

# Treatment of peri-implant mucositis with a chitosan brush—A pilot randomized clinical trial

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## Abstract

**Objective:** This aim of this study was to evaluate a chitosan brush for the treatment of peri-implant mucositis.

**Materials and methods:** A total of 11 patients with a combined total of 24 dental implants and who were diagnosed with peri-implant mucositis were included in this 6-month, split mouth, pilot clinical trial. Implants were randomly assigned to either treatment with a chitosan brush using an oscillating dental hand piece or treatment with titanium currettes. Supportive treatment was provided at 3 months. Two calibrated periodontists, blinded to treatment group, performed all examinations, including probing pocket depths (PPD) and bleeding on probing (mBoP). The changes in clinical parameters were compared between groups at 2 weeks, 4 weeks and 6 months. A Mann-Whitney *U* test with an alpha level of 0.05 was used for the statistical analyses.

**Results:** Both groups demonstrated significant reductions in mBoP between baseline and 6 months. The test implants treated with the chitosan brush had a better improvement in mBoP at 2 weeks and 4 weeks compared to the implants treated with the titanium currettes. The reduction in PPD was significantly better in the test group at 4 weeks. All implants had stable bone levels, as seen on radiographs between baseline and 6 months.

**Conclusion:** Reduced signs of inflammation were seen in both groups 6 months after the baseline treatment and 3 months after maintenance. A chitosan brush seems to be a safe and efficient device for debridement of dental implants.

## KEYWORDS

chitosan, clinical study, dental implants, peri-implant mucositis, peri-implantitis

## 1 | INTRODUCTION

Peri-implant mucositis is a common condition surrounding dental implants and may precede the more severe condition peri-implantitis.<sup>1</sup> To evade progression of mucositis to peri-implantitis, both home-based daily oral hygiene tasks and regular professional maintenance of dental implants are crucial.<sup>2-5</sup> Currently, numerous methods for procuring professional implant cleanings are available, but to date, there is little research that has examined the efficacy

or benefits of such devices or professional cleaning protocols.<sup>6</sup> Considering that ignoring peri-implant mucositis over the long term may lead to peri-implantitis<sup>2</sup> and potentially loss of the implant, as well as morbidity and economic-related consequences for the patient, it is necessary to treat mucositis at an early stage. To date, no device has been developed solely for cleaning dental implants accompanied by mucositis or peri-implantitis; thus, effective methods for straightforward regular professional maintenance of dental implants are necessary. The benefit of using a biodegradable device

when performing debridement of dental implants is that it avoids leaving material remnants of the device on the implant surface that may either hamper the healing of the peri-implant lesion or worsen the implant's condition.<sup>7,8</sup> Leftover titanium fragments released from dental implants after the use of an ultrasonic instrument have been shown to introduce foreign bodies to the peri-implant space, which may aggravate the situation.<sup>9</sup> To easily access affected areas when treating dental implants, both overly contoured and rigid devices do not provide the simple access offered by a brush with a flexible shaft. The natural polysaccharide chitosan (poly-*N*-acetyl glycosaminoglycan) was chosen because it is a nontoxic and bioabsorbable substance that exhibits bacteriostatic and anti-inflammatory properties.<sup>10-12</sup> Villa and co-workers<sup>13</sup> evaluated the effects of a remnant chitosan filament on titanium implant osseointegration using a pull-out force rabbit tibial model. No difference in pull-out force existed between the group with chitosan filaments vs the control group with no filaments. In the chitosan group, however, there was a trend towards pro-inflammatory cytokine reduction, including TNF- $\alpha$  and IL-6. Furthermore, Larsen et al<sup>14</sup> compared debridement of contaminated titanium surfaces using an Er:YAG laser, an oscillating chitosan brush or titanium curettes. Uncontaminated implants

and untreated negative control implants were also included in the experiment. While a similar potential to remove the periodontal pathogen *P gingivalis* was seen in all treatment groups, the titanium-curetted surfaces demonstrated a significantly altered microstructure. The aim of this study was to compare debridement with a chitosan brush against debridement with titanium curettes and to compare their abilities to reduce peri-implant inflammation.

## 2 | MATERIAL AND METHODS

This was a randomized, split mouth, examiner-blinded, pilot clinical trial that occurred over 6 months at the Department of Periodontology, Institute of Clinical Research, University of Oslo between November 2012 and December 2013. The study was approved by the regional ethics committee (2012/791 REK sor-ost).

