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Adjunctive Periodontal Treatment using a Novel, Commercially Available Chitosan Powder

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ABSTRACT

Background: Nonsurgical therapies for periodontal disease are considered the first line treatment. Advances in nonsurgical treatments are being explored. Here we used a chitosan powder in a pilot study to evaluate a novel treatment as an adjunct to Scaling and Root Planning (SRP). This pilot study was a prospective, single arm, open label study to assess the chitosan's ability to perform as an adjunctive treatment for periodontal disease.

Methods and Materials: Subjects with at least one pocket with a depth ≥ 5mm were enrolled at 10 different clinical locations. Subjects were evaluated for pocket depth, bleeding on probing, inflammation and an Oral Hygiene Index. SRP was performed and then chitosan powder was deposited in the pocket. A 30 day follow up was performed and the assessments were recorded.

Results: A total of 49 subjects were evaluated. A statistically significant reduction was observed in the assessments compared to the baseline time point. Against the standard of care, SRP, as a historical control the pocket depth; bleeding on probing; and inflammation showed a marked reduction against SRP alone.

Conclusion: This pilot study has demonstrated the use of a commercially available chitosan powder, PerioStom, as an adjunct to SRP. Its use provided remarkable results in the clinical outcomes for those treated in this study with periodontal disease.

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Introduction

Periodontal disease, a chronic inflammatory condition affecting the supporting structures of the teeth, poses a significant health challenge worldwide. Characterized by the progressive destruction of the periodontal ligament and alveolar bone, untreated periodontal disease can lead to tooth loss and systemic health issues. The primary etiological factor is microbial plaque, but the disease's complexity is influenced by host immune responses, genetic predispositions, and environmental factors. These multifaceted interactions necessitate comprehensive and multifactorial approaches to prevention and treatment.

The mainstay of periodontal disease treatment focuses on controlling infection and halting tissue destruction. Non-surgical treatments, such as scaling and root planning, are the frontline therapies. These mechanical procedures aim to remove plaque and calculus from the tooth surfaces and root, thereby reducing bacterial load [1]. Adjunctive therapies, including the use of local or systemic antibiotics and antimicrobial agents, are often employed to enhance the outcomes of mechanical debridement [2].

In addition to addressing the microbial load, however, evidence is emerging that the destruction of the supporting structures of teeth during periodontal disease is also driven by an inflammatory response to microbial plaque [3]. Therefore, effective treatment of periodontal disease involves not only the reduction of bacterial load through mechanical debridement and antimicrobial agents but also a targeted approach to mitigate the host's inflammatory response. Reducing inflammation is crucial because it addresses the underlying pathophysiology of periodontal tissue destruction. By focusing on inflammation control, treatments can help stabilize periodontal tissues, reduce pocket depths, and prevent further tissue damage, ultimately improving long-term periodontal health outcomes.

The introduction of chitosan, a natural biopolymer derived from chitin, represents a novel and promising approach to periodontal therapy [4,5]. Chitosan possesses unique properties, including antimicrobial activity, anti-biofilm properties, anti-inflammatory properties, biocompatibility, and the ability to promote wound healing. These characteristics make chitosan an attractive treatment for periodontal disease.

This pilot study was a prospective, single arm, open label study to assess the chitosan's ability to perform as an adjunctive treatment for periodontal disease.

Methods and Materials

Subjects presenting with periodontal disease were provided Informed Consent and were evaluated for suitability to be included in the evaluation. Inclusion criteria included at least one site with a pocket depth of at least 5mm where (SRP) is indicated. Exclusion criteria are listed below.

- Active smoker
- Diabetes
- Necrotizing ulcerative gingivitis or necrotizing ulcerative periodontitis
- Local or systemic antimicrobial treatment within the previous 90 days
- Chronic therapy within 1 month prior to evaluation with medications that could affect periodontal status or healing (ex: chemotherapy)
- Chitosan or shellfish allergy
- Subject is or plans to be pregnant withing 6 months of treatment or is currently breastfeeding
- Subject does not provide full consent

During a full mouth evaluation, baseline assessments were established for the subjects' probing depth, bleeding, gingival inflammation, and oral hygiene.

