In Vitro analysis of Nickel ion release from Stainless steel for Preformed Crowns

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CERTIFICATE OF APPROVAL

This is to certify that the
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Introduction:

Stainless steel crowns were first introduced by Rocky Mountain Company and popularized by Humphrey and RJ Engel in 1950 [4]. Ever since they have been considered to be an outstanding choice of treatment for primary teeth.[1, 2,3,4,5] Stainless steel crowns are extremely durable, resistant to tarnish, relatively inexpensive, subject to minimal technique sensitivity during placement. They not only offer the advantage of full coronal coverage of teeth with multisurface caries, developmental defects, and fractured teeth but can also be used as abutments for space maintainers and for the best conservation after endodontic treatment in primary dentition. In addition they have also been widely used for temporary restoration of permanent molars and bicuspids, fractured permanent anterior teeth, developmental defects and young permanent teeth following endodontic treatment.

There is also another side of stainless steel crowns. Despite of all the desirable properties they do lack in a few aspects. In conjunction to the disapproved metallic appearance there is parental dissatisfaction and great psychological trauma to the school going children. Accessibility to the full coverage treatment of the affected teeth is limited by greater need for learning appropriate technique crown cementations. For the longetivity and biocompatibility of the preformed crowns appropriate marginal adaptation, trimming and size selection have been few of the challenges. All these drawbacks have got attention in the past and efforts have been made to overcome these but the last but never the less the least above all is the greatest hazard of release of nickel ions in saliva from the intraoral appliances including but not limited to preformed crowns , orthodontic wires, prosthetic dentures and many other. [4] Though it is hard to believe yet it's true that not much time and effort has been put to solve this rising problem of nickel ion toxicity in children.

Nickel is a silvery-white metal that can be found in nature. It is usually mixed with other metals to produce alloys. Stainless steel is composed of iron, carbon, chromium, nickel, manganese and other metals. For the fabrication of dental appliances Stainless steel contains 11.5-27% chromium and 7-22 % Nickel.[40] Nickel ions are released by the stainless crowns and orthodontic appliances over time in human saliva. This has been proved to increase after tooth brush abrasion and increase in the oral pH.[38, 39]

Allergic contact dermatitis due to nickel is the most prevalent allergy in North America with the incidence of 14.3%. 8.1% Children between 8-12 years of age have been documented to have a positive patch test for Nickel sensitivity.[18, 21]. A nickel allergy is a reaction that develops after initial and/or brief, or repeated and/or prolonged, exposure to nickel or nickel-containing items, depending on the individual's susceptibility. Degree of reaction also varies by person. Specifically, nickel allergy is a contact allergy, which is an allergic skin reaction in response to being exposed to a contact allergen or irritant, such as nickel. A nickel allergy can occur at any age, and typically manifests a few days after first contact as eczema (allergic contact dermatitis), which appears as an itchy, dry/crusty, and red/pigmented skin rash with watery blisters. The affected area is usually restricted to the site of contact, although it could also be found on other parts of the body. Once a nickel allergy has developed, it is usually a chronic condition, often being life-long.[39]

The quantity of nickel ions that is sufficient to induce sensitivity varies with the individual. If the skin is already damaged, sensitization will be induced more quickly and by lower amounts of the solubilized nickel. Temperature, higher pH, abrasion , the presence of other allergic conditions, race, sex and age may also be determining factors on the susceptibility for and the speed of sensitization to nickel [37,38]. Induction of acute contact dermatitis is more common if exposure is combined with skin irritants and/or moist skin.

A sensitized individual, when re-exposed to nickel ions on the skin in sufficient amounts, may have an allergic response within a matter of hours. This is termed the elicitation phase, which often occurs at a much lower concentration of nickel than required for inducing sensitization in the first place. The elicitation of nickel acute contact dermatitis can occur in skin remote from the site of contact with nickel.

A few studies have shown that nickel-sensitive individuals orally given >5000 micrograms nickel (as $NiSO_4$) as a single dose had a dermal allergic response. Nickel at 1-3 mg by intravenous administration has shown severe acute contact dermatitis in sensitized patients.

Literature strongly indicates that dental braces made from a high-nickel alloys (e.g. Ni-Cr with 60-80% Ni) resulted in Ni-tolerance in girls subsequently having their ears pierced compared to a high nickel sensitivity in girls who had their ears pierced, but did not wear such dental braces prior to ear-piercing.
This tolerance may be caused by a mechanism involving low nickel exposure orally over time.
Immunotolerance in animals (mice) has been shown by nickel exposure either intravenously or orally, with T-lymphocytes in Ni-tolerant mice being transferable to other mice to make them Ni-tolerant.

Most of the studies also show a positive correlation between nickel allergy and asthma due to respiratory exposure to soluble nickel even though there are a few studies those do not accept the relation between the two.[41]

Excessive Nickel ion release is also documented to cause CFS (chronic fatigue syndrome) like symptoms which include substantial impairment in short-term memory or concentration, sore throat, tender lymph nodes, muscle pain, multi-

joint pain without swelling or redness, headaches of a new type, pattern, or severity , unrefreshing and/or interrupted sleep, post-exertional malaise lasting more than 24 hours, sensitivity to odors, noise, bright lights, medications, and various foods[14] fibromyalgia, severe periodontitis[20] , gastrointestinal disorders, chronic nephrotoxicity and other diseases of unknown etiology.
Some investigators have also publicized the carcinogenicity associated with the nickel. 22.97% nickel in intraoral alloys seemed to raise circulating eiosinophil, neutrophils and basophile numbers. In various studies it has been concluded that Nickel ion release also cause Immunological changes.[21, 23]

The currently understood mechanisms involved in human nickel allergy is that Ni^{++} by itself is not antigenic, but rather that nickel complexes involving histidines or proteins are bound to Langerhans' cells. These cells, located in the basal layer of the epidermis, actively participate in cutaneous immune regulation and surveillance and are responsible for antigen processing and presenting the antigen to T-lymphocyte cells.
The bound Langerhans' cells migrate to regional lymph nodes where further processing of the antigen occurs and ultimately a population of altered nickel-specific T-lymphocytes are created and recirculated where they may enter peripheral tissue (including the skin). At this point the individual is "sensitized". In the sensitized individual, when antigen-specific T-lymphocytes encounter the antigen, they release lymphokines, which are proteins that cause a wide variety of actions on other cells including stimulation of macrophages and natural killer cells and other responses. This results in tissue inflammation and other allergic responses in an attempt to rid the body of the foreign entity. This integrated response is what causes the allergic dermatitis.

