Original Article

Nickel release from stainless steel and nickel titanium archwires – An in vitro study

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ABSTRACT

Aims: This study was conducted to evaluate and compare the nickel release from stainless steel and nickel titanium archwires in artificial saliva over three months with the use of simulated fixed orthodontic appliances.

Methods and materials: Fifty simulated fixed orthodontic appliances representing half of the dental arch were used for this study. Five groups of ten samples each were made. Group A was the control group without archwires. Groups B and C contained stainless steel archwires from American Orthodontics (Sheboygan, WI, USA) and Dentaurem (Remanium, Ispringen, Germany) respectively. Groups D and E contained NiTi archwires from American Orthodontics (Sheboygan, WI, USA) and copper NiTi from Ormco (Glendora, CA) respectively. The amount of nickel released from the appliances into the artificial saliva were measured after 1 day, 7 days, 1 month, 2 months and 3 months. The mean release from each group was calculated and compared using Kruskal–Wallis test and Mann–Whitney *U* test.

Results: Significant release of nickel was seen in all groups up to the end of first month ($p < 0.05$), the median values of which were; Control Group A (without archwire); 13.75 ppb, Group B; 15.2 ppb, Group C; 14.16 ppb, Group D; 18.6 ppb, Group E; 17.45 ppb respectively. On comparing the nickel release between all groups at each time interval, the result was not significant ($p > 0.05$).

Conclusion: The highest amount of nickel was released from nickel titanium archwires, however, the quantity of nickel released from both NiTi and stainless steel archwires were not significant. The rate of nickel released was high within the first week and continued up to the first month after which the nickel content was stable in all the groups.

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1. Introduction

Orthodontic bands, brackets, and wires are universally made of austenitic stainless steel containing approximately 8–12% nickel and 17–22% chromium. These elements give stainless steel its ductility and corrosion resistance.^{1–3} Since the oral environment is particularly ideal for the biodegradation of metals because of its ionic, thermal, microbiologic, and enzymatic properties, some level of patient exposure to the corrosion products of these alloys could be assumed, if not assured. The corrosion rate is influenced by the composition of the material, the chemical and thermal environment of the material, the surface area, and the degree of surface smoothness.^{4,5}

Nickel forms complexes of arsenides and sulphides, which are known carcinogens, allergens, and mutagens. It is estimated that 4.5–28.5% of the population have hypersensitivity to nickel, with a higher prevalence in females.^{2,4} It has been shown that the level of nickel in saliva and serum increases significantly after the insertion of fixed orthodontic appliances. Nickel is the most common metal to cause contact dermatitis in orthodontics, with more cases of allergic reactions than all the other metals combined. Once hypersensitivity has been established, all oral mucosal surfaces can be involved.^{6,7}

Individualized reports have indicated that insertion of NiTi wire alloys may occasionally lead to rashes, swelling, and painful erythematous lesions in the oral and labial mucosae.⁷ For patients who have a history of hypersensitivity, the use of the nickel-free alloy substitutes or nickel alternatives is suggested.^{4,8}

Hence it is important to quantify the nickel present in orthodontic appliances to prevent unwanted reaction due to its release. The objectives of this study were to assess and compare the

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Fig. 1. Simulated fixed orthodontic appliances.

amount and rate of nickel released into artificial saliva from stainless steel and NiTi archwires placed in simulated fixed orthodontic appliances at different intervals over a period of 3 months.

2. Materials and methods

Fifty simulated fixed orthodontic appliances were fabricated, and each represents half of a dental arch. Brackets (Mini Master Series, AO, Sheboygan, WI, USA) of central incisor, lateral incisor, canine, first and second premolar and buccal tube of the first molar tubes were welded on a band material simulating clinical welding (Fig. 1). No soldering was done to eliminate nickel from solder material. These were divided into five groups of ten each depending on the archwire used.

