

**Evaluation of Omega-3 Polyunsaturated Fatty Acids Plus Low-dose
Aspirin Daily Supplementation in Surgical Therapy to Treat Generalized
Aggressive Periodontitis: Randomized Controlled Clinical Trial**

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Study Protocol

Periodontal destruction results mainly from the exacerbated host inflammatory response to the bacterial challenge. For this reason, research involving the modulation of host response has been developed aiming to facilitate the resolution of inflammation, as well as to promote tissue repair and periodontal stability. Recently, the use of omega-3 polyunsaturated fatty acids (Ω -3 PUFA) and low-dose acetylsalicylic acid (ASA) was related to the production of enhanced lipidic mediators and to better clinical outcomes in the treatment of chronic periodontitis. Thus, the aim of the present randomized controlled clinical trials was to evaluate the use of 900 mg Ω -3 PUFA and 100 mg ASA for 180 days as adjuvants to the treatment of generalized aggressive periodontitis (GAgP). Thirty-four GAgP patients previously submitted to NST with residual pockets were selected and underwent open flap debridement associated with Ω -3 PUFA 3 and ASA (n=17) or placebo (n=17). After 6 months, both therapies led to decreased PD ($p > 0.05$), but only the test group had CAL gain in the intergroup comparison ($p = 0,02$), as well as presented less gingival recession ($p = 0,03$), decreased dentin hypersensitivity ($p = 0,01$), lower consumption of analgesics ($p = 0,02$) and significant intragroup reduction of IL-10 ($p < 0.05$). The microbiological analysis of the residual pockets did not reveal significant changes compared to baseline. It was concluded that the proposed new therapy brought clinical benefits to the surgical treatment of GAgP patients.

Statistical Analysis Plan

Mean and standard deviation were calculated in each of the parameters. PI, BoP, PD, CAL, and GR were submitted to the Shapiro-Wilk test to evaluate the distribution of these data, and then subjected to the variance test for both intra- and intra-group comparison. In addition, the number of pockets $\geq 5\text{mm}$, the frequency of closure of these pockets, the mean reduction in PS and the gain in CAL of these pockets were assessed before and after the therapy by performing intra- and inter-group analyzes. IBM SPSS software was used to data analyses. The concentration of each cytokine/microorganism were analyzed by test of variance for intra and intergroup comparison.