So far there is no known means of reversing immuno-activation (the sensitized condition).

Review of Literature

Recently in 2007 Innes N, Ricketts D, Evans D independently scrutinized 14 studies out of forty seven to see the efficacy of preformed metal crowns for decayed Primary molar teeth. They concluded that even though no randomized controlled trials are present but still this technique is recommended by the British society of pediatric Dentists for use in clinical practice and the clinical outcomes are consistently in favors stainless steel crowns.(1)

During the similar review of the literature concerning the restoration of primary anterior teeth with pre-formed crowns or with the use of crown forms in 2006 Waggoner WF [2] found out that failure rates varied between 0% and 50% for strip crowns; 32-39% for veneered metal crowns. He indicated there is some evidence as to the efficacy and value of using anterior primary teeth crowns because of the improved aesthetics that they achieve. No clinical studies concerning anterior crowns on primary teeth were identified that met all or even a majority of criteria, indicating that there was little, good scientific support for any of the techniques which clinicians have utilized for many years to restore primary anterior teeth.(2)

While, Attari N, Roberts JF [3] in a systematic review of the literature of restoration of primary teeth with crowns in 2006 reviewed fourteen out of 112 papers found and agreed with the conclusions of Waggoner. Their study suggested that success rate of using pre-formed metal crowns for the restoration of badly broken down primary molars was superior to all other restorative materials .However, there was an obvious lack of prospective well-controlled studies and more research is needed.(3)

Since the preformed crowns were gaining the spot light Waggoner WF in 2002 discussed the specific strengths, weakness, and properties of variety of materials available for anterior restorations in primary teeth. Intracoronal restorations of primary teeth may utilize resin composites, glass ionomer cements, resin-modified ionomers, or polyacid -modified resins. Full coronal restoration include crowns that are directly bonded onto the tooth, which generally are a resin material, and those crowns that are luted onto the tooth and are some type of stainless steel crowns. Operator preferences, esthetic demands by parents, the child's behavior, and moisture and hemorrhage control are all variables which affect the decision and ultimate outcome of whatever restorative treatment is chosen.(5)

Directing the concern about esthetics Yilmaz Y. Kocoullari ME compared the clinical success of thirty-three stainless steel crowns made esthetic by open facing or veneering on posterior primary teeth. 18 month study showed that open-face stainless steel crowns had a higher but not significantly different success rate than veneered metal crowns.(9)

Shah PV. Lee JY. Wright JT. also recalled the patients treated with Kinder Krowns within the last 3 years for clinical evaluation and completion of a parental satisfaction survey in this retrospective cross-sectional study. Clinical evaluation was performed for crown retention, facing retention, and resin veneer wear. The parental satisfaction with the preveneered SSCs overall was high, with satisfaction for appearance and the shape being the lowest. (10)

On one hand when the Stainless crowns were gaining all the publicity Burrows D after his study in 1986 recognized that mercury, nickel and chromium were very frequently known to cause sensitization with Nickel being by far the commonest of all. 10 per cent of women were reported to be allergic to nickel; sensitization usually occurred through jewellery or fasteners on articles of clothing. There was little evidence that nickel or chromate in dental materials actively sensitize and it was exceptionally rare to have problems with these metals in prosthesis in someone who was already sensitized. (32)

Two years later in 1988 when Feasby et al did nickel sensitivity patch test for 700 dental patients, aged 5-12 years, one-half of whom were known to have nickel-containing dental appliances they found that girls wearing earrings and the boys and the girls with nickel-containing intraoral devices had more positive results than those without the nickel devices .or than those without earrings. (18)

In 1992 Hensten-Peterson surveyed the similar complaints consisting of intra-oral reactions such as redness, swelling, and pain of the oral mucosa and lips, oral/gingival lichenoid reactions, and a few instances of systemic reactions with nickel toxicity from intra oral prosthesis. They confirmed that in orthodontics, the incidence was 1:100, and about 85% reactions were related to nickel.(19)

Bruce GJ, Hall WB in 1995 documented that there was substitution of up to 69% to 81% nickel in crowns. He also supported the concern of increasing Nickel hypersensitivity in the general population and periodontal responses that are associated with nickel-containing crowns in nickel-sensitive individuals.(20)

Again Sterzl et al in 1999 in their clinical study of patients with or without autoimmune thyroiditis and with or without polyglandular autoimmune activation found that fatigue, regardless of the underlying disease, was primarily associated with hypersensitivity to inorganic mercury and nickel and to evaluate clinical relevance of positive in vitro findings, they replaced existing restoration with metal-free material in some of the patients. At a six-month follow-up, patients reported considerably alleviated fatigue and disappearance of many symptoms previously encountered in conjunction lymphocyte responses to metals decreased as well. Thus they concluded that metal-driven inflammation may affect the hypothalamic-pituitary-adrenal axis (HPA axis) and indirectly trigger psychosomatic multisymptoms characterizing chronic fatigue syndrome, fibromyalgia, and other diseases of unknown etiology.(21)

All these rapidly rising concerns lead Randall RC to review the literature about preformed metal crowns for primary and permanent molar teeth he too agreed that preformed Stainless steel crowns even though are superior to amalgam restorations for multisurface cavities in primary molar teeth had limitations of bad esthetics and nickel toxicity. (4)

As more and more dentists became aware of Nickel release in mouth Rahilly, G. Price, N in 2003 suggested that as stainless steel orthodontic components were very unlikely to cause nickel hypersensitivity alternative products that are nickel free or have very low nickel content, should be appropriate to use in patients diagnosed with a nickel allergy (22)

Following the league Nokiba, Kimihiko recently in 2005 evaluated the peripheral blood mononuclear cells (PBMC) from 18 patients with metal allergy and five healthy volunteers in vitro by lymphocyte stimulation test for diagnosing dental metal allergy. They performed a patch test (PT) with 12 metal reagents, and analyzed the metallic component in mouth. Peripheral blood mononuclear cells from patients with positive patch test showed lymphocyte stimulation test positive for multiple metals primarily nickel sulfate (Ni).(23)