### 2.1 | Inclusion and exclusion criteria

Subjects were included in the study if they had at least two implants that had been in function for longer than 12 months and had



**FIGURE 1** (A and B) PPD measurements with a defined force periodontal probe and (C) test and (D) control treatments

developed peri-implant mucositis, as determined by at least one site having a pocket probing depth (PPD) of at least 4 mm, along with a positive bleeding on probing score and with no perceptible peri-implant bone loss on radiography. Patients diagnosed with periodontitis were required to complete periodontal treatment prior to inclusion in the study. Baseline measurements were performed after careful oral hygiene instruction and on an as-needed basis prior to final inclusion in the study. Included implants should have all 6 surfaces free of plaque. The exclusion criteria were as follows: patients younger than 18 years of age; patients diagnosed with peri-implantitis; patients having undergone or currently on radiotherapy, chemotherapy and systemic long-term corticosteroid treatment; patients who had taken systemic antibiotics within 6 months of baseline; pregnant or nursing patients; patients with anatomical abnormalities around the implants (eg deeply seated implants next to a tooth), anatomy not conducive with submucosal examination/debridement of the site impossible; and patients with prostheses hindering access for debridement of the implant with the chitosan brush.

## 2.2 | Examination and treatment

Clinical examinations were performed at baseline and at 2, 4 and 24 weeks after baseline. All clinical examinations were performed by two board-certified and experienced periodontists (AMA, OCK) blinded to treatment allocation. Clinical examinations included PPD with a defined force 0.2 N (20 g) periodontal probe (University of North Carolina, DB764R, AESCULAP, B. Braun Melsungen AG, Melsungen, Hessen, Germany; Figure 1). PPD and bleeding on probing (mBoP) were recorded using a three-graded index 30 seconds after probing as follows: a score of 0 represented no bleeding, 1 represented isolated spots, minimal bleeding, 2 represented blood forming a confluent red line on the margin, and 3 represented heavy or profuse bleeding.<sup>15</sup> Both PPD and mBoP were recorded at six sites per implant. After the baseline examination, the coin toss method was used to randomize implants to be treated with either a chitosan brush (BioClean, LABRIDA AS, Oslo Norway) using an oscillating dental hand piece (ER10M, TEQ-Y, NSK Inc, Kanuma Tochigi, Japan) or titanium curettes (Langer and Langer, Rønvig, Denmark). Treatment was performed by a separate board-certified periodontist (JCW). Implant pockets were irrigated with sterile saline in both groups after mechanical treatment was completed. Anaesthesia was used, in both groups, for the first treatment but not at the treatments at later time-points, unless demanded by the patient after initiating debridement. The treatment time was 3 minutes in both groups. The exact same treatment at the same locations, according to the randomization, was performed at 3 months by the same specialist. Differences between groups regarding a change in clinical parameters between baseline and later time-points were analysed at 2 weeks, 4 weeks and 6 months.

Radiographs were taken at baseline and 6 months after therapy.

Before agreeing to participate in this study, all patients were provided with sufficient information in terms of a patient information

sheet and a consent form, which had to be signed prior to inclusion. At 3 months, the treatment was undertaken without local anaesthesia. After completing treatment, the patients were asked to grade the level of pain during treatment by using a visual analogue scale (VAS) with a range from 0 (complete absence of pain) to 10 (very high degree of pain).

## 2.3 | Statistical analysis

Since the data were not normally distributed, a Mann-Whitney *U* test with an alpha level of 0.05 was used to compare differences between groups and changes between baseline and the later time-points. The results are presented as the mean values and standard deviations. The power calculation was based on data from a pilot case series evaluating the same test device performed at the Department of Periodontology, University of Oslo (Wohlfahrt et al unpublished data). All statistical analyses were performed using statistical computer software Sigma Plot v 13.0 (Systat Software, Inc, San Jose, CA) and Stata 14 (StataCorp, College Station, TX).

## 3 | RESULTS

Seventeen patients were screened and underwent the initial clinical examination; 13 patients ultimately met all criteria for study enrolment. One patient dropped out of the study after the baseline screening due to his work situation, and one implant in a different patient had to be excluded at the time of analysis due to a technical complication with the supraconstruction (abutment screw loosening repeatedly). Eleven patients with a combined 24 implants were included in the final analysis. Two of the patients were smokers. The implant brands and types included in the study were Astra, Nobel Mark III and Straumann tissue level implants. Except for variations in dimensions, none of the included patients had different implant types between the test and control sites. The implants in the test group were placed in incisor regions ( $n = 2$ ), premolar regions ( $n = 9$ ) and molar regions ( $n = 3$ ). In the control group, the implants were placed in incisor regions ( $n = 2$ ), canine region ( $n = 1$ ), premolar regions ( $n = 8$ ) and molar regions ( $n = 3$ ).