Grading criteria are listed below

1. **Pocket Depth:** Depth of the pocket in mm
2. **Bleeding on Probing:** Yes / No
3. **Gingival Index** [6]

- **0: Normal Gingiva** - no inflammation and no discoloration or bleeding
- **1: Mild Inflammation** - slight change in color and slight edema, but no bleeding on probing
- **2: Moderate Inflammation** - redness, edema and glazing, bleeding on probing
- **3: Severe Inflammation** - marked redness and edema, ulceration with tendency to spontaneous bleeding

4. **Oral Hygiene Index** [7]

- **0: None** - No observable plaque.
- **1: Mild** - A thin layer of plaque; only detectable by scraping with a probe.
- **2: Moderate** - A moderate layer of plaque along the gingival margin and plaque is visible clinically.
- **3: Severe** - Heavy plaque accumulation is detected at the gingival margin and in the interdental spaces.

After the above assessments were recorded, SRP was conducted on the whole mouth. In each pocket with a depth of ≥ 5mm, a single dose of PerioStom was dispensed in those pockets. Up to 5 sites could be treated per subject. PerioStom was not removed by the clinician or patient as it slowly dissolved and was washed away by the saliva. An adhesive or dressing was not required.

Patients were given postoperative instructions including avoiding manipulating or touching the treatment areas; for the first 10 days after treatment avoiding interproximal cleaning devices; and avoiding chewing sticky, hard, or crunchy foods such as gum, taffy, apples, raw carrots, etc. Lasty, subjects were instructed to maintain good oral hygiene by brushing daily.

After 30 ± 5 days, the subjects were reevaluated using the same assessments. Subjects were excluded from analysis if they did not comply with the postoperative instructions.

For evaluating the treatment, the Probing Depth was analyzed using a paired two tailed t-test. Bleeding on Probing (BOP) was analyzed by a two-tailed Fisher's Exact Test. For the Gingival Index and Oral Hygiene Index assessments, a Chi-squared two-tailed analysis was performed. All analyses were performed with a 95% confidence interval.

Results

At 10 clinical locations, a total of 65 subjects were enrolled and 49 were included for analysis. Sixteen subjects were excluded for either loss to follow up or noncompliance with postop instructions. The median age of those enrolled in the study was 57.5 years (range 22 - 77 years) with 24 men and 41 women. The total number of sites treated with chitosan was 127. The mean sites treated per subject was 2.6.

Subjects were instructed to notify the dental office if pain persisted longer than one week post treatment or if other adverse events occurred such as infection or an allergic reaction, including difficulty breathing, swelling, itching, or rashes. No adverse events were reported.

The baseline pocket depth was 5.75 ± 0.84mm (mean ± SD) and at follow up was 4.11 ± 0.94mm. The mean reduction in pocket depth was 1.61mm. The difference from baseline was statistically significant with $p < 0.0001$ (Table 1). From a historical control [8], also reporting data 30 days post treatment, the pocket depth reduction from only SRP was 1.01mm. Bland also provides pocket depth from the investigational group (SRP + minocycline microspheres) which was 1.38mm and statistically significantly different than the SRP group. Although the difference from baseline of this study was greater than Bland (1.61mm vs 1.01mm, respectively), Bland does not provide enough data to definitively determine if the pocket depth reduction in this study is statistically significantly greater than Bland, although it likely is. A similar pocket depth reduction to that of Bland by SRP alone was reported (1.0mm) in a meta-analysis by Ma and Diao [9].

Table 1: Pocket Depth

Pocket Depth (mm)	n	Baseline	30 Day Follow Up	Difference	*p*
SRP + Chitosan	127	5.75 ± 0.84	4.11 ± 0.94	1.61	<0.0001
SRP (Historical Control)†	65	*	*	1.01	
SRP (Historical Control)§	115	*	*	1.0	

* Not provided
† Bland et al.
§ Ma et al

Table 2 displays the results of Bleeding on Probing (BOP). At the baseline, 98.4% of the periodontal sites were positive for BOP. On the 30 day follow up after the SRP + chitosan treatment, the number of sites that were positive for BOP were 26.8%, a dramatic reduction by 71.6%. Bland also reports on the reduction of BOP by only SRP being just 13.8%. Comparing to data from Bland, we can see a marked reduction in BOP when using an SRP + chitosan treatment over that of the standard of care, SRP (reduction of 71.6% to 13.8%, respectively). Again, we do not have enough data from Bland to determine statistical significance between this study and the former, however, given the extremely large difference, it is very unlikely that this difference is not statistically different.