- Group A – Control group without archwire – Brackets welded on band material without archwire
- Group B – Stainless steel archwires, 0.016" × 0.022" – American Orthodontics (Sheboygan, WI, USA)
- Group C – Stainless steel archwires, 0.016" × 0.022" – Remanium, Dentaureum (Ispringen, Germany)
- Group D – Nickel titanium archwires, 0.016" × 0.022" – American Orthodontics (Sheboygan, WI, USA)
- Group E – Copper NiTi archwires, 0.016" × 0.022" – Ormco (Glendora, CA)

The simulated appliances were washed with distilled water and dried. After which each of the appliance was immersed in 50 ml of artificial saliva (Fusayama Meyer's composition)³ in a polyethylene bottle.

The pH of the artificial saliva was maintained at 6.75 ± 0.15 . Each bottle was sealed segregated, according to the groups (Fig. 2) and maintained at 37° in an incubator.

Fig. 3. ICP-OES spectrometer.

Each sample was evaluated for the quantity of nickel released after intervals of 1 day, 7 days, 1 month, 2 months and 3 months. At every interval to measure the release of the metal in the artificial saliva, 5 ml of the sample was aspirated from the bottles with a sterile pipette and introduced into the inductively coupled plasma optical emission spectrometer (ICP-OES) (Thermo Scientific-iCAP 7000, ARML Laboratories Pvt. Ltd, Electronics City, Bangalore) (Fig. 3) and measured in units of parts per billion (ppb or $\mu\text{g/l}$).

The nickel released by each group was quantified at each time interval. Also the groups were compared at various time intervals to determine which archwire group released the maximum nickel in relation to the control group.

Sample Immersed In Artificial Saliva

50 Samples In Bottles Containing Artificial Saliva

Fig. 2. Appliances in artificial saliva.

2.1. Statistical analysis

Statistical analysis was done by applying Kruskal–Wallis test to find out significant difference between the study groups at each time period and Mann–Whitney *U* test was applied to confirm the significance between two independent groups in the parameters measured.

3. Results

As the values of the nickel released by the samples were erratic in all the groups, the median values were taken instead of mean for the purpose of statistical analysis and for the formulation of results.

The results obtained by the analysis of the control group – Group A show that as expected the amount of nickel release was the least as compared to all groups which may be due to the presence of stainless steel bands and brackets in the samples. Highest release was seen in the first month. Median at end of first month: 13.75 ppb.

The nickel ions measured from Group B was third highest in comparison with the other archwire groups. The nickel released in first week was highly significant as compared with day 1. The rate of release was stable after the first month. Median release at end of first month: 15.2 ppb.

Group C revealed the least release among all the archwire groups almost equal to the nickel released by the control group. Maximum release was seen at the end of first month. Median release at end of first month: 14.16 ppb.

Group D showed the highest nickel ion release as compared with all groups. The highest amount of nickel released was seen at end of the first month. Median release at the end of first month: 18.6 ppb.

Group E was second highest among all the archwire groups after Group D. Similar to the other groups the highest amount of nickel was released within the first month. Median release at end of first month: 17.45 ppb.

By comparing the measured values it was observed that nickel released from the NiTi archwire groups (Groups D and E) was higher as compared with the stainless steel groups (Groups B and C).

It was observed that in all groups the amount of nickel released was highest within the first month after which the rate of release reduces and becomes constant.

Statistical analysis and comparison showed that there was no significant difference in the nickel released by the groups at each time interval i.e., comparison of nickel released by both stainless steel and nickel titanium archwires are not significant. However, there was a mild difference between the median values in the control and the other groups which shows that there was a release of nickel due to the archwires in the appliances. Group D showed the highest release at every time interval whereas Group C showed least release among the archwire groups (Table 1, Graph 1).

There was a significant difference in the nickel released at various time intervals in each group. Maximum rate of nickel release was seen up to day 7 and amount of nickel release increases till one month in all five groups after which there was a reduction in the rate of release and the values were almost stable (Table 2, Graph 2).

