ORIGINAL ARTICLE

Adverse patient reactions during orthodontic treatment with fixed appliances

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Introduction: Our aims in this study were to assess adverse patient reactions during orthodontic treatment with nickel-containing appliances and to investigate the need for and the use of nickel-free devices in orthodontic practices in Finland and Norway. **Methods:** A questionnaire was mailed to orthodontists and dentists versed in orthodontics in both countries. They were asked to retrospectively assess the number of patients with adverse reactions and to describe the reactions, the appliances used, and any implications on treatment. Previous history of nickel allergy of patients with adverse reactions, and use of and need for nickel-free appliances in clinical practice were also addressed. **Results:** Forty-six percent of the respondents (n = 298) reported at least 1 adverse patient reaction during the last 5 years. More than half of the reactions had implications for the treatment. Finnish respondents observed significantly more adverse patient reactions than their Norwegian colleagues, and, in Finland, the adverse reactions were most frequently attributed to headgear treatment. Using nickel-containing fixed appliances in nickel-allergic patients was more common in Finland (77% of the respondents) than in Norway (65%). **Conclusions:** Nearly half of the dentists regularly working with fixed appliances had observed at least 1 adverse patient reaction during treatment. Nickel-containing fixed appliances are generally used in most patients—even those with a suspected nickel allergy. (Am J Orthod Dentofacial Orthop 2007;132:789-95)

Patients undergoing orthodontic treatment with fixed appliances are exposed to various biomaterials. Several of these, including alloys, resin-based bonding materials, and latex, are known to release potential allergens that can present a health hazard for patients.[1] Reactions to biomaterials cause a number of symptoms, including mild skin or mucosal irritation, allergic reactions, generalized dermatoses, and even asthmatic reactions.[2]

Bands and brackets of fixed orthodontic appliances are still today predominantly made of stainless steel containing approximately 8% to 12% nickel, whereas other alloys, some containing up to 50% nickel, are used for archwires.[3,4] During treatment, biodegradation of the appliances takes place, and small amounts of nickel, chromium, and other ions are released into the oral cavity.[5]

Nickel allergy is the most common contact allergy in industrialized countries; patch test verified data of general populations in several studies have shown that this allerygy affects 10% to 30% of females and 1% to 3% of males.[6-10] The typical clinical picture is itchy eczema on skin areas directly exposed to metal objects and, on some occasions, systemic eruptions far from the contact site.

Concern about allergic reactions in orthodontic patients has been expressed regularly. However, adverse reactions associated with orthodontic appliances have been reported infrequently, considering the high prevalence of nickel allergy especially among females.[11,12] Two recent surveys from Europe estimated the incidence of adverse patient reactions in orthodontic practice to be approximately 0.3% to 0.4%.[11,12] Adverse reactions attributed to orthodontic appliances have typically been localized extraorally on the face and the lips, and less frequently on the oral mucosa.[11-13] In addition, case reports have described intraoral or extraoral skin and mucosal reactions from various components of metallic orthodontic appliances in nickel-allergic patients.[14-16]

It is known that the elicitation of nickel allergy reaction depends on the conditions of nickel exposure—eg, on hapten concentration on the contact area, open or occluded exposure, presence of an irritant, and degree of contact allergy.[17,18] The elicitation threshold varies between patients and also individually over time.[17-19] Conditions in the oral cavity differ from those on the skin, and the immunology of oral mucosa might

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also differ, with oral mucosa potentially less reactive than skin to contact allergens such as nickel.[18]

Many questions still persist about the role of fixed orthodontic appliances in adverse patient reactions. Studies, along with common clinical practice, have shown that, in general, nickel-allergic patients can wear nickel-containing appliances without adverse reactions.[16,20,21] It is of interest whether certain appliances induce adverse reactions more easily than others, and whether previous history of contact allergy increases the risk of symptoms with fixed orthodontic appliances, as was recently suggested.[22] Another question is to what extent orthodontists in their daily practice avoid nickel-containing appliances in treating patients with a potential nickel allergy.