The list of nickel ion side effects piled even higher after Risti L et al's clinical examination and questioning of one hundred and eighty four patients with different restorations and histopathological analysis of the samples of discolored gingiva encountered the presence of tissue foreign body granulomas with giant cells in which the metal particles, partially as small and partially as large particles. The highest number of examinees with discolored gingiva was in the group with restorations made of Ni-Cr alloy. (24)

In 1980 when McNall EG suspected that nickel was also associated with inducing the respiratory carcinogenicity he conducted various studies to see if inhaled or soluble nickel was linked.(26)

Similar doubts were also researched by Oller.A et al in 1997 and Sivulka.D in 2005. All these studies could not prove any strong correlation between the intraoral devices and lung cancers. It was proposed that more studies needed to be done to pin point what form of nickel is deleterious. (25)

Clayton TH et al also added to the scare by publishing their results of Type IV allergy to nickel (33%) being the most frequent finding in patch test on 500 children , 27% of whom had one or more positive patch test result ,Girls being significantly more compared than boys. They explained that in children Allergic contact dermatitis (ACD) increases with age, and there was a prevalence of 13.3% and 24.5%. (13)

Agreeing with Clayton et al Beattie PE, Green C recently in September 2006 carried out a retrospective case study of 114 children aged from 3 to 15 years who were patch tested over a 3-year period. They concluded from their experiment that Nickel was the most common allergen (20%) in line with previous reports (82% female). Contact allergy should be considered in all children with dermatitis, particularly with eyelid or hand dermatitis, and patch testing should be carried out more frequently.(11)

Their results were soon supported in 2006 by Militello G et al on reviewing the literature that allergic contact dermatitis may affect as many as 20% of the pediatric population and implicated the following chemicals as the most common causes: nickel, topical antibiotics, preservative chemicals, fragrances and rubber accelerators. In the adolescent age group, females have significantly higher rates of allergic contact dermatitis on the face. They outlined the basic pathophysiology, epidemiology and clinical manifestations of allergic contact dermatitis in children.(12)

Seidenari S, Giusti F, in 2005 had also compared the data on contact sensitization in 1094 children during the past 7 years to their previous 1988-1994 findings, in order to identify emerging allergens and update pediatric series. A total of 570 children proved allergic (52.1%). Even then the highest sensitization rate was observed in children under 3 years of age. Neomycin, nickel, wool alcohols, thimerosal, and ammoniated mercury gave most of the positive responses. With respect to 1988-1995 data, allergy to substances such as neomycin, nickel, wool alcohols, thimerosal, ammoniated mercury, propolis, potassium dichromate, and thiuram mix proved more frequent.(15)

In 2005 Fernandez Vozmediano JM, Armario Hita JC. conducted a retrospective study over 10 years of a group of patients aged 15 years or less, with clinical suspicion of acute contact dermatitis. Patch tests were performed in accordance with the standards of the GEIDC. And it was concluded that with increasing age, nickel takes the place of the principal allergen in children. (16)

Silverberg NB et al in 2002 proposed that Nickel allergic contact dermatitis is the most prevalent allergy in North America, with an incidence of 14.3%. They examined a group of 30 pediatric patients who had either a personal history of umbilical or wrist dermatitis, or a family history of nickel allergic contact dermatitis. They suggested that there was need for nickel avoidance, especially in atopic children. (17)

While there was a high alert for Nickel toxicity in 2006 Yaqob A, Danersund A, evaluated the results and clinical relevance of an optimized lymphocyte proliferation test, MELISA, on 513 patients for metal-induced inflammation in patients with chronic fatigue syndrome-like symptoms. Nickel was the most common sensitizer, followed by inorganic mercury, thimerosal, lead, cadmium, palladium and gold. Therefore it was concluded that replacement of incompatible dental materials resulted in down-regulation of metal-induced lymphocyte sensitivity in vitro, as well as in the improvement of health status of majority of patients with unspecific CFS-like symptoms.(14)

Not only the pediatricians or the pediatric dentists were worried but Darabara MS, in 2006 investigated the elemental composition, microstructure, hardness, corrosion properties, and ionic release of commercially available orthodontic brackets and Copper Ni-Ti archwires. Following the assessment of the elemental composition of the orthodontic wire and the six different brackets the ionic concentration of Nickel and Chromium was studied. The orthodontic wire is made up from a Ni-Ti alloy with copper additions, while the orthodontic brackets are manufactured by different stainless steel grades or titanium alloys. Following completion of the galvanic corrosion experiments, measurable quantities of chromium and nickel ions were found in the residual lactic acid solution(34)

Wataha JC, Lockwood PE, hypothesized that acidic environments would increase elemental release from dental alloys during exposure and after the acidic environment was removed based on the known increase in release of nickel from nickel-based alloys in an acidic environment. High-noble, noble, and base metal casting alloys were exposed for 30 minutes to solutions with pH ranging from 1 to 7. They concluded that Transient exposure of casting alloys to an acidic oral environment is likely to significantly increase elemental release from Ni-based alloys.(37)
He also suggested that tooth brushing increases the elemental release from the stainless steel intra oral alloys.(38)

Various researchers were also involved in measuring other elementals released in various solutions suggesting better and accurate ways to conduct experiments. Tufekci E, Mitchell JC, in 2002 measured the in vitro elemental release from a Pd-Cu-Ga alloy and a Pd-Ga alloy into a corrosion testing medium. Specimens of each alloy were immersed 3 times (at 7, 70, and 700 hours) in an aqueous lactic acid/NaCl solution used for in vitro corrosion testing and maintained at 37 degrees C. The specimens were removed after each immersion time, and the elemental compositions of the solutions were analyzed with inductively coupled plasma-mass spectroscopy (ICP-MS). Elemental concentrations for the 2 alloys at each immersion time were compared with Student t test (alpha=.05).(35)

Syverud M, Dahl JE, et al also studied the biocompatibility of palladium-copper alloys by Immersion tests carried out in a solution of 0.1mol/l of NaCl and 0.1mol/l of lactic acid at 37 degrees C for 7 days. The test solutions were analyzed by means of ICP to record the amounts of ions that had leached out from the alloy specimens The metallographic investigations revealed the elemental release from these oxides is substantially larger than that from the corrosion of the metallic structure. They inspired other researchers to use similar analysis methods because of better accuracy. (36)

Statement of problem

Nickel is one of the most common causes of contact dermatitis and other numerous health hazards in children and so is a concern for parents as well as patients with stainless steel crowns. Even though Stainless steel crowns provide the best conservation of the teeth yet not enough efforts have been made to tackle Ni ion release from these alloys over time which may cause lymphocytic reactivity, periodontistis, respiratory(41) diseases, chronic fatigue syndrome and possible carcinogenicity and other fatal outcomes leading to various major health issues in children (7). The incidence of nickel toxicity is more in females than in males. (3).It's metallic look is another psychological trauma for the child when cemented on the anterior teeth along with parental dissatisfaction.