The significance of release between each time interval was tested by Mann–Whitney *U* test by comparing the *p* values at each interval. This test confirms that up to 1 month there was a significant rate of release of nickel present in all groups after which its rate of release decreases (Table 3). Highest significance of rate of release was seen at day 7.

4. Discussion

Most of the alloys used in orthodontics have nickel as a component, varying from 8% in stainless steel to more than 50% in nickel titanium alloys. Nickel has been reported to be one of the most common causes of allergic contact dermatitis.^{7,9} The current consensus about the issue of orthodontics derived nickel as a

Table 1
Comparison of nickel released by all the groups at each time interval.

Visit	Group	N	SD	Median	Min.	Max.	Chi square*	'p' value
Day 1	Group A	10	7.080	3.30	0.6	18.2	2.482	0.648
	Group B	10	8.389	4.70	1.0	25.0		
	Group C	10	2.174	5.45	1.5	9.0		
	Group D	10	7.355	6.50	2.0	23.8		
	Group E	10	3.585	6.30	1.6	13.5		
Day 7	Group A	10	13.578	7.30	1.5	41.0	7.367	0.118
	Group B	10	6.737	12.10	4.6	22.2		
	Group C	10	4.718	7.45	3.0	18.8		
	Group D	10	11.702	12.10	5.3	44.7		
	Group E	10	11.929	10.25	6.4	45.6		
Month 1	Group A	10	22.933	13.75	8.4	78.8	4.653	0.325
	Group B	10	6.789	15.20	8.2	27.3		
	Group C	10	6.557	14.16	11.2	32.7		
	Group D	10	18.971	18.60	12.1	72.5		
	Group E	10	27.669	17.45	11.0	103.0		
Month 2	Group A	10	23.970	13.45	9.8	84.0	5.943	0.203
	Group B	10	7.397	17.75	11.1	31.6		
	Group C	10	7.297	14.65	12.7	36.7		
	Group D	10	17.633	21.40	16.8	72.5		
	Group E	10	31.787	18.60	12.0	118.0		
Month 3	Group A	10	24.842	16.70	10.2	89.0	9.243	0.055
	Group B	10	7.979	19.75	12.8	34.0		
	Group C	10	8.412	17.45	11.0	40.0		
	Group D	10	17.508	23.10	18.8	73.4		
	Group E	10	31.597	20.30	16.2	119.6		

* Kruskal–Wallis test. In the above test *p* value less than 0.05 was taken to be statistically significant.

Graph 1. Comparison of median nickel release between the groups at different time points.

Graph 2. Comparison of median nickel release at different time points in study groups.

sensitizing agent is that the risk is extremely low for patients who are not nickel hypersensitive at the start of orthodontic treatment.^{8,15}

In this study the results show that there was release of nickel from all the groups but the quantity of nickel released was well below the oral daily intake by food and air which is estimated to be between 300 and 600 μg .^{3,4} This is in agreement with the previous studies which indicates that the nickel released from orthodontic appliances is minimal and the quantities released from orthodontic appliances can only cause reactions in patients who are already sensitive to nickel.^{3,8} Since the simulated appliance represents one quarter of the full mouth appliance, we can assess that the release from a complete full mouth fixed appliance is insignificant and it corresponds to the previous studies by Park and Shearer,³ Barrett et al.² However nickel can produce sensitivity when appliances are in place for 2–3 years as nickel hypersensitivity is a delayed type of hypersensitive reaction (Type IV).

In this study artificial saliva under static conditions was used whereas more nickel release could be expected in in vivo situations. In the microenvironment of the mouth the presence of chloride gradient could contribute to the increased metal degradation, as one progresses deeper into the crevice between the teeth.^{4,9–11}

In agreement with previous studies we can see that in this study also nickel release is seen up to 1 month after which the rate of release is reduced. The highest rate of release was seen within the first week in all the groups ($p < 0.05$) (Table 1). There was significant release of nickel up to 1 month in all the groups with the highest significance ($p < 0.05$) being in Groups C and E (Table 2). Two explanations for this behavior have been contemplated in a study by Bishara. First, the nickel present on the surface of the stainless steel may quickly corrode during the first 7 days of the experiment, and then the rate of release drops off as the surface nickel is depleted. Second, corrosion products may have formed on the surface after 7 days slowing the corrosion of nickel.^{2,4,12,13}

Table 2

Comparison of nickel released at various time intervals.

