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**study**

# Are there added benefits from submarginal instrumentation before surgical management of peri-implantitis?

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## Background

The current treatment pathway for peri-implantitis generally mirrors that of periodontitis. This stepwise approach starts with a behavioural intervention and supragingival instrumentation, followed by non-surgical submarginal instrumentation. Patients are then re-evaluated four to eight weeks after non-surgical instrumentation to determine if the successful treatment endpoints have been achieved.

In moderate to severe forms of peri-implantitis, non-surgical instrumentation alone rarely achieves these endpoints and surgical therapy is often required. It has been suggested that non-surgical instrumentation might be considered as an intermediate preparatory phase before further surgical interventions.

However, the use of non-surgical submarginal instrumentation of implants affected by peri-implantitis may lead to an extended treatment timeline, increased costs, and discomfort for patients. As a result, various authors have questioned its value and opted to use only supragingival instrumentation before surgical treatment.

## Aim

To evaluate the added effects of performing non-surgical submarginal instrumentation before the surgical treatment of peri-implantitis.

## Materials & methods

- Randomised multi-centre trial with two parallel groups.
- An *a priori* power calculation required a sample of 42 patients.
- Inclusion criteria: any patient, 18 years or older, with at least one implant in function for at least a year and affected by peri-implantitis. Peri-implantitis was defined as: pocket probing depth (PPD)  $\geq 6$ mm; bleeding on probing (BoP) and/or suppuration on probing (SoP); and radiographic marginal bone loss  $>3$ mm on implants in function for at least a year.
- Exclusion criteria: compromised general health; pregnancy or lactation; chronic use of anti-inflammatory, immune-suppressive, or bone/mucosa-affecting drugs; previous peri-implantitis treatment; and implant mobility.
- Control group: supra- and submarginal instrumentation, local application of 0.12% chlorhexidine + 0.05% cetylpyridinium chloride, followed by surgical therapy six weeks later.
- Test group: supramarginal instrumentation only, followed by surgical therapy two weeks later.
- Clinical measurements (six sites per implant) recorded at baseline, day of surgery, six months, and 12 months:
  - PPD
  - recession
  - BoP
  - SoP
  - keratinized mucosa height (KMh).
- Implant mobility at six and 12 months and presence of profuse BoP at 12 months were also recorded.
- Radiographic marginal bone levels were recorded at two weeks, six months, and 12 months after surgery (digital standardised long-cone intraoral radiographs).
- Primary outcomes:
  - Changes in the deepest PPD with respect to baseline.
  - Various definitions of treatment success criteria were investigated at 12 months (see table).
- Secondary outcomes: total treatment time, early wound healing, self-reported smile aesthetics, surgery difficulty, intra-operative bleeding, and adverse events.
- Patient-level analysis.

**Table:** Treatment success in the included implants

	Overall (N = 52)	Control group (N = 28)	Test group (N = 24)	MD/OR (SE) (only adjusted for clustering)	MD/OR (SE) (adjusted for clustering and surgical approach)
<b>Criterion 1: No implant loss, no bone loss &gt;0.5mm, BoP/SoP, PPD ≤5mm, N (%)</b>					
6 months	6 [11.8]	4 [14.3]	2 (8.7)	NE	NE
1 year	14 [26.9]	6 [21.4]	8 [33.3]	OR = 1.83 [1.16] p = .338	OR = 2.09 [1.38] p = .264
<b>Criterion 2: No implant loss, no bone loss &gt;0.5mm, BoP/SoP, N (%)</b>					
6 months	6 [11.8]	4 [14.3]	2 (8.7)	NE	NE
1 year	14 [26.9]	6 [21.4]	8 [33.3]	OR = 1.83 [1.16] p = .338	OR = 2.09 [1.38] p = .264
<b>Criterion 3: No implant loss, no bone loss &gt;0.5mm, no PPD ≥5 with concomitant BoP/SoP+, N (%)</b>					
6 months	33 [64.7]	20 [71.4]	13 [56.5]	OR = 0.52 [0.31] p = .271	OR = 0.57 [0.35] p = .360
1 year	27 [51.9]	17 [60.7]	10 [41.7]	OR = 0.46 [0.26] p = .173	OR = 0.52 [0.30] p = .256
<b>Criterion 4: No implant loss, no bone loss &gt;0.5mm, BoP+ at maximum one site, no SoP, PPD ≤5mm, N (%)</b>					
6 months	18 [35.3]	8 [28.6]	10 [43.5]	OR = 2.14 [2.01] p = .417	OR = 2.35 [2.31] p = .384
1 year	17 [32.7]	7 [25.0]	10 [41.7]	OR = 2.14 [1.29] p = .205	OR = 2.19 [1.36] p = .205
<b>Criterion 5: No implant loss, no bone loss &gt;0.5mm, no profuse bleeding, no SoP, PPD ≤5mm, N (%)</b>					
1 year	24 [46.2]	13 [46.4]	11 [45.8]	OR = 0.98 [0.55] p = .966	OR = 0.99 [0.57] p = .989