Objective

The objective of this in-vitro study is to measure the Ni ion release from Conventional preformed stainless steel crowns and compare with the Ni ion release from the stainless steel crowns coated with proprietary layer which may provide a possible solution to the Nickel ion release in children.

Hypothesis

It is hypothesized that stainless steel crowns coated with proprietary process have less Ni ion release than conventional stainless steel crowns.

Methods and Materials

A. Dependent variable:
Ni Ion concentration

B. Independent variable:
1. Stainless steel alloy.
2. Stainless steel coated with the proprietary material.
3. Immersion solution
4. Apparatus
5. Time

Materials
0.52 inches diameter circular die cut discs of stainless steel crown alloy
0.52 inches diameter circular die cut discs of stainless steel alloy coated with proprietary material were selected for the study. The preceding nominal compositions (values in wt %) were provided by the manufacturer (9).

Reagents used:-
Lactic acid ($C_3H_6O_3$), 90% analytic grade
Sodium Chloride (NaCl), analytic grade
Water, complying with grade 2 of ISO 3696:1987
Ethanol or methanol (C_2H_5OH or CH_3OH), analytic grade

Apparatus used:-
Borosilicate glass container, complying with ISO 3585
PH meter
Analytical instrumentation
Micrometer

Solution Preparation:-
Prepared fresh immersion solution for each test. Dissolved 1-0+-0.1gm 90%$C_3H_6O_3$ and 5.85+-0.005gm NaCl in approximately 300ml of water. Diluted to 1000+-10ml with water. The ph was 2.3+-0.1.

Static Immersion Test:-

A stainless steel crown alloy and a stainless steel alloy coated with proprietary material were die cut to have a consistent surface area(0.52 diameter=0.424 inches)
The disks were cleaned ultrasonically in ethanol solution. Three specimens of each alloy were placed in a corrosion solution used for in vitro pilot testing of dental alloys, as described in ISO Standard 10271:2001,ADA specification No.97 for 1,10,100 hours. Each sample was placed in a glass container approximately 16mm diameter X approximately 160mm such that the samples did not touch the glass surface except in the minimum support line or point.

pH of the solutions was recorded. Added the 3.25ml solution to each container sufficient to produce a ratio of 1ml of solution per cm^2 of sample surface area. Recorded the volume of solution to an accuracy of 0.1 ml. Closed the container to avoid evaporation of the solution. Maintained at 37+-1^{0}C for 100, 10 and 1 hours. Removed the samples and recorded the pH of the solution. Sent the solutions for elemental analysis.

Elemental analysis:-

Optically Missioned Spectrometry was used to analyze the solutions quantitatively and qualitatively for the Ni ion release.
At least 3 replicate measurements were made for each standard and sample. These measurements were averaged by the analytical system to yield mean values of the concentrations of elements released from each alloy specimen at each measurement time to determine the number of disks (N) needed to carry out the actual study.
The Statistical analysis and power analysis of the results showed that 9 discs of control and 9 discs of coated samples will be sufficient to complete the actual study with 95% accuracy.

The 9 specimens of each alloy were completely immersed in the electrolyte. Since the total surface area of each specimen was known, the ratio of specimen surface area to volume of the corrosion solution was calculated, to make sure it was in accordance to the recommendation for biological studies of medical devices by ISO Standard 10993.25.

Immersion times of 1, 10, 100, and 1000 hours were selected for this study on a logarithmic basis since the time dependence of diffusion phenomena associated with elemental release from the casting alloys was expected to follow such a relationship. The corrosion solutions containing the alloy specimen were not agitated during the study.
The immersion testing for all specimens was concluded at the same time to minimize the effects of any possible errors in the measurement system.
All test specimens were stored in sealed containers in a chamber that was maintained at 37°C. After the proper time was elapsed, specimens were removed from the containers. The specimens were analyzed with inductively coupled optically missioned spectroscopy.

Values for the concentrations of the released Nickel ions was obtained in units of parts per billion (ppb) and converted to units of µg/cm2 of alloy surface area. A single- element standard solution was matrix-matched to the test specimens.

Concentrations of the individual elements released from the 2 alloys at each of the 4 immersion times was compared .
This experimental approach is deemed acceptable since no biological studies are being performed.

Results:

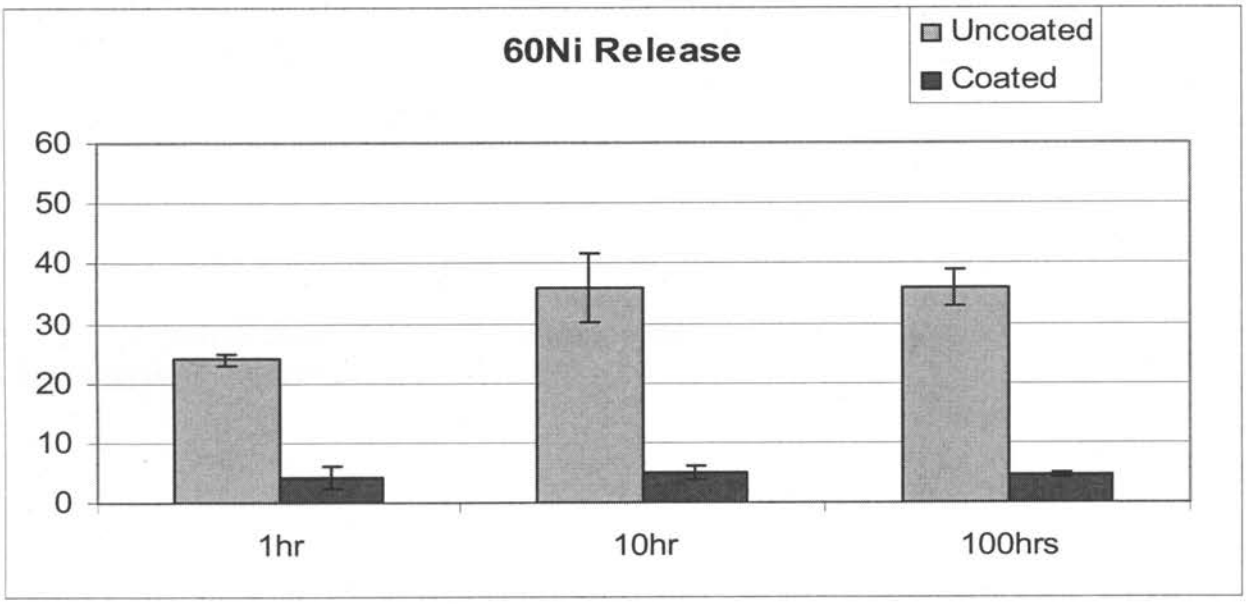
Pilot study results

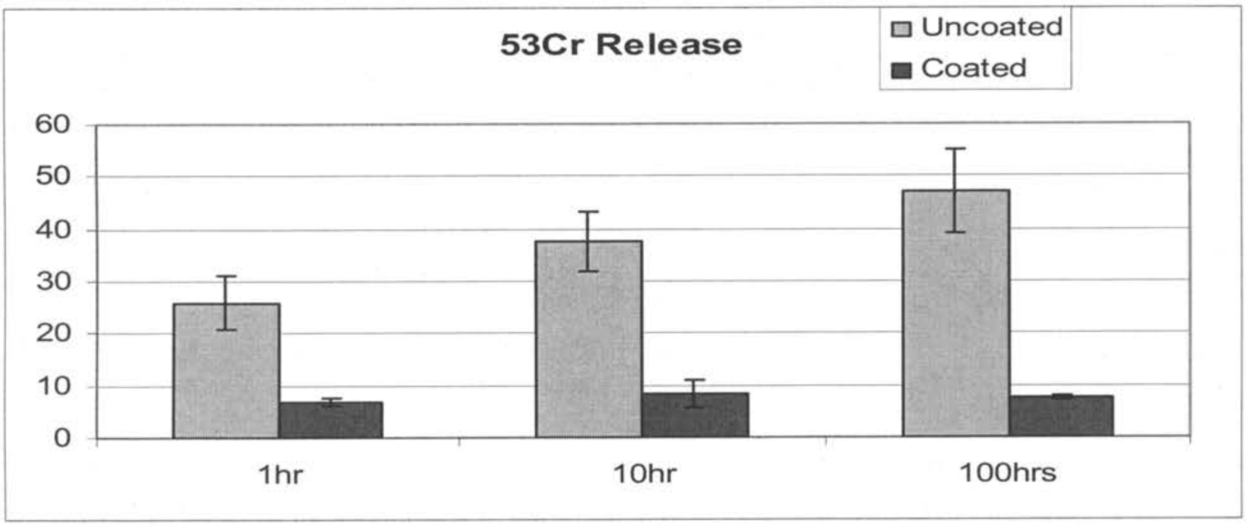
Analyses
12/6/06

Sample	53Cr Conc	57Fe Conc	60Ni Conc
C1	44	730	34
%RSD*	1.48	0.85	1.12
S1	6	76	3.3
%RSD	0.33	0.64	3.02
C2	42	690	33
%RSD	0.95	0.35	1.15
S2	7	88	6.6
%RSD	1.66	1.96	4.73
C3	56	820	39
%RSD	0.49	0.34	0.69
S3	7.3	86	3.2
%RSD	2.03	1.26	8.16
C4	33	610	32
%RSD	0.72	0.61	0.07
S4	6.2	61	3.9
%RSD	5.57	2.49	4.26
C5	36	680	33
%RSD	0.38	0.2	0.76
S5	7.6	73	5.2
%RSD	1.75	1.78	7.11
C6	44	710	42
%RSD	1.39	0.3	0.55
S6	11	96	5.9
%RSD	4.92	1.55	0.69
C7	32	590	25
%RSD	0.95	0.47	1.38
S7	7.1	68	4.4
%RSD	0.55	2.41	1.2
C8	22	480	23
%RSD	1.98	1.16	0.94
S8	7.8	91	4.4
%RSD	5.36	2.63	8.28
C9	24	520	24
%RSD	0.46	0.82	0.7
S9	7.8	76	5
%RSD	1.82	1.47	2.26

*%RSDs
Note: Fe

Sample	53Cr	57Fe	60Ni
C1	44	730	34
C2	42	690	33
C3	56	820	39
C4	33	610	32
C5	36	680	33
C6	44	710	42
C7	32	590	25
C8	22	480	23
C9	24	520	24
S1	6	76	3.3
S2	7	88	6.6
S3	7.3	86	3.2
S4	6.2	61	3.9
S5	7.6	73	5.2
S6	11	96	5.9
S7	7.1	68	4.4
S8	7.8	91	4.4
S9	7.8	76	5