Both the implants treated in the control group and the implants treated in the test group exhibited significant reductions in mBoP between baseline and 6-month measurements ( $P < 0.001$ ; ie 3 months after the supportive therapy). The implants treated in the test group exhibited a significant reduction in mBoP between baseline, 2 weeks ( $P = 0.001$ ) and 4 weeks ( $P < 0.001$ ), while the implants treated in the control group demonstrated no significant reduction in mBoP between baseline and 2 and 4 weeks. Implants treated in the test group exhibited significantly more reduction in mBoP scores at 2 ( $P < 0.001$ ) and 4 weeks ( $P < 0.01$ ) compared to implants treated in the control group. Statistically, significantly more reduction in PPD was seen in the test group at 4 weeks compared to implants treated in the control group ( $P < 0.05$ ) (Table 1).

At 6 months, one implant in the test group and two implants in the control group exhibited no sites with mBoP scores above 0. Six

implants in the test group and four implants in the control group exhibited no sites with mBoP scores above 1 at 6 months (Table 2).

Pain recordings showed a tendency towards a lower VAS pain score in the test sites compared with the control sites (test: 3.49 [ $\pm 2.63$ ] vs control: 4.6  $\pm$  1.8). This difference was not statistically significant, but the power was only 23.7% since only 8 of the 11 patients included in the analysis had recorded their level of pain on the VAS. Only one out of the eight patients in the test group treated with the chitosan brush reported a pain level of five or more, whereas

a pain level above five was recorded by four of the patients in the control group treated with the titanium curette.

All implants demonstrated stable bone levels between baseline and 6 months, as seen on radiographs.

## 4 | DISCUSSION

This split mouth randomized pilot clinical study demonstrated that the use of a chitosan brush on implants with peri-implant mucositis may lead to reduced clinical signs of inflammation. The short-term reductions in parameters of inflammation were statistically significantly more pronounced after the use of a chitosan brush compared with treatment using a titanium curette. Six months after baseline and 3 months after the supportive treatment, both treatment groups demonstrated a reduction in mBoP and PPD; however, the difference between groups was not statistically significant. This is possibly due to the low power in this pilot study.

Recently, Wohlfahrt et al<sup>16</sup> presented a 6-month multicenter prospective consecutive case series performed in six different periodontal specialist centres, and 63 implants in 63 patients were included. The study documented that the debridement of dental implants with a chitosan brush, seated in an oscillating dental hand piece, leads to significantly reduced clinical signs of inflammation at all time-points compared to the baseline measurements. Furthermore, the results were equal at all participating centres, indicating that the results appear to be independent of therapist associated factors.

To date, few studies have reported reproducible results regarding peri-implantitis treatment protocols.<sup>1</sup> To reduce the number of new cases, it is important to take a prophylactic approach to peri-implant mucositis rather than solely focusing on treatment of the disease when the implant as a matter of fact might be impossible to save. Regular implant maintenance must already be emphasized in the treatment planning phase, and the implant patient must be thoroughly informed about the long-term nature of the therapy.<sup>1,2,17</sup> In this context, Fardal and Grytten<sup>18</sup> reported that the cost for maintenance of implants is approximately five times higher than for teeth. The dental specialist must keep this long-term cost perspective in mind when discussing treatment options with the patient and put emphasis on the importance of regular maintenance to reduce the