Group	Visit	N	SD	Median	Min.	Max.	Chi square [*]	'p' value
Group A	Day 1	10	7.080	3.30	0.6	18.2	13.676	0.008
	Day 7	10	13.578	7.30	1.5	41.0		
	Month 1	10	22.933	13.75	8.4	78.8		
	Month 2	10	23.970	13.45	9.8	84.0		
	Month 3	10	24.842	16.70	10.2	89.0		
Group B	Day 1	10	8.389	4.70	1.0	25.0	13.827	0.008
	Day 7	10	6.737	12.10	4.6	22.2		
	Month 1	10	6.789	15.20	8.2	27.3		
	Month 2	10	7.397	17.75	11.1	31.6		
	Month 3	10	7.979	19.75	12.8	34.0		
Group C	Day 1	10	2.174	5.45	1.5	9.0	31.463	<0.001
	Day 7	10	4.718	7.45	3.0	18.8		
	Month 1	10	6.557	14.16	11.2	32.7		
	Month 2	10	7.297	14.65	12.7	36.7		
	Month 3	10	8.412	17.45	11.0	40.0		
Group D	Day 1	10	7.355	6.50	2.0	23.8	22.304	<0.001
	Day 7	10	11.702	12.10	5.3	44.7		
	Month 1	10	18.971	18.60	12.1	72.5		
	Month 2	10	17.633	21.40	16.8	72.5		
	Month 3	10	17.508	23.10	18.8	73.4		
Group E	Day 1	10	3.585	6.30	1.6	13.5	27.471	<0.001
	Day 7	10	11.929	10.25	6.4	45.6		
	Month 1	10	27.669	17.45	11.0	103.0		
	Month 2	10	31.787	18.60	12.0	118.0		
	Month 3	10	31.597	20.30	16.2	119.6		

^{*} Kruskal–Wallis test. In the above test *p* value less than 0.05 was taken to be statistically significant.**Table 3**

Pairwise comparison of visit 'p' value.

Group	Visit	Day 7	Month 1	Month 2	Month 3
Group A	Day 1	0.008	0.013	0.013	0.008
	Day 7	–	0.096	0.070	0.059
	Month 1	–	–	0.596	0.326
	Month 2	–	–	–	0.326
Group B	Day 1	0.008	0.019	0.013	0.006
	Day 7	–	0.173	0.075	0.021
	Month 1	–	–	0.545	0.257
	Month 2	–	–	–	0.326
Group C	Day 1	<0.001	<0.001	<0.001	<0.001
	Day 7	–	0.006	0.001	0.001
	Month 1	–	–	0.104	0.075
	Month 2	–	–	–	0.762
Group D	Day 1	<0.001	0.008	0.002	<0.001
	Day 7	–	0.082	0.023	0.007
	Month 1	–	–	0.186	0.123
	Month 2	–	–	–	0.104
Group E	Day 1	<0.001	<0.001	<0.001	<0.001
	Day 7	–	0.021	0.014	0.010
	Month 1	–	–	0.427	0.140
	Month 2	–	–	–	0.307

Mann–Whitney *U* test. In the above test, *p* value less than 0.05 was taken to be statistically significant.

The quantity of nickel released in this study was observed to be less as compared to previous studies. Studies published in 1983–1993 report significantly higher nickel values, probably due to differences in the technique and methods used at the time^{2,3,14,16,18,19}. On the other hand, similar to this study Gürsoy et al.^{21,22} found a low concentration of Ni (20 µg/l), which can be due to spectrometer used (ICP-AES) with a relatively high limit of detection or materials used.