60Ni Release
Uncoated
Coated
60
50
40
30
20
10
0
1hr
10hr
100hrs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Uncoated
Coated
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40
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20
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1hr
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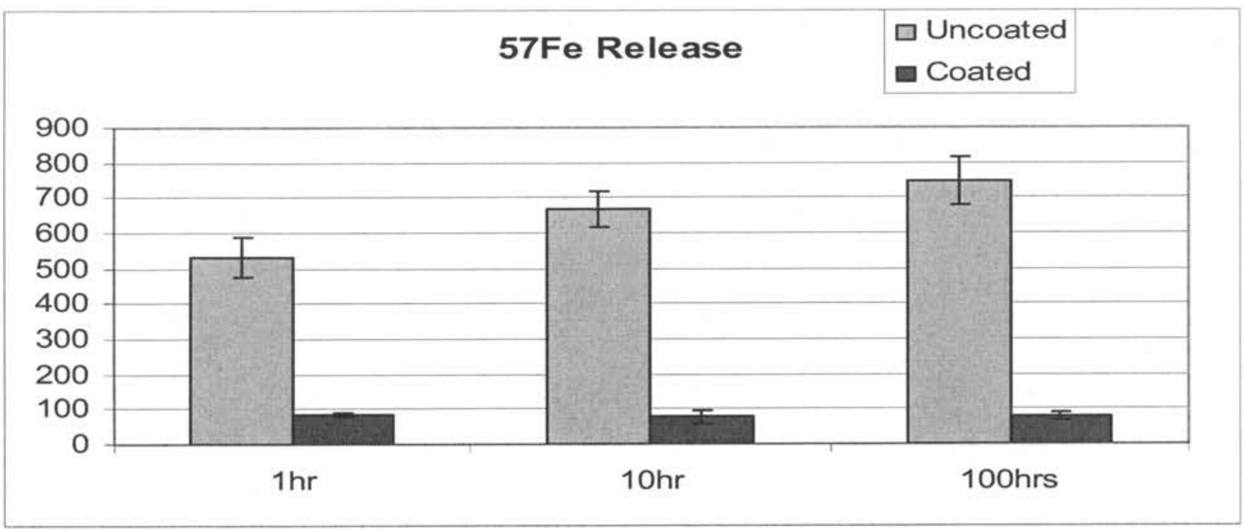
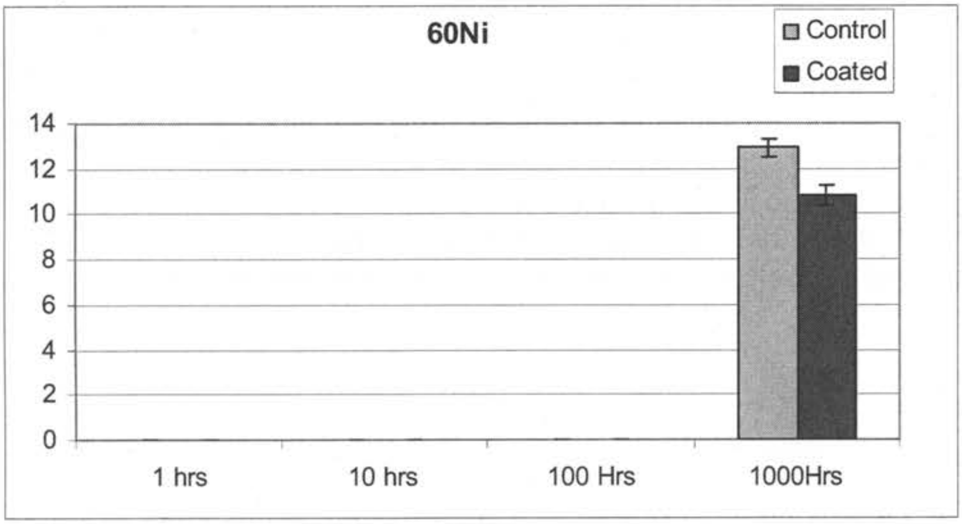
100hrs

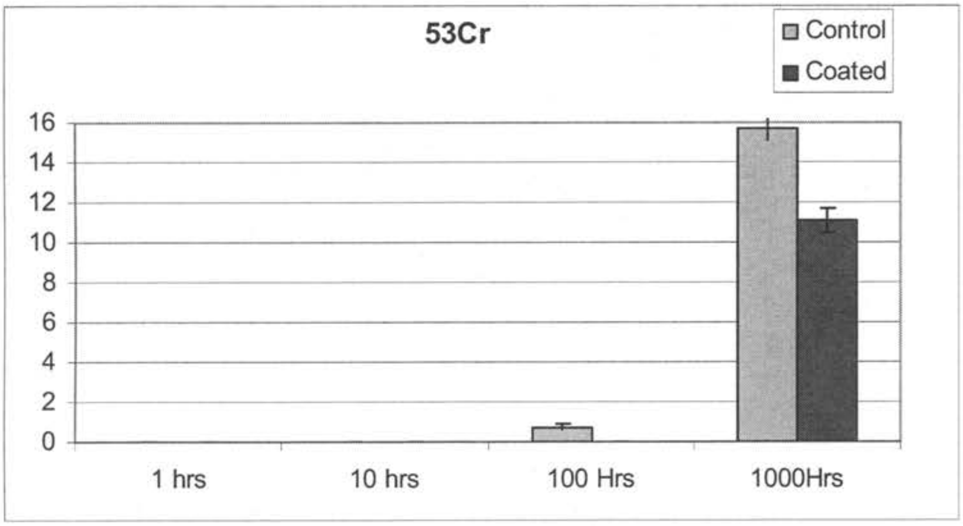

57Fe Release
Uncoated
Coated
900
800
700
600
500
400
300
200
100
0
1hr
10hr
100hrs

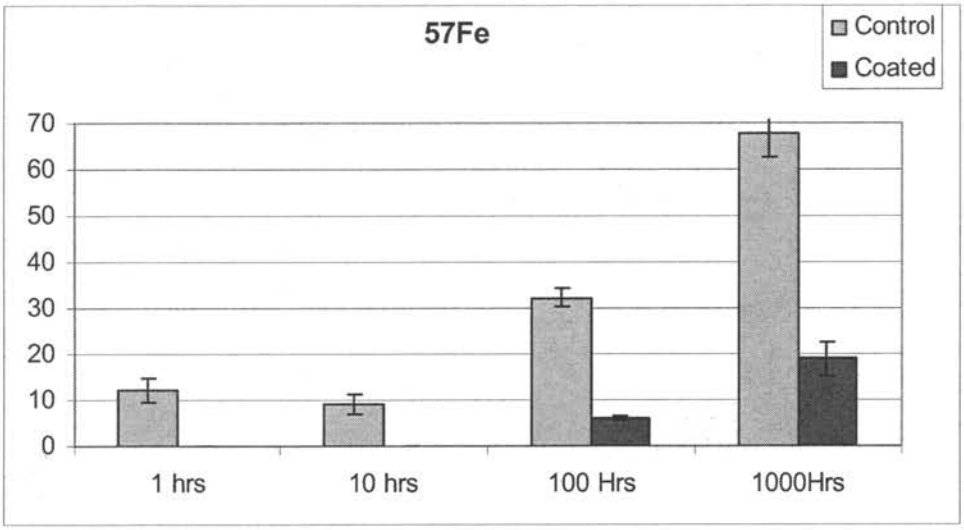
The coated and uncoated discs showed difference in the ionic release at three variable times. There was a trend in both groups that the ion release increased over time and it was more after 100 hours in comparison to the one hour immersion. This trend was consistent for all the ions studied.

