

Press release from Biolight International AB

Danderyd, June 9, 2000.

Biolight[®] produces powerful results for treatment of gingivitis

A controlled study of patients with gingivitis (gum inflammation) has produced very interesting results. The degree of inflammation (gingival index) was reduced by 87 % and 53 % more after 8 and 22 days respectively in patients treated with Biolight[®], as compared to placebo-treated patients. In patients with a more pronounced inflammation, the study shows a difference of 81 % after 8 days and 105 % after 22 days, these figures being in favour of patients treated with Biolight[®]. The actual reduction of the inflammation (gingival index) after treatment with Biolight[®] was 34 % (8 days) and 36 % (22 days) respectively, and in the group with a more pronounced inflammation 36 % and 42 % respectively.

"The result of the study is better than we expected. Our goal was to achieve a difference of at least 30 % compared to placebo. This means that we can offer a new effective tool for the treatment of gingivitis. An important advantage is that Biolight[®] is a non-invasive method, which means that the whole jaw can be treated from the outside at one and the same time. Other methods are invasive and limited to just a few teeth at every treatment session. Dentists and dental hygienists participating in the study have shown great interest in using Biolight[®] in their daily work with patients," says Christer Wallin, president of the company.

Gingivitis (inflammation of the gums) is the most common infection of all in human beings. It develops at the edge of the gums due to bacteria on the surface of the tooth. An estimated 36-54¹⁾ per cent of the adult population in Sweden experience inflammatory changes. In certain cases gingivitis gets worse and turns into periodontitis (loosening of the teeth). Gingivitis does not always lead to tooth loss, but it is important to take preventive measures to stop periodontitis from building up.

A scientifically controlled study including patients with gingivitis (inflammation of the gums) has been carried out at six clinics. The object of the study was to examine the reduction rate in gingival index after treatment with Biolight[®] as compared to placebo treatment. The primary effect variable in the study was the change (reduction) in gingival index in the absence of professional cleaning. The goal was to achieve a difference of at least 30 %.

A mean value has been calculated for each jaw half. The mean value is based on four values per tooth.

The gingival index is a measure of the degree of inflammation and is assessed from 0 – 3, where 0 = healthy gingiva, 1 = mild inflammation, 2 = moderate inflammation, red and swollen, bleeding upon gentle probing and 3 = severe inflammation, tendency to spontaneous bleeding.

Treatment with Biolight[®] and placebo respectively has been carried out at three occasions during the first week of the study. The treatment time was 4.5 minutes on each occasion. Prior to treatment with Biolight[®] or placebo, professional cleaning (deposition) was carried out in the right half of the jaw, while the left half was left uncleaned. The patients were asked to maintain their usual oral hygiene. The results of the treatment were recorded on day 8 and day 22.

The difference in gingival index reduction has been studied, after treatment, on the whole material (72 patients) as well as on patients whose mean gingival index value ≥ 1 (47 patients with a more pronounced inflammation).

NOTE! See data on the following page!

Difference in reduction of inflammation after treatment with Biolight[®], as compared to placebo treatment (%):

All patients, n=72	8 days	22 days
Not cleaned	87% (p=0.035)	53% (n.s)
Cleaned	30% (n.s)	48% (n.s)

Patients with gingival index greater than or equal to one, n=47	8 days	22 days
Not cleaned	81% (p=0.033)	105% (p=0.014)
Cleaned	38% (n.s)	87% (p=0.013)

1) Parodontologi - en introduktion; Björn Klinge – 1994

Biolight International AB is a medical technology company, offering its customers, including patients, nursing staffs and authorities, various products and services based on the company's patented method for the use of pulsating, monochromatic light. The company aims to improve the quality of life for the patients and reduce the time to healing and treatment costs significantly. Through systematically executed clinical trials, Biolight is gradually extending the scientific basis needed to guarantee the method a solid position in the health care field. During the past few years, Biolight has focused on a small number of indication areas grouped around wound healing.

For further information, please visit Biolight's homepage www.biolight.se or contact Christer Wallin, President of Biolight International AB, on +46-(0)8-622 52 70.