Study Of Release Of Nickel And Chromium Ions From Different Brands Of Stainless Steel Brackets”-An Invitro Study.

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Abstract:
Background and objectives: The aim of the study was to investigate the nickel and chromium ion release from the different brands of stainless steel brackets in to the normal saline.

Materials and Methods: Five full set of Dentaurum,3M and Koden brackets were immersed in sterile plastic tube and marked A,B,C respectively, containing 50ml of Normal saline and maintained at 37°C for 3 weeks. The processing was done by using 0.5ml of saliva that was transferred to a 2ml plastic test tube with a micropipette. The chemical analysis for Ni and Cr is performed with an Atomic Absorption Spectrometer. The concentration of Ni and Cr are expressed in micrograms per litre. This process was done by 1st,7th,14th and 21st day. The values are analyzed.

Results: The nickel and chromium release of Koden brackets is high. The least release of nickel and chromium is observed in Dentaurum brackets. The chromium release is insignificant within the groups but it is significant in duration of days. The nickel release is significant within the groups but it is insignificant in duration of days.

Interpretation and Conclusion: Nickel and chromium release from different company brackets are not uniform, it varies. Koden brackets show more amount of nickel release, Dentaurum brackets show least amount of Nickel release.

Keywords: Nickel, chromium, brackets, stainless steel, Release of ions.

I. Introduction

The oral environment is ideal for the biodegradation of metals. The issue of metal release from biomaterials implanted or inserted in various cavities of the human body has attracted the interest of many investigators because the degradation products can elicit a foreign-body reaction or induce pathologic processes. Research has focused on the release of metal ions from stainless steel brackets, mainly involving iron, chromium and nickel, which are the major corrosion products of stainless steel. Although all 3 elements can have adverse effects, nickel has received the most attention because of its reported potential for hazardous effect1 .Likewise, the disintegration of orthodontic appliances has become a critical issue due to its high potential of ionic release. Apart from stainless steel brackets, widely accepted nickel-titanium (Ni-Ti) wires with nickel content of about 50% might also contribute to Nickel source in orthodontic population. Nickel can also originate from other standard treatment auxiliaries including stainless steel archwires and bands, and various treatment utilities such as the stainless steel partitions of removable appliances. The U.S. Environmental Protection Agency (EPA) reference dose for nickel is 0.020 mg/kg/day with a lowest observed adverse effect level (LOAEL) of 50 mg/kg and a “no observed adverse effect level” (NOAEL) of 5 mg/kg.

Even though the biomedical literature indicates carcinogenic2 , mutagenic, and cytotoxic effects for the derivatives of some nickel ions, caution should be used in interpreting these findings, because documented toxicities generally apply to the soluble forms of these elements. Currently, any association between release of metal and any metabolic, immunologic, or carcinogenic toxicity is conjectural. The cause and effect of this in humans have never been demonstrated except that few studies show DNA damage in mucosa cells. The nickel content of medical devices made with such metals presents a safety concern as contact with nickel-containing alloys could lead to problems such as contact dermatitis, inflammation, or even carcinogenic activity3 . Since nickel is abundant in all types of food, nickel deficiency is rare.

Nickel is the most common metal to cause contact dermatitis in Orthodontics, with more cases of allergic reactions than all the other metals combined. A person who is already nickel hypersensitive at the start of the treatment may in rare case show adverse reaction induced by appliance1,4.
An American Iron and Steel Institute (AISI) types 316L or 304 austenitic stainless steel alloys are currently used for bracket manufacturing. These steel alloys typically contain approximately 8% nickel (Ni) and 18% chromium (Cr) with a small amount of manganese and silicon, and a low carbon content (less than 0.1%). AISI type 316L also contains 2 to 3% molybdenum. Besides that, bracket manufacturing includes different processes with or without welding.

There are so many studies conducted to assess the nickel and chromium released from different appliances as well as different brackets and arch wires. But there is no study that compared the nickel release from different brands of stainless steel brackets.