**TABLE 1** Implant level analysis of differences between test and control sites in BoP and PPD after treatment

Variable	Mean ( $\pm$ SD)		P
	Test (n = 12 Implants)	Control (n = 12 Implants)	
PPD baseline	4.27 ( $\pm 1.36$ )	4.29 ( $\pm 1.50$ )	NS
PPD 2 wk	4.09 ( $\pm 1.58$ )	4.27 ( $\pm 1.35$ )	NS
PPD 4 wk	3.88 ( $\pm 0.94$ )	4.17 ( $\pm 1.49$ )	NS
PPD 6 mo	4.09 ( $\pm 1.68$ )	3.95 ( $\pm 1.27$ )	NS
BoP baseline	1.54 ( $\pm 0.78$ )	1.35 ( $\pm 0.85$ )	NS
BoP 2 wk	1.04 ( $\pm 0.80$ )	1.41 ( $\pm 0.79$ )	<0.05
BoP 4 wk	0.71 ( $\pm 0.82$ )	1.08 ( $\pm 0.85$ )	<0.05
BoP 6 mo	0.70 ( $\pm 0.70$ )	0.74 ( $\pm 0.80$ )	NS
Change in PPD			
Baseline to 2 wk	-0.24 ( $\pm 1.11$ )	-0.05 ( $\pm 0.73$ )	NS
Baseline to 4 wk	-0.77 ( $\pm 1.19$ )	-0.26 ( $\pm 1.24$ )	<0.05
Baseline to 6 mo	-0.22 ( $\pm 1.16$ )	-0.50 ( $\pm 1.86$ )	NS
Change in BoP			
Baseline to 2 wk	-0.53 ( $\pm 0.88$ )	+0.07 ( $\pm 1.08$ )	<0.001
Baseline to 4 wk	-1.00 ( $\pm 0.89$ )	-0.32 ( $\pm 1.12$ )	<0.01
Baseline to 6 mo	-0.88 ( $\pm 0.87$ )	0.63 ( $\pm 1.05$ )	NS

**TABLE 2** Baseline and 6 mo; number of sites with mBoP 0, 1, 2, 3 at implants with baseline PPD with sites  $\geq 4$  mm. Site-by-site comparisons, that is only sites measured at both time-points included

mBoP	Test baseline Sites n = 59 (%)	Control baseline Sites n = 65 (%)	Test 6 mo Sites n = 59 (%)	Control 6 mo Sites n = 65 (%)
0	11 (18.6)	15 (23.1)	26 (44.1)	31 (47.7)
1	7 (11.9)	11 (16.9)	25 (42.4)	20 (30.8)
2	43 (72.9)	39 (60.0)	8 (13.6)	14 (21.5)
3	0	0	0	0
0 + 1	18 (30.5)	27 (41.5)	51 (86.4)	51 (78.5)
Number (%) of sites with reduction from score 2 to score 1 or 0			35 (59.3)	29 (44.6)

specific patients risk of peri-implantitis. While the majority of peri-implant mucositis cases will be easily handled solely by thorough oral hygiene instructions, thereby reducing the microbial burden and mucositis, other implants with deeper mucosal crevices will not always respond to patient-performed cleaning procedures.<sup>1,19</sup> Regular professional consultations must be a part of the protocol for such cases. There are, however, few such clinical treatment protocols that have been scrutinized scientifically, especially regarding efficacy. Thus, there is a prompt need to conduct clinical studies on maintenance protocols and the related instruments. The biodegradable chitosan brush that was used in this study is one example of such a device that was specifically developed for the intended use of dental implant maintenance. In a recent meta-analysis, it was reported that a causative treatment approach to peri-implant mucositis, including oral hygiene instruction and mechanical plaque removal, seems to be sufficiently effective and adjunctive measures for biofilm removal such as antibiotics provided no additional benefit over conventional control measures.<sup>20</sup> Ji et al<sup>21</sup> studied the use of glycine powder as an adjunct to an ultrasonic device with a carbon fibre tip performing mechanical debridement on implants with mucositis. This author reported a reduction of the implant pocket depth of 0.5 mm after 3 months, and no difference between the test and control group was identified. Riben-Grundstrom et al<sup>22</sup> evaluated the use of glycine powder air-polishing and an ultrasonic device on patients with peri-implant mucositis and used inclusion criteria similar to what was used in the present study. The inclusion criteria were (a) the presence of one or more implant sites with peri-implant mucositis, with a probing depth  $\geq 4$  mm, combined with bleeding with or without suppuration, and (b) bone loss  $\leq 2$  mm. The authors used dichotomous values for BoP and observed reductions of 27.2% in the air-polishing group and 30.5% in the ultrasonic group after 6 months. In the present study, a graded bleeding on probing index was combined with a defined force periodontal probe, since it has been reported that perforations from the implant probe may lead to false positives.<sup>23</sup> Absence of bleeding, however, seems to be a reliable surrogate marker for both the absence of peri-implant disease<sup>24</sup> and the absence of progressive bone loss.<sup>25</sup> In the present study, reductions from an mBoP score 2 to 0 or 1 were demonstrated for 6 implants in the test group and 3 implants in the control group at 6 months after the baseline examination and 3 months after the second treatment. In 59.3% of the sites treated in the test group and in 44.6% of the sites treated in the control group, the mBoP score was reduced from 2 to 0 or 1. While the complete absence of mucositis was difficult to achieve for most implants, significant and stable reductions in the parameters of inflammation were demonstrated at the majority of peri-implant sites up to 3 months following treatment with the chitosan device.