The mean values and standard deviations for the concentrations of Ni and other elements was determined in the corrosion test solution for the 9 specimens of each alloy at the four immersion times of 1,10, 100, and 1000 hours. As noted above, the original concentrations of released elements in ppb were converted to μg/cm2 to permit comparison with published elemental release data.
The statistical analysis was done.

Study results:







The coated and uncoated discs showed difference in the ionic release at variable times. The ion release increased over time and it was more after 100-1000 hours in comparison to the one or ten hour immersions. This trend was consistent for all the ions studied. There was no nickel and chromium ions release at the one and ten hours for both coated and non coated discs. There was no iron ion release from non coated discs at the one and ten hours.

Discussion:

Trends seen in the actual study were similar to the pilot experiment. The zero nickel and chromium ion release from both samples could be due to the release of such small amounts which are below the instrumental detection level. The only difference seen between the pilot and actual study was the values.
During the storage of the samples at 37 degrees there seemed to be some evaporation. The volumes of the solutions were adjusted by adding lactic acid and calibrating each sample solution by weigh. After the removal of the discs from the immersion solutions it was noted that there was an appearance of black precipitates in all the solutions which were more in 1000 hour samples compared to other samples. These precipitates were more in solutions with non-coated discs as compared to the coated. These precipitates did not dissolve on adding nitric acid; hence it was assumed that these were not inorganic. All the solutions were centrifuged and the precipitates were separated before calibrations. There was also some instrumental drift during the analysis with ICPMS. The values can vary due to temperature or pressure variation during analysis. It could be fluctuation of voltage. Limited availability of the sources outside the campus was another restriction in our study.

Conclusions:

1. There was a measurable release of nickel elements, in the nominal compositions of a stainless steel crown alloy and a coated stainless steel alloy, into an in vitro corrosion test solution over a 1000-hour period (approximately 1 month).
2. Released elements from the alloys attribute to the use for the further studies on conventional stainless steel alloy and coated stainless steel alloys for the purpose of reducing nickel toxicity.
3. The concentration of released Ni from both alloys after 1000 hours of immersion suggested that there was reduced elemental release from the coated discs.
4. If the stainless coated with proprietary material is used for fabricating crowns it might decrease the ion release and perhaps prevent various health hazards in children.

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In Vitro analysis of Nickel ion release from stainless steel for preformed Crown

Abstract

Nickel is one of the most common causes of contact dermatitis and other numerous health hazards in children and so is a concern for parents as well as patients with stainless steel crowns that contain high concentration of Nickel. Even though Stainless steel crowns provide the best conservation of the teeth yet not enough efforts have been made to tackle Ni ion release from these alloys over time which may cause lymphocytic reactivity, periodontistis, respiratory diseases, chronic fatigue syndrome and possible carcinogenicity and other fatal outcomes leading to various major health issues in children. The incidence of nickel toxicity is more in females than in males. .It's metallic look is another psychological trauma for the child when cemented on the anterior teeth along with parental dissatisfaction. The objective of this in-vitro study was to measure the Ni ion release from Conventional preformed stainless steel crowns and compare with the Ni ion release from the stainless steel crowns coated with proprietary layer which may provide a possible solution to the Nickel ion release in children. Nine specimens of each Stainless steel alloy and the alloy coated with proprietary coating were completely immersed in the corrosion solution recommendation for biological studies by ISO Standard 10993.25 for the time period of 1, 10, 100, and 1000 hours .The specimens were analyzed with inductively coupled optically missioned spectroscopy. Values for the concentrations of the released Nickel ions was compared.
Results indicated nickel ion release was either reduced or was none in the coated discs as compared to the non coated.