The aims of this survey were to assess adverse patient reactions during treatment with various fixed orthodontic appliances and to determine the current need for and use of nickel-free devices in orthodontic practices in 2 Scandinavian countries.

MATERIAL AND METHODS

The data were collected by a questionnaire (Fig) mailed to the members of the Finnish Orthodontic Society (in Finnish) and the Norwegian Association of Orthodontists (in Norwegian). Of the Finnish respondents, two thirds were orthodontists, and the rest were dentists versed in orthodontics. In Norway, most were orthodontists. In both countries, a reminder was sent 3 weeks after the first mailing.

Personal data included the respondent's main employment, clinical working time per week, and the share of fixed appliances used in the clinical practice. The questionnaire focused on adverse patient reactions associated with orthodontic treatment with metallic fixed appliances over the last 5 years. The orthodontists were asked to recall the number of patients with adverse reactions, the nature of the reactions, and the type of appliance related to the observed reaction. For patients with adverse reactions, questions on previous history of nickel allergy and eventual change in the treatment because of the reaction were included. Finally, the orthodontists were asked to evaluate their need for, and their use of, nickel-free orthodontic products in their clinical practice.

Statistical analysis

The respondents were the unit used for the analysis. The total number of patients with adverse reactions was determined by adding the numbers reported by each respondent. If the number of patients in a questionnaire was given as an estimate with upper and lower limits, the number recorded was the mean of the 2 estimates. The data were analyzed with statistical analysis software (version 11.0 for Windows; SPSS, Chicago, Ill). The chi-square test was used to test for differences in reported adverse patient reactions, practices, and opinions in using nickel-free appliance alternatives between the Finnish and the Norwegian respondents.

Logistic regression was used to evaluate the effect of country, hours of clinical practice (0, up to 20 hours per week; 1, more than 20 hours per week), and share of fixed appliances used in the practice (2, most of the time; 1, 50%-75% of total time; 0, 25%-50% of total time) for adverse patient reactions.

RESULTS

Seventy-nine percent of the questionnaires were returned. Respondents (n = 30) who were retired and reported working 4 clinical hours per week or less or who used fixed appliances infrequently (less than 25% of their working hours) were excluded from the final data, for a total of 298 completed questionnaires, 136 from Finland and 162 from Norway. However, some respondents did not answer all questions; the number of missing answers ranged from 0 to 17 according to the question.

In their clinical practice, most (98%) respondents used bands and brackets that were predominantly made of stainless steel. Archwires were made of various alloys, of which stainless steel, nickel-titanium, and beta-titanium were the most commonly mentioned types.

Forty-six percent (133 of 298) of the respondents reported at least 1 adverse patient reaction associated with metallic orthodontic appliances during the last 5 years; 6 of them indicated that their report covered more than 5 years. Working with fixed appliances most of time (more than 75% of clinical practice) was more common among the Norwegian respondents than among the Finnish. In the logistic regression analysis, country was the only significant variable predicting adverse patient reactions, whereas the amount of clinical practice per week and the share of fixed appliances in the clinical work were not significant (Table I).

The Finnish respondents observed adverse patient reactions significantly more often than their Norwegian colleagues (Table II). Headgear was the most common appliance to which adverse reactions were attributed. In headgear appliances, on top of the stainless steel outer bow, other metal components, such as rivets and metal clasps of the head cap or the neck strap, were sometimes related to reactions. A contact allergy reaction to the vertical metal bars of a facemask was described by 1 respondent. For intraoral fixed appliances, also including bonding material, the specific component of the appliance

causing the adverse reaction could not always be identified by the respondent. In addition to bands, brackets, and archwires, adverse reactions associated with the quad-helix appliance, the labial bow of the Van Beek activator, and bonded retainers were reported.