**Aims And Objectives**
1. To investigate the nickel and chromium ion release from the different brands of stainless steel brackets in to the normal saline.
2. The differences in the quantity of release of Cr and Ni in different types of brackets available in the market.

**II. Materials And Methods**

**GROUP 1**
- DENTAURUM BRACKETS (very expensive - Germany)

**GROUP 2**
- 3M BRACKETS (expensive - 3M company USA)

**GROUP 3**
- KODEN BRACKETS (less expensive - probably Chinese make)

NORMAL SALINE (0.9%)

Five full sets of each manufacturer’s brackets, consisting of 20 brackets in each set manufactured by 3M UNITEK Gemini MBT Metal Brackets, DENTAURUM BRACKETS and KODEN BRACKETS, were selected for the study. Each group of brackets were immersed in each sterile plastic container containing 50 ml of 0.9% w/v normal saline solution in an incubator and maintained at 37°C.

Then 5ml of sample solution were collected from each container in a wyle tube with a micropipette in 1, 7, 14, and 21st days. The saline solution samples were processed for inductively coupled plasma atomic emission spectroscopy (ICP-AES) with an ICP-AES unit (OPTIMA 4300V, perk Elmer, Norwalk, Conn).

**III. Result**

- The nickel and chromium release of Koden brackets is high.
- The least release of nickel and chromium is observed in Dentaurum brackets.
- The chromium release is insignificant within the groups but it significant in duration of days.
- The nickel release is significant within the groups but it is insignificant in duration of days.

**Graph 1** shows comparison between release of nickel and chromium Dentaurum brands.
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Graph 2 shows comparison between release of nickel and chromium 3M brands.

Graph 3 shows comparison between release of nickel and chromium Koden brands.

According to T test, the release of nickel in Dentaurum and 3M shows the (‘t’ value of -.775) and the (Degree of freedom is 6). The (P value is 1.00), this shows that it is not significant. In case of Dentaurum and Koden, (‘t’ value is -2.6) and (df=6 and 4.4 respectively). The (P value is 0.040), this shows that it is significant. In case of 3M and Koden (‘t’ value is -2.11) and (df=6 and 4.4 respectively), The (P value is 0.199), this shows that it is not significant.

According to T test, the release of chromium ions in Dentaurum and 3M shows the (‘t’ value of -.186) and the (Degree of freedom is 6 and 5.9). The (P value is 0.855), this shows that it is not significant. In case of Dentaurum and Koden, (‘t’ value is -8.66) and (df=6 and 5.2 respectively). The (P value is 0.56), this shows that it is not significant. In case of 3M and Koden (‘t’ value is -2.11) and (df=6 and 4.4 respectively), The (P value is 0.199), this shows that it is not significant.

In case of release of nickel in different brands shows statistically not significant with respect to the duration of days. But there is release of chromium shows statistically marked significant with respect to the duration in days. During the 1st day the release of nickel and chromium is insignificant. But in 7th day the release of nickel is insignificant and release of chromium is significant (P value=0.038). In 14th day, The nickel release is insignificant and the release of chromium cannot be computed because of due to the mean value is 0. In 21st day the release of nickel is insignificant and the release of chromium is highly significant (P value=0.010).

IV. Discussion

A standard orthodontic appliance consist of bands, brackets and both stainless steel and nickel titanium arch wires, which can remain in mouth for 2 years or more. The alloys used in dentistry are exposed to several aggressive physical and chemical events such as higher concentration of oxygen and chloride mixture in saliva, tartar and plaque and acid deposit from microbiologic metabolism. The association of these different metals in the oral environment, where saliva is the connecting media, may produce electro galvanic currents that produce a discharge of ions and metallic compounds when combined with the chemically corroded metal.
The mechanism of carcinogenic activity still remains unclear. Nonetheless, evidence based carcinogenic activity of nickel oxide, crystal sulphides, nickel hydroxide, and metallic nickel in either animals or humans require further research.