Clinical measurements were not recorded in conjunction with the maintenance appointment at 3 months; these measurements consisted of hygiene control and treatment according to the baseline randomized allocation. In hindsight, it would possibly have been interesting to evaluate the findings from these appointments to determine whether they were similar to the findings at 4 weeks. If the reductions were stable, one may consider performing clinical

measurements at even shorter intervals after the debridement of implants and then evaluating which treatments kept sites free of inflammation for the longest period of time.

Clinical measures for careful implant biofilm removal, such as those performed with the test device in this study, appear to yield positive results related to clinical parameters of inflammation. The crux will always be to examine and resolve local aetiological factors. One such factor is cement remnants, which has been a commonly reported finding in recent studies.<sup>26</sup> Solely using a cleaning device with soft bristles, such as the device used in this study, will not be sufficient to remove hard debris. While this study demonstrated reductions in clinical surrogate parameters of inflammation, which may indicate the risk for the progression of mucositis into peri-implantitis, one must always remember that the true endpoint for the success of these therapies is preventing the loss of the actual implant. The impact of losing an implant is often dramatic since it is often difficult to come up with an optimal and cost-effective replacement therapy for the lost implant-supported prosthesis. One must also remember the patient's perspective since the initial therapy is often expensive and has varying degrees of morbidity. It is of significant interest both for the dentist and for the implant patient to avoid peri-implantitis and the associated consequences, for example morbidity-related and economic. An established peri-implantitis lesion is often difficult to treat, and the prognosis is the least unpredictable.

Since implant maintenance at frequent intervals has been shown to be important for avoiding a peri-implantitis lesion, it will be essential to not burden the patient with painful treatment options. A less invasive and less painful treatment will often enhance the level of compliance. Seven out of eight patients treated with the chitosan brush reported that the pain was below five on the VAS. However, the power was low due to the small number of patients who completed the VAS test; thus, it will take more patients reporting their pain scores to further elucidate the trend in this study. This pilot study included implants from three different implant systems as well as including both screw and cement-retained supraconstructions. Smokers were also included. This was a good approximation of the typical patients seen in daily clinical practice. Since cement remnants are a well-documented contributing aetiological factor for peri-implantitis and because smoking may mask clinical signs of inflammation, it will be interesting to verify these early findings in a larger clinical study wherein it would be possible to stratify the analysis based on these variables. The instrument tested in this study appeared to have some merits with regard to reduction of clinical parameters representative of peri-implant mucositis; however, larger multicenter clinical studies will be necessary to scrutinize these early results. A multicenter randomized clinical trial with this aim was recently initiated.

## 5 | CONCLUSION

Both treatment groups exhibited reduced signs of inflammation at 6 months after the baseline and 3 months after maintenance



treatment. A chitosan brush seems to be a safe and efficient device for the debridement of dental implants. To evaluate the effectiveness of this novel implant debridement method, a randomized multicenter clinical trial has been initiated.

## 6 | CLINICAL RELEVANCE

### 6.1 | Scientific rationale for study

Long-term mucositis around dental implants increases the risk of peri-implantitis, but there is little empirical research on safe and effective treatment methods. This study evaluated a chitosan brush for the treatment of peri-implant mucositis.

### 6.2 | Principal findings

Debridement of the implants with either a titanium curette or a chitosan brush led to significantly reduced clinical signs of inflammation. Progression in bone loss was not found at any of the treated patients.

### 6.3 | Practical implications

The clinical use of a chitosan brush may be a valid method to reduce inflammation surrounding dental implants, but more studies are necessary.

## CONFLICT OF INTEREST

Dr Wohlfahrt is inventor and patent holder of LABRIDA BioClean® and is a shareholder in LABRIDA AS. Author 2 and Author 3 report no conflict of interest related to the undertaking of this study. The test brushes (LABRIDA BioClean®) were sponsored by LABRIDA AS.

## AUTHOR CONTRIBUTIONS

JCW, OCK and AMA designed the study. JCW performed all clinical treatments. OCK and AMA were calibrated examiners and performed all clinical examinations. All three authors were involved in the writing of the manuscript.

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