CASE SERIES

A Novel Adjuvant Treatment to Scaling and Root Planing With a Topical Gingival Patch: A Case Series

Aron Saffer* and Noah Samuels†

Introduction: Gingival inflammation often persists despite conventional therapies. A topical gingival patch containing natural extracts has been shown in a randomized clinical trial to reduce gingival inflammation when administered as an independent therapy. We report a case series of patients with moderate-to-severe chronic periodontitis in whom the patch was used together with scaling and root planing (SRP).

Case Series: A series of 20 healthy patients presenting with moderate-to-severe chronic periodontitis (probing depths, 5 to 8 mm) were treated with the patch immediately after treatment with SRP. All patients had bilateral gingival inflammation with a gingival index (GI) ≥2 and bleeding on probing (BOP) on ≥1 site per tooth on two adjacent teeth. After SRP, the patch was applied first by the study periodontist (AS), with two subsequent applications over the next 24 hours by the patient, and reevaluated 2 to 4 weeks later. On a separate visit, the contralateral side was treated with SRP alone and was also reassessed after 2 to 4 weeks. Both the patch and non-patch sides showed improvement after SRP. When comparing the two sides, the patch-treated area showed a significantly greater reduction of inflammation and bleeding, as measured by GI (P < 0.001) and BOP (P < 0.002).

Conclusions: In this case series, the patch is shown to provide a beneficial effect by helping to further reduce inflammation when used in conjunction with scaling and root planing. Additional research of the patch combined with SRP treatment is warranted within the framework of large randomized and controlled trials.

Key Words: Administration, topical; gingivitis; periodontitis; root planing; scaling, dental.

Background

Chronic periodontitis is an inflammatory process that is initiated by bacterial infiltration of the gingival mucosa. This, in turn, results in an inflammatory process that is associated with destruction of the periodontal ligament and alveolar bone.1-3 Periodontitis is accompanied by proinflammatory cytokines and has been associated with an increased risk for coronary artery disease, cerebrovascular events, and complications during pregnancy. At the same time, conditions that are accompanied by impaired immune function, such as diabetes mellitus, can themselves exacerbate gingival inflammation.4,5 Current accepted therapies of periodontitis incorporate the use of mechanical debridement of root surfaces, or scaling, as well as root planing and the occasional use of local and systemic antibiotic therapy.6,7 However, because these treatments are directed solely at the localized bacterial infection, gingival inflammation can often persist and continue to cause destruction, especially in deep periodontal pockets.8 The ongoing inflammatory response to microbial challenge mediating tissue destruction can continue even after the oral pathogens have been removed.9 It is for this reason that

* Jerusalem Perio Center, Jerusalem, Israel.
† Center for Integrative Complementary Medicine, Shaare Zedek Medical Center, Jerusalem, Israel.

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recent strategies for the treatment of periodontal disease are being directed toward both antimicrobial therapies as well as modulation of inflammation.10

A commercially available topical patch‡ contains extracts of three herbs—Centella asiatica, Echinacea purpurea, and Sambucus nigra—that have all been shown to be both safe and effective in reducing gingival inflammation.11-14 These herbs, in combination with other formulatatory agents in the patch, absorb inflammatory fluids and surface exudates from inflamed tissue as well.15 The patch is a registered medical device and was developed to help reduce localized irritation and inflamed gingiva.

The patch has been studied in clinical trials (unpublished data) and has been shown to be both safe and effective in rapidly reducing localized gingival inflammation. In a double-masked randomly controlled clinical trial in patients with moderate-to-severe gingivitis, the patch—administered as a sole treatment modality, without any mechanical plaque debridement of the area—significantly reduced localized gingival inflammation (unpublished data). This finding was quantified by a reduction in the measured gingival index (GI), as well as the gingival crevicular fluid marker β-glucuronidase. β-Glucuronidase is an inflammatory biomarker that correlates directly with the degree of gingival inflammation and neutrophil influx and can reflect a reduction in inflammation even before there are clinical signs of improvement.16-18 The purpose of this case series is to observe the effects of patch treatment as an adjuvant to scaling and root planing (SRP) in reducing gingival inflammation in chronically inflamed, moderate-to-severe periodontitis.

Clinical Presentation

Patients presenting to the Jerusalem Perio Center, Jerusalem, Israel, with localized gingival inflammation are routinely offered treatment with the patch. A consecutive series of 20 patients with localized inflammation who agreed to undergo patch treatment were included in our case series. All patients provided oral consent for participation in the study. Treatments took place in 2010 and the study received approval by the institutional review board at the Shaare Zedek Medical Center. Selected patients presented with chronic periodontitis, with clinical evidence of attachment loss (AL) and probing depths (PDs) ranging from 5 to 8 mm, as well as radiographic signs of moderate-to-severe bone loss, as demonstrated by alveolar bone loss on a radiogram. The GI, an accepted measure of the severity of gingival inflammation described by Löe,19 was ≥2 at the selected sites for all patients. Bleeding on probing (BOP), a widely used clinical sign of inflammation20 and predictor of future AL,21 was present on ≥1 site per tooth on two adjacent teeth. Patients were also asked whether they suffered from pain in the affected area.

Patch treatment and evaluation of outcome measures were conducted by a single dentist (AS) for all patients. The patch was applied to one of the affected sides, in addition to standard SRP treatment according to the method described by Wasserman,22 which includes removal of the inner layer of the gingival tissue. A similar area was treated on the contralateral side with SRP alone to serve as a control at a later visit. The first patch was applied to a selected inflamed site by the study periodontist (AS), and then patients were instructed regarding how to apply one patch twice more over the next 24-hour period. The patch was placed on the gingiva, overlapping onto the bottom third of the tooth and covering the marginal tissue of ≥2 teeth (Fig. 1). On a separate visit, a similar area of gingival inflammation on the contralateral side was treated with SRP alone. Follow-up evaluation of both these sites was completed 2 to 4 weeks after their respective treatments (Table 1).

