

# EFFICACY AND SAFETY OF MONOCHROMATIC PHOTOTHERAPY IN PATIENTS WITH GINGIVITIS

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**A double-blind, randomised, placebo-controlled, parallel-design, multi-centre study for comparison of the efficacy and safety of monochromatic phototherapy vs placebo phototherapy in patients with gingivitis.**

## INTRODUCTION

Pilot studies have indicated that phototherapy using monochromatic light, Biolight<sup>®</sup>, might be effective in the treatment of gingivitis. Therefore, the aim of this randomised, double-blind parallel group study was to investigate the efficacy and safety of monochromatic light phototherapy on gingival inflammation.

## MATERIAL

The study was performed at 6 Swedish dental care centres, the Institute of Odontology, Karolinska Institutet, and 5 private practices, during the period June 1998 to January 2000. All patients were given verbal and written information and signed an informed consent before any study-related procedures were undertaken.

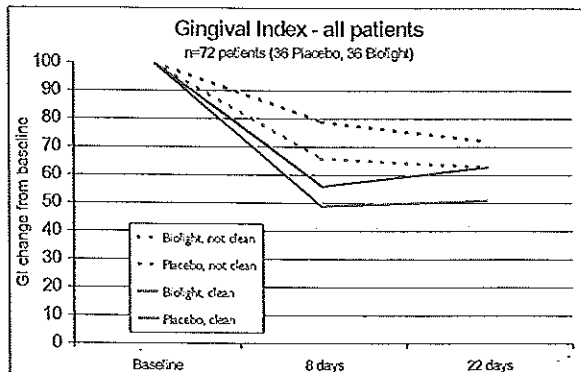
The patients were randomised to either phototherapy with pulsating monochromatic light, Biolight<sup>®</sup>, (n=44) or placebo light (n=42), and the exposure to active or placebo light was made blind. At baseline, gingiva and teeth were examined, and the teeth in the right maxillary and mandibular regions were professionally cleaned. The patients were instructed to continue their normal daily dental hygiene throughout the study.

## METHODS

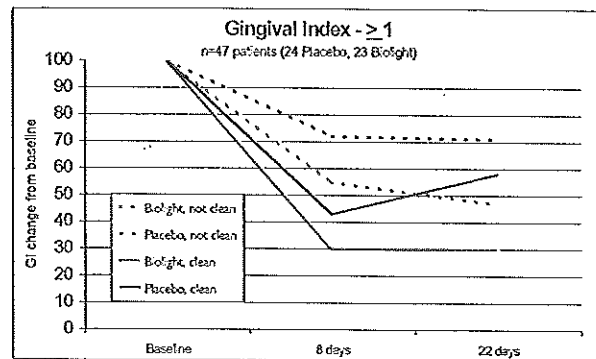
Adult patients (n=90), with gingivitis but no signs of periodontitis, were randomly assigned to either active phototherapy using monochromatic light, Biolight<sup>®</sup>, or placebo phototherapy. At baseline the teeth in the right maxillary and mandibular regions were professionally cleaned. Phototherapy was then given extraorally at 3 occasions with intervals of two days. Response was evaluated after 8-9 and 22-24 days. The primary variable was the gingival index (GI) in the absence of professional cleaning.

## RESULTS

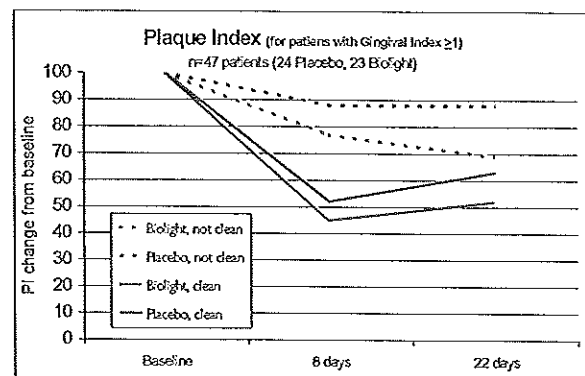
The treatment difference between the two groups was statistically significant at days 8-9 (p=0.035) in favour of active phototherapy, Biolight<sup>®</sup>, but not at days 22-24 (p=0.140).



Treatment with monochromatic light, Biolight<sup>®</sup>, was particularly beneficial in patients with more pronounced gingivitis, i.e. GI  $\geq$  1. Significant treatment differences in favour of active phototherapy, Biolight<sup>®</sup>, was shown at both follow-up visits in the absence of professional cleaning. (p= 0.033 and p= 0.014, respectively) and at the last follow-up in the presence of professional cleaning (p=0.013).



The effect of active phototherapy, Biolight<sup>®</sup>, alone was comparable to that of professional cleaning. The most favourable result was obtained when combining active phototherapy, Biolight<sup>®</sup>, with professional cleaning. In the absence of professional cleaning the amount of plaque decreased significantly in patients treated with active phototherapy, Biolight<sup>®</sup>, at days 8-9 (p=0.001) and days 22-24 (p<0.001) as compared to baseline. This was not true for the placebo group at the two follow-up visits (p=0.067 and p=0.075, respectively).



The overall number of adverse events reported was small. All systemic events were unrelated to the study treatment. The number of local events with a suspected or probable relation to phototherapy, Biolight<sup>®</sup>, (1 patient) was similar to the number reported in the placebo group (3 patients).

