# Nickel-free vs conventional braces for patients allergic to nickel: Gingival and blood parameters during and after treatment

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**Introduction:** Allergic and inflammatory reactions have commonly been associated with the release of metal ions during orthodontic treatment. Our objective was to evaluate prospectively gingival and blood status in patients allergic to nickel. **Methods:** Allergy to nickel was diagnosed using a patch test. Two groups were established: conventional braces (n = 21) and nickel-free braces (n = 21). The gingival index was used to determine gingival status before treatment, periodically for 12 months (evaluations every 3 months), and 1 month after the removal of the braces. Blood status was evaluated with a complete blood count, including the quantification of nickel and immunoglobin E before treatment, during treatment, and 1 month after removal of the braces. The data were analyzed using Mann-Whitney, Student *t*, Wilcoxon, repeated measures analysis of variance, Friedman, and chi-square tests. Either the Pearson or the Spearman correlation coefficients were calculated, when appropriate. **Results:** The number of basophils increased significantly among the evaluations in both groups (conventional, $P = 0.002$; nickel-free, $P = 0.001$), whereas the number of eosinophils and the immunoglobin E levels decreased significantly in the conventional group ($P = 0.004$). Plasma nickel levels were increased before and during treatment, and decreased 1 month after removing the braces in both groups, but the differences were significant only in the nickel-free group ($P = 0.002$). No correlations were found between the concentrations of nickel and immunoglobin E, basophils, or eosinophils, or between the gingival index and either bands or segmented neutrophils ($P \geq 0.05$). **Conclusions:** Patients treated with nickel-free braces had better gingival health and smaller blood changes than did those treated with conventional braces. All abnormalities tended to be eliminated after the removal of the braces. (Am J Orthod Dentofacial Orthop 2016;150:1014-9)

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Alloys containing nickel are widely used in orthodontic appliances and can account for up to 55% of the weight of such devices.[1] However, nickel is considered one of the most common allergens,[2] with up to a 30% prevalence rate of contact allergy, depending on age, sex, and ethnicity.[3]

In general, orthodontic materials are considered highly biocompatible.[4] However, side effects have been reported in the literature, including allergic and inflammatory reactions, cytotoxicty, and mutagenicity.[5] Inflammation seems to play a pivotal role in the initiation of nickel-induced hypersensitivity, promoting the activation and recruitment of immune cells to the exposure area.[6] Thus, studies have indicated nickel to be a cause of changes in periodontal and immunologic statuses in allergic patients.[7-9]

Previous studies by our research group involving patients allergic to nickel and treated with conventional

braces demonstrated that periodontal status was particularly harmed, including a change in the number of neutrophils, but remission occurred with the removal of the braces.[7,10] As a result of these findings, we initiated a new set of experiments involving allergic patients who received nickel-free braces compared with those who received conventional braces, in which the former group demonstrated better periodontal status during treatment.[11] Thus, studies involving a periodontal evaluation in relation to blood parameters in this group were needed for comparisons with previous trials.

Nickel-free devices are reported to release low amounts of nickel ions, which could diminish hypersensitivity among allergic patients.[7,12] Therefore, studies involving nickel-free braces may provide important information by first determining whether nickel is truly responsible for triggering responses of an inflammatory or allergic nature.

The aim of this study was to perform a longitudinal evaluation of gingival and blood statuses among patients allergic to nickel, by comparing conventional and nickel-free braces.

## MATERIAL AND METHODS

A study was conducted with a sample of patients ranging in age from 10 to 45 years. The sample size was calculated using the formula for the comparison of 2 means,[13] and the parameters used were determined in a previous study.[7] Considering a standard deviation of 0.10 plasm levels of nickel in allergic patients, since this is an important variable and patients were allergic to this metal, and a 0.10 difference to be detected between the groups (conventional and nickel-free braces) with 80% statistical power and 5% standard error, we determined that a minimum of 16 subjects were needed in each group. We added 5 subjects in each group to compensate for possible losses. A total of 42 allergic subjects were recruited for this study. After enrollment, we had 28 female and 14 male subjects. Thus, we formed 14 pairs of female and 7 pairs of male subjects. Subsequently, a random allocation was performed in each pair, so that 1 subject received nickel-free braces, and the other received conventional braces.

All patients began treatment at the same time. Before placement of the braces, all participants received prophylaxis with bicarbonate spray and counseling with regard to oral hygiene. Oral hygiene measures consisted of brushing the teeth at least 4 times a day and using dental floss with the help of a needle and mouthwash to facilitate the removal of plaque. Conventional and nickel-free Roth Monobloc Morelli braces (Dental Morelli, Sorocaba, São Paulo, Brazil) were used. The conventional braces contained 16% to 20% chrome, 8% to 13% nickel, and 2% to 3% molybdenum. The nickel-free braces contained up to 18% chrome, 0.2% to 4% nickel, and 3.5% molybdenum.

Data were collected based on a study by Pazzini et al[11] that involved the same sample and is described briefly below.

Before treatment, a skin patch test was used to identify patients with a nickel allergy. According to the allergy evaluation standards of the Brazilian Medical Association and the Federal Medicine Council (Brazilian Study Group on Contact Dermatitis, 2000), this is the most efficient method for confirming the etiologic diagnosis of allergic contact eczema. After 48 hours, the patches were removed, and 1 reading was performed in compliance with the norms of the International Contact Dermatitis Research Group.[14]

Clinical gingival characteristics (color, volume, and bleeding) were assessed. A standardized probe with a millimeter ruler was used to determine the presence or absence of gingival bleeding around the maxillary and mandibular first premolars at 4 points on the vestibular, palatine/lingual, and mesial and distal faces. These teeth were selected because of their locations at the halfway point of each quadrant of the oral cavity. The gingival index was used for this evaluation, with qualitative changes in the gingival tissues taken into consideration.[15,16] Gingival assessments were conducted by a blinded, duly calibrated examiner (R.J.J.) (kappa $>0.90$) before the start of treatment (T0) and at regular 3-month intervals for 12 months with the braces in place (T1, T2, T3, and T4) as well as 1 month after removal of the braces (T5). After the periodontal evaluation, prophylaxis was performed at each session with a bicarbonate spray.

All participants underwent a full blood test, with the determination of the total immunoglobin E (IgE) and the amount of circulating nickel in the blood before treatment (examination 1), 9 months into orthodontic treatment (examination 2), and 1 month after removal of the braces (examination 3).[7] The examination before treatment had not been performed in the previous studies.

For the blood count, analyses were performed of leukocytes, basophils, eosinophils, bands, segmented neutrophils, platelets, lymphocytes, and monocytes. Fecal examinations were performed on all participants to determine parasitic infestations (helminth eggs and larvae or protozoan cysts), since parasitic infections can affect the IgE and white blood cell count, especially the number of eosinophils. All laboratory examinations were performed by a duly trained pharmacist-biochemist, and no patient exhibited parasitosis.