Many studies have been conducted to assess the release of nickel from brackets and other appliances but limited research has been conducted on the role of archwires in metal ion release. In this study we can see that although not significant, but there is a small

difference between the nickel ion release from the control group and the archwire groups which indicates that archwires do have a part in the overall nickel release from orthodontic appliances. We can estimate the approximate quantity of release of nickel from archwires in this study by calculating the mathematical difference between the median release by the control group (without archwire) and the individual archwire groups. As the nickel released was significant only till the end of the first month in all the groups we considered the median values of this time point for this calculation. According to which, the highest release was seen in the NiTi (AO) group (4.85 ppb), followed by the copper NiTi group (Ormco) (3.7 ppb), followed by stainless steel group (AO)

(1.45 ppb) and the least release was seen in the stainless steel group (Dentaurum) (0.41 ppb). Previous studies which have been conducted state that NiTi alloys are highly corrosion resistant and form a passivating layer along with titanium that is corrosion resistant and due to this there is lesser release of nickel from NiTi alloys compared with stainless steel.¹⁷ But the amounts of nickel release should be proportional to the nickel composition of the alloy-leached out. This was proved in a study that related Ni release to both the composition and the method of manufacture of the appliance. Hence the difference in the nickel released could be attributed to the high composition of nickel in NiTi alloys and the manufacturing process by which it is provided.²³

Bour et al.²⁴ suggested that a threshold concentration of approximately 30 ppm of Ni is sufficient to elicit a cytotoxic response. Mechanical irritation, skin ulceration, or oral mucosal injuries that may occur in orthodontic treatment along with temperature variation in the oral cavity and duration of exposure may also be contributing factors to release of nickel from appliances. Contact stomatitis, peri-oral rash, loss of taste, metallic taste, numbness, burning sensation, soreness at the side of the tongue angular cheilitis and severe gingivitis are signs and symptoms of nickel allergy. For an allergic reaction in the oral mucosa, an antigen must be 5–12 times greater than that needed for skin allergy.^{9,11,18}

Hence dental alloys with high nickel content must be avoided in nickel sensitive patients. NiTi archwires have been reported to cause increased hypersensitivity reactions in some patients.²⁰ It is important to make a correct diagnosis of nickel allergy, symptoms of which may occur either within or remote to the oral environment. A comprehensive history must be taken to avoid and prevent unwanted reactions. Alternatives include twistflex stainless steel and fiber-reinforced composite archwires. Wires such as TMA, pure titanium, and gold plated wires may also be used without risk. Altered nickel-titanium archwires also exist and include plastic/resin-coated nickel-titanium archwires. Ion-implanted nickel-titanium archwires have their surface bombarded with nitrogen ions, which forms an amorphous surface layer, conferring corrosion resistance and displacing nickel atoms. Manufacturers claim that these altered nickel-titanium archwires exhibit less corrosion than stainless steel or non-coated nickel-titanium wires, which results in a reduction of the release of nickel and reduces the risk of an allergic response.^{11,25}

5. Conclusion

- The quantity of release of nickel from fixed orthodontic appliances is not significant either by use of stainless steel or nickel titanium archwires. The cumulative release is well within the daily dietary intake of nickel.
- Although not significant there is more nickel release in all the four archwire groups in relation to the control group which shows that archwires do have a role in the nickel release from fixed appliances and NiTi (American Orthodontics) showed highest release followed by Cu NiTi and stainless steel (American Orthodontics) archwires. The least release was seen from stainless steel (Remanium, Dentaurum). Hence, nickel titanium archwires tend to release more nickel than stainless steel archwires.
- Release of nickel is seen up to the first month after which it stabilizes and there is a reduction in the rate of nickel release

from the appliances in all the groups. Highest release is seen from the first week up to end of the first month.

- The use of NiTi archwires should be limited in nickel sensitive patients as even small amounts of nickel in saliva may cause reactions.

Conflicts of interest

The authors have none to declare.

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