## CONCLUSION

Phototherapy using monochromatic light, Biolight<sup>®</sup>, has an effect on the plaque formation process and the gingival inflammation, especially in patients with more pronounced gingivitis.

## THE EFFECT OF BIOLIGHT TREATMENT IN COMBINATION WITH MECHANICAL ANTI-BACTERIAL TREATMENT OF PERIODONTITIS

Bengt Rosling

### Introduction

A soft and mineralised bacterial plaque is what constitutes the main etiological factor for the development of gingivitis and periodontitis (1).

A great number of studies have been published during the last few decades clearly indicating that the success frequency regarding treatment of periodontitis can be related to absence or presence of plaque in the treated area (2).

In principle the treatment comprises two important clinical stages: (i) the bacterial films are removed from the teeth both supra- and subgingivally, and then (ii) this treatment is combined with further measures that prevent new build-up of heavy plaque accumulation in the treated area.

Equally good results can be achieved regardless of whether surgical or non-surgical techniques are used for the subgingival cleaning (3). On the other hand, the results of certain studies suggest that subgingival mechanical cleaning does not produce adequate pocket reduction, nor does it lead to complete healing of the periodontal inflammation in patients who display postoperative plaque in the treated area (4, 5).

Reports from clinical studies of the late 1970s (Ramfjord et al. 1973, 1976) and the early 1980s by Badersten et al., whose results were later confirmed in studies presented by Westfelt et al. in Gothenburg, all showed that optimal subgingival deputation without surgical exposure of the infected root surfaces led to complete healing of severe periodontal lesions (PPD 5-8 mm) with ceased or considerably retarded periodontal progression. Healing remained at the same level as in processes where deputation was combined with good plaque control and surgical technique (Rosling et al. 1976).

At the department in Helsingborg we decided in the early 1980s to test these findings in a continued field study. Basic diagnostic routines for evaluation of treatments included registration of the following variables:

1. Changes in probeable pocket depth.
2. Visible plaque (Silness & Løe).
3. Gingival inflammation (bleeding upon probing).
4. Changes in probeable, clinical attachment level (evaluation – 1 year).
5. Bacterial sample (culture; *Porphyromonas gingivalis* P.g., *Prevotella intermedia* P.i. and *Actinobacillus actinomycetemcomitans* A.a.) and the total number of bacteria.

Based on evaluation since 1981, the results show unequivocally that deputation without surgery leads to good healing and stable periodontal conditions for a long period of time, provided that good oral hygiene can be established during that same period. Simultaneously however, we can state that about 8-10 per cent of the

patients relapse despite optimal and regular follow-up treatment. The latter patient material is of the same dimensions as the one presented by Knowles (4) after a wider analysis of Ramfjord's material (2). Similar experiences can be found at the other specialist clinics in the country.

Different methods have been tried to enhance basic periodontal treatment with an aim of reducing this portion of incompletely healed injuries. However, no significant success has been recorded to date.

In 1996 we established contact with Biolight International AB. They presented promising results from local treatment using the Biolight method on pilot dental cases regarding healing after oral surgery, as well as pilot cases regarding the healing of chronic wounds, mainly decubitus ulcers.

The Biolight method is a Swedish innovation based on treatment with monochromatic, mainly infrared light, controlled and varied as to wavelength, strength and pulsation. The method is used to treat injuries and illnesses locally and/or via the acupuncture system. Specific treatment programs are being developed for each indication. For chronic conditions the light treatment may be combined with nutritional additives. A special mineral and vitamin preparation has been developed for this purpose. No side effects have been reported after treatment with the Biolight method.

As all previously tested treatment methods have, in fact, displayed a certain number of failures (about 10 % – smokers, patients with bad plaque control, etc.) we decided to examine the possibility of enhancing the effect of "non-surgical debridement" through applying the Biolight method on this group of patients.

## Method

Six severely affected patients were included in the study. All six had previously received two consecutive basic, non-surgical subgingival debridement treatments without showing any subsequent healing.

The patients were divided into two groups of three patients each. All received renewed basic treatment as well as treatment with the Biolight method. Each patient received a total of 12 treatments with the Biolight method during a six-week period. Each treatment lasted for about ten minutes. One of the groups also received nutritional additives in the form of the Biolight Vitamin and Mineral preparation for 15 days (12 tablets per day) directly after the basic treatment. Follow-up of probeable pocket depth and gingival inflammation (bleeding after probing) was carried out three months after the basic treatment.

## Result

The result of this limited study shows that remaining periodontal lesions were clearly reduced in all patients (appendix 1). Furthermore, the reduction frequency of the lesions seems to be much greater in those patients who received nutritional additives

in combination with the Biolight treatment. Another interesting observation was made in relation to this group of patients, who, without any specific question from our side, pointed out that they experienced a strong feeling of euphoria, described as "a kind of kick".

As regards the gingival inflammation, no obvious change could be observed.

## Conclusion

The results point to a possible positive effect on the healing process in a group of patients, who up till now have required most extensive treatment resources without reaching any acceptable level of healing.

My opinion is that further controlled studies should be carried out to develop an effective treatment method for these so called "treatment resistant" patients, who lose many teeth despite long and resource-heavy treatment. It is important to emphasise that though these patients normally require considerable reconstructive treatment with dental bridges of various kinds, many of them are still hit by toothlessness. A functioning treatment method will have great economic importance for both patients and society.

Helsingborg, August 11, 1997

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