Skin reactions near the contact area—redness, papules, and itching eczema—were the most common reactions attributed to metallic appliances (Table III), followed by adverse reactions on the lips or the oral mucosa—redness, swelling, sores, and blisters. The site of systemic eruption was not specifically asked, but arms, palms, legs, and eyelids were mentioned by a few respondents. In 1 patient, flaring up of an existing eczema after placement of fixed appliances was considered a systemic reaction. One respondent reported a patient with swelling of the eyelids and breathing difficulties within half an hour after bracket bonding.

More than half (57%) of the 133 respondents who reported adverse patient reactions stated that the patients had had no previous history or no suspicion of nickel allergy, most commonly 1 to 3 patients per respondent. One third (33%) of the respondents reported reactions in patients with a previous history of nickel allergy. The number of patients recalled to have adverse reactions was 370, of which 88 patients had self-reported the nickel allergy, 92 had some suspicion of a nickel allergy, and the rest had no previous history of nickel allergy. The number of adverse patient reactions recalled by the Finnish respondents was twice that of the Norwegian, 250 and 120, respectively. Most (72%) of the respondents reporting on adverse patient reactions also stated that the reaction affected the treatment. The reactions resulted in either changing the appliance or discontinuing the treatment for 214 of the 370 patients with adverse reactions (58%). Less than a quarter of all patients with adverse reactions (84 of 370) were referred for a nickel patch test by the orthodontist to verify an allergy.

Most respondents (70%) had used and would use nickel-containing fixed appliances regularly even in patients who self-reported a nickel allergy (Table IV). Orthodontists in Norway reported using nickel-containing appliances to treat these patients less often than their Finnish colleagues (Table IV). However, several respondents in both countries mentioned precautions, such as testing beforehand with 1 or 2 brackets, using only plastic-coated headgear outer bows, and avoiding certain items such as nickel-titanium archwires. More than half (55%) of the respondents had used nickel-free alternatives due to allergy risk for at least 1 patient (Table IV), but typically those patients were no more than a few per respondent. Only 7% of the respondents had used nickel-free appliances in more than 10 patients (range, 10-45) during the last 5 years. A quarter of the respondents expressed no need for nickel-free orthodontic devices; the rest expressed either an occasional need (57%) or a slight, but constant need (18%).

DISCUSSION

Our results agree with previous reports that adverse patient reactions are infrequently associated with fixed orthodontic appliances.[11,12] Keeping in mind the relatively high prevalence (10%-30%) of nickel allergy in women, our finding that about half of the respondents who were regularly treating patients with fixed appliances did not recall any adverse reactions in their patients supports the idea that nickel allergy is not a major hindrance for orthodontic treatment with fixed appliances in general. However, as also was witnessed in our study, orthodontic appliances can sometimes cause adverse reactions in patients with presumed nickel allergy.[14-16]

The total number of patients with adverse reactions was taken from the respondents' estimates. The results are thus based on the ability of dental professionals to recall unusual cases over a stipulated period, and a moderate recall bias toward underreporting is to be expected, as has previously been observed from retrospective self-reports of hand eczema.[23] The time of 5 years in our study might not be considered long. Regarding hand eczemas, Meding and Järvholm[24] recently found that the rates of symptoms reported more than 10 years in retrospect were about 20% lower than the rates reported more recently. In our study, some underreporting can also be expected because some respondents (5%-10%) did not estimate the number of patients with reactions, and thus they are missing from the total.

The considerably higher number of adverse patient reactions reported by the Finnish respondents compared with the Norwegian orthodontists was unexpected. Neither clinical working time nor time share for fixed appliances explained the adverse patient reactions recalled. Differences in educational background is not a likely explanation, especially because the Norwegian respondents, who observed fewer cases, were a more homogenous group in respect to postgraduate education. Instead, the explanation might be the different orthodontic strategies in the 2 countries. In Finland, where early timing of treatment is generally favored, headgear is typically and widely used, and 3 of 4 adverse patient reactions were attributed to headgear. In Norway, treatment generally starts later and involves comprehensive fixed appliances; headgear plays a minor role. Another potential explanation might be the long tradition in Norway of educating dentists in the risks of dental biomaterials; this might have increased