**Note:** One six-months radiograph from the test group resulted unreadable, reducing in this group the sample size to 23 implants for treatment success outcomes.

**Abbreviations:** BoP, bleeding on probing; MD, difference in means; NE, not estimable; OR, odds ratio; PPD, probing pocket depth; SoP, suppuration on probing.

## Results


- Study population group: 21 patients per treatment group (control = 29 implants, test = 24 implants, n=53), 61.9% female, mean age 61.36 years (SD±12.27 years), mean baseline bone level of 4.96mm (±1.65mm).
- One implant in one patient from the test group was removed; one patient from the control group was lost to follow-up after the two-week examination.
- The overall change in deepest PPD at 12 months was 3.03mm (±1.96mm) with 2.96mm (±1.85mm) in the control group and 3.11mm (±2.12mm) in the test group. These differences were not statistically significant.
- Treatment success (no implant loss, no bone loss >0.5mm, BoP/SoP and PPD ≤5mm) was achieved in 26.9% of all study implants, with marginally better but not statistically significant results for the test group (33.3% test vs 21.4% control).
- Radiographic examination at 12 months demonstrated that 12.0% of the implants presented with bone loss >0.5mm (OR = 1.04; SE = 1.13; p = .97), while 60.0% of the implants presented a bone gain >0.5mm (OR = 1.49; SE = 3.88; p = .88).
- No statistically significant differences were observed for early wound healing, self-reported smile aesthetics, surgery difficulty, intraoperative bleeding, and adverse events.
- The duration of non-surgical treatment was longer in the control group. However, when considering total treatment time there was no statistically significant difference between groups.

## Limitations

- The observed standard deviation (SD) for PPD changes was higher than the SD used when the sample size calculation was performed, which means that the study was underpowered.
- Lack of blinding of non-surgical operators and patients regarding their treatment group.
- The type of surgical therapy was not standardised.
- Variable levels of operator experience.
- Adjunctive local antimicrobial therapy was used only in the control group.
- Only limited patient-reported outcomes were recorded. No cost-benefit analysis was carried out.

## Conclusions & impact

- No added benefit was demonstrated in performing submarginal instrumentation six weeks before the surgical treatment of peri-implantitis.
- Overall findings regarding the clinical parameters included a PPD reduction of approximately 3mm and a recession reduction of approximately 2mm.
- No definitive conclusion can be reported regarding the discomfort experienced by patients undergoing additional submarginal instrumentation before the surgical management of peri-implantitis.
- Further studies with a larger population are required.
- Patient discomfort, treatment duration, and costs can potentially be reduced by avoiding submarginal instrumentation in the management of peri-implantitis before surgical therapy.

 JCP Digest 108 is a summary of 'Effect of sub-marginal instrumentation before surgical treatment of peri-implantitis: a multi-centre randomized clinical trial.' *J Clin Periodontol.* 49(12):1334-1345. DOI: 10.1111/jcpe.13713

 <https://www.onlinelibrary.wiley.com/doi/10.1111/jcpe.13713>

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