Research Figures

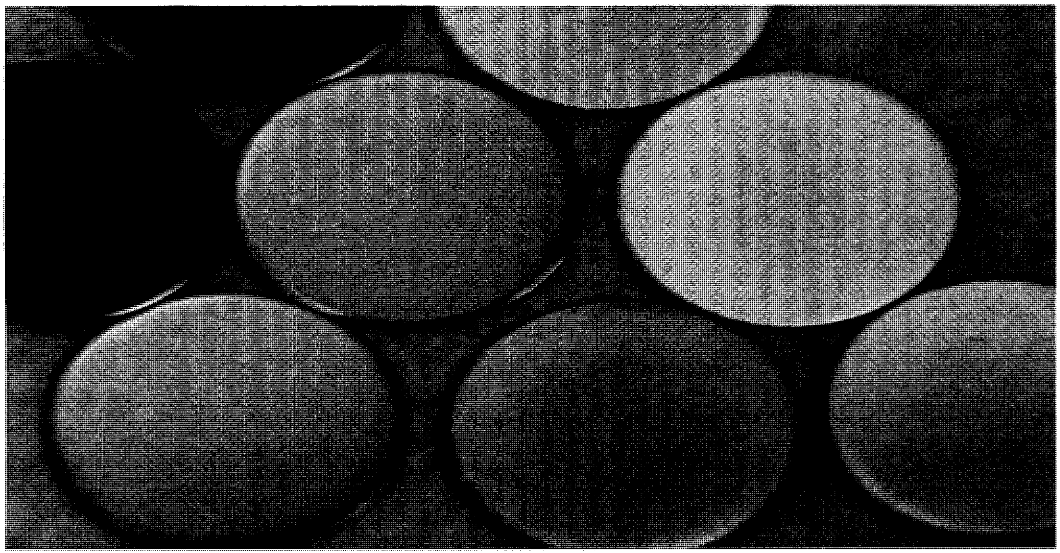

Fig: 1 The Stainless steel discs and coated discs

Fig: 2 The Reagents for Immersion Solutions

Fig: 3 The pH Buffers

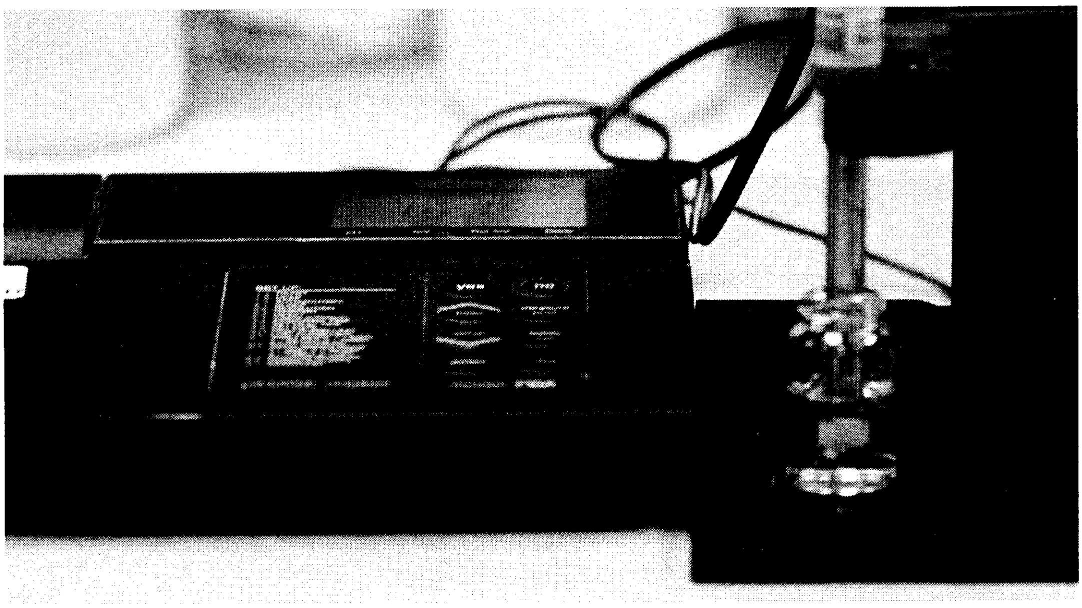

Fig: 4 pH Probe

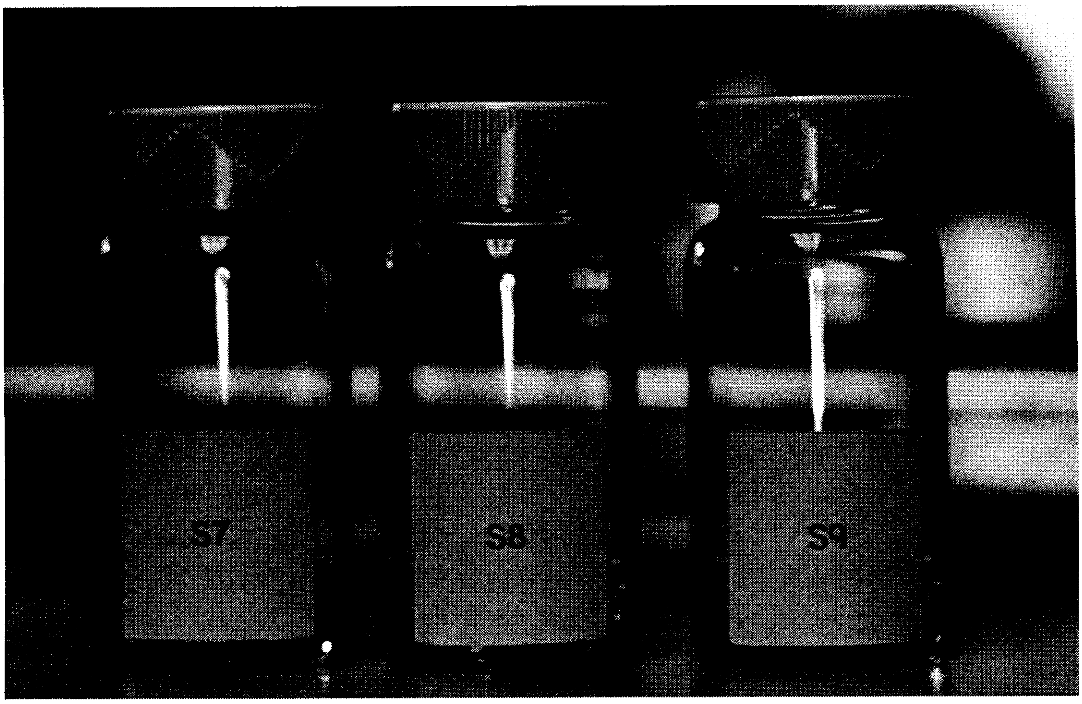

Fig: 5 The Samples immersed in solution

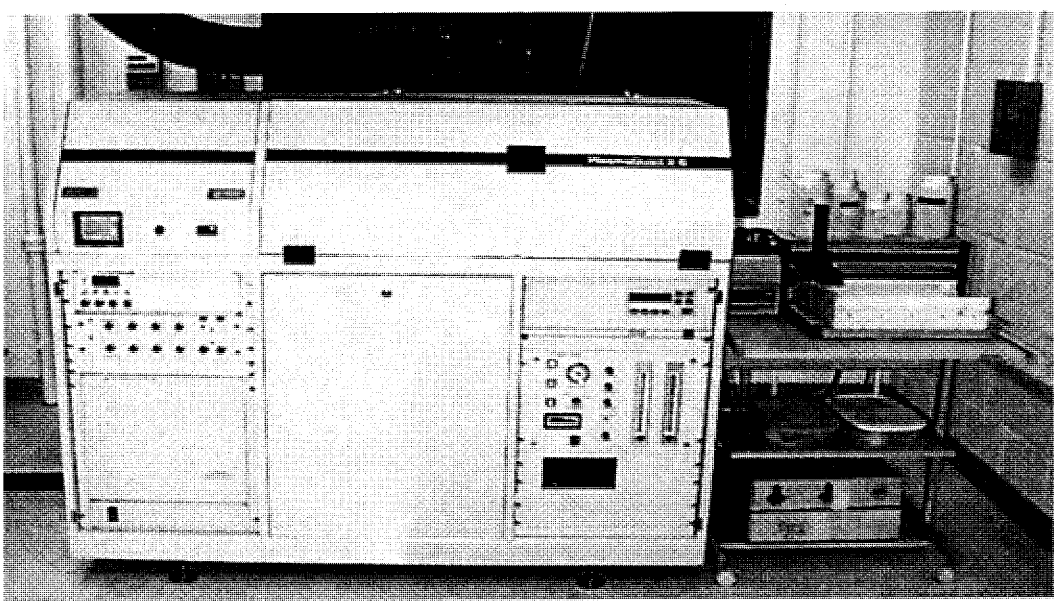

Fig: 6 ICPMS- Inductively coupled plasma mass spectrometry

In Vitro analysis of Nickel ion release from Stainless steel for Preformed Crown

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