The questionnaire used (translated from Finnish/Norwegian versions):

Circle the option that is best corresponding to your work

1. My main occupation is in
   a. Health center
   b. Central hospital
   c. Private sector
   d. Elsewhere _____

2. My clinical working time is on the average ___hours/week, out of which I work with fixed orthodontic appliances
   a. Most of the time (more than 75%)
   b. at least half or more of the time
   c. less than half of the time
   d. only little or not at all

3. The bands, brackets and face bows that I use in the practice are usually made of stainless steel
   Yes No

4. IF you answered NO to the previous question, please give the main reason why not:

5. During the last five years have you or your patients observed any skin or intra-oral mucosal reactions (symptoms) in association with fixed orthodontic appliances (other than mechanical irritation on the gingiva/ oral mucosa from the braces)?
   Yes No

IF you answered NO to the previous question (# 5), move to question # 14. Questions 6 to 13 are addressed to the orthodontists who have had at least 1 patient with skin and/or mucosal reactions in association with fixed orthodontic appliances. In this section, "number of patients" means the approximate number of patients you can recall from memory during the last 5 years.

6. Patients have had reactions/symptoms in association with

a. Orthodontic bands	Yes	No
b. Metallic brackets	Yes	No
c. Face bow	Yes	No
d. Other metallic appliances	Yes	No

7. Type and location of the reactions (circle one or more of the given options):
   a. redness, itching, swelling and /or vesiculation close to the contact site <u>on the skin of the face</u>
   b. redness, vesiculation and /or other symptoms <u>on the oral mucosa or/and on the lips</u>

Fig. Questionnaire.

c. Distance symptoms on the skin outside the face and neck
d. Other reactions, please specify the type and site_____

8. The reactions have occurred
a. Within a few days after insertion of the appliances
b. Later on during the treatment
c. Don't remember

9. Have you had patients who did get reactions/symptoms in association with orthodontic appliances and who had previously verified nickel hypersensitivity?
No Yes (number of patients ____)

10. Have you had patients who did get reactions/symptoms in association with orthodontic appliances and who had previous suspicions of nickel hypersensitivity?
No Yes (number of patients ___)

11. Have you had patients who did get reactions/symptoms in association with orthodontic appliances but who had had no previous symptoms hinting to nickel hypersensitivity?
No Yes (number of patients ___)

12. Have you ever stopped treatment, or changed appliance because of an acertained or suspected nickel hypersensitivity?
No Yes (number of patients ___)

13. Have you ever referred a patient to patch testing during orthodontic treatment because of suspicion of nickel hypersensitivity?
No Yes (number of patients ___)

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14. If a patient reports being allergic to nickel, do you still use normal nickel-containing stainless steel fixed appliances as a first choice?
Yes, in general No

15. During the last 5 years, have you ever chosen a nickel-free option of fixed appliances (brackets, face bows, arch wires etc.) because of risk of nickel allergy?
Yes (number of patients ___) No

16. In your clinical practice, have you experienced a need for nickel-free orthodontic products?
Yes, regularly on a small scale Seldom No

THANK YOU VERY MUCH

Fig. Continued

Table I. Odds ratios (OR), 95% confidence intervals (CI), and significance (P) of the independent variables in logistic regression model for the respondents' reported experience of adverse patient reactions (n = 298)

	Respondents' reported experience of adverse patient reactions			
Independent variables	*OR*	*CI lower*	*CI upper*	P
Country (Finland)	2.13	1.23	3.68	.007*
Hours of clinical practice per week	0.98	0.49	1.96	.96 (NS)
Share of fixed appliances in the practice	0.93	0.62	1.42	.75 (NS)

*$P < .01$; *NS,* not significant ($P > .05$).