Utilization of nickel is mandatory for fabrication current orthodontic materials: shape-memory feature makes nickel containing archwires the only ones suitable for biologically compatible levelling. Nickel released to the oral environment may result in either electrogalvanic processes or allergic response. Alloys subjected to saliva together with metal ions submerged in this electrolyte create a galvanic cell. Stimulation of tissues with electric impulses accompanied by poisoning or allergic effect of metals cumulated in organism result in an ailment of electrogalvanic nature.

According to Singh et al., statistically significant quantity of the element in saliva was noted just within the first months after bonding of appliances whereas Kocadereli et al. and Agaoglu et al. reported no difference in the level of nickel ions, established in orthodontic patients after several months of treatment and in untreated individuals. Apparently different levels of nickel ions associated with lack of allergic syndromes concerning oral mucosa not only indirectly confirm thesis suggested by Spiechowicz, but also prove that nickel concentration necessary to cause pathological symptoms on the oral mucosa is greater than the concentration responsible for skin lesion. Nonetheless, since question, whether a small dose of nickel released during orthodontic treatment permanently impairs function of cells, still remains unanswered, treatment with nickel-free appliances should be the approach of choice in patients with hypersensitivity to the discussed element.

Several in-vitro and in-vivo methods have been used to study the release of metals and their contents in biologic fluids, including saliva and blood. These studies have shown that metals were released during the first 4 or 5 months of orthodontic treatment and were actually absorbed by the patient systemic distribution. The main conclusion of these studies were that measurable amount of metals released from the orthodontic appliances in saliva or blood samples were significantly below the average dietary intake and did not reach the toxic concentrations.

Although the orthodontic appliance had no effect on the general levels of the metals, it cannot be excluded that even nontoxic concentration might be sufficient to induce important biologic effects in cells of oral mucosa. Pillai et al. conducted a study to determine whether the nickel released from the stainless steel brackets have any cytotoxic effects on gingival fibroblast that study has corroborated that nickel solution at minimal concentration of 1.18 µg could damage human gingival fibroblast and the nickel released from the different brands of the brackets are not uniform.

Experimental and epidemiological studies suggest that exposure to nickel components is associated with lung and nasal cancer. Even if a genotoxic potential has been demonstrated in certain systems the mechanism underlying this feature is largely unknown. But several possible pathways seems to be involved such as the interaction of metal with DNA, the generation of oxidative DNA damage or interference with DNA repair and replication process.

Since we are dealing with a biologic system, factors like biocompatibility, cytotoxic potential etc should be taken into consideration. This study shows that there is significant amount of nickel released from all the groups of samples. There have been many studies conducted to assess the nickel release and no standardization has been given yet regarding the amount of nickel that can be leached since the carcinogenic effect of the nickel has been proved.

Manufacturer’s claim bracket superiority without valid research and Orthodontists are mainly concerned about the brands and various systems incorporated into the brackets. This study was conducted to assess whether the amount of nickel leached from the different bracket manufacturers has any correlation and to assess the superiority they claim is applicable as far as the biocompatibility is concerned.

The natural in-vivo environment of the oral cavity cannot be simulated in the currently available in-vitro experimental setups. This is because storage media, including electrolyte or acidic solutions, cannot simulate intraoral conditions. It is known that the corrosion potential of stainless steel is increased in acidic environments. The standard protocols fail to simulate clinical factors such as bracket archwire ligation and the movement of these might induce fretting corrosion. Most importantly, there is a lack of simulation of the complex intraoral flora, plaque accumulation, and its byproducts, which have proven corrosive action. The inability of in vitro protocols to simulate clinical conditions has given rise to retrieval analysis that furnishes critical information on the service history and alterations of materials. Nonetheless, this type of study precludes the clarification of mechanisms underlying the phenomena occurring in vivo because the study of specimens is that of a post hoc type. Since the carcinogenic effect of nickel is established it is high time to think about other alloys without involving the heavy metal nickel which can be used or to find standardization for the nickel leach out from the appliance.

With all these limitations we have to find a solution that will help in the standardization of the release of nickel ions from the systems used in orthodontic practice.
References