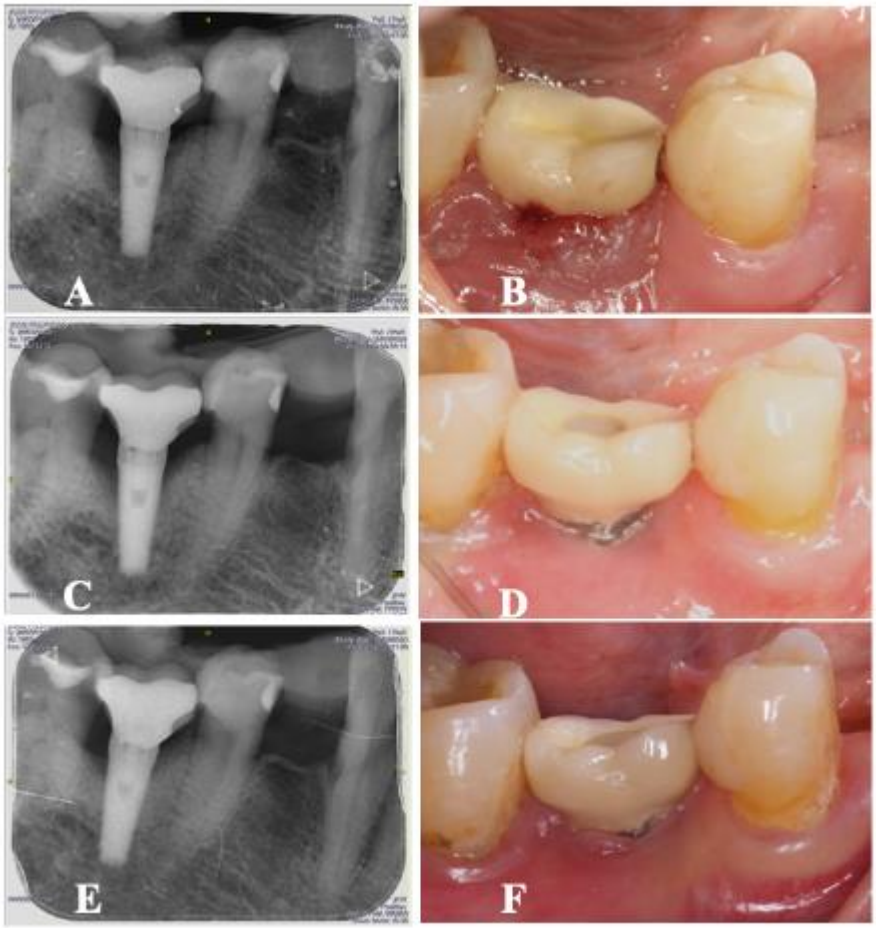

Figure 3. Reconstructive group (RG): Initial examination (A and B), baseline 12 weeks after flapless therapy (C and D), reconstructive therapy (E-J) and 12 months examination (K and M).

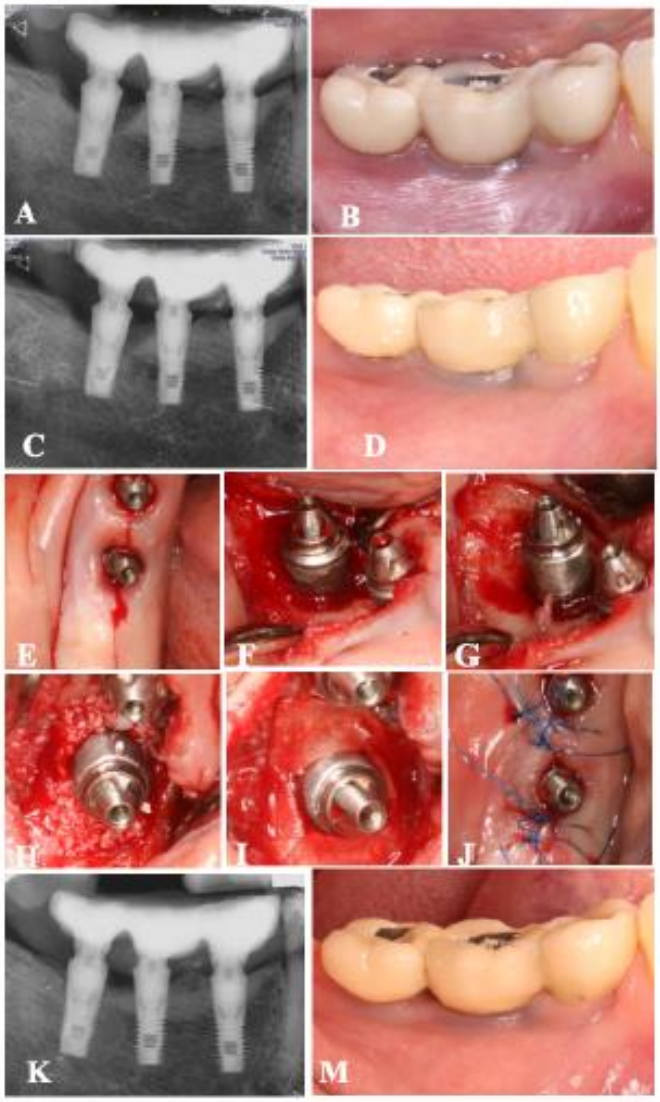

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Figure 4. Flow chart of the study

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