Table II. Distribution of respondents having observed adverse patient reactions and type of appliance attributed to reaction (n = number of respondents)

	Number of respondents		
	Finland (n = 136)	*Norway (n = 162)*	P
Respondents having observed adverse reactions	77 (57%)	56 (35%)	<.001
Extraoral appliance (headgear)	58 (43%)	22 (14%)	<.001
Intraoral appliances (bands, brackets, archwires)	48 (35%)	34 (21%)	NS

NS, not significant.

Table III. Localization of adverse patient reactions as recalled by the respondents (1 respondent could have observed adverse reactions in more than 1 location; adverse patient reactions were reported by 133 of 298 respondents)

Location of reaction	*n*	*%*
Facial skin near contact area	98	33
Mucosal area (lips, oral mucosa)	66	22
Systemic eruption outside contact site	18	6
Other	4	1

their general interest in biomaterials and risk awareness. Our finding that orthodontists in Norway were more careful than those in Finland in using nickel-containing appliances in patients with a suspected nickel allergy supports this explanation, and the difference in attitude could have had an impact on the fewer adverse reactions in Norway. However, more extensive use of nickel-free appliances in Finland seems contradictory in this context. The finding might be linked with the overall higher number of adverse reactions in Finland. The concept of nickel-free appliances might also be differently understood—from completely nickel-free appliances to partially nickel-free alternatives—and this could have caused some inconsistency.

In agreement with previous studies, we found that adverse reactions occurred more often extraorally than in the oral mucosa or the lips.[11-13] It has been established that elicitation of a contact allergic reaction depends on anatomic location and physiologic conditions.[17,18] Unlike in the skin, the concentration of haptens from nickel-containing fixed appliances in the oral mucosa is likely to be reduced by salivary flow and thus remain below the provocation threshold, explaining perhaps the higher frequency of reactions in the skin than inside the mouth. The potential immunologic difference between oral mucosa and skin regarding contact allergy reactions is unclear.

In the design of the questionnaire, special care was taken to tell respondents to exclude reactions caused by mechanical irritation during treatment. Even though mechanical irritation was excluded, there are other alternatives besides allergy; eg, increased plaque accumulation due to deficient oral hygiene in association with fixed appliances might cause adverse gingival reactions. Without patch testing, the final role of nickel allergy in the reported adverse reactions is unverified, although previous reactions to metallic items are known to increase the probability of an allergy.[7,10,25] In our study, diagnosis was infrequently verified by testing. The number of allergic reactions to nickel is likely to be lower than the number of reported adverse reactions,[7,10] especially for patients with no previous history of symptoms from nickel-containing items. Although the test results of individual patients were not included in the questionnaire, a few respondents pointed out that the nickel patch test had negative results. The use of cutaneous testing for verifying mucosal, intraoral allergic reactions might need justification, and other methods have been investigated.[26] Currently, however, no method for verifying orally elicited allergic reactions is available in practice, making the search for the true mechanism of adverse reactions difficult.

CONCLUSIONS

Nearly half of the respondents reported adverse patient reactions associated with orthodontic treatment during the last 5 years. The number of recalled adverse reactions was more than double in Finland compared with Norway, and headgear was most often attributed to

Table IV. Distribution of Finnish and Norwegian respondents in relation to their opinion of using nickel-containing appliances in nickel-allergic patients and to their history of using nickel-free appliances

	Finland (n = 136)			*Norway (n = 162)*			
	Yes n (%)	*No n (%)*	*Missing n (%)*	*Yes n (%)*	*No n (%)*	*Missing n (%)*	P
Do you regularly use nickel-containing appliances in patients with reported nickel allergy?	100 (74)	29 (23)	7 (5)	104 (64)	56 (35)	2 (1)	<.05
Have you used nickel-free alternative devices due to allergy risk during the last 5 years?	85 (63)	51 (37)	0	78 (48)	82 (51)	2 (1)	<.05

the reaction, especially in Finland. More than half of the reactions had implications for the treatment. Although most respondents in both countries used nickel-containing fixed appliances regularly for patients who self-reported a nickel allergy, orthodontists in Norway tended to select nickel-free appliances more often for these patients.

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