‡ PerioPatch, Izun Pharmaceuticals, New York, NY.
Case Management
During the initial visit, patients received a detailed explanation of the patch and were instructed on how to self-apply the patches. The patches are placed over the affected areas of the gingiva, and each patch is used only once and then discarded. The patches have an inner, light-colored side and an external, dark-colored side. The light-colored side is applied directly to the affected area, with the darker side dislodging by itself within 2 hours after application, after which it can be discarded. The inner side of the patch forms a seal over the treated area, remaining in place for ≤5 hours (Video 1).

Clinical Outcomes
A total of 20 consecutive patients (eight males and 12 females, aged 19 to 76 years; mean age: 51.5 years) received the topical patch treatment. None of the patients had an underlying illness, and none were taking any medication, including antibiotics or anti-inflammatory drugs. The mean baseline GI value of the patch-treated area was 2.15 (range: 1.66 to 3.00), with a mean BOP rate of 89.0% (range: 66% to 100%). Only seven patients complained of gingival pain at the start of treatment. At the follow-up visit, the mean GI of the area treated with the patch had decreased to 1.09 and BOP to 29.7%, demonstrating a reduction in GI of 1.01 and BOP by 60% (Table 2). All patients at follow-up were pain free in treated areas, and none of the patients reported any difficulty applying the patches or any adverse effects associated with the treatment.

On the contralateral side, the non-patch-treated area had a mean baseline GI score of 1.75 (range: 1.66 to 2.00), decreasing at the follow-up visit to 1.49. The mean baseline BOP score was 81.3% (range: 33% to 100%), decreasing at follow-up to 53.2%. Thus, the net decrease in GI was 0.29 and 32% in BOP. The differences in GI and BOP reduction between the patch-treated areas and the non-patch-treated areas were statistically significant (GI reduction, P <0.001; BOP reduction, P = 0.002). The treated and untreated sides were considered as independent samples. The data for GI, BOP, and pain were treated as non-parametric variables. The difference between the pretreatment and post-treatment values (δ) for the two samples were compared using the Mann-Whitney U test (Table 2).

Discussion
The present report is a case series of 20 gingivally inflamed patients with chronic periodontitis, who were treated with a self-applied topical gingival patch as an adjuvant to standard SRP therapy. The patch-treated side showed a significantly greater reduction of inflammation and bleeding than the side treated with SRP alone, as shown by GI and BOP scores. Reduction of gingival inflammation and bleeding 2 to 4 weeks after SRP is a well-known response to treatment.23,24 The percentage of BOP reduction after SRP alone found in this case series is similar to that found in previous SRP studies.25-27 The addition of an adjuvant treatment of areas of localized moderate-to-severe gingival inflammation with the topical patch was found to be safe and feasible. It would seem that the patch has potential benefit as an adjuvant treatment to SRP, in patients with moderate-to-severe gingival inflammation.

As with reports of case series, our findings are purely observational and focus strictly on clinical measures of inflammation. The small sample size of only 20 patients limits the statistical power of the findings as well. Still, the results are encouraging, and, although the statistical analysis is limited by the small sample size, they are supported by similar findings in the double-masked randomized controlled trial mentioned above, in which patients were treated with the patch alone, without mechanical plaque removal. Future clinical trials (randomized, controlled, and double-masked) are planned to measure the adjuvant effect of the patch over a longer period of time, as well as study its effect on PD and clinical attachment level.

### Table 1 Treatment Schedule After SRP

<table>
<thead>
<tr>
<th>Visit</th>
<th>Time Frame</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit 1</td>
<td>Day 0</td>
<td>SRP + patch and identification of similar contralateral site</td>
</tr>
<tr>
<td>Visit 2</td>
<td>Weeks 2 to 4</td>
<td>1) Evaluation of SRP + patch, and 2) SRP without patch contralateral quadrant</td>
</tr>
<tr>
<td>Visit 3</td>
<td>Weeks 6 to 8</td>
<td>Evaluation of SRP without patch</td>
</tr>
</tbody>
</table>

### Table 2 Changes in GI and BOP After Standard Therapy, With or Without Patch Treatment

<table>
<thead>
<tr>
<th>Outcome</th>
<th>With Patch</th>
<th>Without Patch</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improved GI</td>
<td>1.01/0.08</td>
<td>0.29/0.07</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Improved BOP</td>
<td>0.60/0.06</td>
<td>0.32/0.07</td>
<td>0.002</td>
</tr>
<tr>
<td>Reduced pain</td>
<td>0.22/0.08</td>
<td>0.01/0.01</td>
<td>0.03</td>
</tr>
</tbody>
</table>
**Summary**

<table>
<thead>
<tr>
<th>Why are these cases new information?</th>
<th>This case series describes a new and innovative adjuvant treatment for localized gingival inflammation.</th>
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<tr>
<td>What are the keys to successful management of these cases?</td>
<td>The apparent synergism between standard mechanical plaque debridement and the herbal patch adds a novel method of improving standard of care.</td>
</tr>
<tr>
<td>What are the primary limitations to success in these cases?</td>
<td>Although none of the patients reported difficulty in applying the patches, compliance to the treatment regimen is probably the primary limitation to success with this treatment.</td>
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</table>

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**CORRESPONDENCE:**

Dr. Aron Saffer, Jerusalem Perio Center, 9 Radak St., Jerusalem 92301, Israel. E-mail: perio@bezeqint.net.
References