Table 2: Percentage of Sites with Bleeding on Probing

% of Sites with BOP	n	Baseline	30 Day Follow Up	Difference	*p*
SRP + Chitosan	123	98.4%	26.8%	71.6%	<0.0001
SRP (Historical Control) †	65	*	*	13.8%	

* Not provided
† Bland et al.

Similarly, Table 3 demonstrates the reduction in the Gingival Index (GI), a measure of inflammation. For the treatment of SRP + chitosan, there was a large and statistically significant reduction in GI from the baseline to the 30 day follow up. As before, we can compare these clinical results to that of SPR monotherapy for the Gingival Index [10] as a historical control. The difference from baseline for the SRP + chitosan group was larger and statistically significant from SRP alone in Anuradha (1.35 vs 0.93, respectively).

Table 3: Gingival Index

Gingival Index	n	Baseline	30 Day Follow Up	Difference	*p*
SRP + Chitosan	127	2.20 ± 0.49	0.85 ± 0.78	1.35 ¶	<0.0001
SRP (Historical Control)◊	30	1.73 ± 0.11	0.8 ± 0.11	0.93 ¶	<0.0001
SRP (Historical Control) §	146	*	*	0.67	

¶ Statistically significant between each other
* Not provided
◊ Anuradha et al.
§ Ma et al

Lastly, the Oral Hygiene Index (OH) was evaluated, shown in Table 4. While there was a statistically significant decrease in the OH score when using SRP + chitosan in the OH from baseline, there was no statistical difference than over SRP alone [10].

Table 4: Oral Hygiene Index

Oral Hygiene Index	n	Baseline	30 Day Follow Up	Difference	*p*
SRP + Chitosan	127	1.82 ± 0.72	0.83 ± 0.74	0.99	<0.0001
SRP (Historical Control)◊	30	1.92 ± 0.02	0.96 ± 0.2	0.96	<0.0001

◊ Anuradha et al.

Discussion

This pilot study has demonstrated the ability of a commercially available chitosan to treat periodontal disease. This is an exciting advancement considering PerioStom is not a drug, yet can effectively treat periodontal disease as an adjunct to SRP.

Previous research has shown a beneficial effect of chitosan on periodontal disease and this pilot study has confirmed those former results [4]. However, this is the first study known to use a commercially available chitosan product. PerioStom, the product used in this study, was cleared as a medical device by the FDA in 2022 as an oral wound dressing. With it, we have found exceptional utility in the treatment of periodontal disease.

Chitosan is a natural biopolymer derived from the shells of crustaceans. This bioadhesive polymer has several properties which are beneficial in the treatment of periodontal disease. First, chitosan has shown to have antimicrobial activity against P. gingivalis [5]. Second, chitosan has been shown to inhibit biofilm production [11]. Additionally, chitosan has been shown to interrupt the inflammatory pathways in vitro and in vivo in multiple tissue types [12]. In this study, inflammation was evaluated clinically via the Gingival Index assessment. This study is in accord with the non-clinical manuscripts that suggest the application of chitosan would be beneficial in the treatment of periodontal disease. As expected, there was a statistically significant improvement in all the assessments over the baseline at the 30 day follow up. But more importantly, we saw a significant advantage in outcomes over the standard of care, SRP, for the reduction of pocket depth, bleeding on probing, and inflammation.

On the clinical report form, clinicians were allowed to provide feedback on the results. A majority of the responses indicated that the results they observed when using the chitosan powder were better than the other adjunct therapies they have used previously. The free form feedback provided was exceptionally positive and they indicated their eagerness to use the product in the future.

A major limitation of this study was the lack of a contemporaneous control group. While there are inherent deficiency of single arm using a historical control, we have attempted to find peer reviewed studies using the same methodology, timing, and assessments. We are currently evaluating a single blind, two-arm study.

We have demonstrated that the use of a commercially available chitosan powder as an adjunct to SRP is well tolerated and provides dramatic beneficial results in clinical outcomes for those with periodontal disease.

Conflict of Interest: The authors and clinicians have no conflict of interest in the product described in this manuscript. Forward Science provided the product, Periostom, for this study.

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